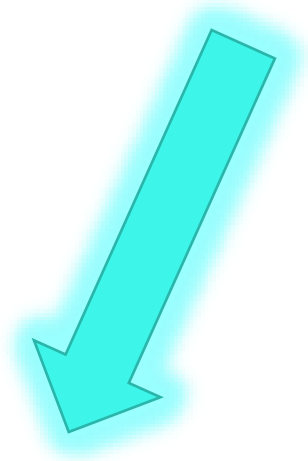
IMDRF International Medical Device Regulators Forum

Medical Device Cybersecurity Update

US FDA & Health Canada Co-chairs



Provide your feedback on this Working Group!

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September 2023

Overview

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
- **April 2023: Published Final Legacy and SBOM Documents**

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Thank you/Questions

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