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

KMDIA Virtual Seminar

Advancement of Global Medical Device Regulation: Cybersecurity

Industry Perspective on Cybersecurity

Ken Zalevsky

Chair of DITTA Cybersecurity WG

Thursday 29, July 2021

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DITTA 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

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DITTA: 10 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

Cybersecurity WG

IMDRF

IEC ISO

AHWP

IAEA International Atomic Energy Agency

World Health Organization

WORLD BANK GROUP

BASEL CONVENTION

UNEP

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As an international trade association DITTA can contribute to medical device cybersecurity by

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)

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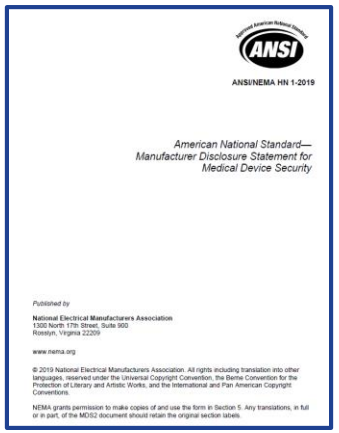
3-1 MDS2: MITA (DITTA member association, USA)

Manufacturer **D**isclosure **S**tatement for **M**edical **D**evice **S**ecurity (MDS^2)

- MDS^2 v1.0 published in November 2004
- Last version of MDS^2 published October 2013
- Current official release published October 2019
- https://www.medicalimaging.org/mita-news/view/mita-releases-national-standard-for-medical-device-security

Four new categories in current MDS^2 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

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Software Bill of Materials (SBoM)

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

- SBOM gaining global recognition and being referenced in laws and regulatory guidance
  - US President Biden signed Executive Order 14028 into law on May 12, 2021 – SBOM required by Feb 12, 2022
  - USFDA, Health Canada, Australian Therapeutic Goods Association (TGA), EU MDR, others…

- Standard SBoM format and elements developed as part of Executive Order 14028
  - **SBOM elements:** Supplier Name, Component Name, Component Version, Unique ID, Dependency, Author, Timestamp
  - **SBOM format:** Software Identification (SWID) tags, Software Package Data Exchange (SPDX), CycloneDX

- 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!

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