



DRIVING QUALITY HEALTH SERVICES

## Reprocessing and Sterilization of Reusable Medical Devices standards

CHICA conference  
May 12, 2009 Mireille Cyr-Hansen



ACCREDITATION CANADA  
AGRÈMENT CANADA  
*Accredited by ISO9001*

---

---

---

---

---

---

---

---

### Outline

- About Accreditation Canada
- **Reprocessing and Sterilization of Reusable Medical Devices Standards**
- Existing standard refinements
- Distinction Program
- Next steps



© ACCREDITATION CANADA 2

---

---

---

---

---

---

---

---

### About Accreditation Canada



© ACCREDITATION CANADA 3

---

---

---

---

---

---

---

---

## Who is Accreditation Canada?

- Major national accreditation body for organizations across all health sectors in Canada
- An independent, non-governmental, non-profit organization
- Accredited by the International Society for Quality in Healthcare - 2006



© ACCREDITATION CANADA

4

---

---

---

---

---

---

---

---

## Accreditation Canada's Vision and Mission

- Vision**  
The leader in raising the bar for health quality
- Mission**  
Driving quality in health services through accreditation
- Accreditation Canada Values**  
With an environment focused on clients and committed to quality of worklife, partnerships and personal growth, our values are:  
→ *excellence, integrity, respect, and innovation*

© ACCREDITATION CANADA

5

---

---

---

---

---

---

---

---

## What is Accreditation?

- Process that organizations use to evaluate and to improve the **quality** of their services
- Involves **examining** everyday activities and services **against standards of excellence**

© ACCREDITATION CANADA

6

---

---

---

---

---

---

---

---



**Criteria with highest % of Green flags**

8.12 The package or container has an externally visible chemical indicator to differentiate between processed and unprocessed packages (95%)

8.13 The team places an internal chemical indicator in each package or container...to verify that sterilizer penetration has occurred (95%)

9.4 The team follows manufacturer instructions for both the sterilizer and the devices being sterilized (83%)

© ACCREDITATION CANADA 10

---

---

---

---

---

---

---

---

**Criteria with highest % of Green flags**

9.5 Following the sterilization cycle and before unloading, the appropriate team member verifies that the required parameters have been met (87%)

9.6 During unloading, the team inspects all packs, including the results of external chemical indicators (87%)

9.7 The team repeats reprocessing for any items with a damaged pack or seal, or those that are compressed, torn, wet, or have been dropped on the floor (87%)

© ACCREDITATION CANADA 11

---

---

---

---

---

---

---

---

**Criteria with highest % of Red flags**

Where sterilization & reprocessing services are contracted to external providers, the organization

1.7 ...establishes and maintains a contract with each service provider that requires consistent levels of quality and adherence to accepted standards of practice (79%)

1.8 ...regularly monitors the quality of services provided (79%)

1.9...annually reviews each contract and records all aspects of the contract and negotiations in its files (79%)

© ACCREDITATION CANADA 12

---

---

---

---

---

---

---

---

**Criteria with highest % of Red flags**

3.5 ...regulates the air quality, ventilation, t° and relative humidity, and lighting in decontamination, reprocessing and storage areas (52%)

11.4 ...maintains a dedicated bank of neurosurgical and ortho-spine devices (94%)

12.3...quality management documents are accessible to staff and team members (46%)

12.4...as part of its quality management system, the team trains staff to identify, assess, prioritize, reduce, and communicate risks in the reprocessing unit or area (46%)

© ACCREDITATION CANADA 13

---

---

---

---

---

---

---

---

**Preliminary results based on site surveys**

Successes:

- Orientation to safe work practices
- Hand hygiene content (training and access to supplies)
- Maintaining a complete record of each sterilization cycle
- Preventing the on-site reprocessing or sterilization of SUDs

© ACCREDITATION CANADA 14

---

---

---

---

---

---

---

---

**Preliminary results based on site surveys**

Successes:

- Properly packaging contaminated equipment for reprocessing
- Preventing the contamination of reprocessed devices
- Clearly identifying sterilized packages and distinguishing them from non-sterilized items
- Tracking sterilized items

© ACCREDITATION CANADA 15

---

---

---

---

---

---

---

---

**Preliminary results based on site surveys**

Challenges (38% unmet):

- 3.3 The physical space prevents cross-contamination of sterilized and contaminated devices or equipment, isolates incompatible activities, and clearly separates different work areas
- 5.2 The unit or area's hand hygiene facilities are equipped with faucets supplied with foot, wrist or knee operated handles or electric eye controls
- 12.1 The team has a documented quality management system for its reprocessing and sterilization services that integrates principles of quality assurance, risk management, and continual improvement

© ACCREDITATION CANADA

---

---

---

---

---

---

---

---

Of note:

- Content on contracting reprocessing and sterilization services was rated by surveyors as not applicable in 71% of sites visited
- Content on maintaining a dedicated bank of neurosurgical and ortho-spine devices was rated by surveyors as not applicable in 71% of sites visited

© ACCREDITATION CANADA

---

---

---

---

---

---

---

---

**2010 Refinements of the Reprocessing and Sterilization of Reusable Medical Devices standards**

- Additional references to CSA guidance documents
- Content on selecting between manual or mechanical cleaning
- Reference to Public Health agency guidelines for suspected CJD contamination
- Enhanced content on monitoring the quality of services provided by external providers

© ACCREDITATION CANADA

---

---

---

---

---

---

---

---

Existing standard refinements



---

---

---

---

---

---

---

---

- **Infection Prevention and Control**
  - Enhanced endoscopy content
  - Changes to differentiate between handling contaminated equipment and cleaning reusable medical devices
- **Diagnostic Imaging**
  - Replaced the term “sterilization” with “reprocessing” DI equipment and devices
- **Obstetrics/Perinatal & Ambulatory Care**
  - Added content on following a preventive maintenance program and a schedule of cleaning and sterilization to ensure optimal performance of all devices and equipment.

© ACCREDITATION CANADA 20

---

---

---

---

---

---

---

---

- **Operating Room**
  - 12.3...selecting disinfectants...
  - 12.4...for each disinfectant, following manufacturer recommendations...
  - 12.6...transporting contaminated items..
  - 12.7...when transporting contaminated equipment and devices, complying with regulations...
  - 12.9...keeping a record of each use of flash sterilization and documenting...
  - 12.13...verifying education, certification, competency of staff involved in reprocessing in the OR

© ACCREDITATION CANADA 21

---

---

---

---

---

---

---

---

Reprocessing and Sterilization of Reusable Medical Devices **Distinction** Program



---

---

---

---

---

---

---

---

**Guiding Principles**

- Value-add, optional product for organizations
- Very specific, addressing priority areas for quality improvement
- Partnership with Canadian Standards Association to develop standards
- Evaluators with special expertise in Reprocessing and Sterilization

© ACCREDITATION CANADA 23

---

---

---

---

---

---

---

---

**Reprocessing and Sterilization Distinction Process**

- Recognizes organizations for a commitment to excellence in Reprocessing and Sterilization services
- Organizations who have successfully achieved accreditation
  - Non-accredited organizations and those engaged in Accreditation Primer are not eligible

© ACCREDITATION CANADA 24

---

---

---

---

---

---

---

---

**Next Steps**

- Continue to monitor compliance with reprocessing and sterilization standards and existing standards
- Annually review accreditation program standards
- Continue developing distinction product

© ACCREDITATION CANADA 25

---

---

---

---

---

---

---

---

**Questions?**

© ACCREDITATION CANADA 26

---

---

---

---

---

---

---

---



www.accreditation-canada.ca

*The leader in raising the bar for health quality*



---

---

---

---

---

---

---

---