



IMDRF/DITTA Joint Virtual Workshop

Monday 21 Sept. 2020

Cybersecurity - Where are we today?

Regulatory Update in Japan Introduction of IMDRF Guidance

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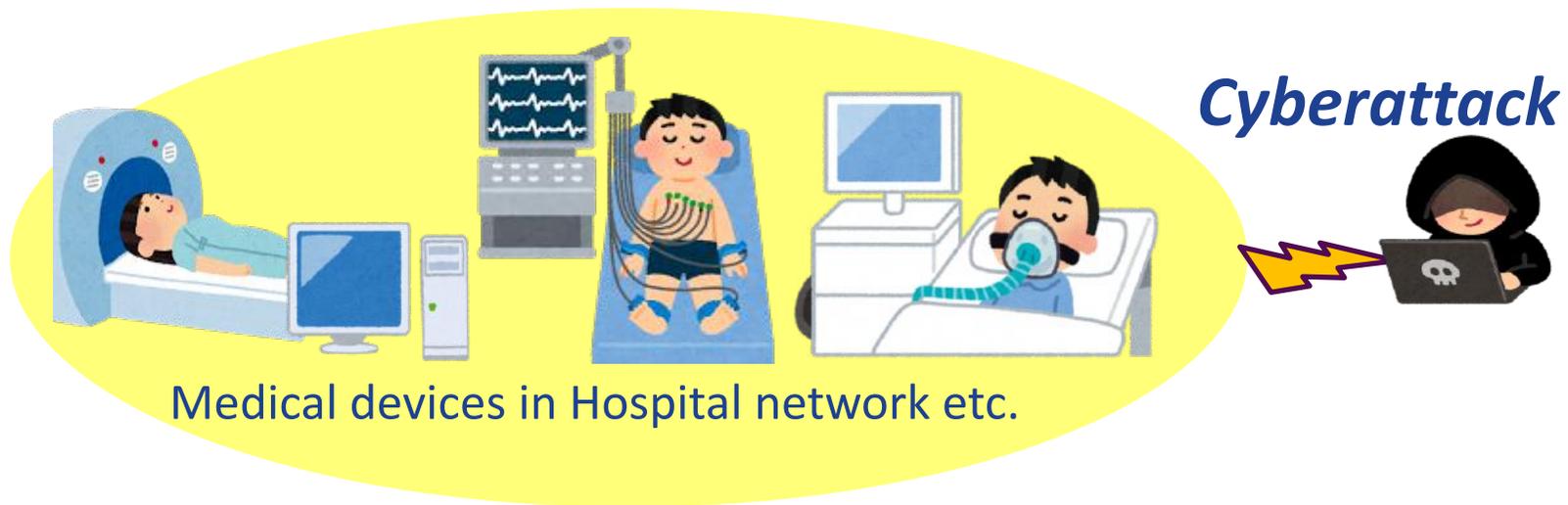
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Recent Trends in Cybersecurity Assurance of Medical Devices in Japan

The following risks are assumed in the event of a cyberattack on a medical device

- ***Suspension of diagnosis or incorrect diagnosis*** (e.g., Testing or Diagnostic system)
- ***Interruption of treatment*** (e.g., Therapeutic device),
- ***Excessive or inadequate irradiation*** (e.g., Radiation therapy system).



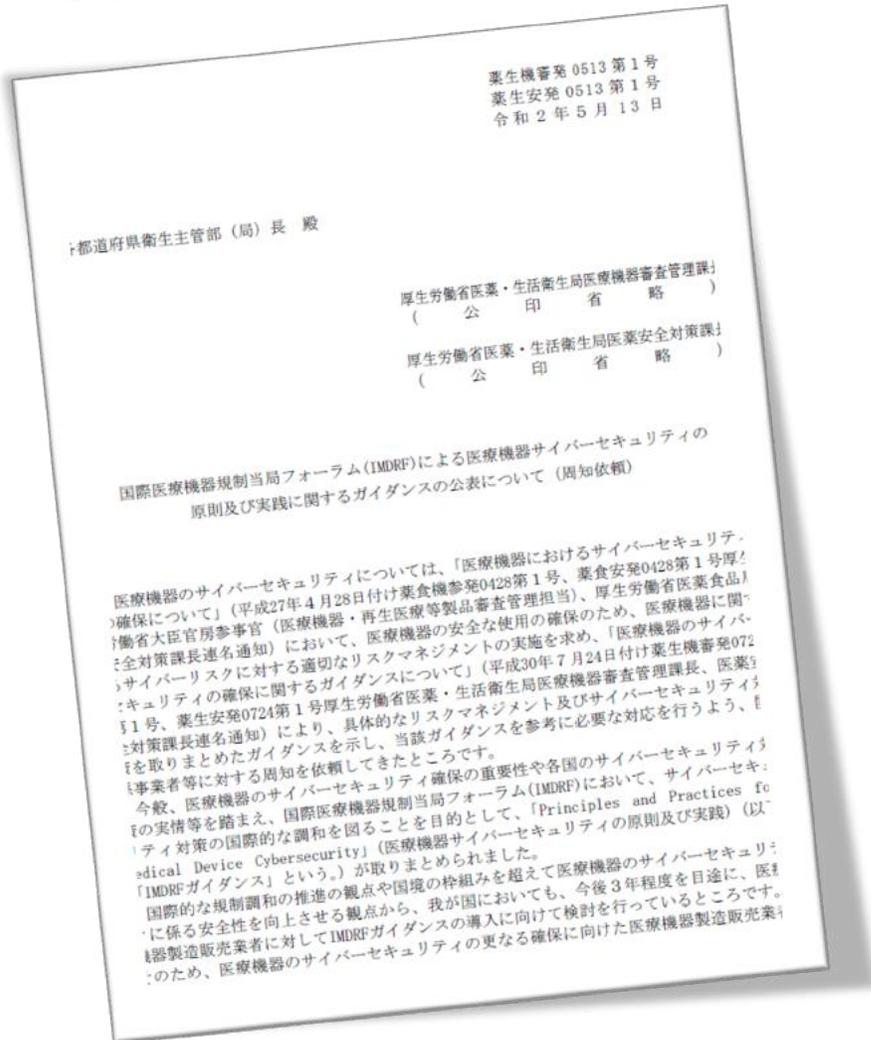
MAHs for medical devices:

Requested evaluate the cybersecurity risks properly

By notification; “Guidance on Ensuring Cyber Security of Medical Devices”, July 24, 2018



Notification regarding IMDRF Guidance



*To Japanese Stakeholders
Informed “IMDRF Guidance” released
(May 13, 2020; Administrative notification)*

➡ Contribute to improve the safety of medical device cybersecurity.
(e.g.; SBoM, CVD, etc. are important for cybersecurity)

**This notification enhances medical device cybersecurity in Japan
(For Japanese manufacturers/other stakeholders)**

How to introduce the IMDRF Guidance to Japan?

2020.03

IMDRF Guidance

FIX

Taking in...

Japanese Guidance for Cybersecurity of medical device

“Guidance on Ensuring Cyber Security of Medical Devices” , PFSB/ELD/OMDE/C0428 No.1 and PFSB/SD 0428 No.1,
April 28, 2015
“Guidance on Ensuring Cyber Security of Medical Devices” , PSEHB/MDED0724No.1 and PSEHB/PSD 0724 No.1,
July 24, 2018

Next guidance?

Main Tasks (Methodology for implementation)

- *Discussion with stakeholders such as...
MAHs, medical staff (Dr, Ns, etc.), IPA, PMDA, etc.,
- *Assignment of roles such as...
Reporting for Adverse events, Cybersecurity incidents, etc.,



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



IMDRF International Medical
Device Regulators Forum

Thank you!