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Developments of eHealth security in standards and regulations

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Normkonferansen 2019

innovation + you

Healthcare is increasingly depended on ICT

Systems are increasingly connected

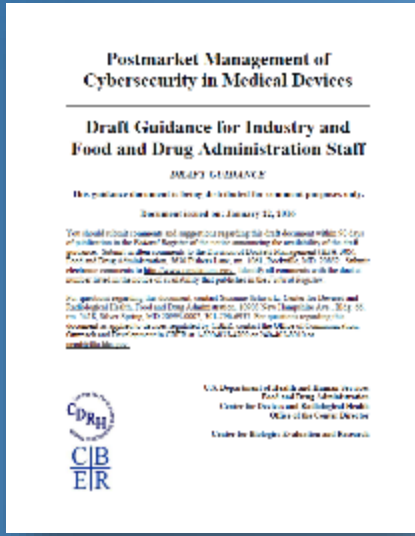
Increase in Health-IT services

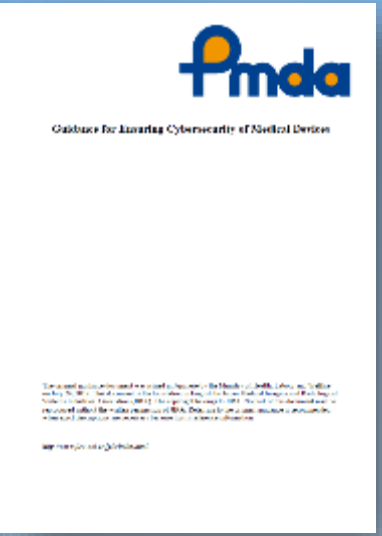
Digital transformation also increases security risks

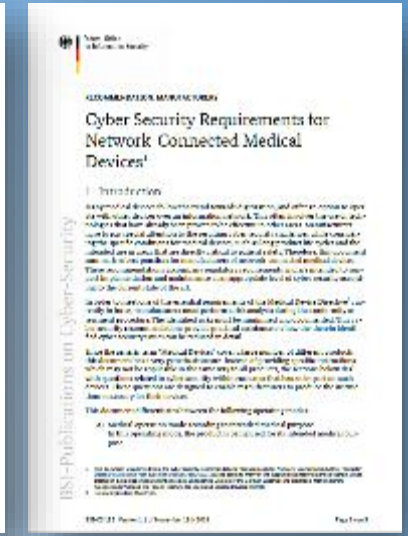
Safety versus Security

Safety versus Security

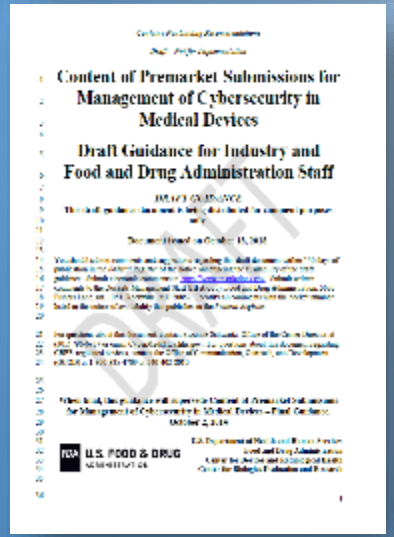
There is a lot of regulatory security guidance out there…

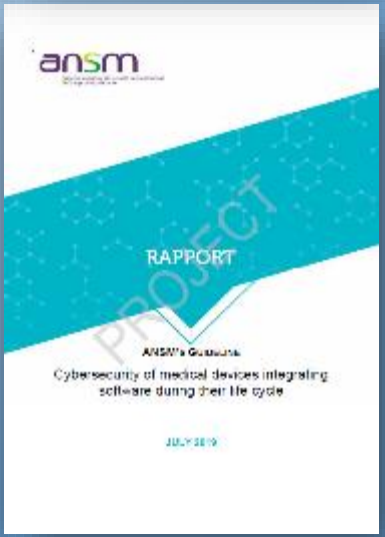


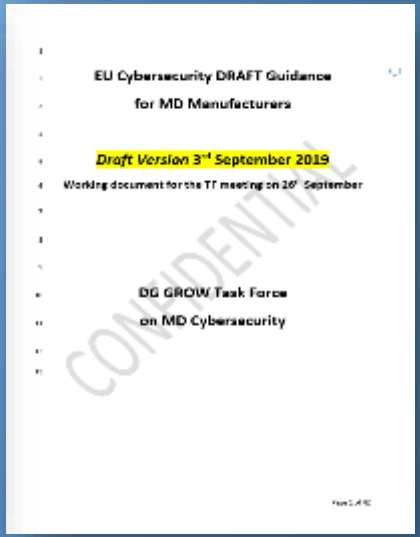




In development ➔







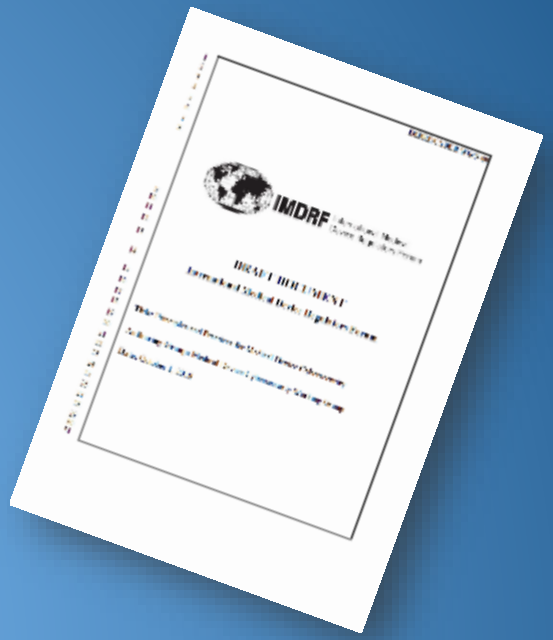
Australian Guidance

- Total lifecycle approach (TPLC)
- References NIST Framework
- Recognizes AAMI TIR 57, UL 2900, ISO 27799, ISO/IEC 29147, ISO/IEC 30111, and others
- Stress on information sharing and vulnerability disclosure
- Stress on supply chain assessment
- References FDA guidance, NIST, IMDRF, but also South Korean and ECRI

Canadian Guidance

- Total lifecycle approach (TPLC)
- References NIST Framework
- Strong reference to TIR 57, NIST 800-30 and UL 2900
- Expect post market patching/monitoring plan in submission
- Expect a security risk management in parallel with safety risk management – in line with TIR 57, i.e. a dedicated security risk management process

DRAFT IMDRF Principles and Practices for Medical Device Cybersecurity



- Currently out for public consultation, closes on 2 Dec. http://www.imdrf.org/consultations/cons-ppmdc.asp
- Details concepts around
  - Total lifecycle approach (TPLC)
  - Shared responsibility
  - Information sharing
  - Documentation
  - Post market requirements
  - Coordinated vulnerability disclosure
- References to many standards and other guidance's, e.g. ISO 80001

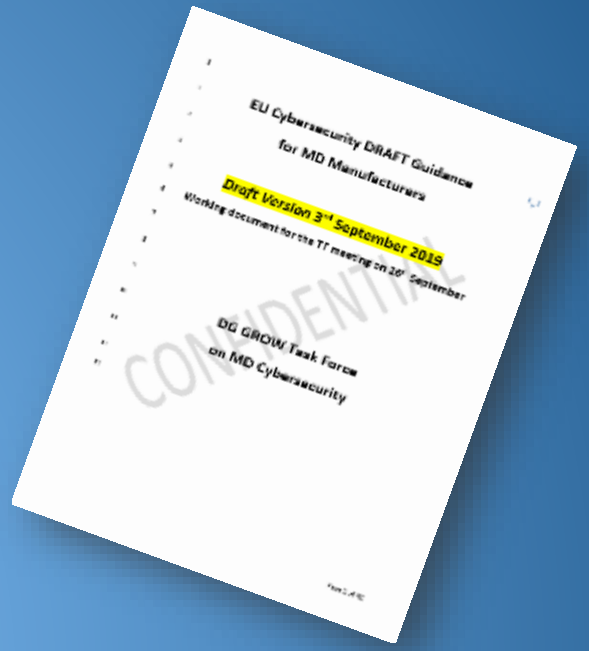
European Medical Device Regulation
Security specific requirements

Organization: State of the art information security manufacturing.

Annex I.17.2

Device: **Environment** Annex I.14.2.(d)	**Device:** **Repeatability** Annex I.17.1	**Device:** **Reliability** Annex I.17.1	**Device:** **Performance** Annex I.17.1	**Device:** **Access Control** Annex I.17.4 Annex I.18.8	**Labeling:** **security measures** **network characteristics** Annex I.17.4 Annex I.23.4(ab)

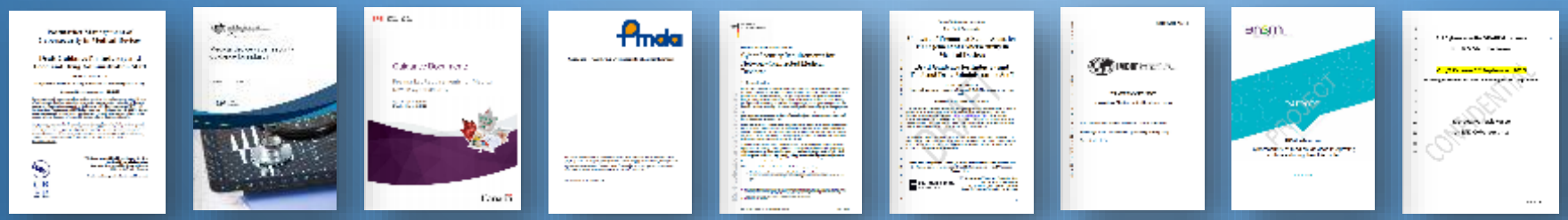
DRAFT MDR & IVDR security guidance


EU Cybersecurity DRAFT Guidance
for MD Manufacturers
Draft Version 3rd September 2019
Working document for the TF meeting on 26th September
DG GROW Task Force
on MD Cybersecurity
CONFIDENTIAL

- Being developed by DG Grow, Joint Research Center, European regulators, ENISA, notified bodies, hospitals and industry associations
- Details concepts around
  - Relation between safety and security risk management
  - Shared responsibility
  - Security requirements for the operating environment
  - Documentation
  - Post market surveillance and vigilance
- References to ISO 80001 series, IEC 62443, 27001, 14971 and 31000
- Expected to be approved during the MDCG meeting, December 13

Consistent items across regulations

- **Security Risk Management**
- **Security by Design** (and by default)
- **Shared Responsibility**
- **Total lifecycle with post market security requirements:**
  - Vulnerability and Patch management
  - Coordinated Vulnerability Disclosure
- **Standards**



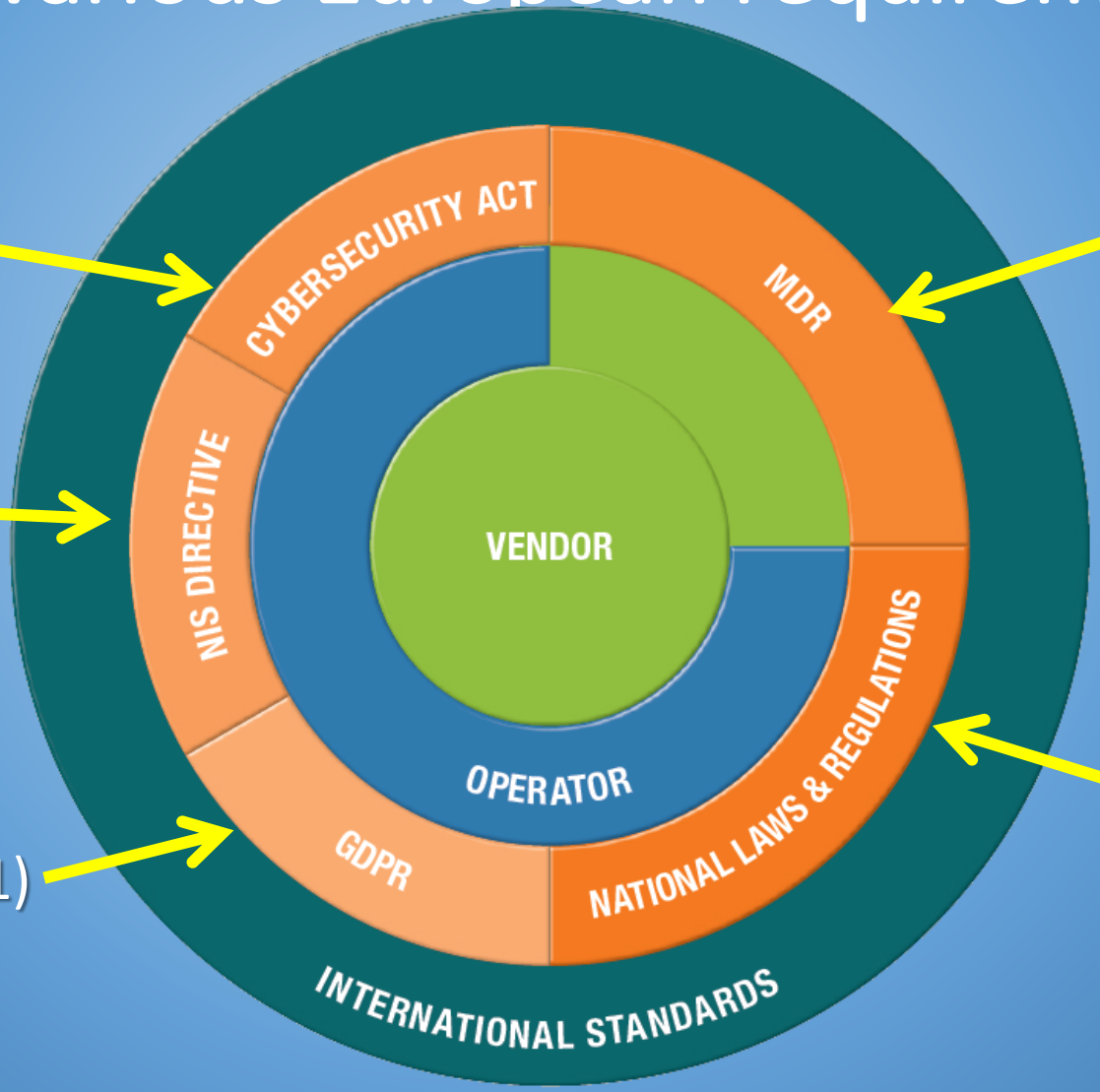
Do we manage on Risk or on Compliance?

Product compliance to which security standard? A view on the various European requirements

ISO 27000 series,
ISO 15408, and… ?

ISO 15408, IEC 62433,
ISO 27000 series, and… ?

ISO 27000 series (new 27701)



……?
(IEC 80001-2-8,
IEC 62443 ?)

National standards,
ISO 27000 series,
and… ?

Security requirements for the operating environment

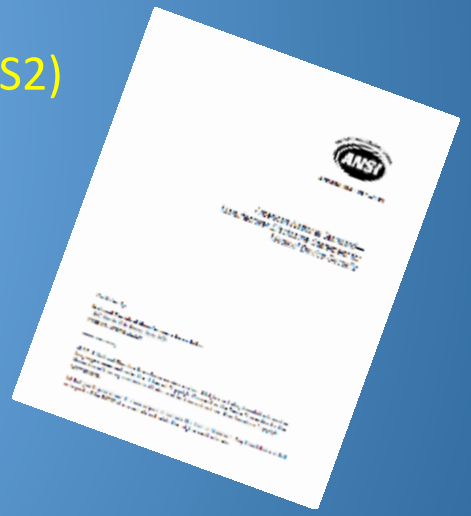
Shared responsibility

Healthcare specific security standards

- There are security elements in several medical device standards (e.g. IEC 60601-1 Ed 3.1) but there are no specific security standards which are directly applicable to medical devices or medical software.
- Only a few standards focus on healthcare security but mainly address the Health Delivery Organizations, e.g.:
  - ISO 80001 series – Application of risk management for IT-networks incorporating medical devices
  - ISO 27799 – Information security management in health using ISO/IEC 27002

ISO / IEC 80001 series

- 80001-1 Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities
- 80001-2-1 Step-by-Step Risk Management
- 80001-2-2 Communicating Security Needs, Risks & Controls
  - ➔ Manufacturers Disclosure Statement for Medical Device Security (MDS2)
- 80001-2-3 Wireless Guidance
- 80001-2-4 HDO Implementation Guidance
- 80001-2-5 Distributed Alarm Systems
- 80001-2-6 Responsibility Agreements
- 80001-2-7 Conformance Self-assessment Guidance
- 80001-2-8 Mapping Security Controls to the 19 Capabilities of 80001-2-2
- 80001-2-9 Security Assurance Case for the 19 Capabilities of 80001-2-2



“Base” security standards

There are a large number of security standards from (inter)national Standards Development Organisations and many other organisations, e.g.:

- ISO 27000 series – Generic Information security
- IEC 62443 series – Industrial control systems security
- National Institute of Standards and Technology (NIST) – Risk Management / Cybersecurity frameworks
- Open Web Application Security Project (OWASP)
- etc..

There is not a single silver bullet! Selecting the best fit:

- Security has to be balanced against safety and performance
- Security has to fit the intended use and intended operating environment
- Security has to fit the used technologies
- Operational Security versus Information Security

  IT → Confidentiality, Integrity, Availability

  OT → Availability, Integrity, Confidentiality

ISO/TC215 and IEC/TC62 development activities related to MDD/Health-IT security

Update ISO/IEC 80001-1(:2020-Q1)
Health informatics — Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software - Part 1: Application of risk management

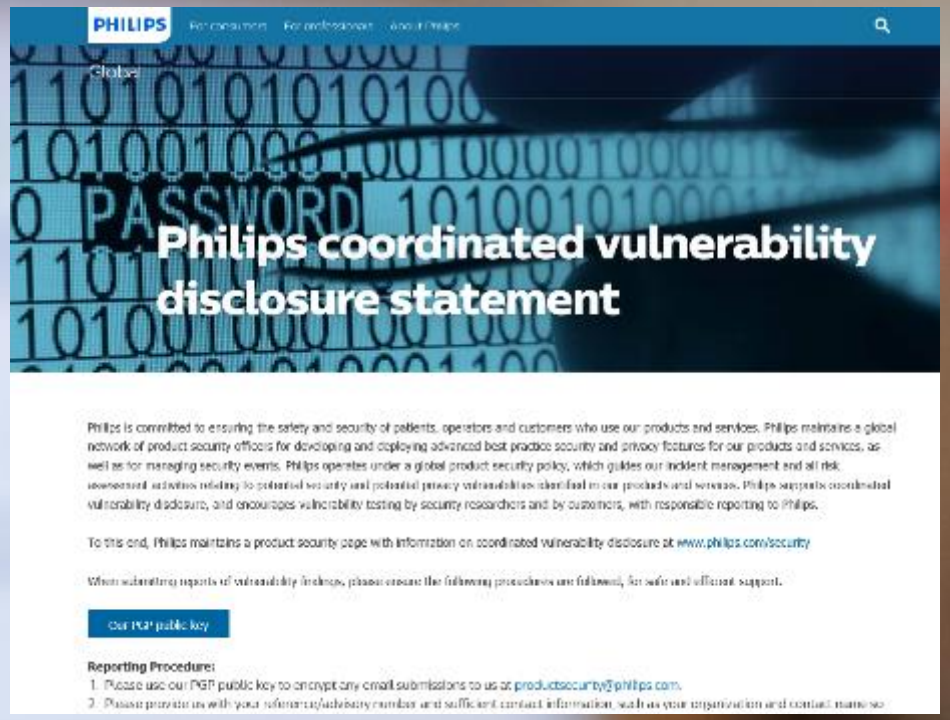
NWIP ISO/IEC 80001-5-1(:2021-Q4) [***Based on IEC 62443-4-1***]
Health informatics — Safety, security and effectiveness in the implementation and use of connected medical devices or connected health software – Part 5: Security – Sub-Part 5-1: Activities in the Product Lifecycle

NWIP IEC TR 60601-4-5(:2020-Q2) [***Based on IEC 62443-4-2***]
Medical electrical equipment – Part 4-5 Guidance and interpretation – Safety related technical security specifications for medical devices

NWIP ISO/IEC 81001-1(:2020-Q4)
Health informatics — Health software and health IT systems safety, effectiveness and security — Part 1: Foundational principles, concepts and terms

NWIP ISO/IEC 82034-2(:2021-Q2) [*Started as a CEN/TC 251 project, based on BSI PAS 277*]
Health informatics —Quality and reliability criteria for health and wellness apps

Coordinated Vulnerability Disclosure



ISO/IEC 29147; Vulnerability Disclosure

ISO/IEC 30111; Vulnerability Handling process

- Determine market specific requirements for product and of the environment
- Develop your state of the art
- Address the total lifecycle

Questions?

Security

Fast response

In Control

Minimized risk

There are some viruses doctors can't treat.