Regulatory Update from Health Canada

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Health Canada Santé Canada

IMDRF International Medical Device Regulators Forum

Overview

- Addressing Future Public Health Emergencies
- Advancing Agile Licensing for Medical Devices
- Recent Public Consultations
- Recent Scientific Advisory Committee Meetings
- Piloting eSTAR Functionality

Addressing Future Public Health Emergencies

- **In February 2023, Health Canada introduced a permanent regulatory framework under Part 1.1 of the *Medical Devices Regulations* to allow faster access to COVID-19 medical devices for which there is an urgent public health need**

- **In January 2024, we have broadened these regulations to apply to future public health emergencies**
  - To provide more information, a guidance on medical devices for an urgent public health need was also published

Advancing Agile Licensing for Medical Devices

- **As part of our Agile Licensing initiative, Health Canada is proposing expanded Terms and Conditions (T&Cs) to support the life cycle approach for regulating medical devices**
  - Health Canada also plans to publish information about T&Cs that have been imposed on medical device licences, to increase transparency and communicate risks

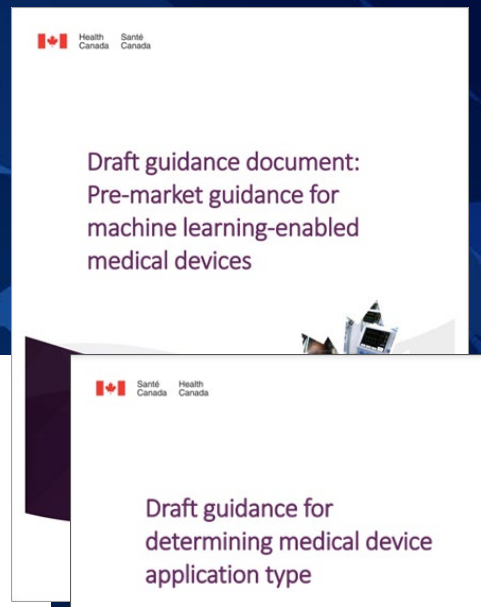
- **In Spring 2023, we held a public consultation on the proposed regulatory amendments to broaden the scope of terms and conditions on Class II to IV medical devices**
  - Overall, stakeholders were supportive of the proposed regulatory changes
  - Work continues to finalize the regulations and accompanying guidance

Recent Public Consultations

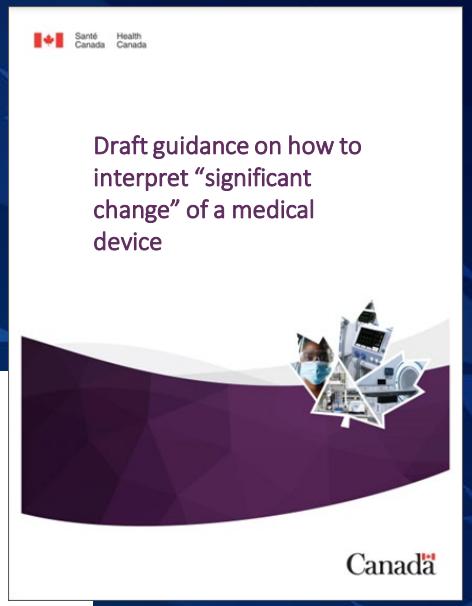
In the Fall 2023, we held public consultations on two draft guidance documents:

- **Draft Guidance: Machine Learning-enabled Medical Devices**
  - Outlines expectations for demonstrating safety and effectiveness for pre-market submissions

- **Draft Guidance: Medical Device Application Type**
  - Assist applicants in determining whether certain devices, including components and parts, should be combined and submitted as one application



Recent Public Consultations



Recently, we launched a new public consultation:

- **Draft Guidance: Interpretation of "significant change"**
  - Assists manufacturers in determining when a proposed change is significant and requires a licence amendment
  - Updates reflect Health Canada's current thinking and provide additional examples
  - Public consultation launched on February 7, 2024, and closes April 22, 2024

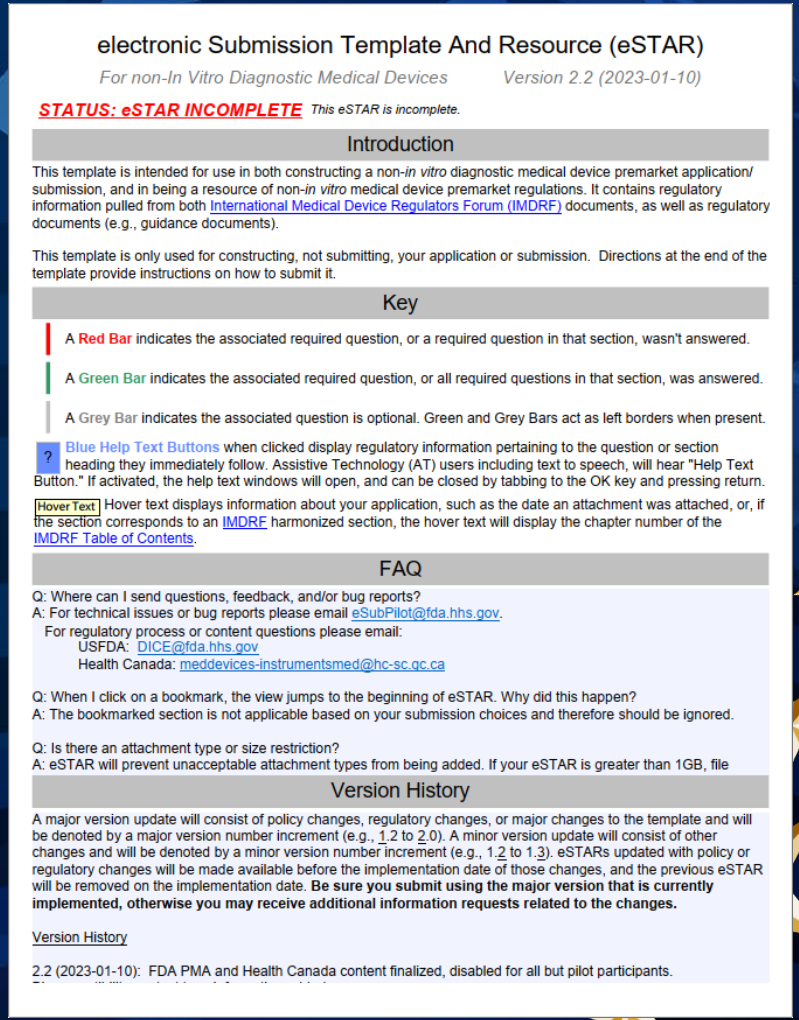
Recent Scientific Advisory Committee Meetings

- **SAC-Digital Health Technologies (January 2024)**
  - Discussion topics included:
    - Transparency considerations around machine learning-enabled medical devices
    - Monitoring of machine learning models throughout the lifecycle

- **SAC-Medical Devices Used in the Cardiovascular System (November 2023)**
  - Discussion topics included:
    - Pulse field ablation
    - Portable and home use devices in cardiovascular medicine

Piloting eSTAR Functionality

- **eSTAR: dynamic template to help build comprehensive device submissions**
- **Health Canada is conducting two pilots to assess the tool's functionality:**
  - Joint pilot with the U.S. FDA for submissions sent to both jurisdictions
  - Health Canada-only pilot
- **Participants are being surveyed on their experience**



electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 2.2 (2023-01-10)*

STATUS: eSTAR INCOMPLETE *This eSTAR is incomplete.*

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*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.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: For technical issues or bug reports please email eSubPilot@fda.hhs.gov.
For regulatory process or content questions please email:
USFDA: DICE@fda.hhs.gov
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

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. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.2 (2023-01-10): FDA PMA and Health Canada content finalized, disabled for all but pilot participants.

Thank you!

Questions?

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Health Canada

Medical Devices Directorate

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