

# Medical Devices Reprocessing

## Accreditation Process

*September 9, 2014*



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# Accreditation Canada

- National accreditation body for organizations across all health sectors in Canada and around the world
- An independent, non-governmental, non-profit organization funded by its members
- 55+ years in existence
- National standards of excellence across the health care sector
- Over 500 surveyors conducting a minimum of 300 surveys annually
- Accredited by the International Society for Quality in Healthcare



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# Benefits of Accreditation

- Increased communication and collaboration, sharing of information, generating ideas and plans
- Powerful change management tool
- Effective self-assessment
- Educational process that benefits staff
- Enhances use of indicators
- Increases credibility and demonstrates accountability
- Improves communication among teams



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# Accreditation Canada: Former Qmentum Program Cycle



## QUALITY IMPROVEMENT Three-year Cycle



22

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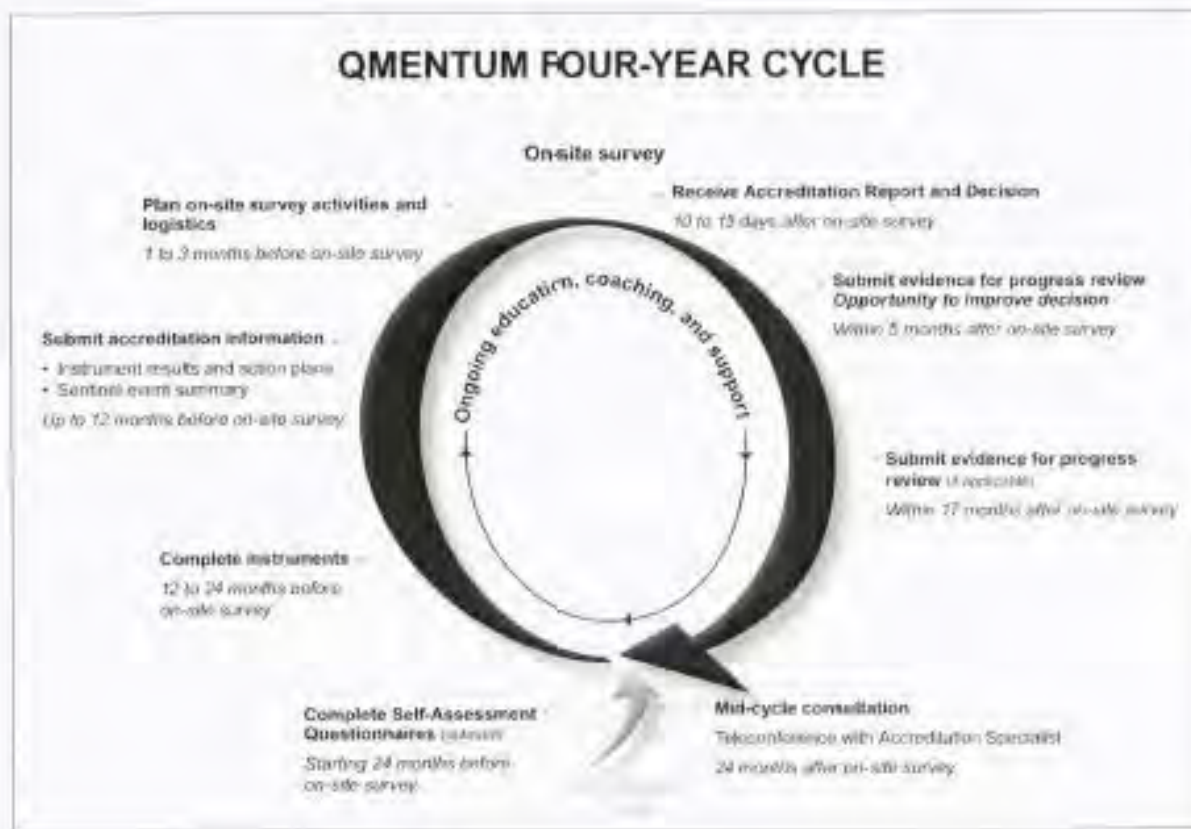


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# Accreditation Canada: Current Qmentum Program Cycle



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# Accreditation Canada: Qmentum Program

- Effective respected evaluation process
- Assesses quality using national standards
- Works on 4 year cycle
- Focus on quality improvement



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# Accreditation Canada: Survey Process

**Three Participant groups in Accreditation Canada accreditation process:**

1. Organization - Staff
2. Surveyors
3. Accreditation Canada Staff



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# Accreditation Canada: Survey Process

## Process Involves:

1. Standards
2. Priority Processes
3. Tracer Methodology



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# Accreditation Canada: Standards

- Standards set the bar for health care practice
- Different types of standards for different clinical settings
- Standards reflect clinical and managerial best practices, emerging trends
- Organization/teams are assessed against standards to identify strengths and areas to improve
- Standards are developed with input and guidance of experts
- Standards are updated regularly
- New standards are developed as needed



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# Accreditation Canada: Survey Process

Organization will develop a survey plan with 2 components:

## 1. Preparing for the survey

Doing self assessments using questionnaires

Addressing issues which arise from self-assessments

## 2. Experiencing the on-site survey



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# Accreditation Canada: Survey Preparation

## Organization will:



- Establish accreditation teams based on clinical services/priority processes to be surveyed
- Complete self-assessments using confidential online questionnaires:
  - Governance Questionnaire completed by Board of Governors
  - Patient Safety Culture Survey completed by staff
  - Worklife Pulse Survey completed by staff
  - Clinical Service Questionnaires completed by interdisciplinary staff of each service



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# Accreditation Canada: Survey Preparation

## Questionnaire follow up:

- Completed questionnaires are forwarded to Accreditation Canada for collation
- Questionnaire findings are collated and forwarded to hospital/teams
- Risk ratings are provided for each question for each of the surveys
- Ratings are red (High risk), yellow (Medium risk), or green (No risk) flags
- Quality Performance Roadmaps are developed.
- Actions to address the red and yellow flags are entered onto the roadmap in preparation for the onsite survey



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# Accreditation Canada: Quality Performance Roadmaps

## Quality Performance Roadmap

Standard: Cancer Care and Oncology Services — Team: Cancer Care Team

View Legend

**Legend:**

- Red flags serve as alerts to the organization. Organizations should review the red flags to determine which ones require further investigation. Also review the relevant standards section to learn more about the full standards requirements, and to identify gap areas. Then, prioritize the areas for improvement. Where improvements are necessary, an action plan is recommended and evidence of action taken should eventually be submitted to Accreditation Canada via the QPR.
- Yellow flags indicate areas where some improvement may be required. Again, the organization should examine the relevant Accreditation Canada standards section to determine where gaps exist. The organization should then follow similar steps to prioritize improvements, develop action plans and eventually submit evidence of action taken.
- Green flags indicate areas that do not require improvement at the time the report is generated. Evidence of action taken is not required.

**Quality Performance Roadmap Filters**

<b>Flag:</b>	<b>Source:</b>
Red & Yellow ▾	Show All ▾
<b>Accreditation Canada Priority:</b>	<b>Follow-up Status:</b>
Show All ▾	Show All ▾
<input type="button" value="OK"/>	

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**Working with the roadmap**

**Viewing the legend**  
To view the legend, click on "View Legend" at the top of the page.

**Filtering results**  
To refine the roadmap results, filter by selecting the appropriate items in the filter box, then click "OK".

**Sorting results**  
Columns in the roadmap may be sorted by clicking on their respective column titles.

**Viewing standards**  
To review a standard that a roadmap item is based on, simply click on its number.

**Viewing interpretations**  
Certain action items have additional interpretation information. To view this information, click on the ? button below the question.

**Ending follow-up with evidence**  
Evidence may be entered by clicking on the "Share Evidence". To complete a follow-up, you must fill in all fields, check follow-up complete and click the Save button.



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# Accreditation Canada: Experiencing the Onsite Survey

Purposes of the on-site Survey:



- To observe and evaluate compliance with standards and their criteria
- To provide a forum to give advice on how to address areas of concern
- To discuss the organization's progress to address risks identified in the self assessments



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# Accreditation Canada: On-site Survey Activities

Surveyors will review and evaluate compliance with the standards using priority processes. Tracer methodology will be used to evaluate the priority processes.

- STANDARDS
- PRIORITY PROCESSES
- TRACERS



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# Accreditation Canada: Standards Relating to MDR

**Infection, Prevention and Control** standards have 2 substandards, #12 and #13 related to MDR.

Examples:

#12 The organization follows manufacturers' recommendations and accepted standards of practice to clean and reprocess reusable medical devices

-Has 22 criteria to be met. Eg, The organization prevents the onsite reprocessing of single-use devices

#13 The organization follows specific requirements to reprocess endoscopy devices

-Has 14 criteria to be met. Eg, All endoscope reprocessing areas are physically separate from client areas



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# Accreditation Canada: Standards Relating to MDR

## Reprocessing and Sterilization of Reusable Medical Devices standards

Examples:



#2.4 Supervisors and staff members involved in reprocessing have completed a recognized course in reprocessing and sterilization

#10.6 The team transports sterile devices and equipment using clean, enclosed, or covered carts and bins, or plastic bags.

97 criteria to be evaluated



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# Accreditation Canada: Standards Relating to MDR

- Surgical Care Services
- Obstetrical Services
- Ambulatory Care Services
- Medical devices and Equipment (part of Leadership Standards)



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# Accreditation Canada: Priority Processes

**Definition:** Critical areas and systems within an organization that are known to have a significant impact on the quality and safety of care and services. Examples:

- Human Resources (Part of Leadership Standards)
- Planning (Part of Leadership Standards)
- Episode of care - Surgical Services
- Infection, Prevention and Control
- Medical Devices and Equipment (Part of Leadership Standards)



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# Accreditation Canada: Tracers

Two types:

1. CLINICAL (Surgical care, Reprocessing and Sterilization)
2. ADMINISTRATIVE (Human capital, Communications)



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# Accreditation Canada: Tracers

**Definition:** Interactive process concentrated on direct observation to gather evidence about the organization's quality and safety of care and services

**Example of a clinical tracer in the MDR department:** Trace a dirty instrument from the time it leaves the scrub nurse's table in the OR until that instrument is reprocessed and returned as part of a set of sterile instruments or individually wrapped to the OR.

Staff involved in each step of the process will be observed and interviewed about:

- Roles and responsibilities
- Education/certification of staff
- Policies, procedures and processes



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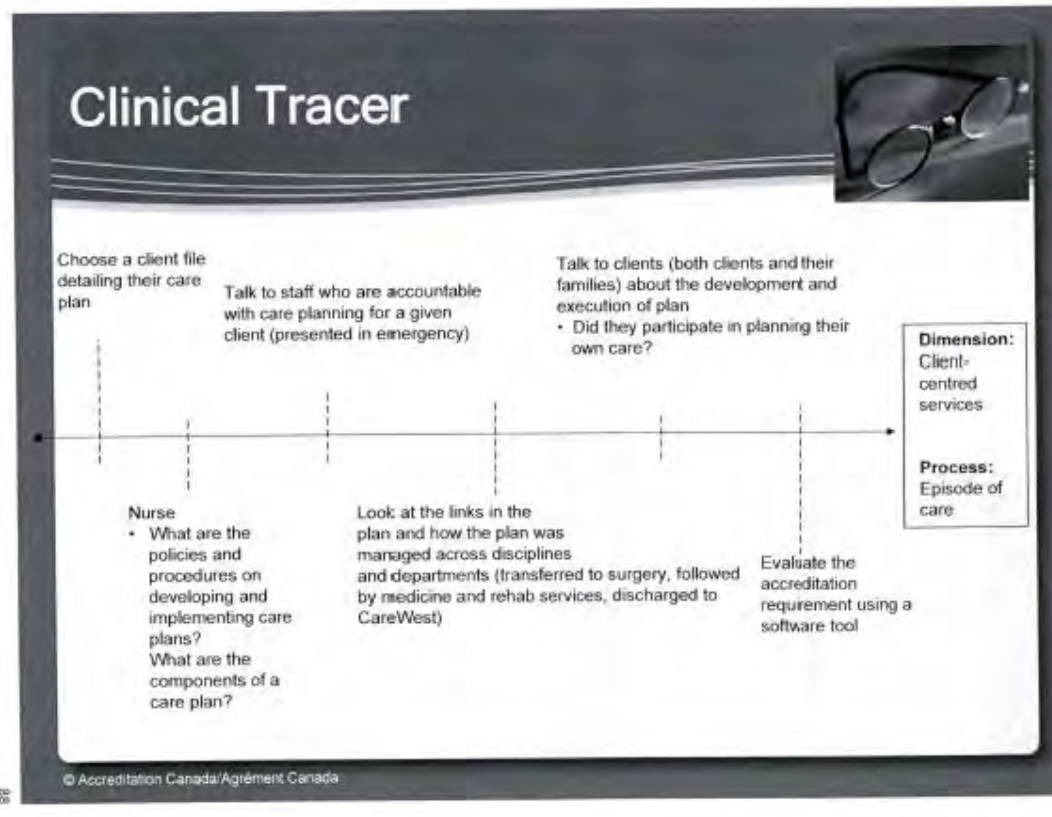


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# Accreditation Canada: Clinical Tracer

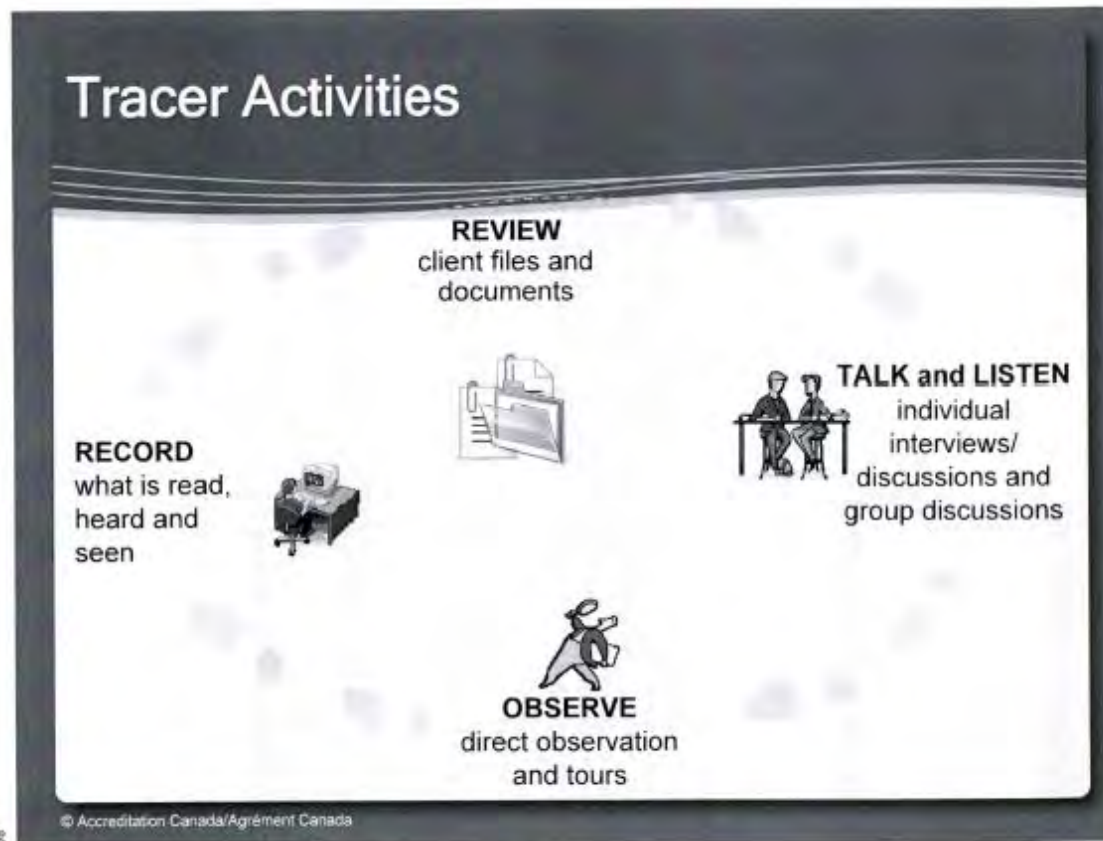


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# Accreditation Canada: Tracer Activities



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# Accreditation Canada: Required Organizational Practices

**Definition:** It is an essential practice that organizations must have in place to enhance patient/client safety and minimize risk. It is a specific requirement for organizations in the accreditation program.

- currently 35
- regularly updated and new ones added
- located in the standards

ROPs are laid out differently in the standards. They include:

- Definition of the practice.
- Guidelines
- Tests for compliance



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# Accreditation Canada: Required Organizational Practices (ROPs)

One ROP applies directly to the MDR

**ROP Statement:** “The organization monitors its processes for reprocessing equipment, and makes improvements as appropriate”

**Guideline:** Organizations reprocess equipment according to manufacturer’s instructions. If the organization does not perform the reprocessing of equipment, it must have a process to ensure equipment has been appropriately reprocessed prior to use

## Tests for Compliance:

1. There is evidence that reprocessing processes and systems are effective
2. Action has been taken to examine and improve reprocessing processes where indicated.



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# Accreditation Canada: Required Organizational Practices (ROPs)

Other general ROPs apply such as Hand Hygiene, Workplace Violence Training, etc.

Surveyors may ask staff questions about these other ROPs as well as questions about orientation to the MDR, ongoing education, performance appraisals and other topics



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# Accreditation Canada: Surveyor On-site Survey Activities

Activities include:

- Priority processes and tracer activities
- Rating each criteria, yes or no or non-applicable
- Surveyor information exchange
- Debriefing
- Leave report on-site



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# Accreditation Canada: Accreditation Decision

DECISION LEVEL	ROP TESTS FOR COMPLIANCE	INSTRUMENT THRESHOLDS	GROUPINGS	
			HIGH PRIORITY CRITERIA	OTHER CRITERIA
Accredited	Two or more major tests unmet at onsite survey	Not met	Met 84% or less	Met 84% or less
Accredited with Commendation	One major test unmet at onsite survey	Met	Met 85% to 94%	Met 85% to 94%
Accredited with Exemplary Standing**	All tests met at onsite survey	Met at onsite survey	Met 95% or more at onsite survey	Met 95% or more at onsite survey

\* **Not Accredited:** Organizations receiving a Not Accredited decision have the opportunity to improve their decision to Accredited by undergoing a focused visit.

\*\* **Accredited with Exemplary Standing** cannot be achieved if an organization has had its Board dismissed and/or is under supervision at the time of the onsite survey.



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# Accreditation Canada: Distinction Programs

## Current Distinction Programs:

**Stroke Distinction Program**



## New Distinction program:

**Trauma Distinction Program**



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# Questions



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# Thank You



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