IMDRF International Medical Device Regulators Forum

# Health Canada Regulatory and Policy Updates

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# Overview

- Government of Canada Red Tape Reduction initiative
- Planned regulatory amendments
- Key guidance updates
- Launch of additional Health Canada eSTAR pilot

Health Canada Santé Canada

# Government of Canada Red Tape Reduction initiative

- On July 9th, 2025, the Government of Canada launched an initiative for departments to review regulations and propose actions to reduce red tape.

- Ministers were asked to report to the President of the Treasury Board on their organizations' progress and next steps within 60 days

    - Health Canada and the Public Health Agency of Canada's report on red tape reduction was published on Sept 8th, 2025

# Modernizing the Medical Device Establishment Licensing (MDEL) framework

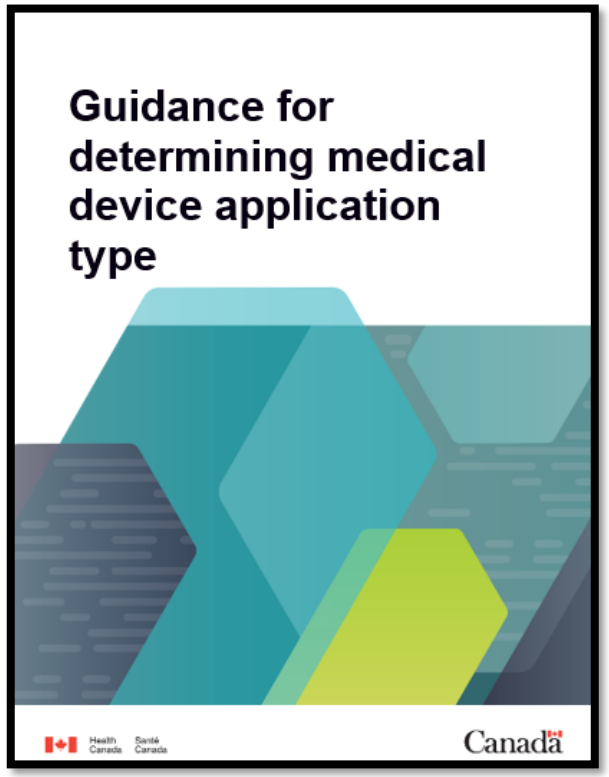
**Phase I:**

- Regulatory changes included:
  - Updating Recall requirements
  - New authority to apply terms & conditions on MDELs
  - Modernize MDEL application requirements
- Came into force on December 14, 2024

**Phase II:**

- 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 standard operating procedures
- Notice of Intent published November 9, 2024

# Recent guidance publication




[Final guidance for determining medical device application type]

- Published August 29, 2025
- Updated to reflect current practices in determining when certain medical devices can be combined together and submitted as one application.

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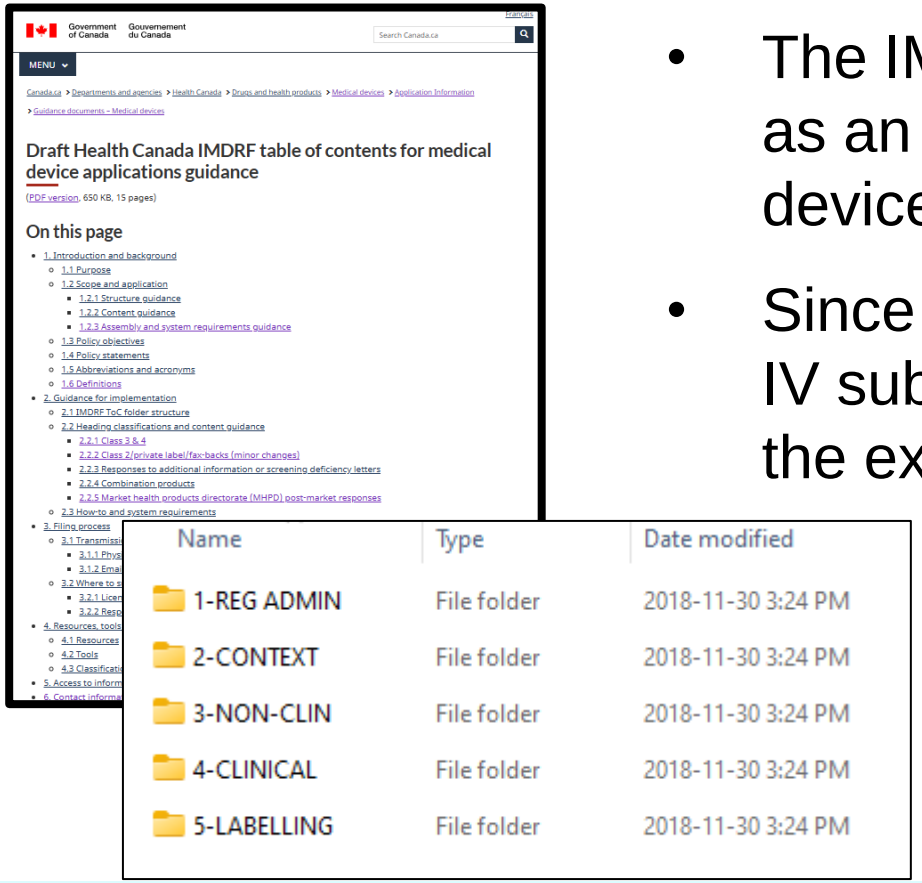
# Health Canada's use of the IMDRF Table of Contents




- The IMDRF Table of Contents (ToC) was developed as an internationally harmonized format for medical device submissions
- Since 2019, Health Canada has accepted Class II, III, IV submissions using the IMDRF ToC in addition to the existing Health Canada format
  - As of January 1, 2026, use of the **IMDRF ToC format will be required for Class II, III, and IV medical device submissions**

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# 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 in January 2026

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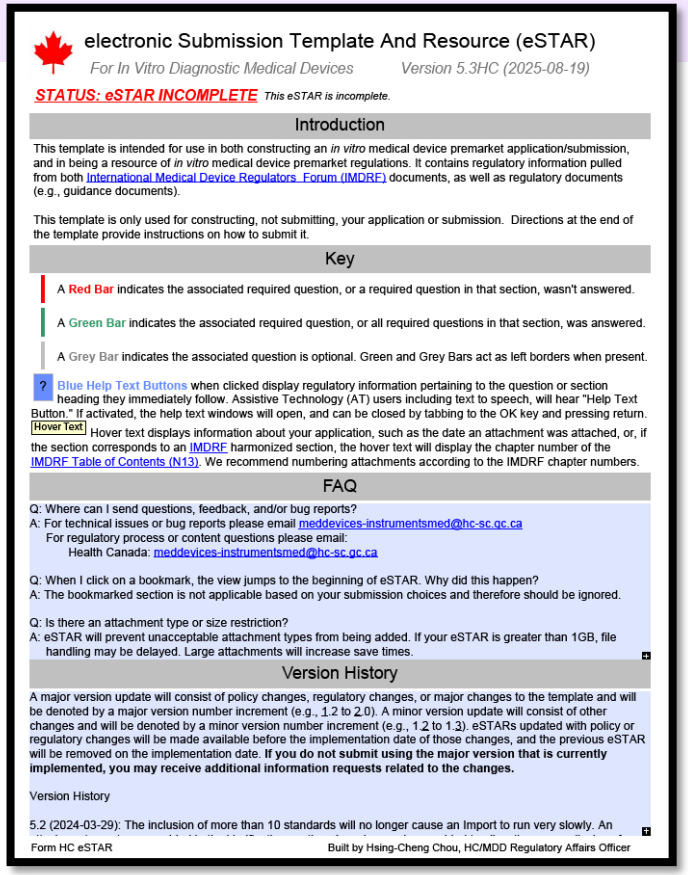
# Advancing harmonization for premarket submissions – Health Canada eSTAR pilot program

- eSTAR is a dynamic pdf form, developed by the US FDA, that assists manufacturers in submission building
- In 2023, HC and the FDA conducted a joint pilot to test manufacturers' use of eSTAR to submit premarket applications to both jurisdictions
- HC also conducted an additional HC-only pilot for Class III and IV non-IVD submissions



electronic Submission Template And Resource (eSTAR)

*For In Vitro Diagnostic Medical Devices* *Version 5.3HC (2025-08-19)*

***STATUS: eSTAR INCOMPLETE*** *This eSTAR is incomplete.*

**Introduction**

This template is intended for use in both constructing an *in vitro* medical device premarket application/submission, and in being a resource of *in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

**Key**

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? **Blue Help Text Buttons** when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents (N13). We recommend numbering attachments according to the IMDRF chapter numbers.

**FAQ**

Q: Where can I send questions, feedback, and/or bug reports?
A: For technical issues or bug reports please email meddevices-instrumentsmed@hc-sc.gc.ca
For regulatory process or content questions please email:
Health Canada: meddevices-instrumentsmed@hc-sc.gc.ca

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?
A: eSTAR will prevent unacceptable attachment types from being added. If your eSTAR is greater than 1GB, file handling may be delayed. Large attachments will increase save times.

**Version History**

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **If you do not submit using the major version that is currently implemented, you may receive additional information requests related to the changes.**

Version History

5.2 (2024-03-29): The inclusion of more than 10 standards will no longer cause an Import to run very slowly. An

Form HC eSTAR Built by Hsing-Cheng Chou, HC/MDD Regulatory Affairs Officer

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# Health Canada eSTAR pilots demonstrated positive results

- Most users found the eSTAR template to be user friendly and intuitive
- Manufacturers highlighted that the eSTAR helper text was useful, and suggested incorporating IMDRF ToC section numbers and some design enhancements
- Health Canada screeners noted tool-generated submissions did not differ significantly from regular submissions
- Stakeholders would like to see pilot expansion, including for the use of IVDDs and Additional Information requests

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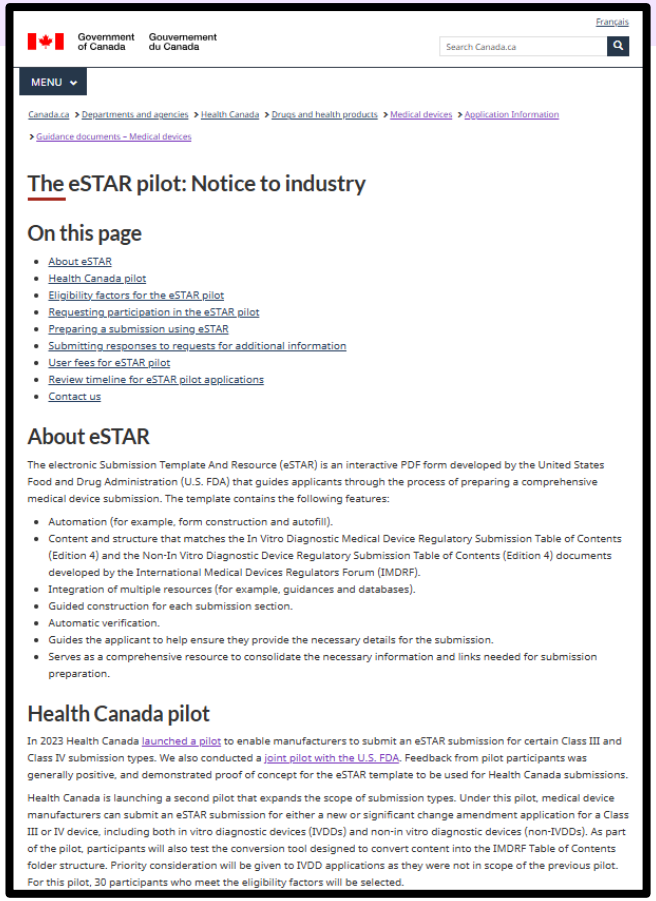
# Launch of additional Health Canada eSTAR pilot

- On August 20th, 2025, Health Canada launched an additional eSTAR pilot, expanding submission types:
  - New or significant change amendment applications for Class III/IV devices
  - Responses to Additional Information requests
- 30 pilot participants will be selected, with priority for in vitro diagnostic device (IVDD) applications
- Participants will also test the conversion tool designed to convert eSTAR contents into the IMDRF Table of Contents folder structure



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## The eSTAR pilot: Notice to industry

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### About eSTAR

The electronic Submission Template And Resource (eSTAR) is an interactive PDF form developed by the United States Food and Drug Administration (U.S. FDA) that guides applicants through the process of preparing a comprehensive medical device submission. The template contains the following features:

- Automation (for example, form construction and autofill).
- Content and structure that matches the In Vitro Diagnostic Medical Device Regulatory Submission Table of Contents (Edition 4) and the Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (Edition 4) documents developed by the International Medical Devices Regulators Forum (IMDRF).
- Integration of multiple resources (for example, guidances and databases).
- Guided construction for each submission section.
- Automatic verification.
- Guides the applicant to help ensure they provide the necessary details for the submission.
- Serves as a comprehensive resource to consolidate the necessary information and links needed for submission preparation.

### Health Canada pilot

In 2023 Health Canada launched a pilot to enable manufacturers to submit an eSTAR submission for certain Class III and Class IV submission types. We also conducted a joint pilot with the U.S. FDA. Feedback from pilot participants was generally positive, and demonstrated proof of concept for the eSTAR template to be used for Health Canada submissions.

Health Canada is launching a second pilot that expands the scope of submission types. Under this pilot, medical device manufacturers can submit an eSTAR submission for either a new or significant change amendment application for a Class III or IV device, including both in vitro diagnostic devices (IVDDs) and non-in vitro diagnostic devices (non-IVDDs). As part of the pilot, participants will also test the conversion tool designed to convert content into the IMDRF Table of Contents folder structure. Priority consideration will be given to IVDD applications as they were not in scope of the previous pilot. For this pilot, 30 participants who meet the eligibility factors will be selected.

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# Thank you /ありがとうございます

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