Cybersecurity across the healthcare continuum

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Healthcare is increasingly depended on ICT

Systems are increasingly connected

Systems are increasingly wireless

Systems become more ‘intelligent’

Shift from products to services

Safety versus Security

Exchange of security information is essential

Integration of networks and responsibilities?

Shared responsibility

Digital transformation also increases security risks


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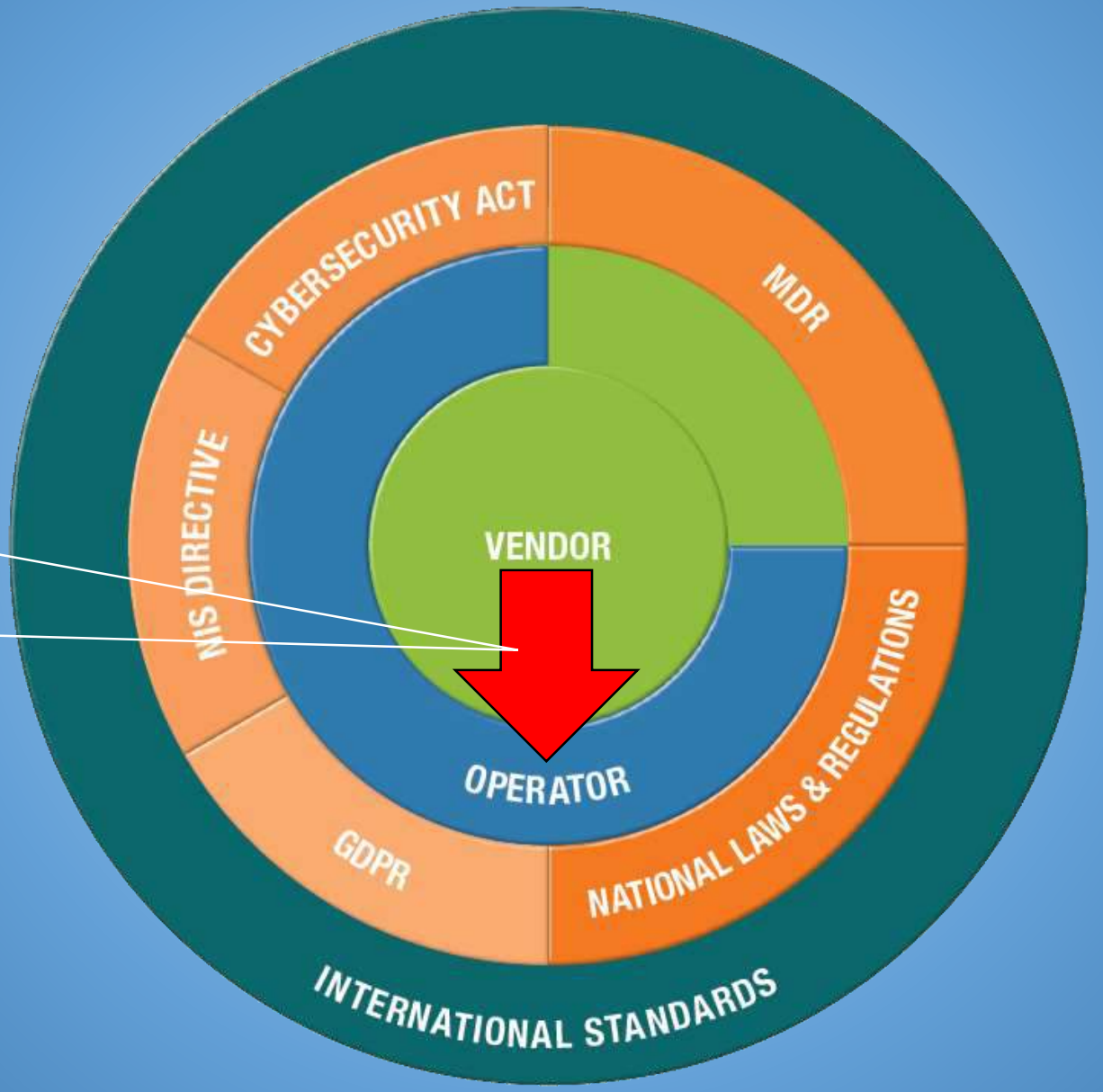
Video Assessment
Do we manage on Risk or Compliance?

Compliance to which security requirements?

Define minimum requirements for the "intended environment"



Note: this is a simplified view, which does not show the entire complexity

To support secure healthcare in Europe, COCIR has developed the following recommendations for consideration by European, national and regional regulators:

1. **SET UP** a broad European discussion to establish good security practices in all regulatory frameworks, in order to reduce market access limitations, conflicting requirements and unnecessary administrative burden.
2. **PROMOTE** regulatory convergence between EU Member States and industry sectors.
3. **DEVELOP** European guidance that clarifies the concept of shared responsibility, including criteria for determining the device's intended environment.
4. **ADOPT** the new MDS2 form (currently under revision and expected to be adopted in Summer 2019) as a means of documenting and communicating medical device security and privacy features in Europe.
5. **COORDINATE** an European approach to security-related incident reporting, in order to avoid duplication and confusion.
6. **SAFEGUARD** a level playing field by ensuring that consistent and effective market surveillance measures are in place to warrant compliance with the existing regulatory framework.
7. **AVOID** multiple certification schemes for the same technologies and processes.

Examples of security related (Healthcare) standards that can be used in the life cycle of medical devices and health software

Pre-market process	*Product Features*	*Documents*	*Post-market process*
Establish secure development lifecycle	**Build products with the appropriate security controls**	**Specify secure use**	**Security Management (updates and upgrades)**

ISO/IEC 27034, IEC 62443-4-1, IEC 62304*, 82304, 80001-5-1*

NIST FIPS 199 Security Categorization

Threat/Risk Analysis
ISO 14971*
NIST SP800-30
IEC 62443-3-2*
ISO 20004
ISO 27005
ISO 31000

ISO 270xx (Lifecycle)
ISO 12207
ISO 15228
NIST SP800-160
SAFECode
OWASP
MITRE CWE & CAPEC

IEC 60601-1 Safety
EN 45502-1 & ISO 14708-1 Active implants
ISO 22696 PHD Identification & Authentication
IEC 60601-4-5 Safety related security spec*
ISO 11633-1/2 Remote Service
ISO 13606-4 EHR
IHE IT Infrastructure Profiles
NIST SP800-53 Security C
ISO 15408 Common Crite

ISO
18004 Timestamps
18033 Encryption
18367 Crypto algorithms
18370 Digital Signatures
19592 Secret Sharing
19772 Auth. encryption
27040 Secure Storage

NIST FIPS
140-2 Crypto Mod
180-4 Hashing
186-4 Digital Signatures
193 Platform Resilience
197 Encryption
198-1 Hash Msg Auth
200 Min Security Reqmts
201 Person Authentic
202 SHA-3

ISO 15026-1/2
Assurance case

ISO 15443-1/2
Security assurance

IEC 80001-2-2
IEC 80001-2-8
IEC 80001-2-9
HIMSS NEMA
MDS2*
CLSI AUTO-11-A2

ISO/IEC 29417 Disclosure
ISO/IEC 30111 Vul./Incident

ISO 270xx Information Security Management (Product operations)

Black = Healthcare specific
*** = New or being revised**

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

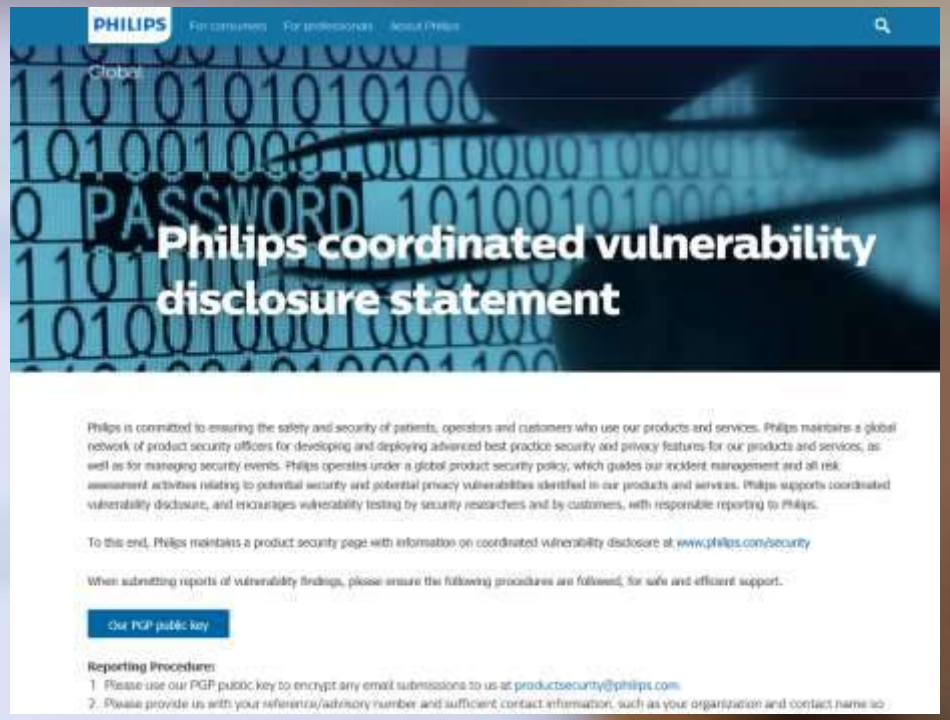
NWIP ISO/IEC 80001-5-1(:2021-Q4)
Health informatics — Safety, security and effectiveness in the implementation and use of connected medical devices or connected health software – Part 5: Security – Sub-Part 5-1: Activities in the Product Lifecycle

NWIP IEC TR 60601-4-5(:2020-Q2)
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

Update IEC 62304 ED2 (:2020-Q2)

Coordinated Vulnerability Disclosure



ISO/IEC 29147; Vulnerability Disclosure

ISO/IEC 30111; Vulnerability Handling process

ADVANCING

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MARCH 2019

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European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

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Sustainable Competence in Advancing Healthcare

Security

Fast response

In Control

Minimized risk

There are some viruses doctors can't treat.