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?

Best Practice Security Documentation

Ken Zalevsky

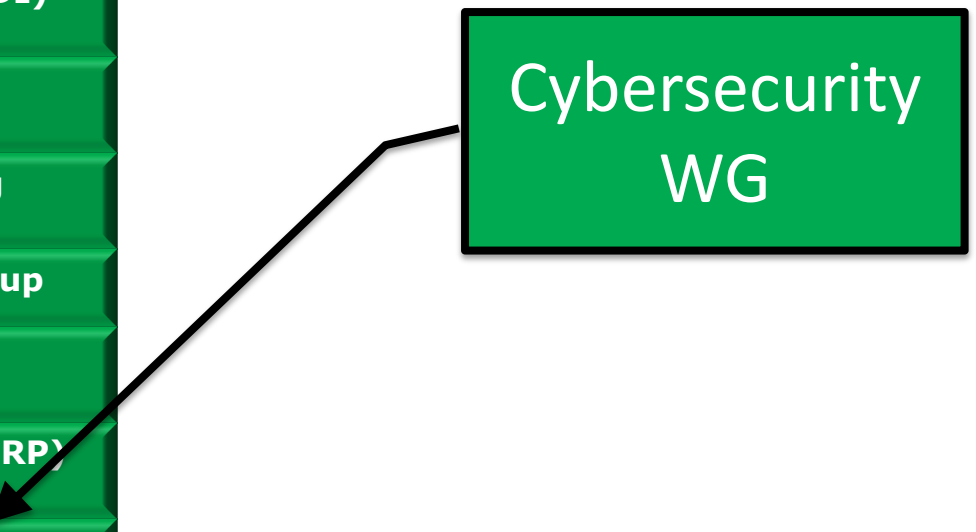
Chair of DITTA Cybersecurity WG

Global Presence

2018: DITTA as a recognized non state actor in official relations with WHO
2016: DITTA MoU with the World Bank
2015: DITTA was granted a NGO status with WHO
2014: DITTA has official liaison with AHWP

Working Groups

1. Regulated Product Submission (RPS) Working Group
2. Medical Device Single Audit Program (MDSAP) Working Group
3. Unique Device Identification (UDI) Working Group
4. Standardisation (STA) Working Group
5. Clinical Evaluation (CE) Working Group
6. Global Health (GH) Working Group
7. Environmental Policy (ENVI) Working Group
8. Good Refurbishment Practice (GRP) Working Group
9. Cybersecurity Working Group
10. Medical Software & AI (MSW & AI) Working Group



Contribution to Medical Device Cybersecurity

1. Development of **best practice documents**

2. Supporting harmonization of significant **international standards**

3. Encouraging **information sharing** between manufacturers and healthcare providers via **security documents** such as the **MDS²** (Manufacturer Disclosure Statement for Medical Device Security) and **SBoM** (Software Bill of Materials)

MDS²

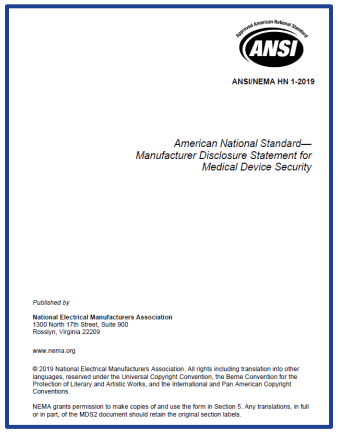
Manufacturer **D**isclosure **S**tatement for **M**edical **D**evice **S**ecurity (MDS²)

- MDS² v1.0 published in November 2004
- Last version of MDS² published October 2013
- Current official release published October 2019

  https://www.medicalimaging.org/2019/10/09/mita-releases-national-standard-for-medical-device-security/

Four new categories in current MDS² release

1. RMOT: Remote Service and Administration
2. **SBoM: Software Bill of Materials**
3. CONN: Connectivity Capabilities
4. MPII: Management of Personally Identifiable Information



ANSI

ANSI/NEMA HN 1-2019

American National Standard—
Manufacturer Disclosure Statement for
Medical Device Security

Published by

National Electrical Manufacturers Association
1300 North 17th Street, Suite 900
Rosslyn, Virginia 22209

www.nema.org

SBOM

Software Bill of Materials (SBoM)

- Actively maintained list of software components in a medical device
  - May also include vulnerabilities associated with those components

- Has been gaining global attention and being referenced in guidance docs
  - USFDA, Health Canada, Australian Therapeutic Goods Association (TGA), EU MDR, others…

- MDMs being requested to provide to customers and prospective customers

- US National Telecommunications and Information Administration (NTIA) developing a standardized SBoM format across all verticals, including healthcare

- USFDA is closely following NTIA activity as they prepare to release ***Content of Premarket Submissions for Management of Cybersecurity in Medical Devices***

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Thank you!