DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

IMDRF/DITTA Joint Virtual Workshop

Monday 21 Sept. 2020

Cybersecurity - Where are we today?

DITTA Cybersecurity Activity

Keiichiro Ozawa

Vice-chair of DITTA Cybersecurity WG

1. Cybersecurity Activities in IMDRF

1. Activities in IMDRF

1-1 Promote and raise the global momentum of Cybersecurity

- IMDRF SaMD Guidance (IMDRF/SaMD WG/N12*) describes the importance of *information security with respect to safety considerations* in Sec. 9.3. (2014)

1. DITTA has recognized the worldwide importance of cybersecurity since then and promoting cybersecurity as the IMDRF work item.
2. DITTA held the **1st workshop** on cybersecurity in Brasilia (2016)
3. DITTA released the **1st white paper** on cybersecurity (2016)

- FDA released "Post Market Management of Cybersecurity" (2016)

**** http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf***

1. Activities in IMDRF

1-2 Development of New Work Item Proposal of IMDRF

4. DITTA held the **2nd workshop** on cybersecurity accompanying IMDRF meetings in Shanghai (March 2018).
   - Raising the cybersecurity awareness of both regulators and industries in the medical device field
   - Discussion on New Work Item Proposal among regulators.

5. DITTA Developed the **New Work Item Proposal** (March – May 2018)

6. Submission of NWIP to IMDRF Management Committee (June 2018)
   - **IMDRF MC approved the NWIP** (Beijing, Sep. 2018)

7. DITTA presented the importance of the global harmonization of cybersecurity in AHWP Annual Meeting(Kuala Lumpur, Nov. 2018)

1. Activities in IMDRF

1-3 Three important points in NWIP

Topic 1: Shared responsibility among stakeholders

Cybersecurity is a shared-responsibility among all stakeholders, including manufacturers, healthcare providers, regulators, patients, and others.

Topic 2: Information sharing

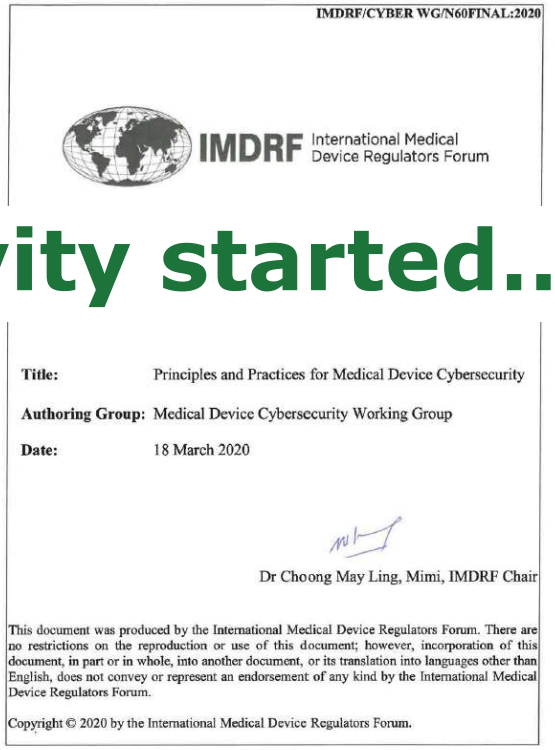
Broad information-sharing policies to have clearly established legal guardrails and create incentives for participation.

Topic 3: Definition

Define the terms and clarify the current understanding on medical device cybersecurity. It is necessary to clarify and define that medical device cybersecurity is different from information security which maintains confidentiality, integrity and availability.

1. Activities in IMDRF

And WG activity started… (Jan. 2019)



IMDRF/CYBER WG/N60FINAL:2020

IMDRF International Medical Device Regulators Forum

Title: Principles and Practices for Medical Device Cybersecurity

Authoring Group: Medical Device Cybersecurity Working Group

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

1. Activities in IMDRF

1-4 Suggestion by DITTA in the IMDRF cybersecurity work item

1. **DITTA has been and will be supporting the IMDRF activity**
   - DITTA organizes mirror groups and supports the activities in IMDRF!
2. **Scope and definition**
   - The scope is well described in the Guidance Document. But DITTA would like to put more stress on the **difference between "medical device cybersecurity" and "information security"**.
3. **Feasibility of the guidance document**
   - Currently the implementation of the Document attracts much attention from stakeholders. The key is the feasibility. DITTA would like to recommend each jurisdiction would consider one's own regulatory background and implement the document.

2. DITTA Whitepapers

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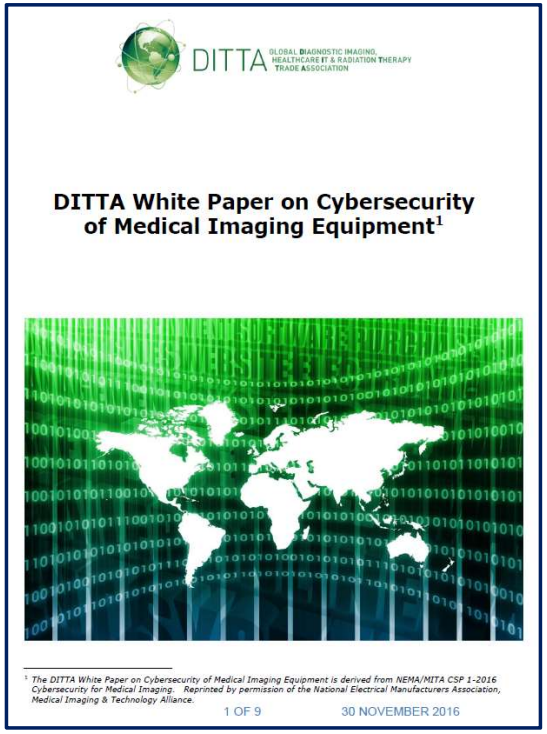
2-1 DITTA White Paper on Cybersecurity of Medical Imaging Equipment

- Issued in November, 2016
- Based on NEMA/MITA Cybersecurity for Medical Imaging
- Detailed cybersecurity best practices for manufacturers, suppliers and healthcare providers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DITTA White Paper on Cybersecurity of Medical Imaging Equipment[1]

[1] The DITTA White Paper on Cybersecurity of Medical Imaging Equipment is derived from NEMA/MITA CSP 1-2016 Cybersecurity for Medical Imaging. Reprinted by permission of the National Electrical Manufacturers Association, Medical Imaging & Technology Alliance.

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http://www.globalditta.org/fileadmin/user_upload/Level_home/Press_releases/2016/DITTA_Cybersecurity_paper_29_Nov._2016_final_clean.pdf

2. DITTA Whitepapers

2-2 DITTA White Paper on Cybersecurity: Best Practices in the Medical Technology Manufacturing Environment

- Issued in February, 2019
- Based on NEMA CPSP 2-2018 Cyber Hygiene Best Practices
- A set of industry best practices and guidelines within the medical technology manufacturing facility and engineering processes

https://www.globalditta.org/uploads/media/DITTA_White_paper_on_Cybersecurity_-_Feb._2019_-_Final.


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DITTA White Paper on Cybersecurity:

Best Practices in the Medical Technology Manufacturing Environment

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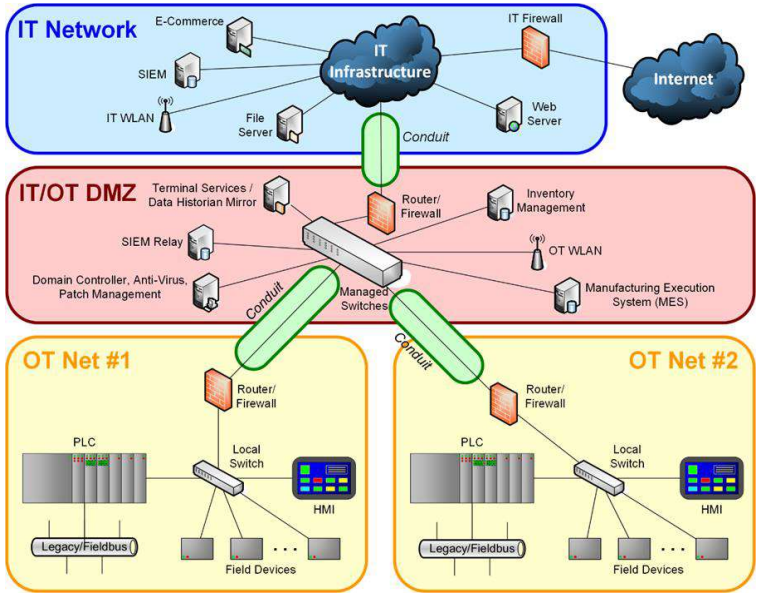
2. DITTA Whitepapers

Seven fundamental principles for manufacturing facility and engineering process

1. Segmenting Networks
2. Understanding Data Types and Flows
3. Hardening Devices
4. Monitoring Devices and Systems
5. User Management
6. Updating Devices
7. Providing a recovery plan/escalation process



Segmenting networks

2. DITTA Whitepapers

2-3 DITTA White Paper on Cybersecurity: *Title tbd*

- In progress to be issued this year
- Based on NEMA CPSP 3-2019 Cyber Hygiene Best Practices Part 2
- Industry best practices and guidelines that medical technology imaging manufacturers may consider when providing cybersecurity information to their customers
- It provides suggestions for how customers can work with their respective manufacturers.

3. DITTA Perspective on Cybersecurity

3. DITTA Perspective on Cybersecurity

As an international trade association we can contribute to medical device cybersecurity in terms of manufacturers by

1. Continuing development of **best practice documents** which are practical, feasible and promising quick effect
2. **Recognizing significant international standards**
3. Encouraging **information sharing** between manufacturers and healthcare providers by MDS2*

* SBoM and MDS2 will be discussed by the next speaker.

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THANK YOU!

Keiichiro Ozawa

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