HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026

Health Canada Regulatory and Policy Updates

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Health Canada

Overview

- REP implementation
- Planned regulatory amendments
- Key guidance and notice updates

Regulatory Enrolment Process (REP) implementation

- REP is a common intake process across Health Canada's business lines using web-based templates instead of traditional application forms

- It enables:
  - Receipt of transactions via the Common Electronic Submission Gateway (CESG)
  - Automated import of transaction and metadata into Health Canada's internal systems

- Following a successful multi-year pilot, REP opened for manufacturers' voluntary use in July 2024 and will become mandatory on April 1, 2026

Planned regulatory amendments

- Expanded Terms and Conditions (T&Cs) came into force on January 1, 2026
- The *Medical Devices Regulations* were amended to allow the Minister of Health to impose and amend T&Cs at any point during a device's lifecycle and to expand the scope of use of T&Cs
- Several guidance documents are being updated to reflect the new regulatory language

Planned regulatory amendments

Medical Device Shortages

- Regulatory package to:
  - Streamline and update reporting, including submissions to third-party website
  - Clarify scope of the exceptional importation framework
- Proposed amendments published in December 2024
- Publication of final regulations targeted for Spring 2026

Establishment Licensing (MDEL)

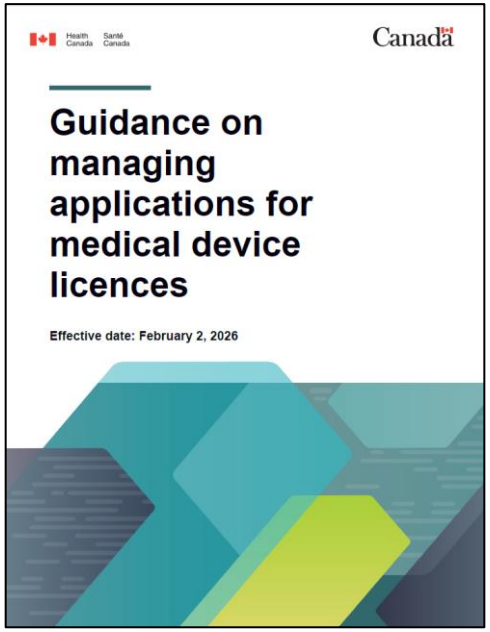
- Proposed regulatory amendments:
  - Risk-based approach to licensing distributors outside of Canada
  - MDEL requirement to provide supplier lists
  - Explicit requirements for MDEL holders to implement and maintain SOPs
- Proposed amendments published in November 2025

Recent guidance publications

[Health Canada IMDRF table of contents for medical device applications guidance]

- Published November 25, 2025
- Incorporates IMDRF N9 and N13 Ed 4 as well as updated HC guidance
- As of April 1, 2026, IMDRF ToC format will be required for Class II, III, and IV medical device submissions

Recent guidance publications



[Guidance on managing applications for medical device licences]

- Came into effect February 2, 2026
- Key changes
  - Streamlining the reconsideration process to a single level of appeal
  - Introduction of Additional Information – noncompliance (AI-N) letter

Recent notice publications

Device Licence Applications for Diagnostic Ultrasound Systems and Transducers: Notice to Industry

- Published January 19, 2026
- Highlights key considerations for Class III/IV diagnostic ultrasound systems and transducers

Recent notice publications

Notice to Industry: Change in classification of COVID-19 testing devices

- COVID-19 testing devices were classified as Class IV devices as SARS-CoV-2 was considered a life-threatening disease with high transmission risk
- Health Canada recently revised the risk classification so regulatory oversight remains proportional to the risk presented by the medical device
- COVID-19 testing devices are now classified as follows:
  - Laboratory-based testing devices: Class II
  - Point-of-care and self-testing devices: Class III

Thank You!

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