



**IMDRF**  
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Regulators Forum

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*Chair*

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# Medical Device Cybersecurity (USA / Canada)



**Daniel Yoon**

Acting Manager, International Programs

Health Canada



# Medical Device Cybersecurity Update

US FDA & Health Canada Co-chairs

March 2023

# Overview

## **New Work Item Extension**

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Expansion and Implementation of Legacy

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Expansion and Implementation of Software Bill of Materials (SBOM)

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## **Progress and Planned Milestones**

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# New Work Item Extension

How stakeholders should implement and operationalize:

- Software Bill of Materials (SBOM)
- Legacy conceptual framework

# New Work Item Extension

**Goal:** To increase international alignment and improved safety and security by:

- **Addressing implementation of an SBOM**
  - Topics include: generation, distribution, management, and use of an SBOM
- **Operationalizing the legacy device conceptual framework** articulated in the N60 document in a related, but separate document
  - Topics include: additional definitions, legacy device best practices, TPLC framework, communications, risk and vulnerability management, risk transfer, and considerations for once device no longer supported

# Progress and Milestones

- February 3, 2021: New Work Kick-off Meeting
- April 2021: Final Document Outline
- April-October 2021: WG Meetings every two weeks
- November 2021: 3-day WG Meeting
- **February 2022: Submission of draft Legacy Document to IMDRF MC**
- April 2022: Public Consultation of Legacy Document
- **May 2022: Submission of draft SBOM Document to IMDRF MC**
- July 2022: Public Consultation of SBOM Document
- November 2022: 3-day WG Meeting
- January 2023: Final documents submitted to IMDRF MC
- **March/April 2023: Publish Final Legacy and SBOM Documents\***

# Thank you/Questions

Marc Lamoureux  
[marc.lamoureux@hc-sc.gc.ca](mailto:marc.lamoureux@hc-sc.gc.ca)

Suzanne Schwartz/Aftin Ross  
[Suzanne.Schwartz@fda.hhs.gov](mailto:Suzanne.Schwartz@fda.hhs.gov)/[Aftin.Ross@fda.hhs.gov](mailto:Aftin.Ross@fda.hhs.gov)

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