IMDRF Stakeholders Forum
Sept 2021

Medical Device Cybersecurity Update

US FDA & Health Canada Co-Chairs

Presentation Outline

- New Work Item Extension to expand on and advise on <u>implementation</u> of two concepts introduced in N60: Legacy and SBOM

- Progress and Planned Milestones

Presentation Outline

- New Work Item Extension to expand on and advise on <u>implementation</u> of two concepts introduced in N60: Legacy and SBOM

- Progress and Planned Milestones

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

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

Thank You

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