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

IMDRF International Medical Device Regulators Forum

IMDRF/DITTA Joint Virtual Workshop

12 September 2022

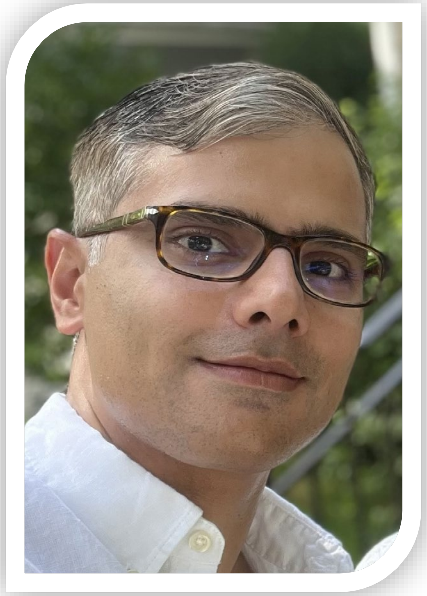
Health Software Standards – Security

Needs & Challenges

Varun Verma

Philips Healthcare / DITTA Cybersecurity WG Vice-Chair

BIO



Varun Verma
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Global Manager – Regulations & Standards at Philips Healthcare

- In the medical device industry for a little over 12 years in varying roles within R&D, engineering and global regulations and standards
- Current areas of focus include but are not limited to security and privacy in the healthcare field

Leadership role within DITTA:

- Vice-Chair of DITTA Cybersecurity Working Group

Expert Roles:

- In various national and international standards technical committees and working groups (ISO, IEC, AAMI), public private entities like HSCC, U.S. based trade associations including AdvaMed, MITA, HSCC, MDMA, CTA.

AGENDA

- Brief overview of security* related standards
- Considerations for developing healthcare related security standards
- Need for regulatory stakeholder collaboration
- Key challenges

* **NOTE:** Terms security and cybersecurity are used interchangeably.

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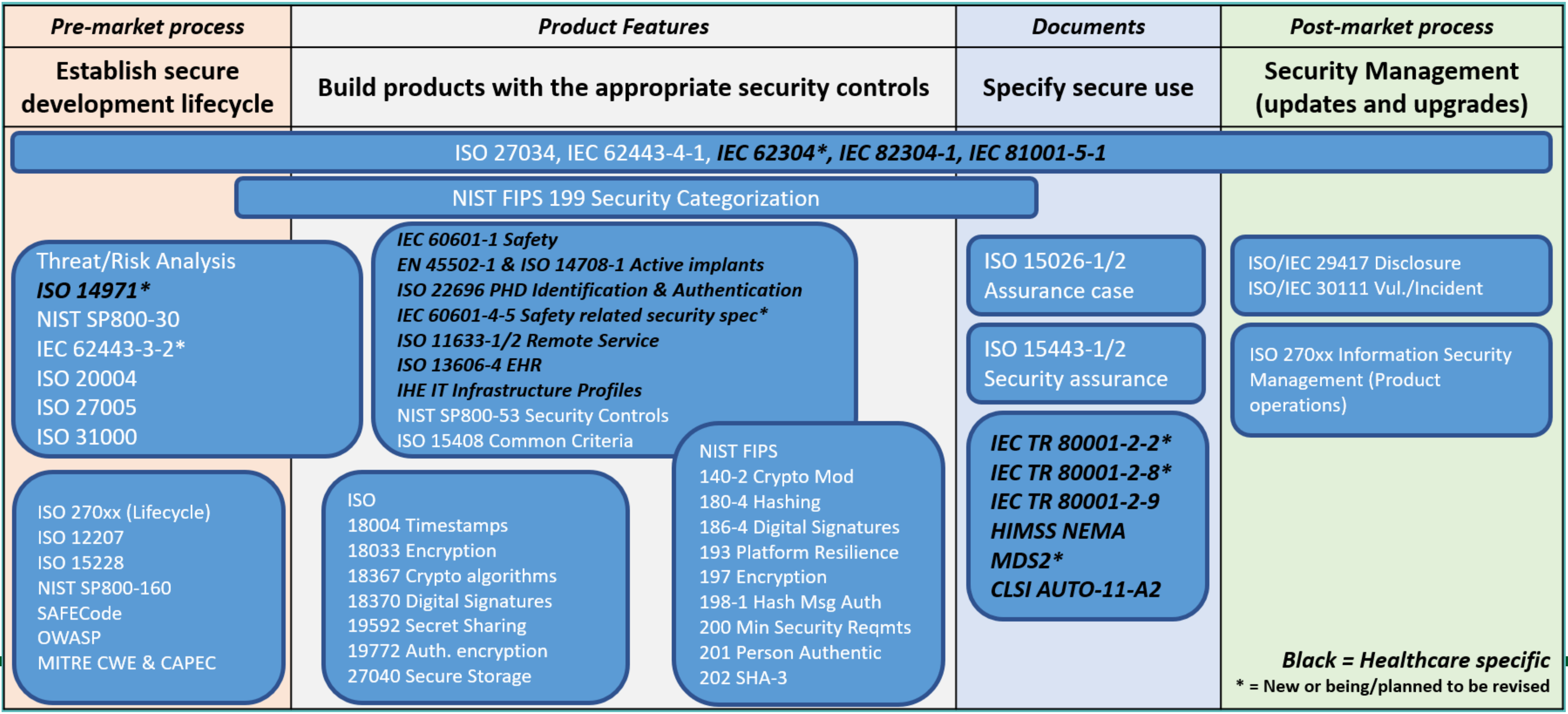
OVERVIEW OF SECURITY RELATED STANDARDS PUBLICATIONS

IMDRF



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 27034, IEC 62443-4-1, ***IEC 62304*, IEC 82304-1, IEC 81001-5-1***

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 Controls
ISO 15408 Common Criteria

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 TR 80001-2-2*
IEC TR 80001-2-8*
IEC TR 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/planned to be revised

CONSIDERATIONS FOR HEALTH SOFTWARE - SECURITY STANDARDS

Security requirements need to:

- Consider safety and performance
- Consider that security risk mitigation is a shared responsibility
- Be appropriate for the intended use and the environment of use
- Be appropriate for the technologies used
- Consider that existing and well accepted works can be adapted with little modification to the healthcare sector and health software
- Reflect that harm is harm regardless of the source of harm

There are many security standards developed by different TCs for specific purposes.

STAKEHOLDER COLLABORATION IS KEY!

- Collaboration among healthcare technology stakeholders adds tremendous value — ***regulators and health software developers*** have worked well together and can continue to work together.

Harmonize conformity assessment through use of standards developed with conformity assessment in mind!

- ***Propose new work items!***

GET
INVOLVED

- **Regulators** have been involved with several **valuable initiatives** to the industry, but similar initiatives **are encouraged** to **improve availability of state-of-the-art security** standards globally.

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CHALLENGES

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- Timely recognition of standards
- Adoption with national deviations of existing international standards
- Harmonization of security standards in the EU

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EU Standards strategy – common specifications

- Regulator stakeholder participation

Thank you!