



IMDRF

International Medical
Device Regulators Forum

IMDRF Stakeholders Forum Sept 2021

Medical Device Cybersecurity Update

US FDA & Health Canada Co-Chairs



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Presentation Outline

- New Work Item Extension to expand on and advise on implementation of two concepts introduced in N60: Legacy and SBOM
- Progress and Planned Milestones



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New Work Item Extension

How should stakeholders implement and operationalize:

- SBOM
- Legacy conceptual framework



New Work Item Extension

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

1. Addressing implementation of SBOM, as well as transparency in the use and support of third-party software;
 - Topics include: generation, distribution, management, and use of an SBOM as well as best practices for 3rd party software beyond SBOM.
2. 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



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Progress and Planned Milestones

- February 3, 2021: New Work Kickoff Meeting
- April 2021: Final Document Outline
- April-October 2021: WG Meetings every two weeks
- November 2021: 3/4-day WG Meeting
- February 2022: Submission of draft to IMDRF MC
- April 2022: Public Consultation*
- April-October 2022: WG Meetings
- October/November 2022: 4-day WG Meeting
- March 2023: Publish Final Document(s)*

* Pending IMDRF MC Approval



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Thank You

- IMDRF Cybersecurity WG
- IMDRF Management Committee
- IMDRF Secretariat
- IMDRF Webmaster