MEDICAL DEVICE CYBERSECURITY WORKING GROUP UPDATE

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GOALS

- To facilitate international regulatory convergence on medical device cybersecurity with open discussion and sharing best practices that are understandable and feasible for all stakeholders.

- Specifically, the WG goal is to produce a document providing medical device cybersecurity guidance for all responsible stakeholders, including manufacturers, healthcare providers, regulator, and users across the entire device lifecycle.

SCOPE

This document is intended to:

- Provide recommendations to aid in minimizing cybersecurity risks across the **total product lifecycle**;
- Recognize that cybersecurity is a **shared responsibility** among all stakeholders which are not only manufacturers but also healthcare providers, patients, regulators, and researchers;
- **Define terms** consistently and clarify the current understanding on medical device cybersecurity;
- Promote broad **information sharing policies** for cybersecurity incidents, threats, and vulnerabilities.

Linkages with Existing IMDRF Documents

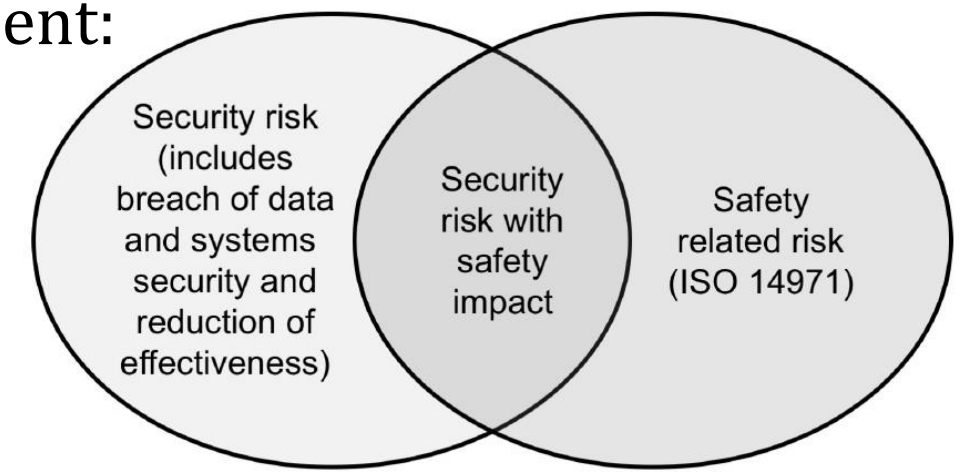
- IMDRF/GRRP WG/N47 FINAL: 2018, in sections 5.5.2 and 5.8 describes information security, IT environment and cybersecurity.

- IMDRF/SaMD WG/N12 FINAL: 2014 describes the importance of information security with respect to safety considerations in Section 9.3.

- It is the intent of this WG to further elaborate on and provide additional clarity and granularity on these topics.

LINKAGES WITH EXISTING IMDRF DOCUMENTS

- For example, the delineation between “information security” and “cybersecurity” needs further clarity and references in N47 and N12 could potentially be mapped to an accepted concept in security risk management:



AAMI TIR57: 2016 Principles for medical device security – Risk Management

ACTIVITIES TO DATE

- Kick-off meeting was in January 10, 2019.
- Meetings are occurring every 2 weeks
- Draft guidance document outline: January 24, 2019
- Final guidance document outline: February 7, 2019
- Guidance section drafting and iterative review February 21,2019 to April 7, 2019

Workplan and Milestones

1. Draft guidance document outline: January 24, 2019
2. Final guidance document outline: February 7, 2019
3. Guidance section drafting and iterative review February 21,2019 to April 7, 2019
4. 1st guidance draft: April 18, 2019
5. 2nd guidance draft: May 23, 2019
6. In-person WG working meeting: June 10-13, 2019, Medical Imaging & Technology Alliance (MITA) office in Arlington, Virginia
7. Submit draft Guidance to IMDRF Management Committee : August 2019

WORKPLAN AND MILESTONES

8. Proposed document plan to be out for Public Consultation: October and November 2019
9. Review and Organize Public Comments: December 2019
10. In-person meeting to produce a final guidance document: January 2020
11. Submit Final Guidance for approval to Management Committee Meeting: February 2020

Next Steps

- 1st guidance draft: April 18, 2019
- 2nd guidance draft: May 23, 2019
- June 10-13, 2019: In-person WG meeting, Arlington, VA, USA
- August 2019: Draft Guidance to IMDRF Management Committee

THANK YOU