IMDRF International Medical Device Regulators Forum

# Regulatory and Policy Updates Health Canada

Sally Prawdzik

A/Director, Bureau of Policy and International Programs, Medical Devices Directorate

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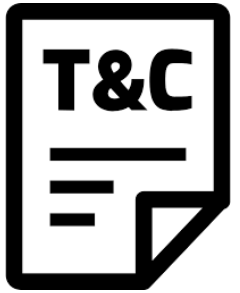
# Overview

- Proposed Regulations to Address Future Public Health Emergencies
- Proposed Regulations to Expand Medical Device Terms and Conditions
- Current Public Consultations
- Upcoming Public Consultation
- IMDRF Working Group Updates

# Proposed Regulations to Address Future Public Health Emergencies

- On February 22, 2023, Health Canada established a permanent regulatory framework for COVID-19 medical devices, resulting in the creation of Part 1.1 of the Medical Devices Regulations
  - Part 1.1 maintains many of the flexibilities afforded by the previous temporary regulations (known as Interim Orders)
- In order to enable faster access to devices that have an Urgent Public Health Need, Health Canada is proposing to amend these Regulations to expand the scope to address future public health emergencies
- A public consultation was held in Spring 2023 to help inform the Regulations and accompanying policy

# Expanding Device Terms and Conditions



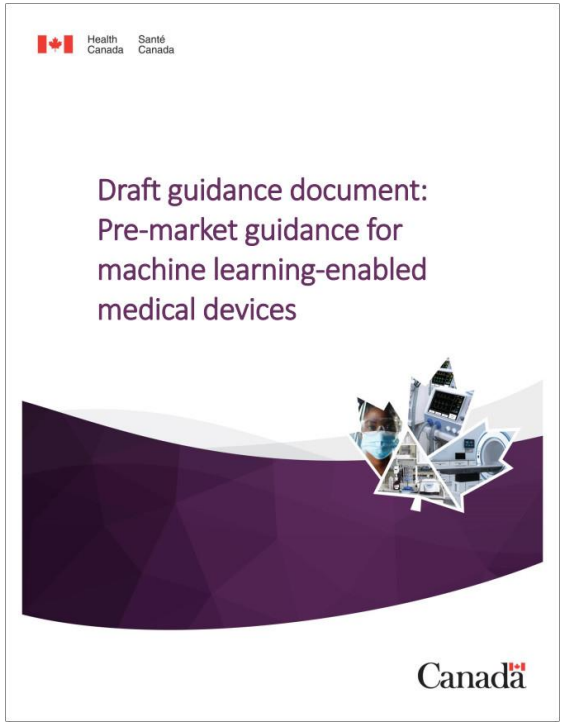

- As part of our **Agile Licensing** initiative, Health Canada is proposing expanded Terms and Conditions (T&Cs) regulations to support the life cycle approach for regulating medical devices

- These proposed regulations would provide us with authorities to:
    - expand the scope of use of T&Cs and;
    - impose or amend T&Cs at any time during the medical device lifecycle

- Health Canada also plans to publish information about T&Cs that have been imposed on medical device licences, to increase transparency and communicate risks

- A public consultation on the proposed regulations and draft guidance document was held in Spring 2023, stakeholder feedback is currently being analyzed

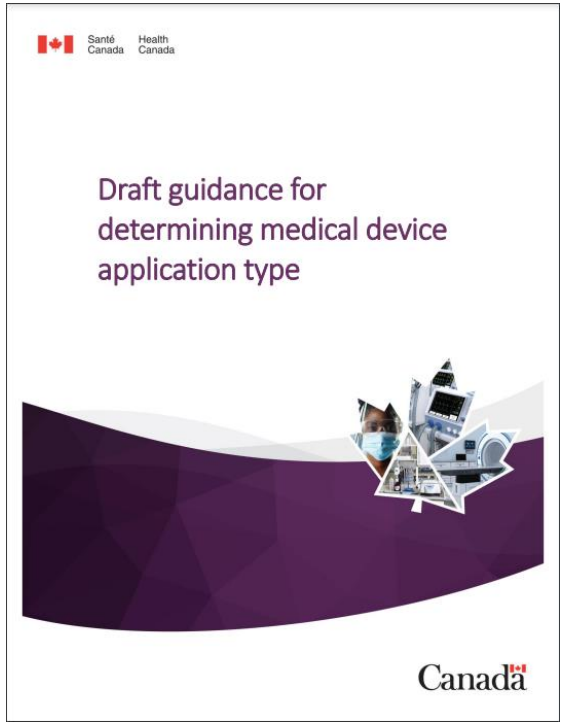
# Public Consultation: Draft Guidance on Machine Learning-enabled Medical Devices (MLMD)




Draft Guidance Consultation launched in August 2023

- Intended to help manufacturers submitting an application for an MLMD
- Outlines expectations for demonstrating safety and effectiveness
- Introduces a mechanism for Health Canada to pre-authorize planned changes to address risks through a pre-determined change control plan
- Consultation closes on October 29th, 2023

# Public Consultation: Draft Guidance on Determining Medical Device Application Type




Draft Guidance Consultation launched in September 2023

- Explains the different application types
- Assist applicants to determine whether certain devices, including components and parts, should be combined and submitted as 1 application
- Takes into account authorizations issued for COVID devices
- Consultation closes on November 10th, 2023
- Will replace the current *Guidance for the Interpretation of Sections 28 to 31: Licence Application Type*

# Upcoming Public Consultation

- Draft Guidance: How to Interpret Significant Change of a Medical Device
  - Guidance assists manufacturers in determining when a change proposed to a licensed Class III or Class IV medical device is considered significant and requires an amendment to a medical device licence
  - Guidance is being updated to reflect Health Canada's current thinking and include additional examples
  - When finalized, will replace the existing *Guidance for the Interpretation of Significant Change of a Medical Device*
  - Public consultation is targeted for later this year

# IMDRF Working Group Updates

**Cybersecurity (Co-Chairs: Health Canada/FDA)**

- Final documents approved at the March IMDRF meeting
  - N70: Principles and Practices for the Cybersecurity of Legacy Medical Devices
  - N73: Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity

**Regulated Product Submission (Co-Chairs: Health Canada/FDA)**

- Public consultation for N9 and N13 closed in May 2023
  - Over 200 comments from 8 stakeholders received
  - Comments focused on improving clarity, terminology changes, minor text changes/additions, layout/organizational changes
- Working group is currently analyzing comments

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# Thank you/Questions

**Email** sally.prawdzik@hc-sc.gc.ca