Medical Devices Directorate Policy and Guidance Update

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Objective

To give an update of key policy initiatives and an overview of the revisions to two guidance documents for medical devices.

- Key policy updates
- Management of applications guidance
- Significant change guidance

Key policy initiatives for medical devices

Published Guidance

Terms and conditions for Class II to IV devices

Using standards to support compliance with the regulations

Machine learning-enabled medical devices

Application type

Management of applications

Health Canada IMDRF table of contents (ToC)

Guidance Finalization

Significant change

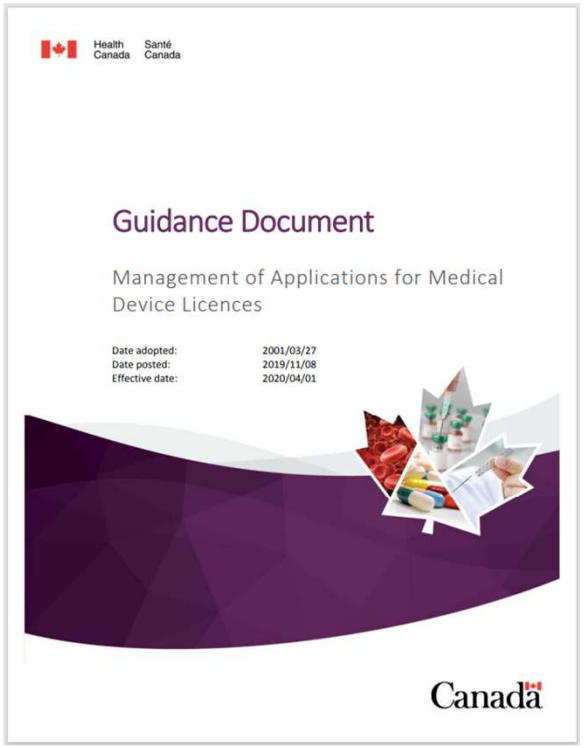
Policy Development

Unique device identification (UDI) system

COVID-19 test classification

What is the management of applications guidance?

- The guidance on managing applications for medical device licences outlines how Health Canada manages the following:
  - new and amendment Class II applications
  - new and amendment (significant change) Class III and IV applications
  - minor change applications and
  - new and amendment private label applications



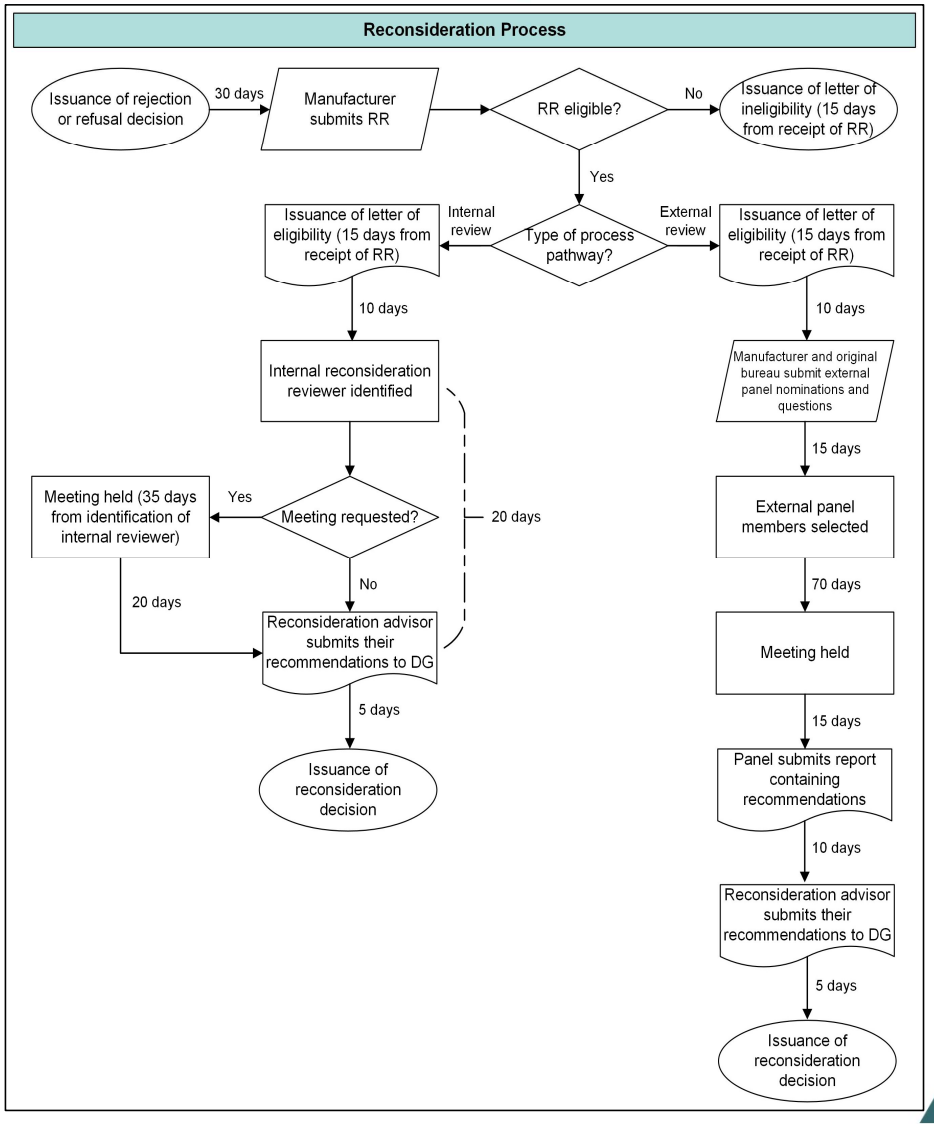
Revisions to the management of applications guidance

- The updated guidance was published on November 21, 2025.
- The guidance document includes 3 main revisions:
    1. Revised reconsideration process
    2. Introduction of the Additional information – noncompliance letter (AI-N) for significant deficiencies/omission or any false or misleading statements in the application
    3. Addition of process maps to show the flow of applications and the revised reconsideration process

Revised reconsideration process

Key process changes include:

- Streamlining the process to a single level of appeal to the Director General; and
- Inclusion of timelines at key steps in the process to provide greater transparency and consistency.



What we heard from the public consultation

- Consultation on the Draft guidance on managing applications for medical device licences ran from February 20, 2025, to April 21, 2025.
- Recommendations from stakeholders included:
  - Including information on filing applications using the Regulatory Enrolment Process
  - Adjusting response timelines for manufacturers
  - Adding application management process maps
- All feedback received was considered in finalizing the guidance document.

Management of applications guidance: next steps

- The updated guidance document will come into force when the Regulatory Enrollment Process (REP) becomes mandatory in early 2026.

Assess the feedback received
(Status: Complete)

→

Update the document for final publication
(Status: Complete)

→

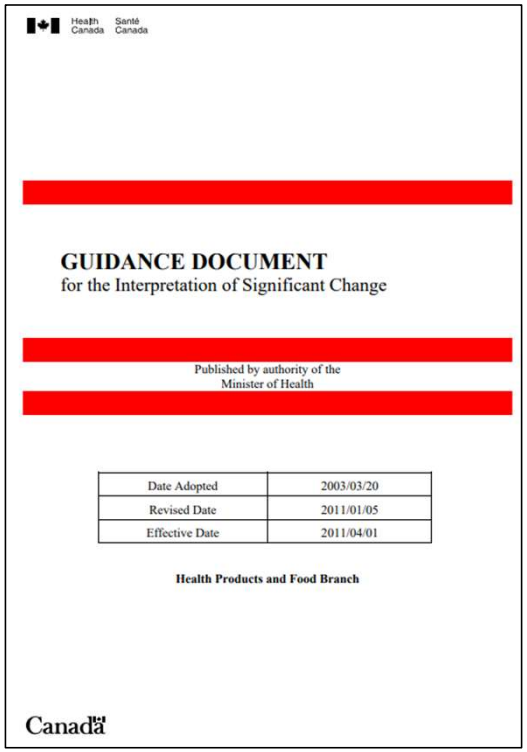
Publication of final guidance
(Status: Complete)

→

Coming into force
(Target: Early 2026)

Purpose of the significant change guidance

- This guidance assists in determining whether a proposed change to a Class III or IV medical device is significant — that is, whether it could reasonably be expected to affect the device's safety or effectiveness.
- This also applies to a change to a compatible Class II device that may affect the safety or effectiveness of a Class III or IV device with which it interacts.



Health Canada Santé Canada

GUIDANCE DOCUMENT
for the Interpretation of Significant Change

Published by authority of the
Minister of Health

Date Adopted	2003/03/20
Revised Date	2011/01/05
Effective Date	2011/04/01

Health Products and Food Branch

Canada

What is a significant change?

significant change means a change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to any of the following:

(a) the manufacturing process, facility or equipment;

(b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;

(c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and

(d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry date. (*modification importante*)

Medical Devices Regulations (s. 1 Interpretation)

Manufacturers are required to submit an amendment application when a Class III or IV medical device is proposed for significant change under Section 34 and Section 68.14 of the MDR.

Updating the significant change guidance

- The Significant Change guidance document was last updated in 2011.
- The process to update it started several years ago, driven by:
  - feedback received over the years; and
  - advances in technologies used in medical devices (e.g., software).
- Consultation on the Draft guidance on how to interpret ‘significant change’ of a medical device ran from February 7, 2024 to April 22, 2024.

What we heard from the public consultation

- 187 comments were received from 11 stakeholders
- Most comments were focused on the types of changes section
- Feedback included:
  - Requesting the reinstatement of flowcharts
  - Requiring additional clarity for the impact of compatible devices
  - Clarifying how to document non-significant changes in annual renewal
  - Providing more details for examples
  - Improving the overall clarity and readability

Structure of the guidance

General principles section

Provides high level concepts that apply through out the guidance

Types of changes

Changes to manufacturing processes, facilities or equipment
Changes to manufacturing quality control procedures
Changes in design
Changes to sterilization and sterile barrier packaging
Changes to software
Changes in materials for non in vitro diagnostic devices
Changes in materials for in vitro diagnostic devices
Changes to labelling
(new) Class III/IV amendment requirements due to compatible Class II devices
(new) Changes to diagnostic ultrasound systems

Guidance on significant change: next steps

Assess the feedback received
(Status: Complete)

Update the document for final publication
(Status: On-going)

Prepare internal documents, training, etc. to enable implementation of the revised guidance
(Status: On-going)

Publication of the final guidance
(Target: End of Fiscal Year)