IMDRF Stakeholders Forum – Medical Device Cybersecurity Update

US FDA & Health Canada Co-chairs

September 2022
Overview

New Work Item Extension 3
Expansion and Implementation of Legacy 4
Expansion and Implementation of Software Bill of Materials (SBOM) 4

Progress and Planned Milestones 5
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 Planned 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: 3/4-day WG Meeting
- January 2023: Final documents submitted to IMDRF MC
- **March/April 2023**: Publish Final Legacy and SBOM Documents*

* Pending IMDRF MC Approval
Thank you/Questions

Marc Lamoureux
marc.lamoureux@hc-sc.gc.ca

Suzanne Schwartz/Aftin Ross
Suzanne.Schwartz@fda.hhs.gov/Aftin.Ross@fda.hhs.gov