IMDRF International Medical Device Regulators Forum

IMDRF Stakeholders Forum March 2021

Medical Device Cybersecurity Update

US FDA & Health Canada Co-Chairs

Presentation Outline

- IMDRF/CYBER WG/N60 Final Guidance, published March 2020
  - Purpose and Scope
  - General Principles
  - Introduction of Legacy and Software Bill of Materials (SBOM)

- New Work Item Extension to expand on and advise on implementation of Legacy and SBOM concepts

- Progress and Planned Milestones

Guidance Purpose & Scope

- Purpose:
  - To provide fundamental concepts and considerations on the general principles and best practices on medical device cybersecurity
- Scope:
  - Considers cybersecurity broadly in the context of medical devices that either contain or composed of software, and not just network connected devices
  - Excludes information security and directly state scope includes medical device safety and performance
  - Includes recommendations to all stakeholders, not just manufacturers

General Principles

1. **Global Harmonization**: Stakeholders are encouraged to harmonize their cybersecurity approaches across the entire life cycle of the medical device.

2. **Total Product Life Cycle (TPLC)**: Risks associated with cybersecurity threats and vulnerabilities should be considered throughout all phases in the life cycle of a medical device.

General Principles cont'd

3. **Information Sharing**: Stakeholders are encouraged to engage in information sharing to increase transparency and collaboration to enable the safe and effective use of medical devices.

4. **Shared Responsibility**: All stakeholders must understand their responsibilities and work closely with other stakeholders to respond to potential cybersecurity risks and threats.

Two Concepts introduced in N60

- **Legacy Medical Device:** medical devices that cannot be reasonably protected (via updates, and/or compensating controls) against current cybersecurity threats.

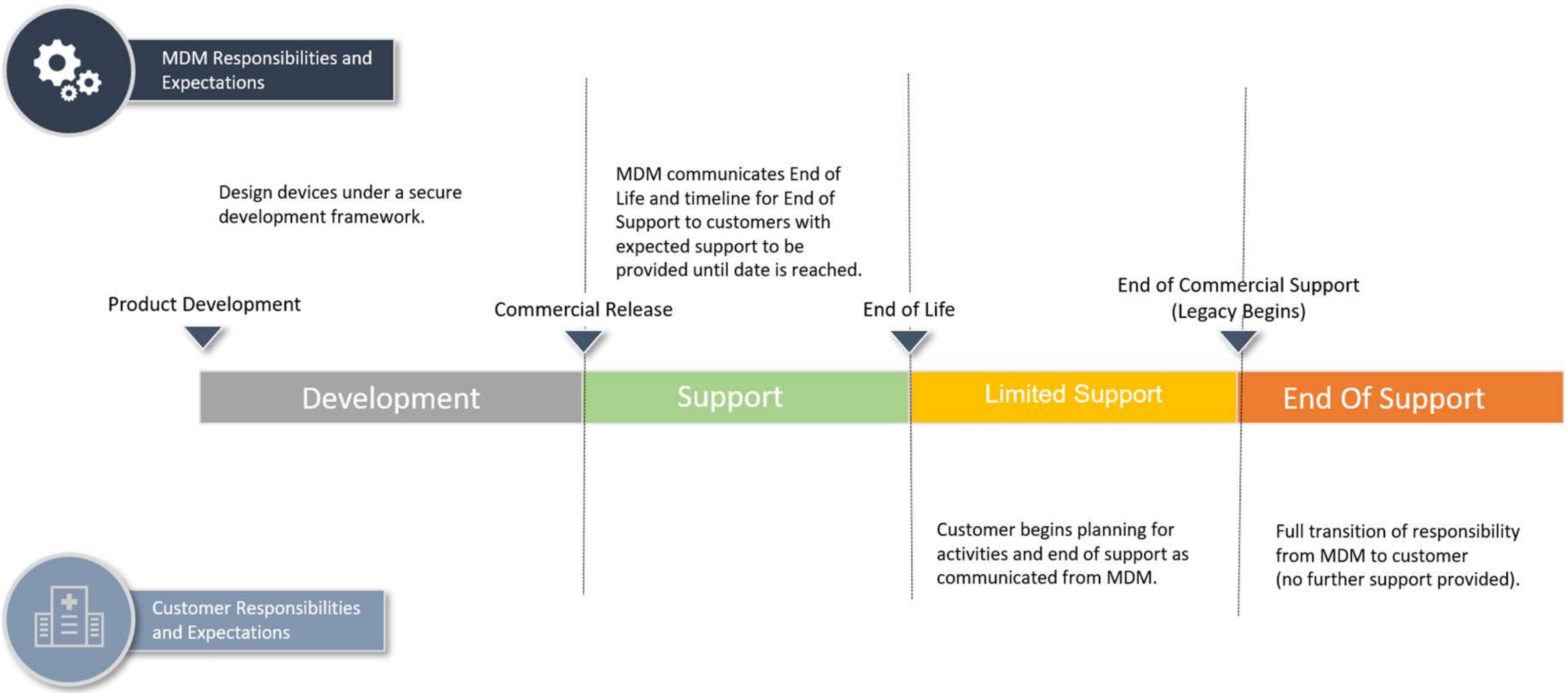
- **Software Bill of Materials (SBOM):** a list identifying each software component by its name, origin, version and build of any commercial, open source, or off-the-shelf software components which are included in the medical device.

Legacy Conceptual Framework

- N60 defined a conceptual framework to define the responsibilities between manufacturer and customer throughout the total product life cycle.
- N60 emphasizes that device age is not a sole determinant of legacy status.
- N60 provides some recommendations to both the manufacturer and the customer throughout the different stages of the total product life cycle.

Legacy Device Conceptual Framework as a Function of TPLC

Cybersecurity and the Total Product Life Cycle



MDM Responsibilities and Expectations

Design devices under a secure development framework.

MDM communicates End of Life and timeline for End of Support to customers with expected support to be provided until date is reached.

Product Development

Commercial Release

End of Life

End of Commercial Support (Legacy Begins)

Development

Support

Limited Support

End Of Support

Customer begins planning for activities and end of support as communicated from MDM.

Full transition of responsibility from MDM to customer (no further support provided).

Customer Responsibilities and Expectations

Medical Device Manufacturer (MDM) follows regional guidance for medical device responsibilities, support levels may vary and as agreed upon with customers.

Software Bill of Materials (SBOM)

- SBOMs can enable device operators to manage their assets and related risks.

- Device operators can use the SBOM to facilitate work with the device manufacturer in identifying software that may have vulnerabilities, update requirements, and performing appropriate security risk management.

- The SBOM can help inform purchasing decisions by providing prospective buyers with visibility into the components used in applications and determining potential security risk.

- Manufacturers should leverage industry best practices for the format, syntax and markup used for deployment of the SBOM.

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 may include: lessons learned regarding construction, granularity, distribution, use, and support of third-party software including SBOM.

2.Operationalizing the legacy device conceptual framework articulated in the N60 document in a related, but separate document.

- Topics may include: additional definitions, legacy device best practices, post-market vulnerability management, economic and regulatory incentives, etc.

Progress and Planned Milestones

- February 3, 2021: New Work Kickoff Meeting
- April 2021: Final Document Outline
- April-October 2021: WG Meetings every two weeks
- October/November: 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