Singapore Standards Council

DukeNUS Centre of Regulatory Excellence

Standards Development Organisation

The 1st TC Meeting on Healthcare and Health Informatics

Venue: Robertson 3 @ The Robertson House

29 Jan 2024, 9 AM – 11 AM

Meeting Logistics

WiFi Access

#TheRobertsonHouse_MeetingRoom

No password required

Video Recording

This meeting will be recorded for the purpose of creating accurate meeting minutes. If you have any concerns about this, please contact the secretariat. When speaking, please use a microphone to facilitate sound recording.

TC WhatsApp Group

Join TC WhatsApp Group via the QR code on the back of your badge

Exit and Washroom

Accessible on either side of the corridor outside this room.

Parking Tickets

Parking redemption tickets are available solely for on-site hotel parking. Kindly collect them from the secretariat during the break.

CoRE-SDO Introduction

Background

In April 2023, the Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School, appointed by Enterprise Singapore, established a new Standards Development Organisation (SDO), to provide support for the Biomedical and Health Standards Committee (BHSC), its Technical Committees (TCs) and Working Groups (WGs).

Team

Ms Yang Fan (Head)

Ms Tan Li Ping (Assistant Manager)

Mr Wong Siow Kay (Scientific Officer)

Website coresdo.org

LinkedIn core-sdo

DukeNUS Centre of Regulatory Excellence | Standards Development Organisation

CoRE-SDO Steering Committee

Prof John LIM (Chair)
Executive Director
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

A/Prof Silke VOGEL (Deputy Chair)
Deputy Director
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

Dr Tarun MAHESHWARI (Member)
Head
Business Development and Industry Alliance
Duke-NUS Medical School

Dr Chern Chet YONG (Member)
Chair
Biomedical and Healthcare Standards Committee
Head of Asian Ecosystem
22Health Ventures

BHSC

Ms Wai Ling LEUNG (Member)
Deputy Director-General
Quality & Excellence
Enterprise Singapore

Mr Aik Lam KHOR (Alternate Member)
Director (Manufacturing)
Standards Division
Enterprise Singapore

Meeting Agenda

S/N	Item Description	Start Time	Duration	By
1	Welcome Address	9:00 am	5 mins	Dr Adam Chee (TC Chair)
2	Member Introduction	9:05 am	15 mins	All
3	TC Overview and Workplan	9:20 am	15 mins	Secretariat
4	Standard Review Plan	9:35 am	10 mins	Secretariat
5	CLS(MD) Briefing	9:45 am	15 mins	Dr Alvin Lee (MOH)
6	Break	10:00 am	5 mins	All
7	Proposal on Adoption of ISO 7101	10:05 am	15 mins	Ms Sharon Tay (SKH)
8	NEHR Data Standard Proposal	10:20 am	5 mins	Secretariat
9	New Standardisation Strategy	10:25 am	5 mins	Ms Celine Tan (EnterpriseSG)
10	New Standard Exploration	10:30 am	20 mins	All
11	SPS Invited Guests Nomination	10:50 am	10 mins	All
12	ISO/IEC Membership	11:00 am	10 mins	All
12	AOB	11:10 am	5 mins	All
	Meeting Adjournment	11:15 am		

For information

Welcome Address

Dr Adam Chee

Chair, Technical Committee for Healthcare and Health Informatics

Technical Committee Composition

Name	Role	Representation	Attendance
Dr Adam Chee	Chair	Individual Capacity	Present
Mr Lee Suen Ming	Deputy Chair	Individual Capacity	Present
Dr Arsen Batagov	Member (New)	Mesh Bio (Singapore) Pte Ltd	Present
Mr Peter John Forbes	Member	National University Health Systems (NUHS)	Absent with apologies
Mr Yanto Fu Yong Ping	Member	Synapxe Pte Ltd	Present
Dr Goh Min Liong	Member	SingHealth Group	Absent with apologies
Dr Alvin Lee Yong Chee	Member (New)	Ministry of Health (MOH)	Present
Mr Lee Seng Beo	Member (New)	Taggle Pte Ltd	Present
Mr Lin Anle	Member	Health Sciences Authority (HSA)	Present
Mr Andy Tan Kian Soon	Member	Individual Capacity	Present
Dr Rex Tan	Member	Aevice Health Pte Ltd	Present
Prof Teo Yik Ying	Member (New)	National University of Singapore (NUS)	Present
Mr Thomas Wee	Member (New)	IHH Healthcare Singapore	Present
A/Prof Eric Wong Ming Hai	Member (New)	National Healthcare Group (NHG)	Absent with apologies
Prof Steven Wong	Member	Singapore Institute of Technology (SIT)	Present

For information

TC Overview and Workplan

Overview of Biomedical and Health Standards Committee

EnterpriseSG appoints the SSC and provides strategic directions and secretariat support for SSC

Mr Tay Jih-Hsin
Chair
Managing Director, Swee Hin Power Systems Pte Ltd

Mr Andrew Chow
Deputy Chair
Executive Vice President / Head Strategy, Urban Solutions
ST Engineering

Singapore Standards Council

Coordinating Committees (CC)


Smart Nation


Cybersecurity


Silver Industry

Standards Promotion Committee

12 Standards Committees (SC)


Biomedical & Health


Food


Manufacturing


Safety & Quality


Building & Construction


Transportation


Chemical


Environment & Resources


Electrical & Electronic


Information Technology


Services


Trade & Connectivity

CoRE-SDO | NYP-SDO | SMF-SDO | IES-SDO | SCIC-SDO | NTU-SDO | IMDA

60 Technical Committees (TC)

180 Working Groups (WG)

Structure of BHSC

- New working Groups expected to be formed
- Working Groups to be reviewed for restructuring or discontinuation
- WG to be transferred from TC-BTLT to TC-CMHP

BHSC

TC on Biotechnology and Laboratory Testing

Working Groups

1) Biotechnology (NMWG for ISO/TC 276)
2) Microbiological Methods (NMWG for ISO/TC 147/SC 4)
3) Forensic sciences (NMWG for ISO/TC 272)
4) Clinical laboratory testing (NMWG for ISO/TC 212)
5) Specifications for BSL3 facilities (SS 696)
6) Assessment of antimicrobial and antiviral protection
7) Validation of miRNA diagnostics (SS 656)

TC on Healthcare and Health Informatics

Working Groups

1) Healthcare organisation management (NMWG for ISO/TC 304)
2) Health Informatics (NMWG for ISO/TC 215)
3) Supply and delivery of medication (SS 644)
4) Remote vital signs monitoring (TR 45)
5) Connected medical device security (TR 67)
6) HCSA data standards

TC on Medical Devices and Quality Management Systems

Working Groups

1) Biological and clinical evaluation of medical devices (NMWG for ISO/TC 194)
2) Implants for surgery (NMWG for ISO/TC 150)
3) Tissue-engineered medical products (NMWG for ISO/TC 150/SC 7)
4) Particular medical equipment, software, and systems (NMWG IEC/TC 62/SC 62D)
5) Ophthalmic & optics (NMWG for ISO/TC 172)
6) Ophthalmic optics and instruments (NMWG for ISO/TC 172/SC 7)
7) Non-systemic contraceptives (NMWG ISO/TC 157)
8) Quality management (NMWG ISO/TC 210)
9) Thermal imager (SS 582)
10) Good distribution practice for medical devices (SS 620)

TC on Complementary Medicine and Health Products

Working Groups

1) TCM devices (NMWG for ISO/TC 249)
2) TCM general safety (NMWG for ISO/TC 249)
3) TCM manufacturing and herb (NMWG for ISO/TC 249)
4) Cosmetics (NMWG for ISO/TC 217)
5) Indexing of Artemisiae Argyi
6) Authentication of Edible Bird's Nest
7) TCM nomenclature and prescription labeling (SS 613 and SS 614)

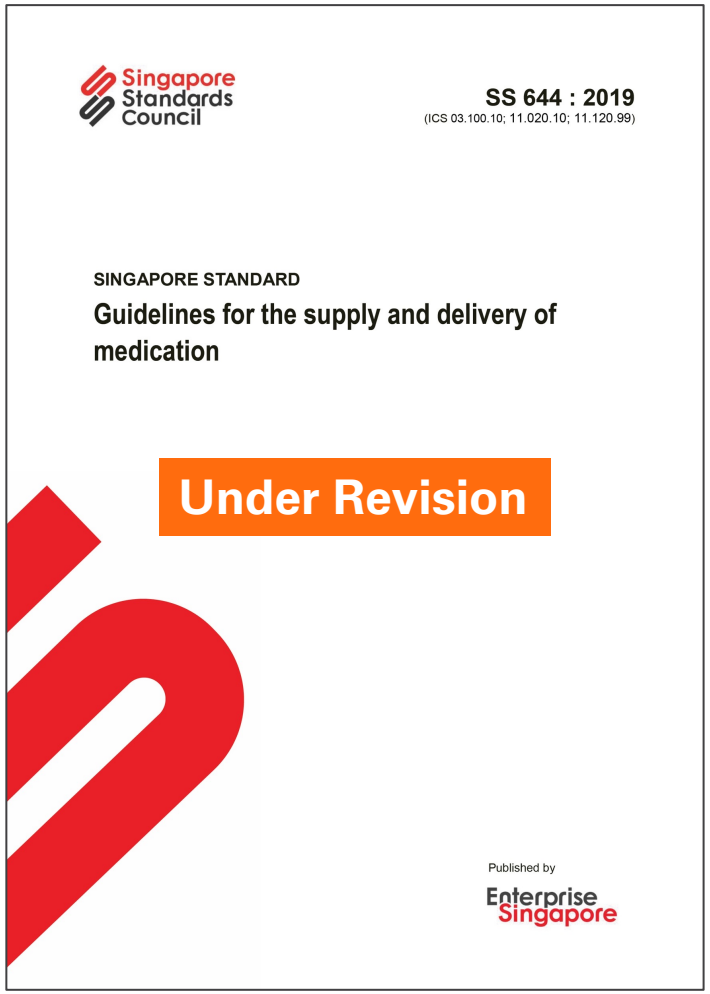
Technical Committee on Healthcare and Health Informatics

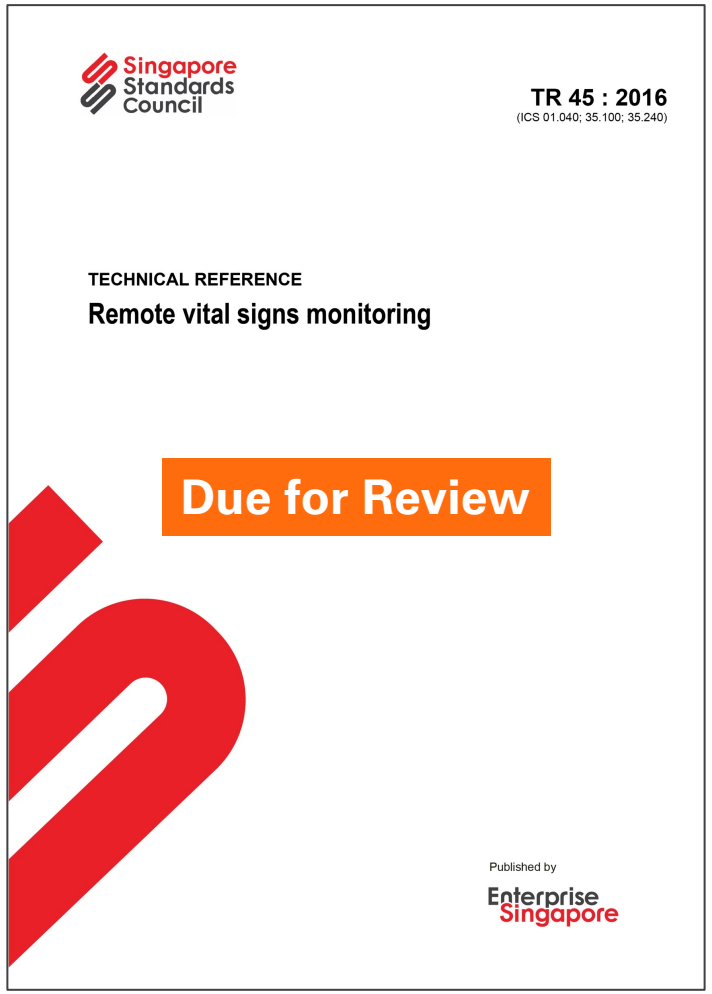
Scope

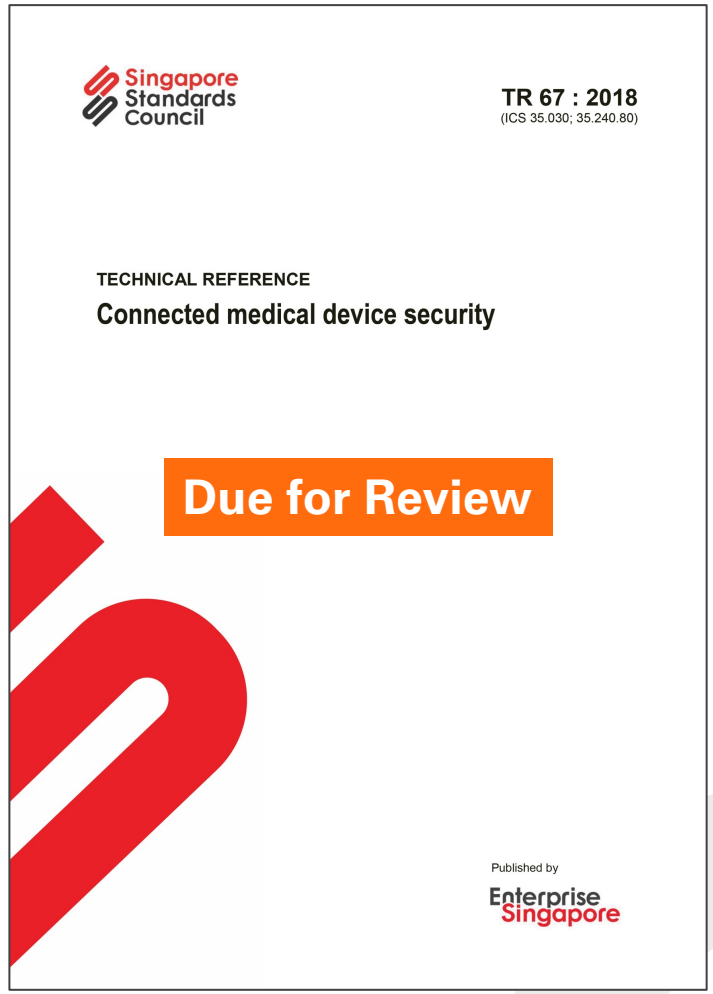
This committee will develop, review and promote standards and any related standardisation activities through identification of standardisation needs and gaps in the areas of:

- healthcare management and healthcare service delivery
- health informatics, software, data and systems inter-operability, AI, and cybersecurity to support and enable all aspects of the healthcare ecosystem.

Current Standards under our TC







Singapore Standard vs Technical Reference

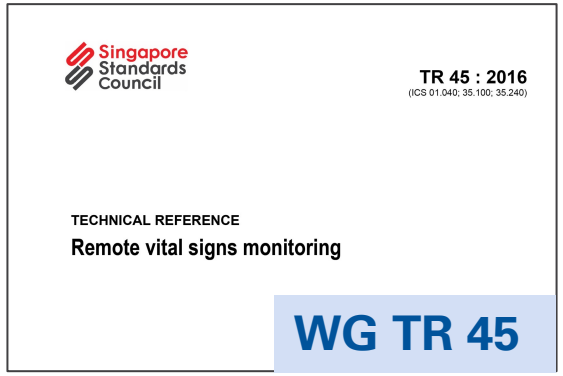
Singapore Standard (SS)	Technical Reference (TR)
Singapore Standards (SS) are nationally recognised documents, established by consensus. They are functional or technical requirements in the form of specifications for materials, product system or process, codes of practice, methods of test, terminologies and guides.	Technical References (TR) are transition documents developed to help meet urgent industry demand on a particular product, process or service in an area where reference standards are not available. Unlike Singapore Standards, TRs are not gazetted and are issued without the Public Comment consensus process.

Standard Type	Stability Period	Review Period	Validity Period
Singapore Standard (SS)	5 Years	≤ 3 years	≤ 8 Years
Technical Reference (TR)	3 Years	≤ 2 years	≤ 5 Years

Working Groups (WGs) under the purview of our TC

1. **WGs for existing standards**
2. **WGs for new standards**
3. **NMWGs for international involvements**

WG SS 644



WG TR 45

WG TR 67

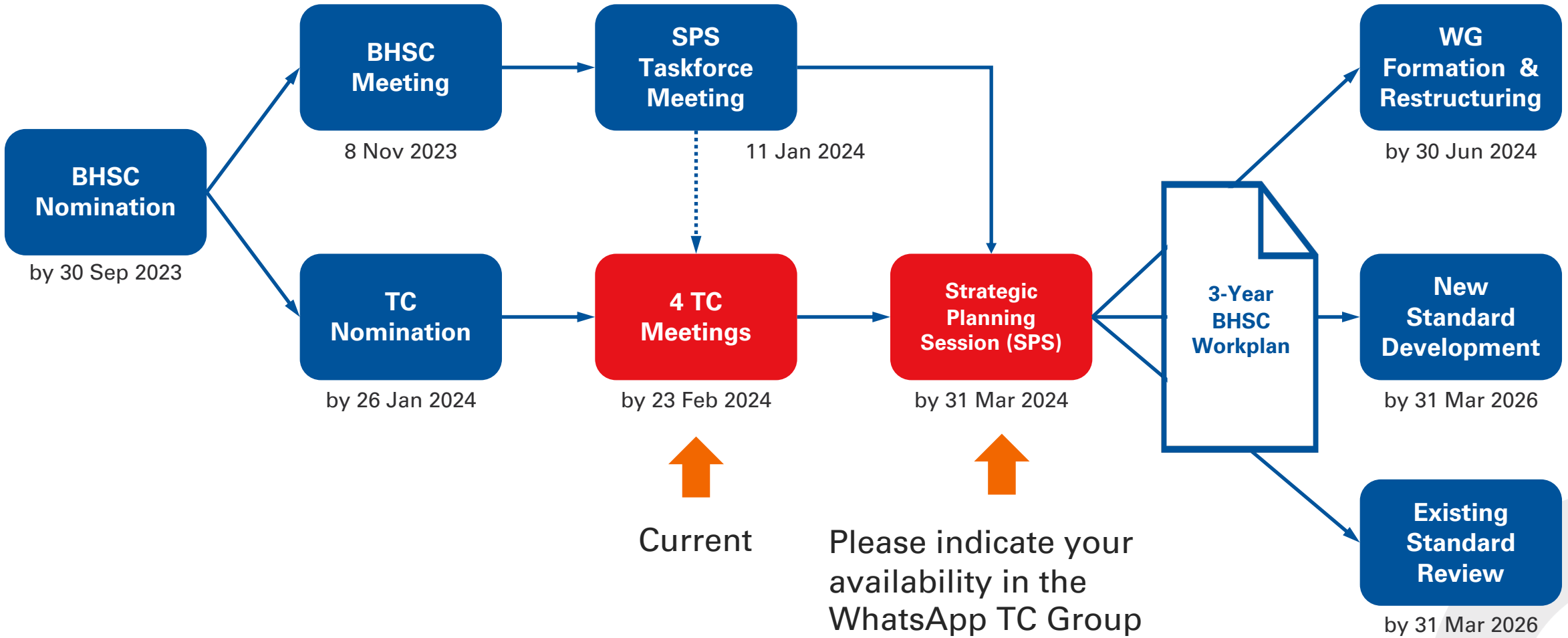
WG for Implementation Guideline for NEHR Data Standards — Proposed by Synapxe

WG for Adoption of ISO 7101 — Proposed by Sharon Tay

Health Informatics (NMWG for ISO/TC 215) – O Member — TC acting as NMWG

Healthcare Organisation Management (NMWG for ISO/TC 304) — To be considered

Development Timeline for Workplan



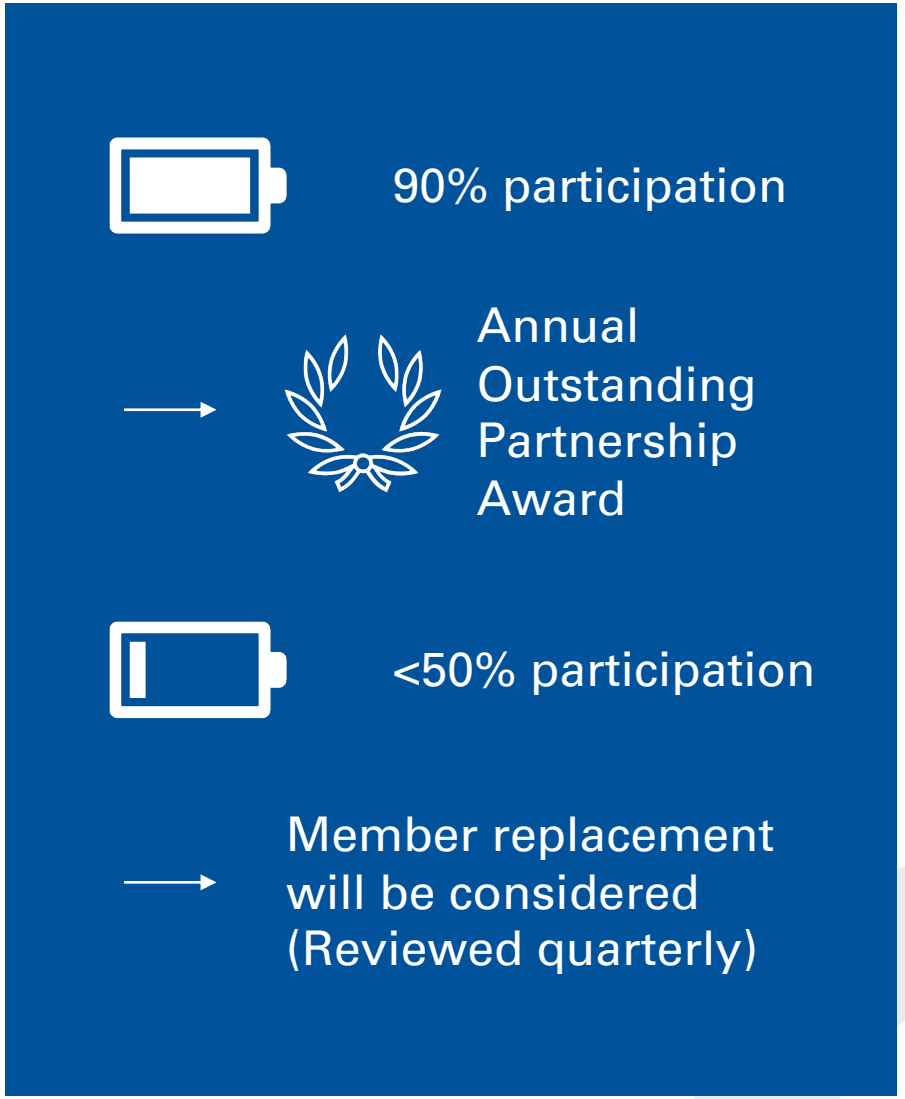
TOR of the TC

1. Oversight of working groups (WGs) under TC
2. Review standards developed by the WGs
3. Participate in international standardisation activities
4. Consider ad-hoc requests for standard revision
5. Assist in answering enquiries on standards
6. Notify patent rights contained in standards
7. Support implementation and adoption of standards and promotional activities

TC Partner Participation

TC members will receive requests for:

- TC meeting participation twice a year
- Strategic Planning Session participation once per term
- Standards review and approval
- WG member nomination and composition approval
- Ballot casting for ISO/IEC
- Other related matters



For information

Standard Review Plan

DukeNUS Centre of Regulatory Excellence

Standards Development Organisation

Typical Standards Development Process

1.5M

2M

2~15 M

0.5M

2 M

0.5 M

2M

SDO requests TC's inputs on:

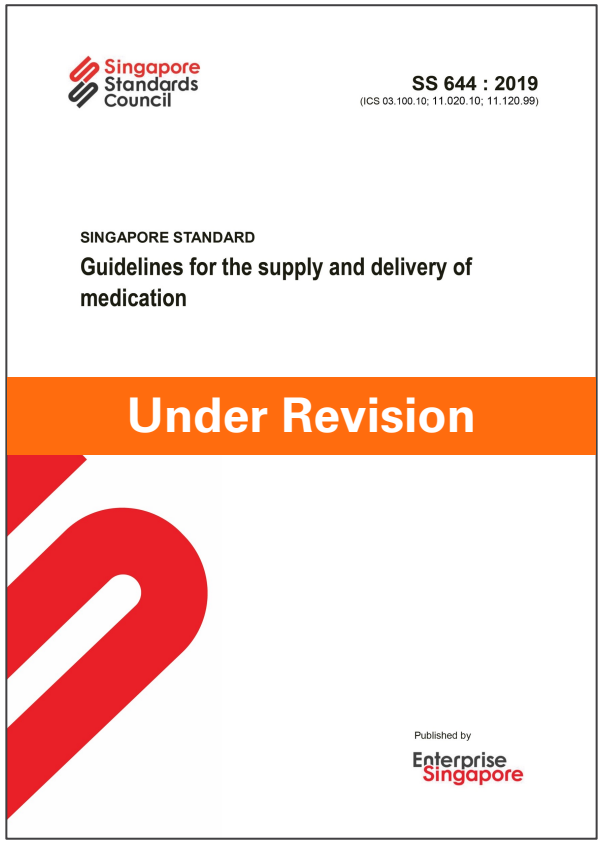
- Relevance and significance of a WIP
- Endorsement on raising a WIP
- Recommendations for suitable WG members
- WG composition approval
- Suggestion for adoption users

SDO requests TC's approval for:

- New standard draft, or
- Existing standard review outcome:
  - Confirmation
  - Revision
  - Amendment, or
  - Withdrawal

*Technical Reference (TR) skips Stage 4

SS 644:2019 Guidelines for supply and delivery of medication



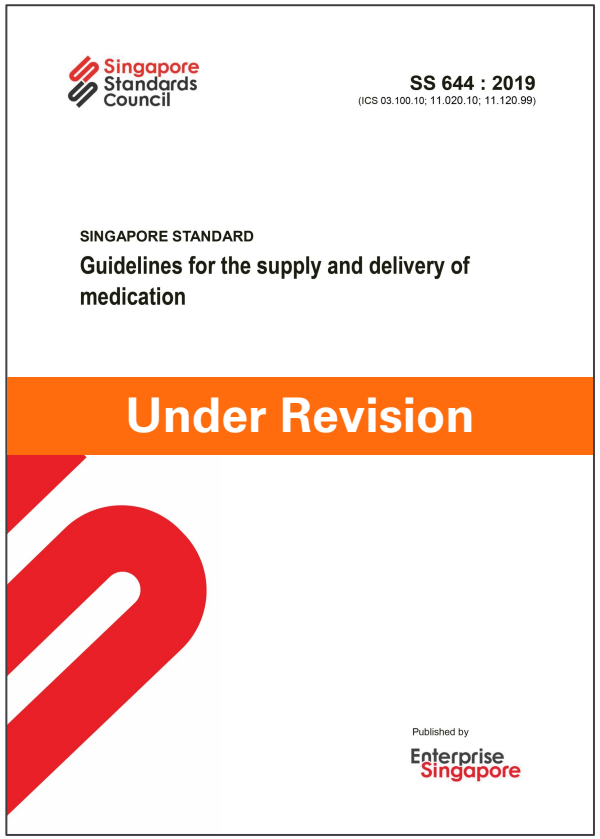
Background

SS644 was published in 2019 as the first Singapore Standard governing the supply and delivery of medications locally. The release was timely as it provided the much-needed guidance during the COVID Pandemic where there is a spike in demand for other medication supply options, such as doorstep delivery or receiving medications from a collection point as opposed to the traditional model of self-collection at Pharmacies.

Motivation for Revision

Post-pandemic, providing access to medication via last mile logistics has become a new norm. With the growth in medication last mile logistics as well as rapid and widespread adoption of SS 644 over the last 3 years, new learnings, developments and requirements have emerged. This includes the upcoming National Central Fill Pharmacies, involvement of GPs in medication delivery especially in the light of HealthierSG, as well as revision in the regulations pertaining to Controlled Drugs delivery.

SS 644:2019 Guidelines for supply and delivery of medication

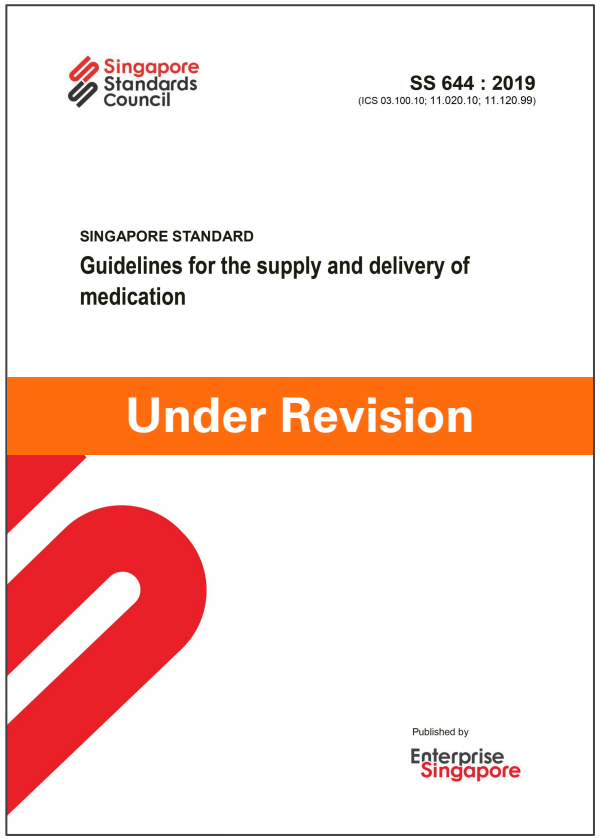


Ms Corrinne Tan
Convenor
National Healthcare Group

Mr Lee Boon Shim
Deputy Convenor
Pick Network

SS 644 is currently under revision by a WG comprising domain experts representing regulatory bodies (MOH, HAS), clinician (SMA, WhiteCoat, SpeedDoc), pharmacy (SGH, SingHealth, TTS, NHG, Whatson's, Guardian, Alps), logistics (SingPost, Pick Network, FairPrice, ST Logistics, etc.), and research (SUSS) perspectives.

SS 644:2019 Guidelines for supply and delivery of medication



Stage 0: Evaluation of the Work Item Proposal (WIP)

Stage 1: Formation of Working Group (WG)

Stage 2: Drafting/Reviewing of Standards by WG ← Current

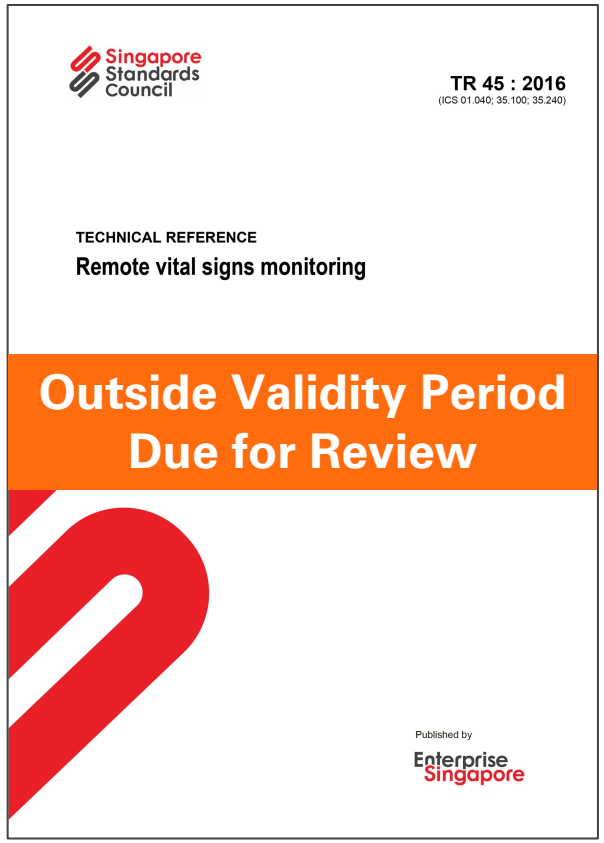
Stage 3: Technical Committee (TC) Approval ← 1st Quarter 2024

Stage 4: Public Comment (PC)*

Stage 5: Standards Committee (SC) Approval

Stage 6: Publication ← 1st Half 2024

TR 45:2016 Remote vital signs monitoring

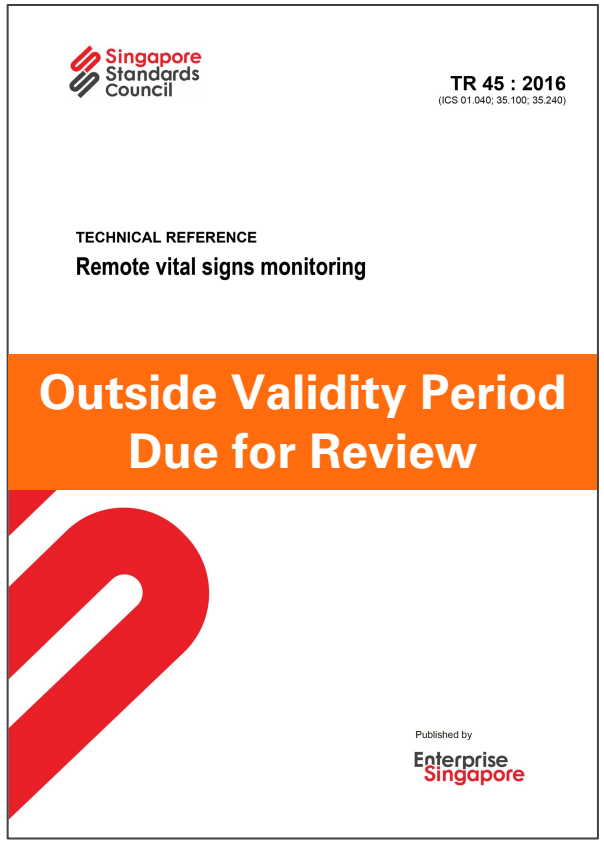


Background

This TR was prepared by the previous Healthcare Informatics TC under the direction of the Information Technology Standards Committee (ITSC) in line with the Smart Nation initiative.

This TR is a provisional standard made available for application over a period of two years. The aim is to use the experience gained to update the TR so that it can be adopted as a SS.

TR 45:2016 Remote vital signs monitoring



Scope

This TR provides guidance on information and exchange standards needed to:

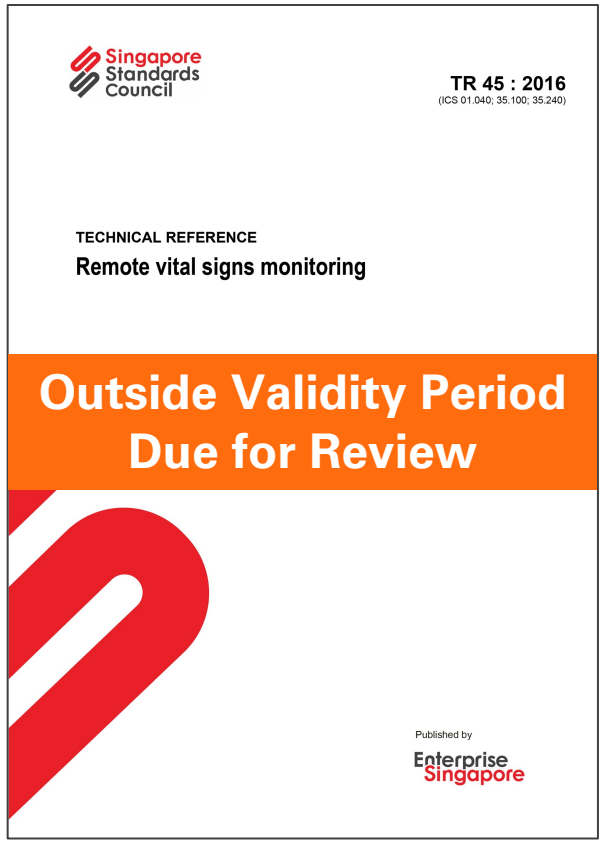
- Improve the interoperability of patient data collected by the remote vital signs monitoring services and their integration with the EMR and PHR systems, reducing the cost of deploying medical device integration solutions.
- Ease the development of innovative applications that utilize vital signs data collected by medical devices, based on industry standards.

The TR applies to the following two use cases:

1. Self-monitoring by well and at-risk cohorts
2. Remote monitoring for chronic cohort

The TR provides process flow, system architecture, service (e.g. AddVitalSigns, GetVitalSigns) specification, data model and dataset definition, products mapping, sequence diagrams, JSON payload, etc.

TR 45:2016 Remote vital signs monitoring



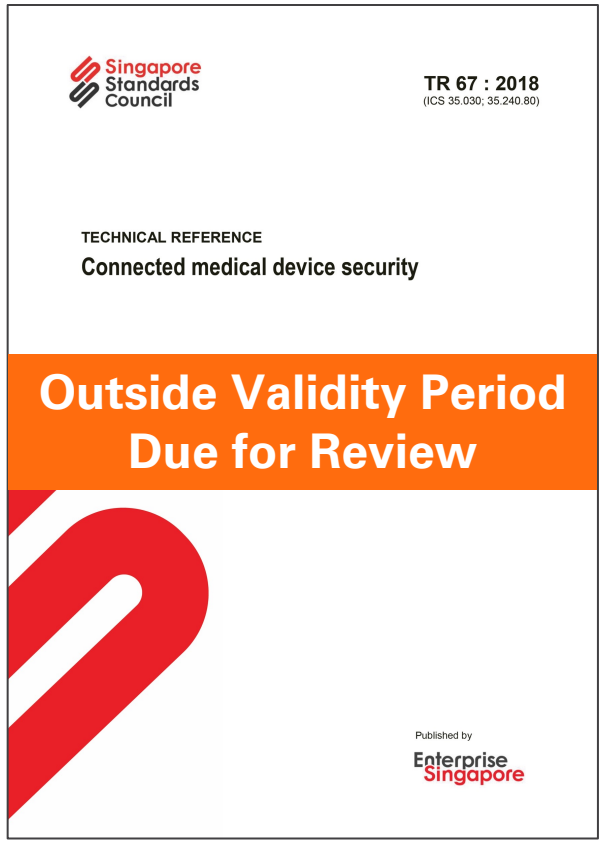
Stage 0: Evaluation of the Work Item Proposal (WIP)

Current

For Actions:

- Nominate a Requester (WG Convenor) to lead the review
- Assess the Review Course:
  1. Confirmation as a TR
  2. Revision or Amendment as a TR
  3. Revision towards SS
  4. Withdrawal and replacement by another standard

TR 67:2018 Connected medical device security



Background

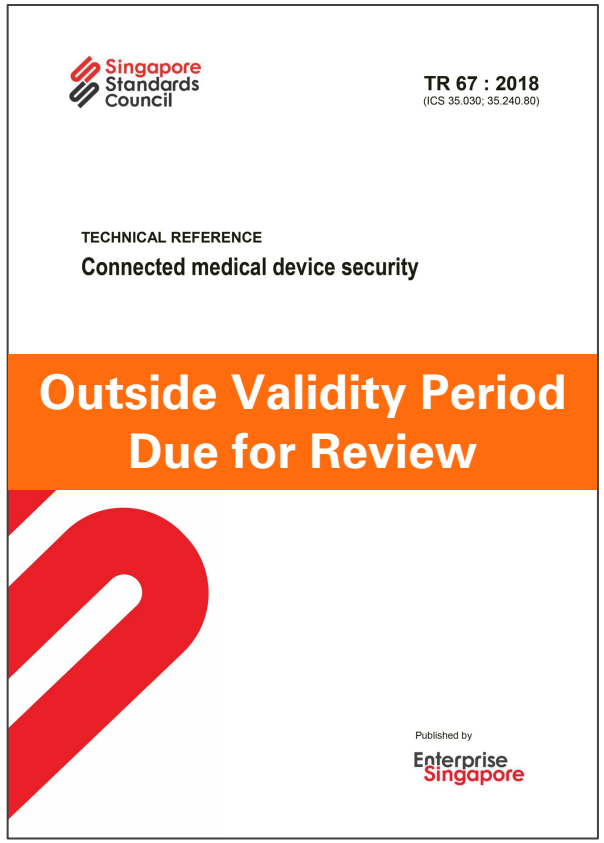
This TR was prepared by the WG on Connected Medical Device Security appointed by the TC on Health Informatics under the direction of the ITSC.

Scope

This TR intends to provide a framework for healthcare institutions and professionals to mitigate the security risks of connected medical devices in the following scenarios:

- Procurement of new connected medical devices
- Day-to-day operations of existing connected medical devices

TR 67:2018 Connected medical device security



New Development

Four agencies, namely MOH, HSA, Synapxe, and CSA, have collaboratively established a Cybersecurity Labelling Scheme for Medical Devices (CLS(MD)). This scheme delineates distinct cybersecurity levels and their corresponding requirements. Currently undergoing a sandbox phase, the initiative aims to transition into full operational status by the end of 2024, presenting the possibility of replacing TR 67.

For information

CLS(MD) Briefing

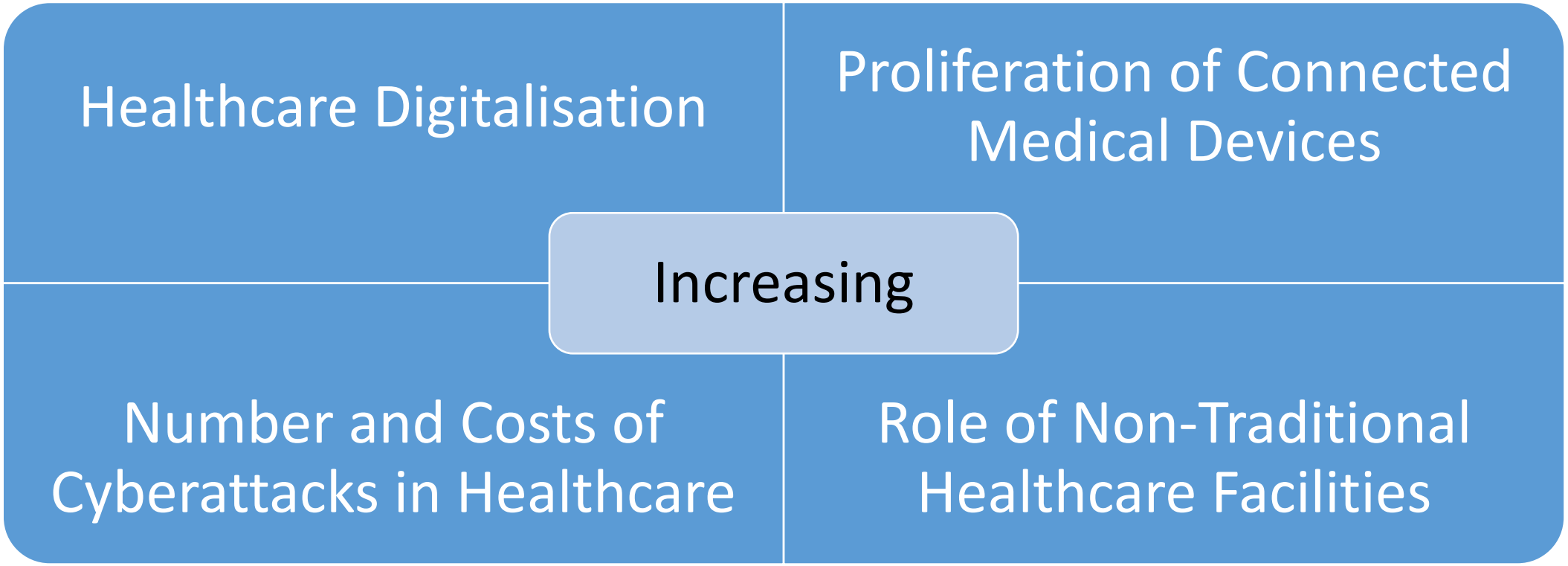
Dr Alvin Lee

Deputy Chair, Analytics and Capacity Building, Ministry of Health (MOH)

Member, Biomedical and Health Standards Committee (BHSC)

Cybersecurity labelling Scheme for Medical Devices – CLS(MD)

Key Trends and Impact



Patient Safety

a) Alteration of medical information e.g. dosages on insulin pumps, images, test results

b) Modification of program or tampering of batteries resulting in malfunction e.g. on pacemakers, gastric stimulators

c) Ransomware causing denial of service e.g. failure of imaging equipment

Data Privacy

a) Exfiltration of data for public release or onto the dark web, cyber-espionage

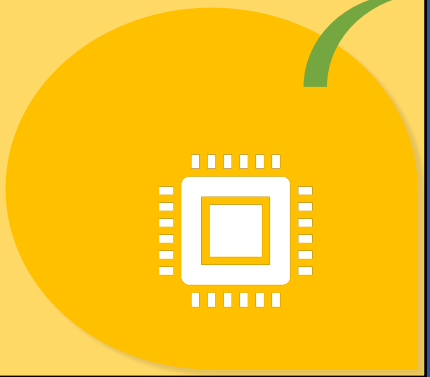
b) Malicious activities spreading across corporate network, crippling the entire IT network of a hospital

Life-Cycle Approach to Managing Connected Medical Devices

Pre-Market

Development & Market entry

- ❑ Promoting security-by-design
- ❑ Setting cybersecurity standards
- ❑ Supporting policies and regulations



Post-Market

Procurement

- ❑ Incorporating cybersecurity requirements into procurement process
- ❑ Compiling detailed inventory

Clinical Use

- ❑ Compliance to policy and standards for usage, maintenance, deployment, asset management & discovery, and decommissioning
- ❑ Ongoing risk assessment and treatment

Incident & Threat Detection and Management

- ❑ Developing real-time monitoring of MDOT network traffic and vulnerabilities
- ❑ Threat Management
- ❑ Incident reporting and management (detection, response and recovery)

Policy and Governance

- ❑ Developing cybersecurity policy, standards and guidelines for secure use through the lifecycle e.g. architecture, operating procedures etc.
- ❑ Promote awareness and culture, develop capabilities and build competencies, both in professional and consumer setting

Cybersecurity Labelling Scheme (Medical Devices)

Cybersecurity Labelling Scheme
FOR MEDICAL DEVICES
BY CYBER SECURITY AGENCY OF SINGAPORE

- Aims to improve Medical Devices security, raise overall cyber hygiene levels and better secure Singapore's cyberspace.
- Medical devices that are in scope will be rated according to their level of cybersecurity provisions.
- Enable consumers and healthcare providers to identify products with better cybersecurity provisions and make informed decisions.
- Incentivise manufacturers to develop more cyber-secure products.

Applicability

Both new and existing medical devices that are in scope can apply for a CLS(MD) label.

Minimum Baseline

For medical devices to attain baseline cybersecurity capabilities amidst growing cyber threats.

Phased Approach

Starting as a voluntary scheme;

The CLS(MD) will be aligned with the purchasing requirements of the public healthcare institutions in the future.

Joint initiative between:

MINISTRY OF HEALTH SINGAPORE

CSA SINGAPORE

HSA Health Sciences Authority

synapxe
Inspiring Tomorrow's Health

In partnership with:

APACMed
The voice of MedTech

Singapore Manufacturing Federation
新加坡制造商总会

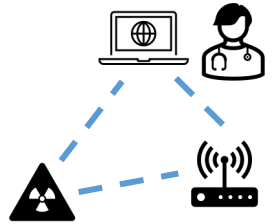
Medical Devices In-Scope for CLS(MD)

The CLS(MD) is a **voluntary scheme**.

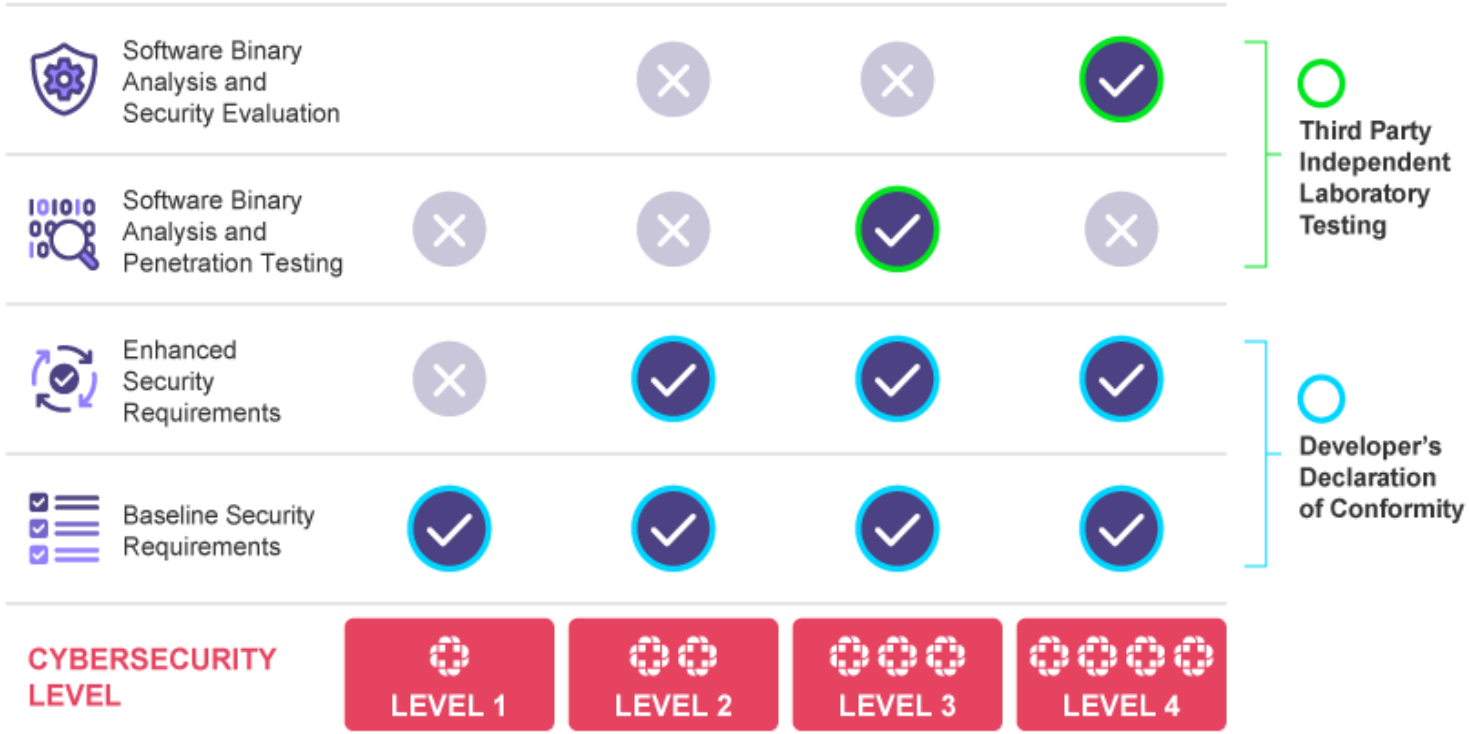
The scope of the CLS(MD) applies to **medical devices** as described in the First Schedule of the Health Product Act (Cap122D, 2008 Rev Ed) **and** have any of the following characteristics:

i. Handles personal identifiable information (PII) and clinical data and has the ability to collect, store, process, or transfer such data;

ii. Connects to other devices, systems, and services - Has the ability to communicate using wired and / or wireless communication protocols through a network of connections.



CLS(MD) Framework: Overview

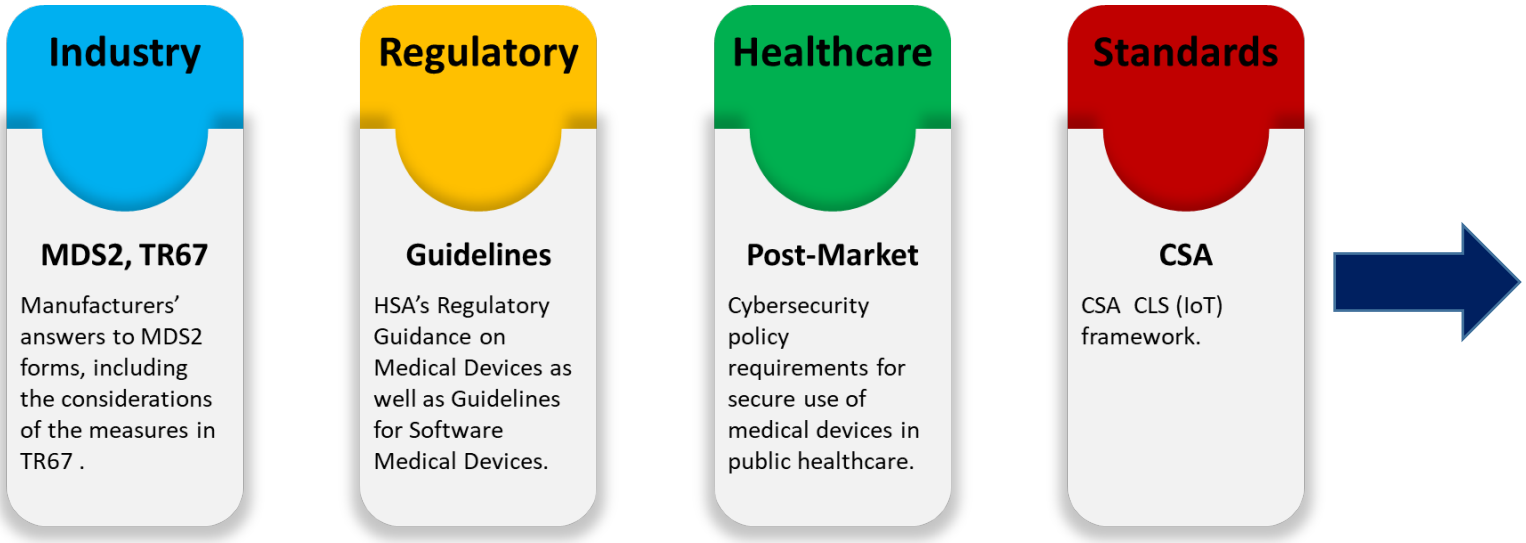


Levels	Descriptions
1 +	Manufacturers need to meet the existing mandatory HSA requirements based on international standards adopted by major MD regulatory bodies (e.g. US FDA, Health Canada, Japan MHLW, TGA Australia) **&** Two additional cybersecurity requirements: Not using universal default password; and possessing anti-brute force mechanism.
2 ++	Manufacturers need to meet the enhanced security requirements titrated from MDS2, post-market policies and existing CLS standards.
3 +++	The software of the medical device (i.e., firmware, mobile applications, if available) undergo automated binary analysers to ensure no known critical software weakness, vulnerabilities or malware. **&** The device will also undergo a timebound penetration testing[(1)] to provide basic level of resistance against common cybersecurity attacks.
4 ++++	The software of the medical device (i.e., firmware, mobile applications if available) undergo automated binary analysers to ensure no known critical software weakness, vulnerabilities or malware. **&** The device will also undergo a timebound security evaluation[(2)] to provide higher level of resistance against cybersecurity attacks.

[(1)] *Penetration test: Evaluator performs testing using only limited information (i.e. only user guidance manuals that is provided with the device).*

[(2)] *Security evaluation: Evaluator is provided with information on the design/implementation of certain security functionalities (i.e. cryptographic functions). With more information, evaluator would be able to devise targeted tests and better assess the security functionalities of the device.*

CLS(MD) Framework: Development of the Security Requirements



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4 ++++	The software of the medical device (i.e., firmware, mobile applications if available) undergo automated binary analysers to ensure no known critical software weakness, vulnerabilities or malware. **&** The device will also undergo a timebound security evaluation(2) to provide higher level of resistance against cybersecurity attacks.

CLS(MD) Level 1

Level 1 seeks to ensure that medical devices conform to a set of **Baseline Security Requirements** consisting of **not having universal default passwords**, **implementing adequate anti-brute force mechanism** on the authentication interface, as well as **cybersecurity requirements currently in use by HSA** in the review of medical devices seeking registration in Singapore.

Manufacturer Lifecycle Requirements
Vulnerability disclosure program (i.e. ISO/IEC 29147, etc.)
On-going plan to remediate cybersecurity vulnerabilities
Post-Market plan to proactively monitor and identify newly discovered cybersecurity vulnerabilities, assess their threat and respond.
Consider cybersecurity risks/ vulnerabilities as part of their overall risk management process throughout the lifecycle of the medical device.

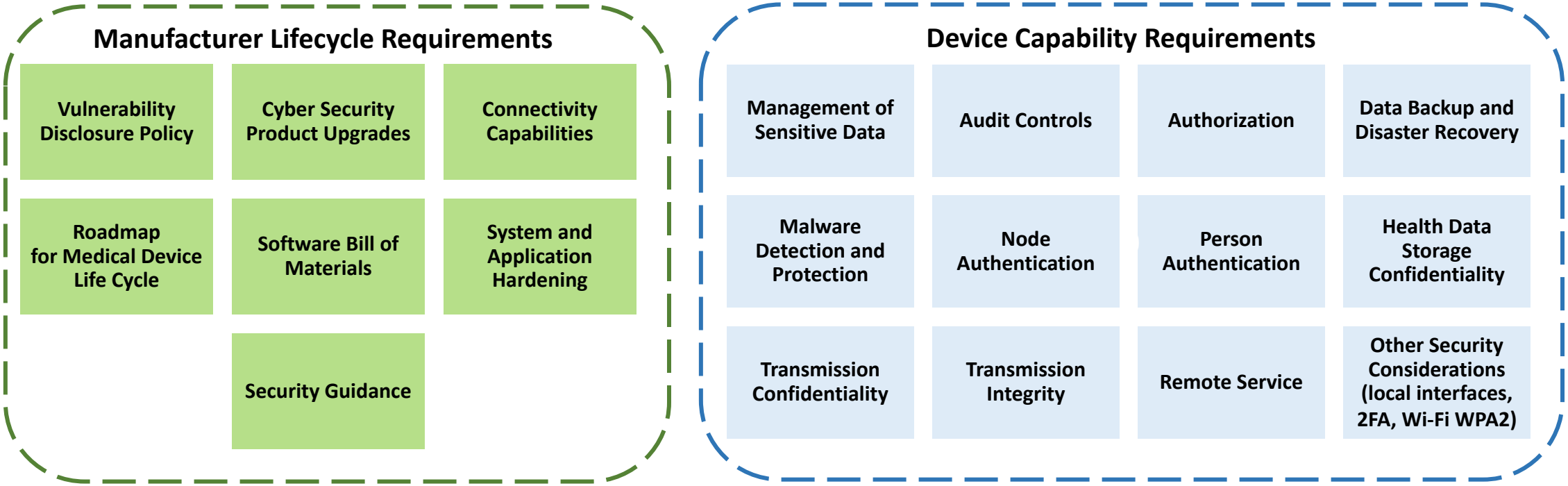
+

Device Capability Requirements
Where passwords are used and, in any state, other than the factory default, the **medical device passwords shall be unique per device or defined by the user**. Where pre-installed passwords are used, they shall be unique per device and sufficiently random.
The device shall have a mechanism available which **makes brute force attacks on authentication mechanisms impractical**.

CLS(MD) Level 2

Level 2 seeks to ensure that medical devices conform to a set of **Enhanced Security Requirements** consisting of the following:

- Level 1 Requirements (6 Clauses)
- Other cybersecurity requirements across these Manufacturer Lifecycle/Device requirements (32 Clauses)



CLS(MD) Level 2 – details on the additional 32 Clauses

- #2- Management of sensitive data
- #3 - No storage of sensitive data in clear text
- #4 - Ability of device logging
- #5 - Authorised access
- #6 - Segregation of roles
- #8 - Process on patch/software updates
- #9 - Installation of only approved software
- #11 - Data Backup capability
- #12 - System Configuration backup and restore
- #13 - Malware protection measures/mechanisms
- #14 - Network access control mechanisms
- #15 - List of communication channels
- #16 - Authentication for all user roles
- #17 - Capability to change authentication value
- #21 - Secure product development lifecycle process
- #22 - Channels for security info and update
- #23 - 3rd party component EOL Process
- #24 - SBOM
- #25 - Hardening
- #26 - Software integrity checking
- #27 - Disable unrequired resources & services
- #28 – Disable all comm ports/ protocols not used
- #29 - Security guidance documentation
- #30 - Permanent deletion of sensitive data
- #31 - Factory created account documentation
- #32 - Encryption at rest
- #33 - Encryption prior to transmission (Transmission Confidentiality)
- #34 - Mechanism to prevent data modification during transmission (Transmission Integrity)
- #35 - Indication of active remote session
- #36 - Authenticated remote session
- #37 - Industry standard Wi-Fi security protocols
- #38 - Disable unrequired local interfaces

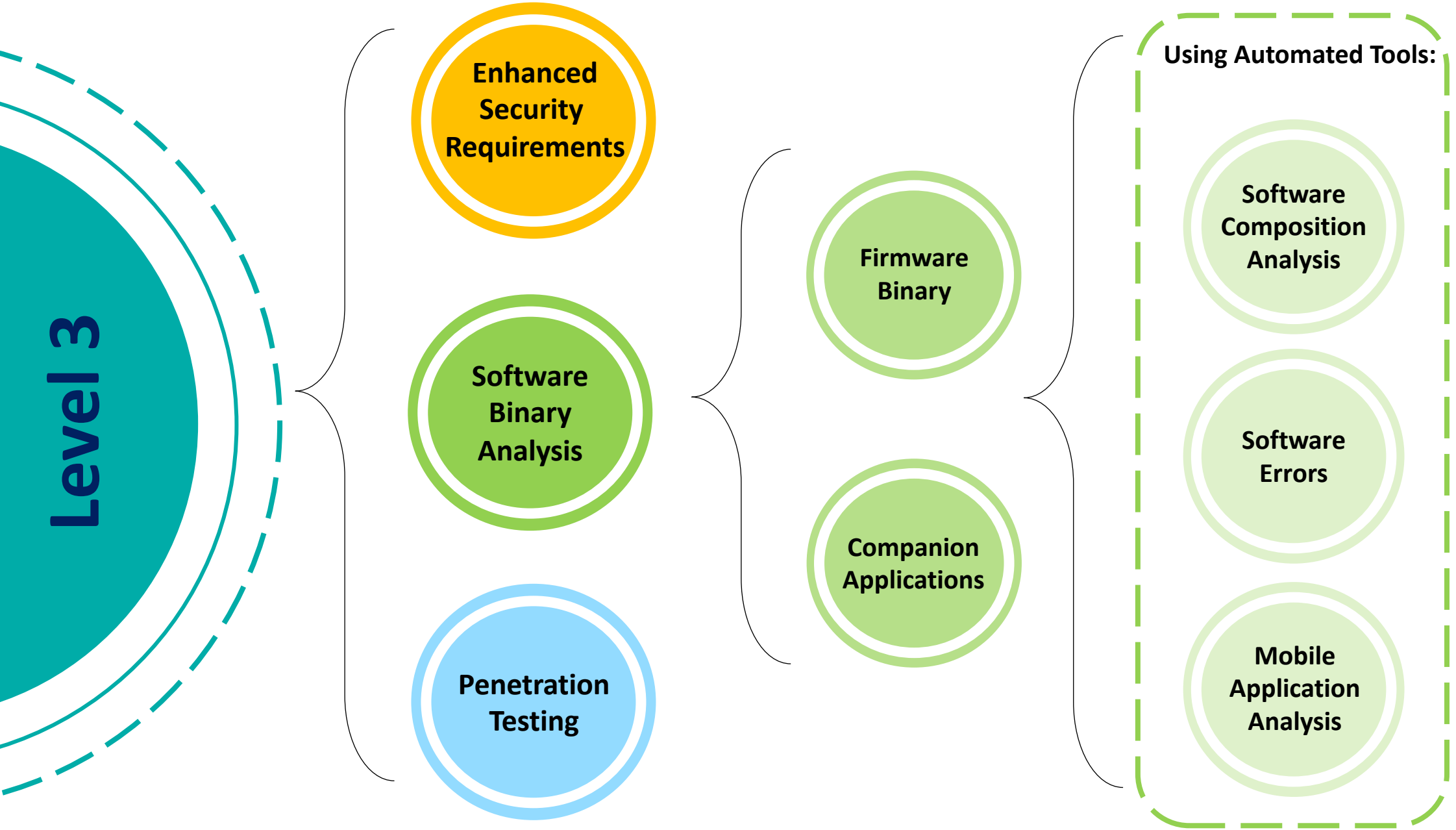
CLS(MD) Level 3

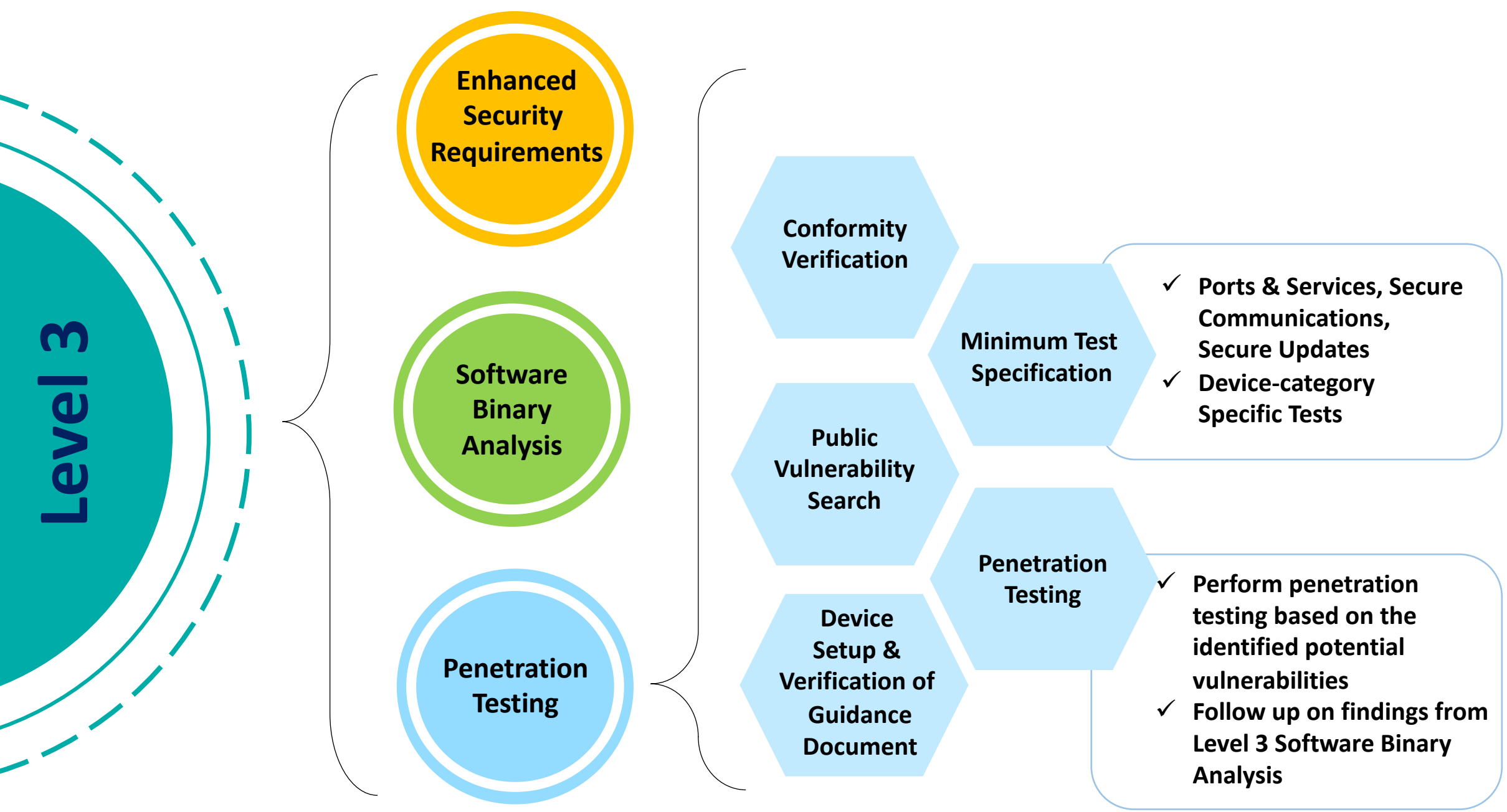
CLS(MD) Level 3 contains three (3) components:

a. **Meeting the Enhanced Security Requirements** – To ensure that devices meet the set of enhanced security requirements.

b. **Software Binary Analysis** – To analyse the device's software (device firmware and companion applications such as desktop or mobile applications) for malware, known vulnerabilities in third party libraries used, and for software weaknesses.

c. **Penetration Testing** – To assert that the medical device is reasonably resistant to common attacks and to prove that there are no obvious or critical vulnerabilities.


Level 3
Enhanced Security Requirements
Software Binary Analysis
Penetration Testing
Firmware Binary
Companion Applications
Using Automated Tools:
Software Composition Analysis
Software Errors
Mobile Application Analysis


Level 3
Enhanced Security Requirements
Software Binary Analysis
Penetration Testing
Conformity Verification
Minimum Test Specification
Public Vulnerability Search
Device Setup & Verification of Guidance Document
Penetration Testing
✓ Ports & Services, Secure Communications, Secure Updates
✓ Device-category Specific Tests
✓ Perform penetration testing based on the identified potential vulnerabilities
✓ Follow up on findings from Level 3 Software Binary Analysis

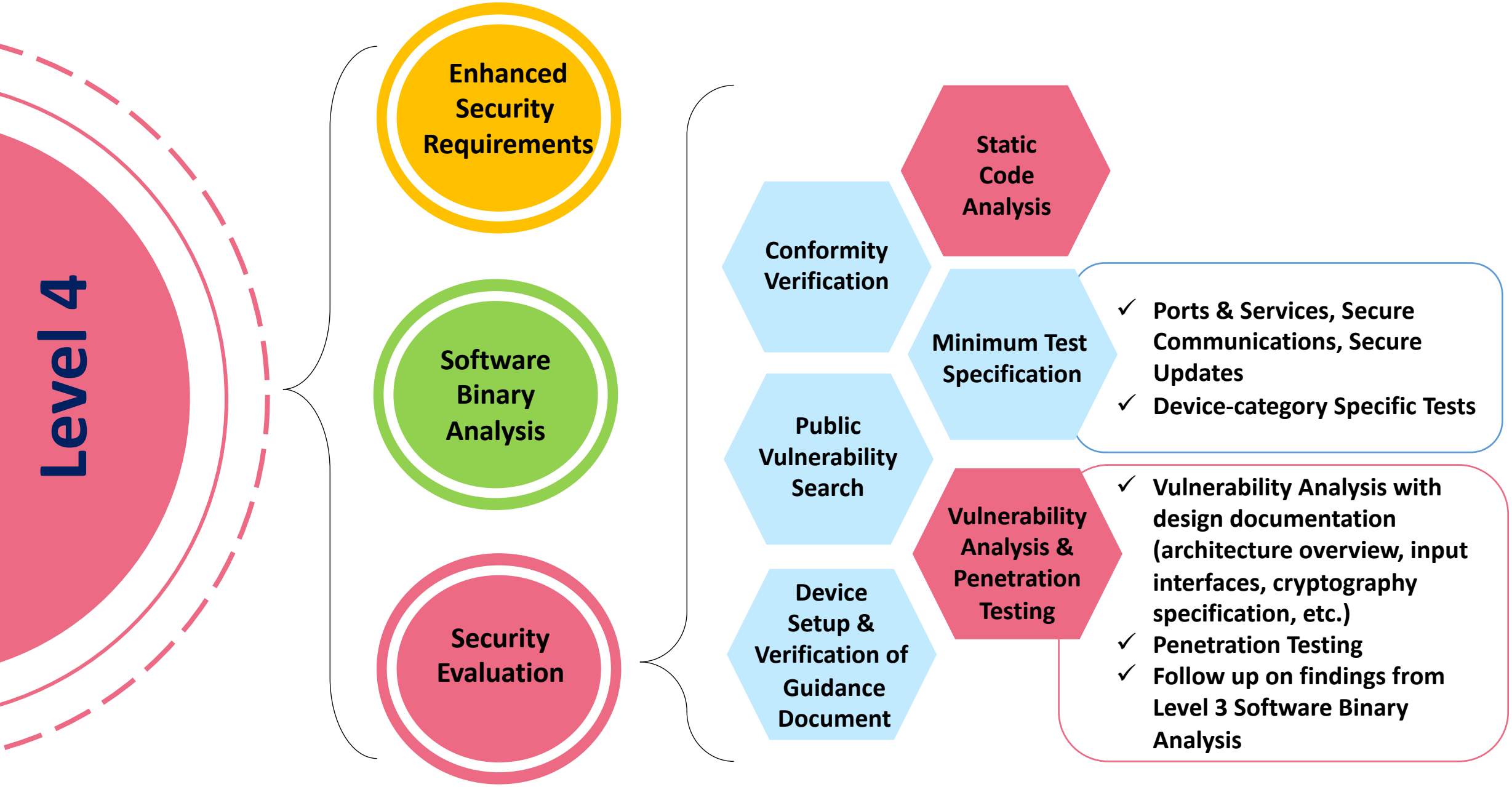
CLS(MD) Level 4

CLS(MD) Level 4 contains three (3) components:

a. **Meeting the Enhanced Security Requirements** – To ensure that devices meet the set of enhanced security requirements.

b. **Software Binary Analysis** – To analyse the device's software (device firmware and companion applications such as desktop or mobile applications) for malware, known vulnerabilities in third party libraries used, and for software weaknesses.

c. **Security Evaluation** – To assert that the medical device is reasonably resistant to enhanced attacks and to prove that there are no obvious or critical vulnerabilities.


Level 4
Enhanced Security Requirements
Software Binary Analysis
Security Evaluation
Conformity Verification
Static Code Analysis
Minimum Test Specification
✓ Ports & Services, Secure Communications, Secure Updates
✓ Device-category Specific Tests
Public Vulnerability Search
Vulnerability Analysis & Penetration Testing
✓ Vulnerability Analysis with design documentation (architecture overview, input interfaces, cryptography specification, etc.)
✓ Penetration Testing
✓ Follow up on findings from Level 3 Software Binary Analysis
Device Setup & Verification of Guidance Document

CLS(MD) Milestones

Apr 2022

Pilot

SICW Oct'22

Announcement of the Cybersecurity Labelling Scheme for Medical Devices


THE STRAITS TIMES

New cyber-security labelling scheme for medical devices in the works

The Cybersecurity Labelling Scheme for Medical Devices will assess the safety of healthcare equipment and certify

January 2023

Industry Consultation

August 2023

- Publish of Industry Consultation Closing Note

SICW Oct'23

Launch of Sandbox

Q4 2024 (TBC)

- Mainstream Launch of the CLS (MD)

CLS(MD) Sandbox

- Allow stakeholders (applicants, certifiers, testers) to work through the finer aspects and details of the scheme before mainstreaming it.
- Provide test bed experience to industry, offer first mover advantage and to market the scheme.
- Sandbox will run for 9 months starting from 20 Oct 2023.
- Both new and existing medical devices can apply.
- Successful sandbox applicants to be awarded the CLS(MD) label.

Qualified Test Labs

TÜV SÜD
riscure
UL
T-Systems
AN SECURITY
SETSCO
@SEC the information security provider
SGS brightsight

Next Step: Adoption

- Regulators are key to buy-in
- Submission of CLS(MD) to make it into a set of standards
- Evolve internal policies to nudge the use of labelled devices
- Continuous engagements with the industry

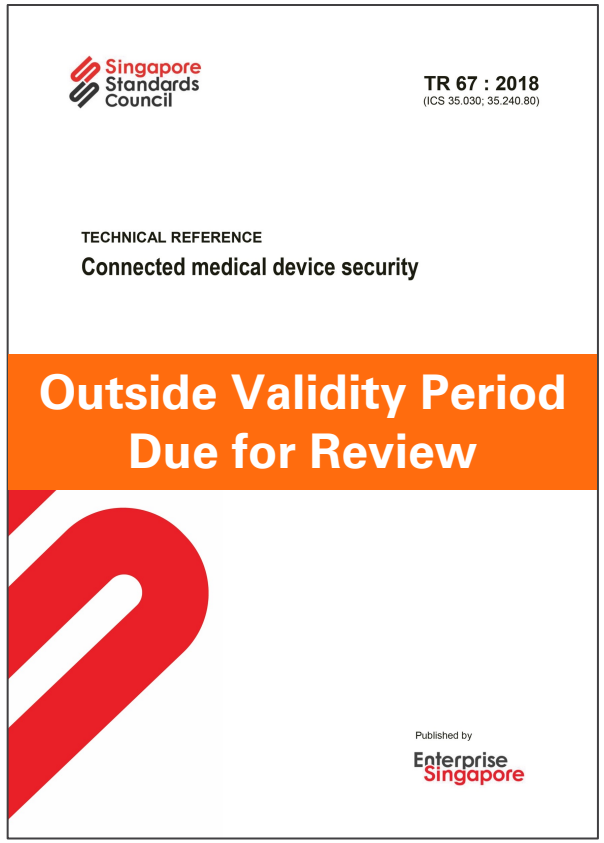
Scheme Details

More details at www.csa.gov.sg/our-programmes/certification-and-labelling-schemes/cls-md

Sandbox publications

- **CLS(MD) Pub 1 – Overview of CLS(MD)** (0.8mb)
- **CLS(MD) Pub 2 – Scheme Specifications** (0.7mb)
- **CLS(MD) Pub 3 – Requirements for Testing Laboratory** (0.4mb)
- **CLS(MD) Pub 4 – Assessment Methodology** (1.2mb)
- **CLS(MD) Pub 5 – Minimum Test Specifications** (0.5mb)
- **CLS(MD) Declaration of Conformity** (0.2mb)
- **CLS(MD) Supporting Evidence Template** (0.2mb)

TR 67 vs SS CLS(MD)



Stage 0: Evaluation of the Work Item Proposal (WIP) ← Current

For Actions:

Assess the Review Course:

1. Withdraw TR 67 before development of new standard for CLS(MD)
2. Withdraw TR 67 after the publication of new standard for CLS(MD)

For CLS(MD) standard development:

- Nominate a Requester (WG Convenor) to lead the standard development
- Discuss Timeline Consideration for standard development

For information

After the Break…

- New standard exploration
- SPS planning
- ISO membership

For discussion

New Standards Exploration

DukeNUS
Centre of
Regulatory Excellence

Standards
Development
Organisation

For information and discussion

ISO 7101 Healthcare Organisation Management

Ms Sharon Tay

Senior Manager, Office of Operations Quality, Sengkang General Hospital

DukeNUS Centre of Regulatory Excellence

Standards Development Organisation

Proposal to Adopt ISO 7101 as Singapore Standard

Prepared by: Sharon Tay
(individual capacity)

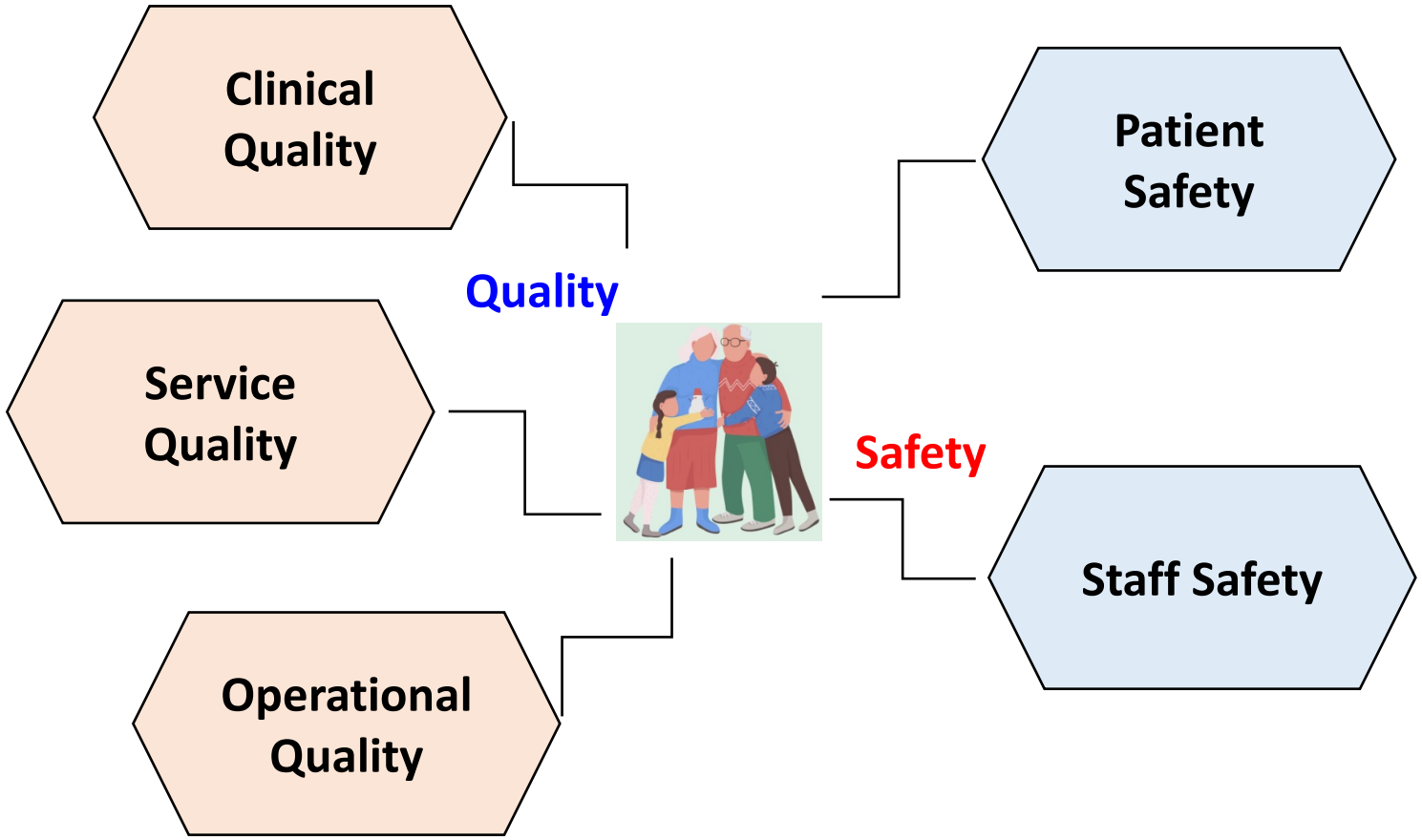
Self-Introduction

- Senior Manager, Office of Operations Quality
- Work experience: Sengkang General Hospital (9 years) and SGH (16 years)
- Worked in various quality functions in manufacturing (9 years)
- Re-engineer career from manufacturing to healthcare industry in 1998. Mainly managing integrated management systems (ISO, JCI) and MOH licensing for past 25 years
- Registered Workplace Safety & Health Officer (2006)
- ASQ Certified Manager for Quality/Organisational Excellence (CMQ/OE) (2008)
- Degree in Human Factors in Safety (UniSIM, 2014)

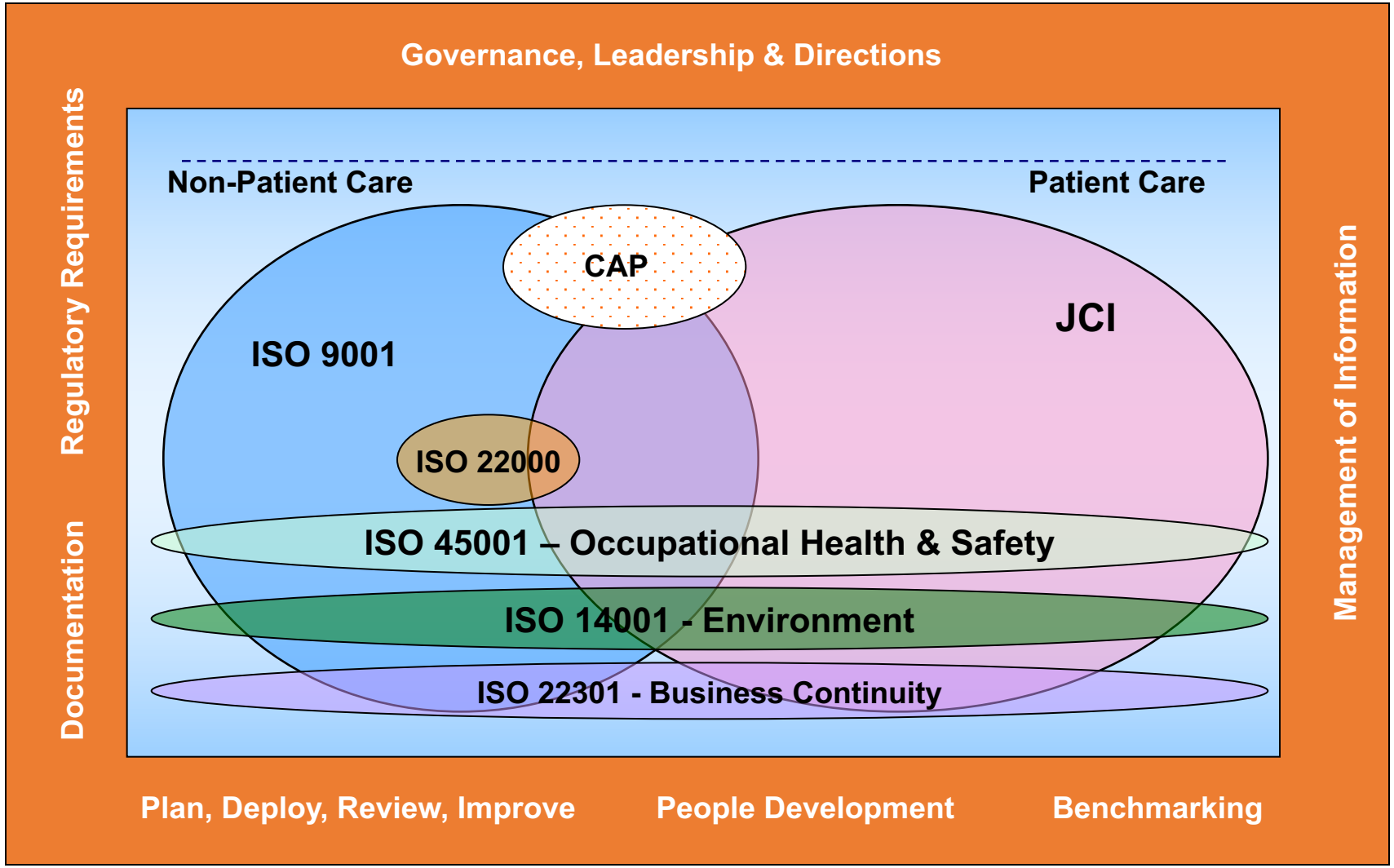
Current status of Management System Standards in Healthcare

Standards	Scope	Remarks
ISO 9001	Administration and operations management	• May not cover patient care (clinical) process. • All hospitals has withdrawn ISO 9001 certification.
ISO 45001 / OHSAS 18001	Entire hospital operations	• Main purpose is to meet Workplace Safety & Health regulatory requirements. • A few hospitals still retain certification.
Joint Commission International (JCI)	Includes patient care and management processes for entire hospital	• JCI accreditation progressively withdrawn since 2015. • MOH re-introduced contextualised JCI std under Ensure Safer Systems programme in year 2022 • JCI accreditation not required.

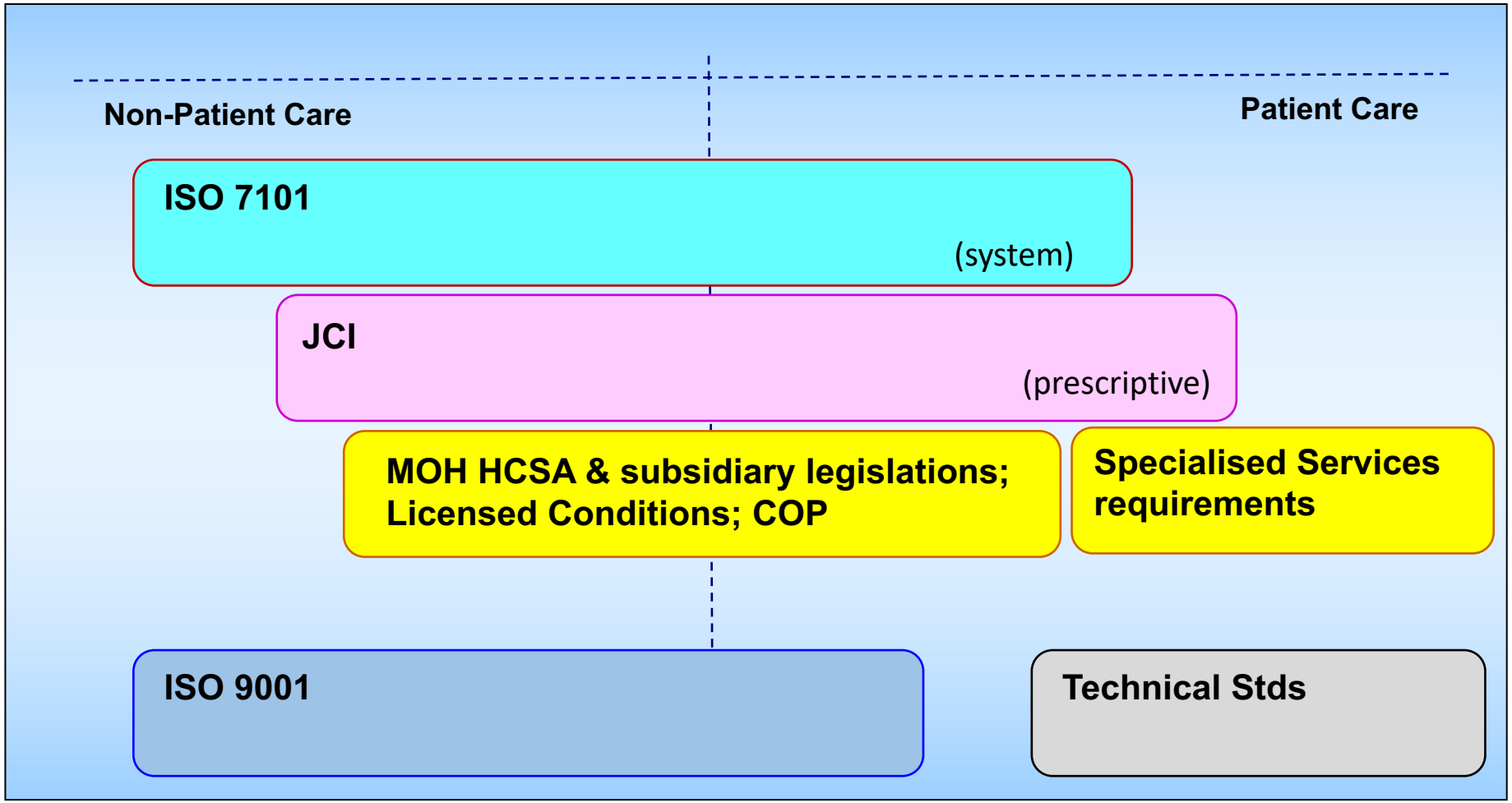
Quality & Safety in Healthcare



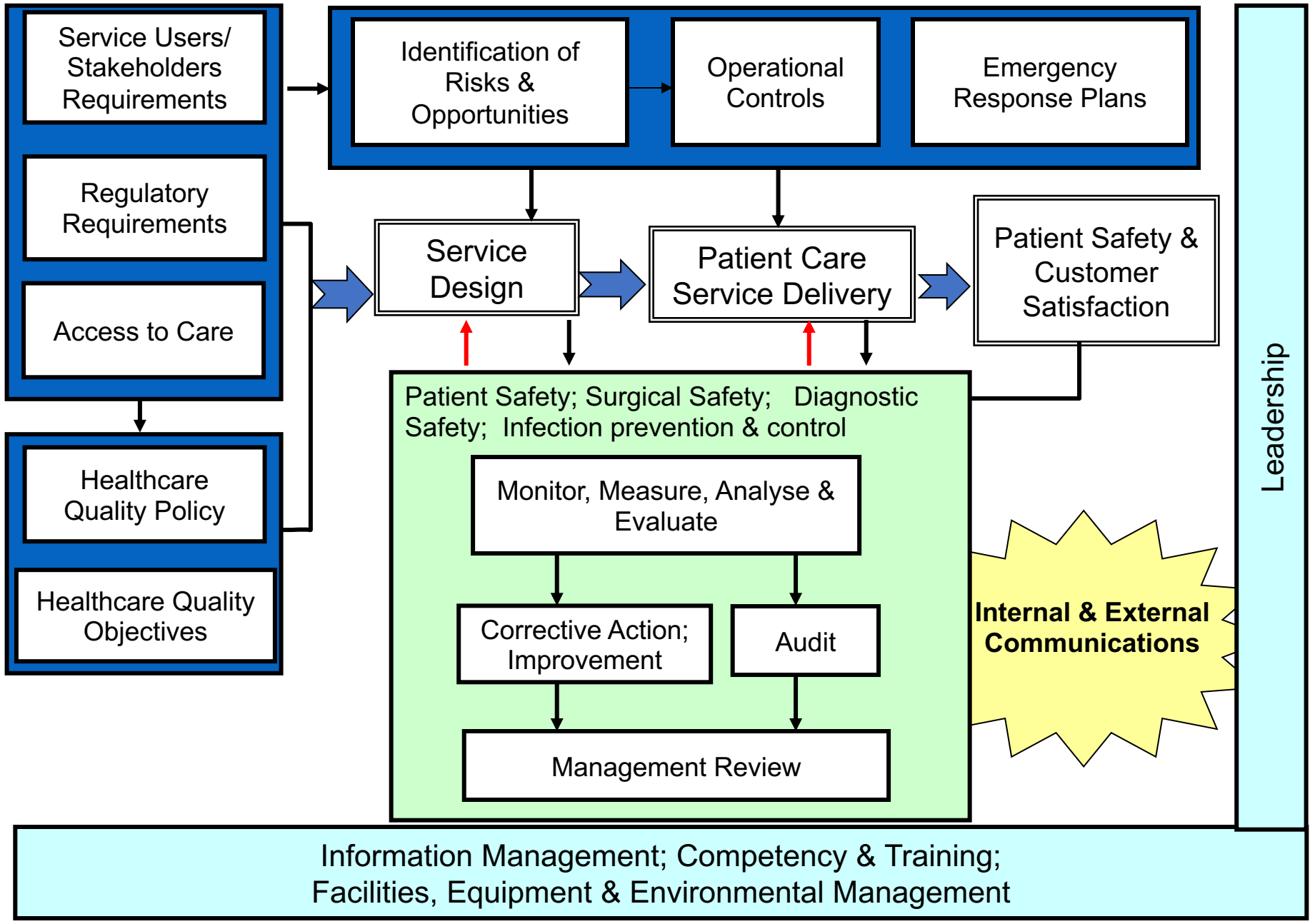
Quality Standards Scope & Integration



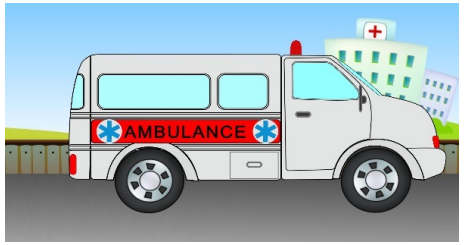
ISO 7101, JCI & MOH Regulatory Requirements



Framework of ISO 7101



Interrelation of JCI Hospital Standards



ACC

GLD

AOP
COP
PCC
IPSG

ASC
MMU
PCI
FMS

SQE QPS MOI

JCI Standard for Hospital (7th Edition)

(I) Accreditation Requirements:

APR: Accreditation and Participation Requirements

(II) Patient-Centred Standards

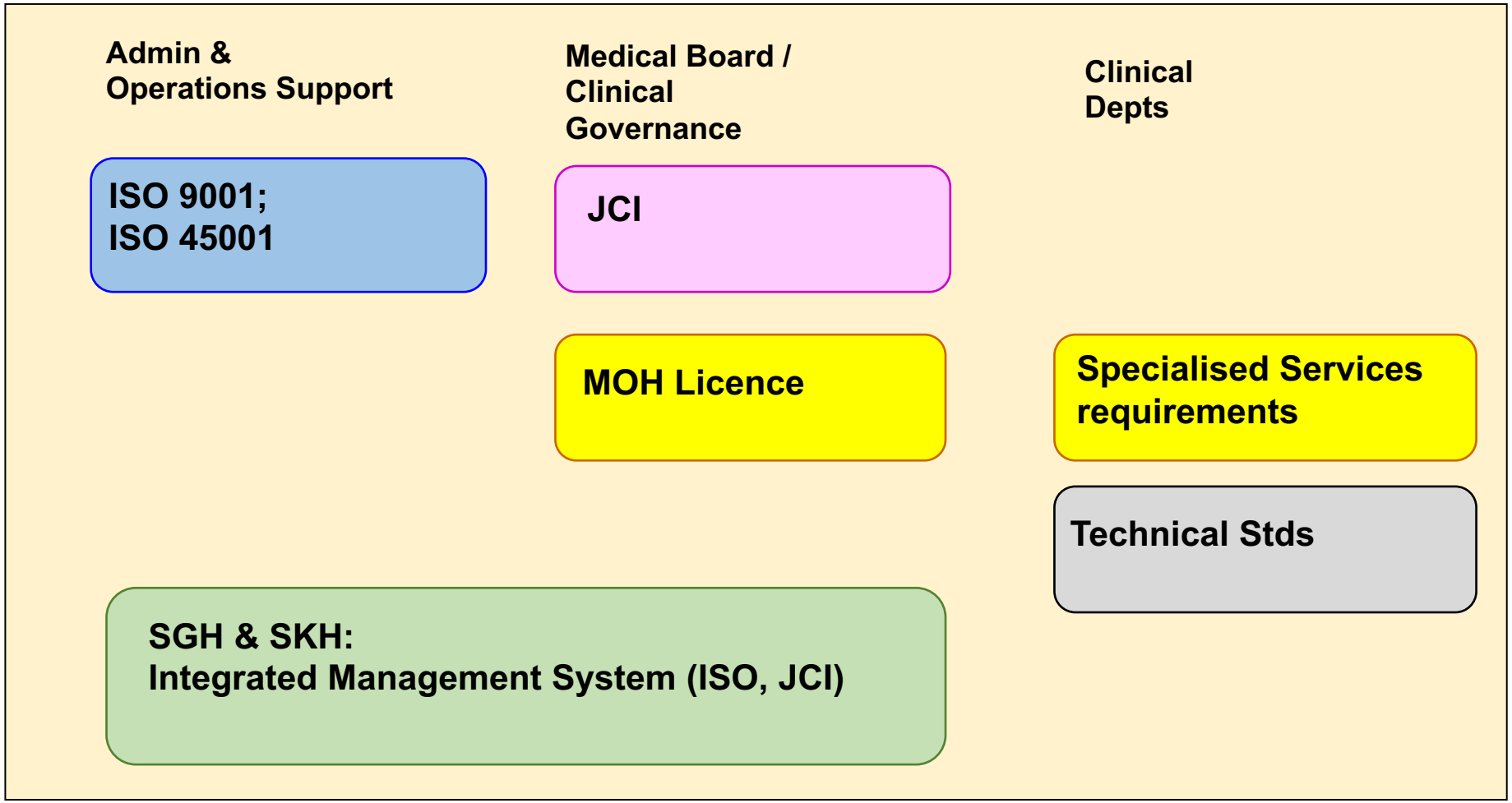
- ****IPSG:** International Patient Safety Goals
- **ACC:** Access to Care and Continuity of Care
- **PCC:** Patient-Centred Care
- **AOP:** Assessment of Patients
- **COP:** Care of Patients
- **ASC:** Anesthesia and Surgical Care
- ****MMU:** Medication Management and Use

(III) Healthcare Organisation Management Standards

- ****QPS:** Quality Improvement and Patient Safety
- **PCI:** Prevention and Control of Infections
- **GLD:** Governance, Leadership, and Direction
- ****FMS:** Facility Management and Safety
- **SQE:** Staff Qualifications and Education
- **MOI:** Management of Information

***have contextualized std issued by MOH in collaboration with JCI.*

Who Manages the various Standards & MOH Licence?



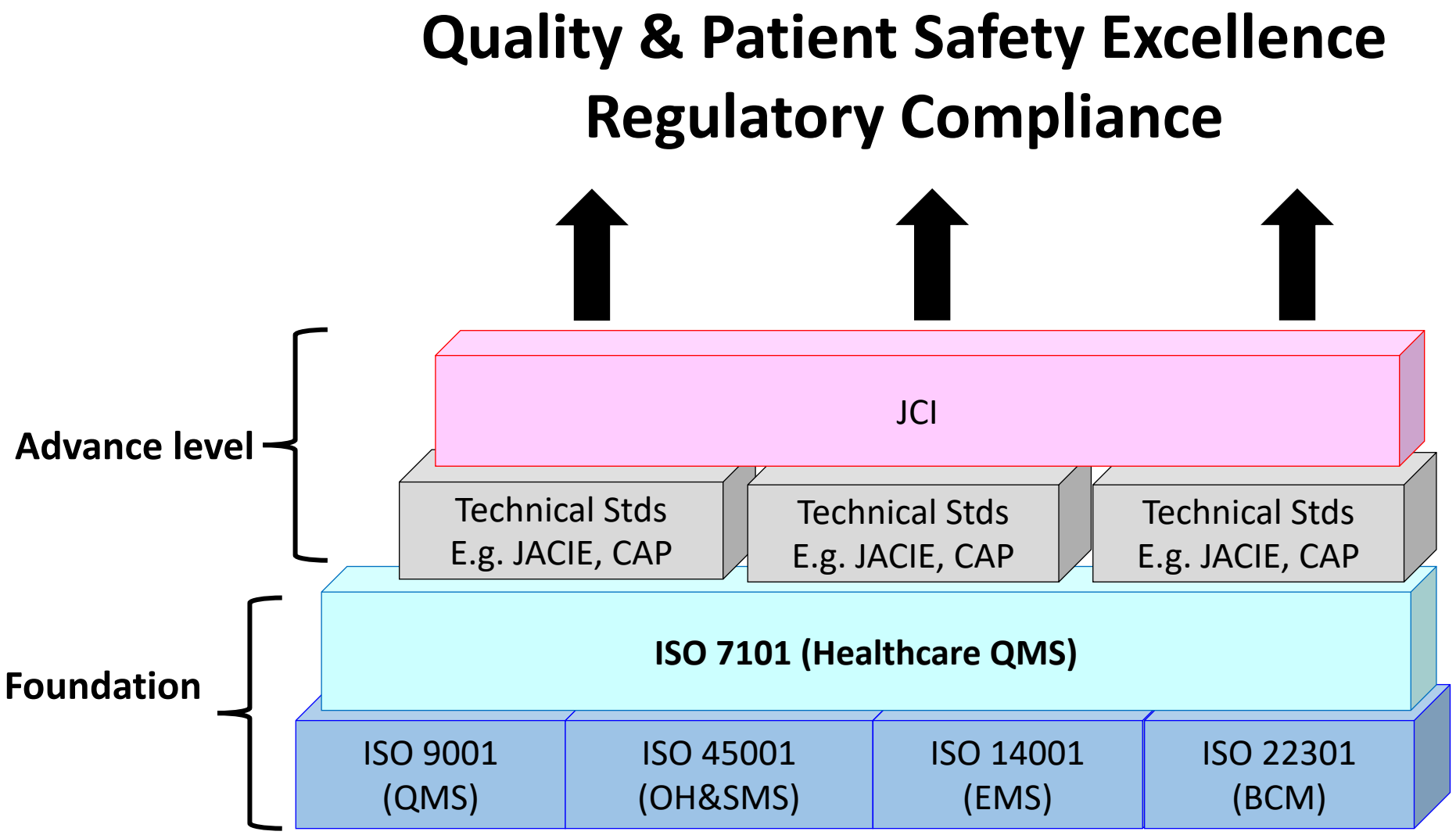
What is Lacking in terms of Quality & Safety

- A structured framework to manage quality & safety for both patient and non-patient care processes
- A Common language in quality & safety understood by everyone
- A standard to integrate quality, patient safety, and regulatory requirements
- A standard to complement & support MOH regulatory requirements
- A framework that is consistent, and yet allows organisation the flexibility to improve and achieve excellence in quality & patient safety

Why Adopt ISO 7101

- Provides a more structured framework to implement a QMS
- Generic requirements, less prescriptive and easier to implement (as compared with JCI).
- Provides a consistent & standardized approach, and yet allow flexibility for organisations to improve and go beyond the standards requirements.
- Can complement with MOH Licence Conditions.
  E.g. QMS for clinical lab, radiological and nuclear medicine services.

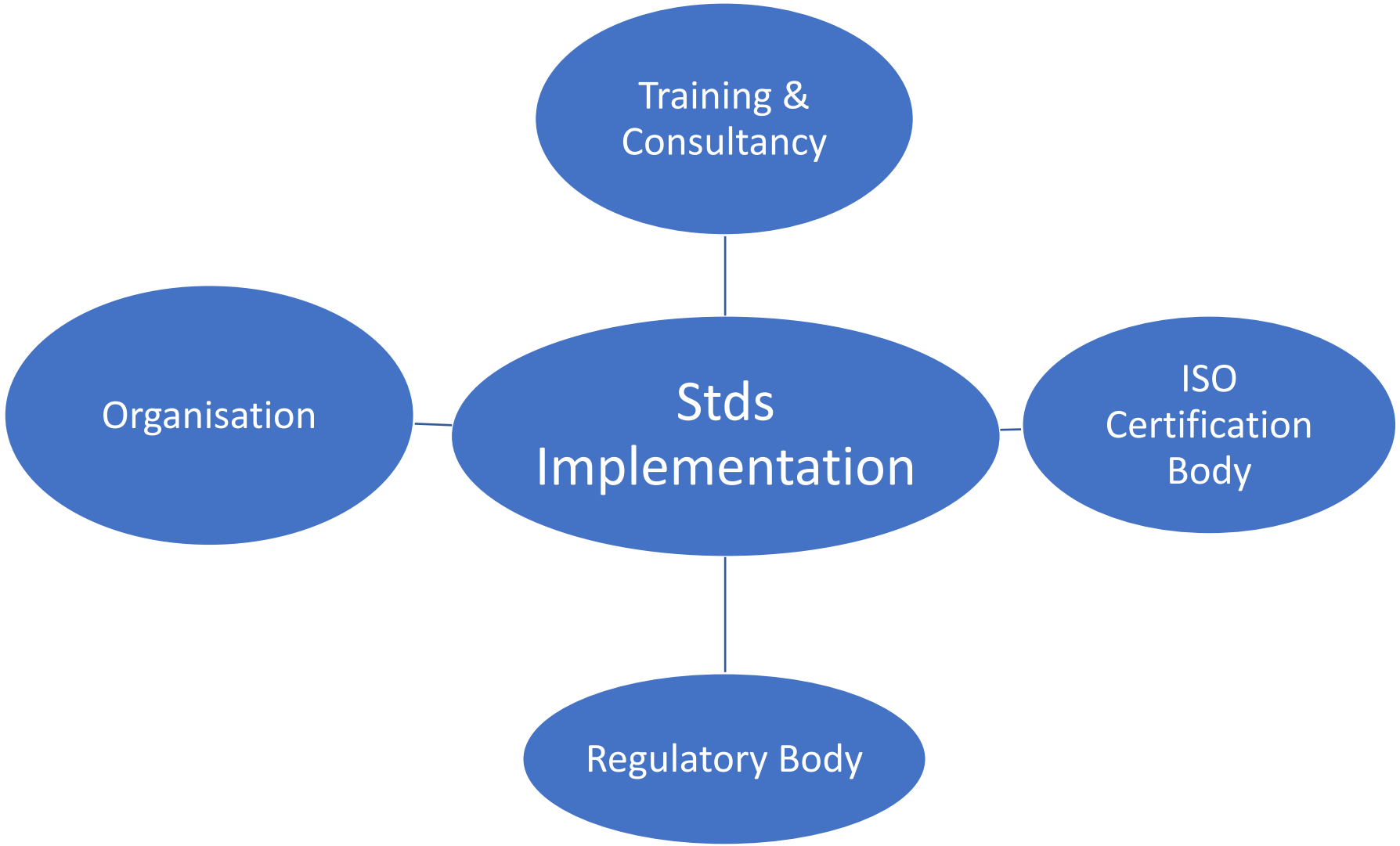
➔ **Act as a foundation to start journey towards quality of care delivery & outcome (patient safety)**


Quality & Patient Safety Excellence
Regulatory Compliance
Advance level
JCI
Technical Stds
E.g. JACIE, CAP
Technical Stds
E.g. JACIE, CAP
Technical Stds
E.g. JACIE, CAP
Foundation
ISO 7101 (Healthcare QMS)
ISO 9001
(QMS)
ISO 45001
(OH&SMS)
ISO 14001
(EMS)
ISO 22301
(BCM)

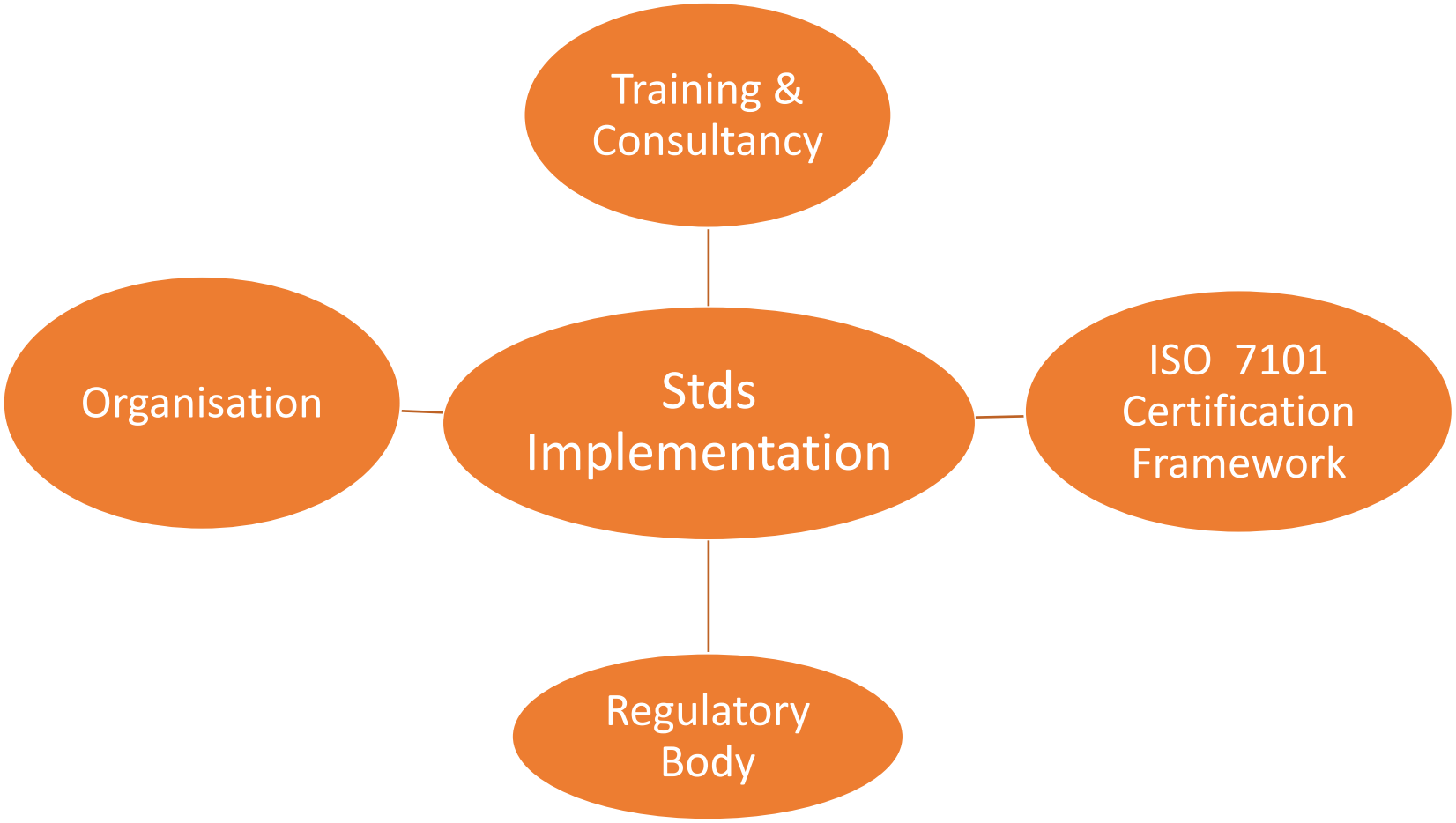
A Typical Medical Eco-System

Source: Akendi

Typical ISO Eco-System



Future ISO 7101 Eco-System (?)



Proposal: ISO 7101 Eco-System

	Proposal	Remarks
Regulatory Body (MOH)	• Review regulatory framework • Tap on Licence Conditions (LCs) QMS with Tap on ISO 7101 to build an effective QMS to manage quality & patient safety. Extend QMS requirement beyond clinical lab, radiology & nuclear medicine services. • With ISO 7101, MOH can use risk management approach to determine inspection frequency and/or focus area.	May make reference to MOM BizSafe framework
ISO 7101 Certification Framework	• Audit team comprise of healthcare professionals, admin & operations staff. • Tap on pool of auditors trained in Advance JCI Tracer under MOH ESS initiative. • Conduct cross-institution audit on QMS. • Long term: ISO Certification Body to build up expertise to provide third party audit.	In US, DNV Global Health provided ISO certification *(refer ASQ QM Journal.)*
Training and Consultancy	• Build expertise at cluster / institution level	

Challenges in proposed ISO 7101 Eco-System

- MOH is the Regulatory Body, as well as the sponsor for the Certification framework.
  - Organisation will implement because of “MOH” (e.g. current ESS-JCI initiative) and not self-driven.
- Healthcare Services Act (HCSA) will be the key determinant
  - E.g. how to integrate ISO 7101 QMS into HCSA regulatory framework.

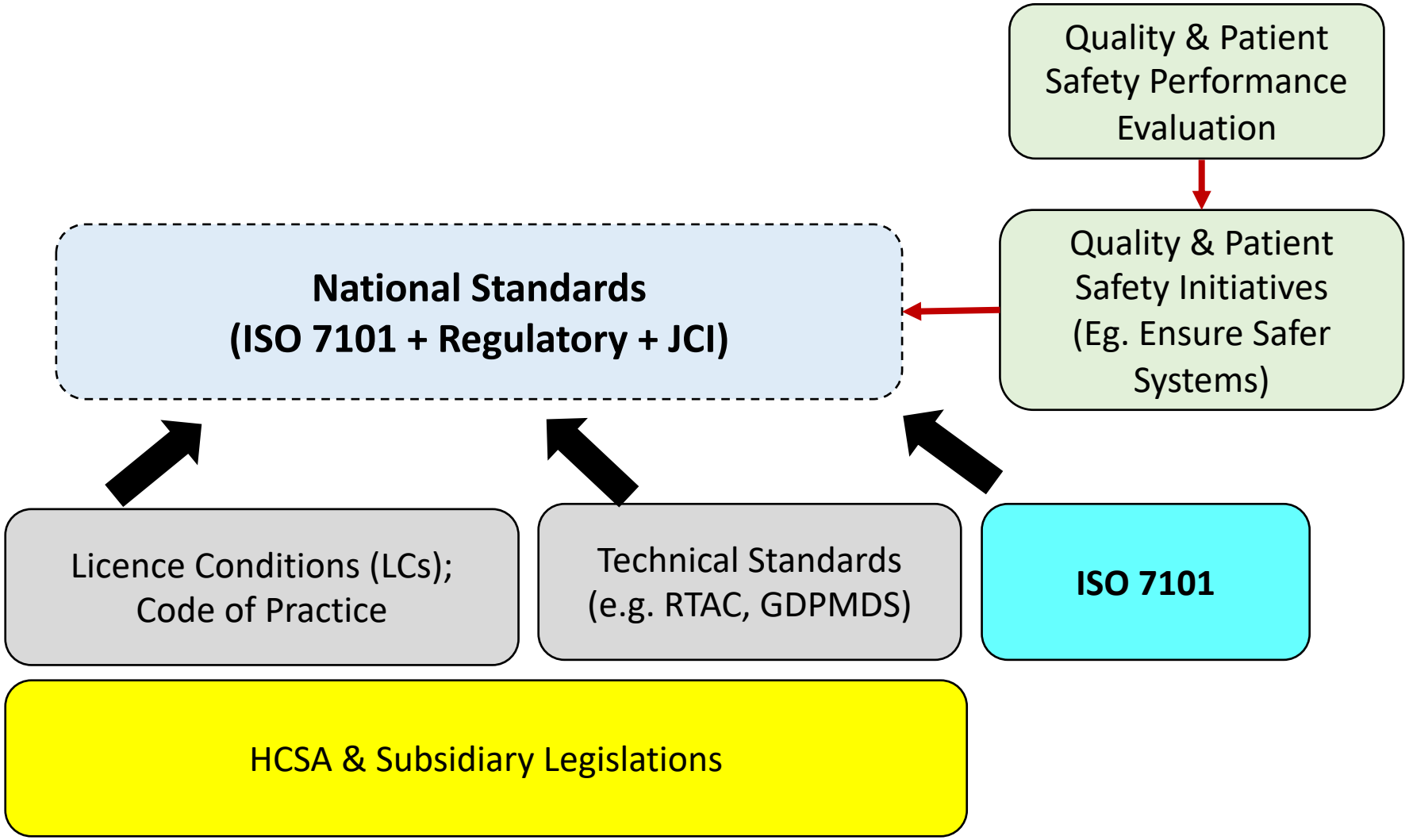
- **Long term:**
  Appointing a 3rd Party Certification Body may be challenging as the regulatory requirements is highly dependent on MOH.

Adopting ISO 7101 as a Singapore Standard

- Leveraging on the greater ISO system framework:
  - **Longer continuity** as it is the most comprehensive international ISO standard for healthcare industry todate.
  - **Bigger / Wider** eco-system for **Integrated** QMS. Organisations only need to manage “one” QMS, covering both patient care and non-patient care processes.
  - ISO 7101 as the **foundation** “base” for other standards to build on.
  - Common language, Consistent requirements as compared to implementing different standards.

➔ **Better efficiency & Less waste for organisations**

National Quality & Safety Framework



RTAC refers to Reproductive Technology Accreditation Committee.
Certification Body designated by MOH under LC.

Reference

Example: HCSA-QMS Map to ISO 7101

HCSA-QMS Map to ISO 7101 as at 12 Jan 2024

https://sso.agc.gov.sg/SL/HSA2020-S1036-2021?DocDate=20230622&ProvIds=P13-#pr11-

Clinical Lab or Radiological Service Reg #11 (2):	Mapped to Key ISO 7101 Std
(a) implementation of a system for appropriate accountability, roles, responsibilities and continuing educational programmes;	4.4 management system for quality in healthcare organisations 5.3 Roles, responsibilities and authorities
(b)measures to ensure that the provision of the service complies with any written law governing the service and licence conditions imposed under section 13(1) of the Act;	8.7 Service design in healthcare 8.12 Patient safety 5.5 Access to care 8.9 Provision of services 8.11 Ethics 8.1 Operational planning & control 8.2 Healthcare facilities management and maintenance
(c)implementation of protocols to ensure compliance with Parts 4 to 6 and for the physical safety of the licensee's personnel, patients and visitors;	8.2 Healthcare facilities management and maintenance 8.12.6 Infection prevention and control

HCSA QMS map
ISO 7101 example

ISO 7101 Map to JCI Hospital Stds

Mapping JCI standards to ISO 7101 19-Nov-23

(Note: This is a "big picture" comparison, not in detail.)

JCI Hospital Standards (7th Edition)			ISO 7101:2023	Key Relevant JCI Chapter
Section: Patient-Centered Stds				
IPSG	International Patient Safety Goals		4 Context	
ACC	Access to Care and Continuity of Care		4.1 Understanding the organisation and its context	ACC; GLD; GHI
PCC	Patient-Centered Care		4.2 Understanding the needs and expectations of stakeholders	ACC; GLD
AOP	Assessment of Patients		4.3 Determining the scope of the management system for quality in healthcare	ACC; GLD
COP	Care of Patients		4.4 Management system for quality in healthcare organisations	All; MOI
ASC	Anaesthesia and Surgical Care		5 Leadership	
MMU	Medication Management and Use		5.1 Leadership and commitment	GLD; QPS; SQE
Section: Healthcare Organisation			5.2 Healthcare quality policy	***Nil***
QPS	Quality Improvement and Patient		5.3 Role, responsibilities and authorities	GLD; SQE

ISO 7101 map to JCI

Quality Management Journal

Taylor & Francis
Taylor & Francis Group

ISSN: 1068-6967 (Print) 2575-6222 (Online) Journal homepage: https://www.tandfonline.com/loi/uqmj20

The Effectiveness of ISO 9001-Based Healthcare Accreditation Surveyors and Standards on Hospital Performance Outcomes: A Balanced Scorecard Perspective

William J. Ritchie, John Ni, Eric M. Stark & Steven A. Melnyk

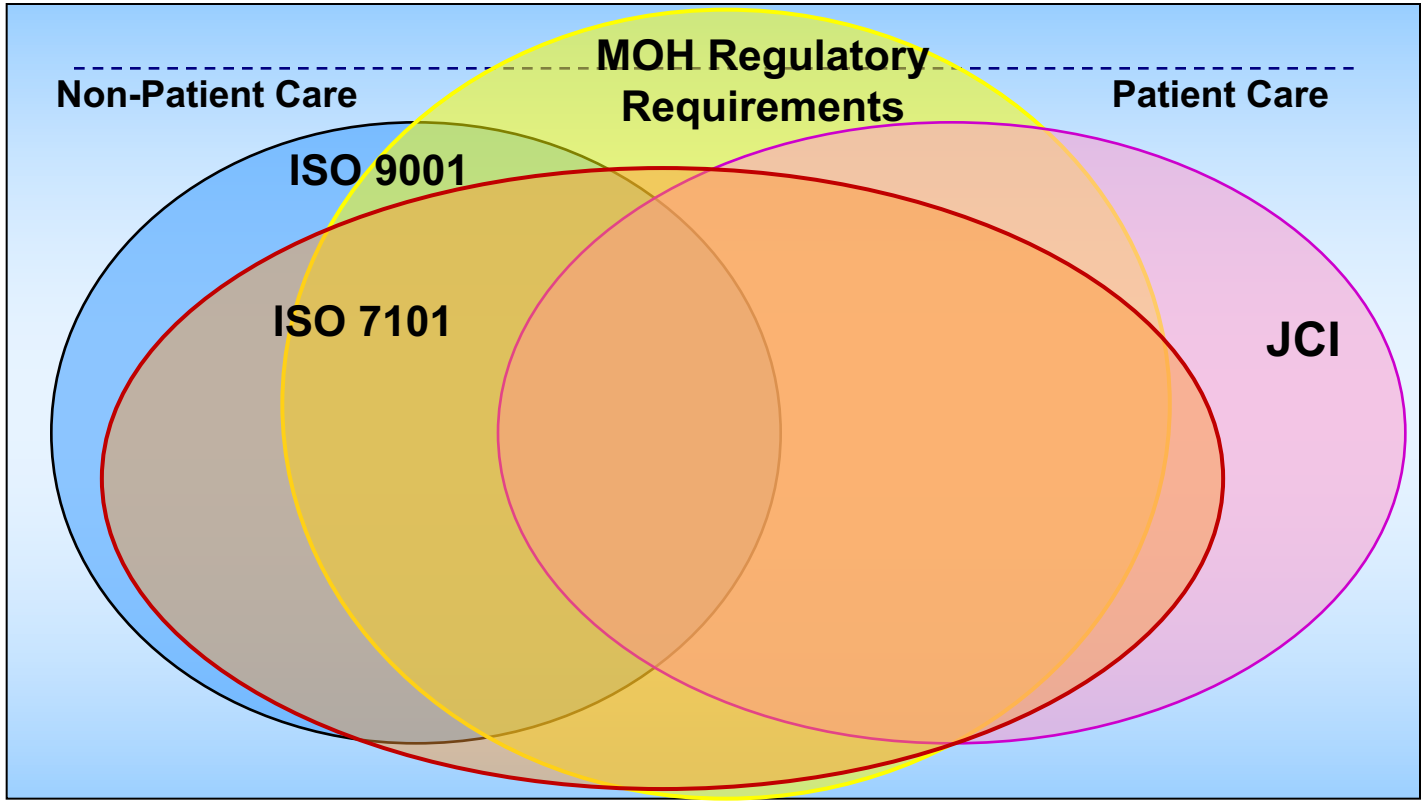
To cite this article: William J. Ritchie, John Ni, Eric M. Stark & Steven A. Melnyk (2019) The Effectiveness of ISO 9001-Based Healthcare Accreditation Surveyors and Standards on Hospital Performance Outcomes: A Balanced Scorecard Perspective, Quality Management Journal, 26:4, 162-173, DOI: 10.1080/10686967.2019.1647770

To link to this article: https://doi.org/10.1080/10686967.2019.1647770

Adobe Acrobat Document

Standby Slides

ISO 7101, JCI & MOH Regulatory Requirements



Discussion on ISO 7101 Adoption

Stage 0: Evaluation of the Work Item Proposal (WIP) ← Current

For Discussion:

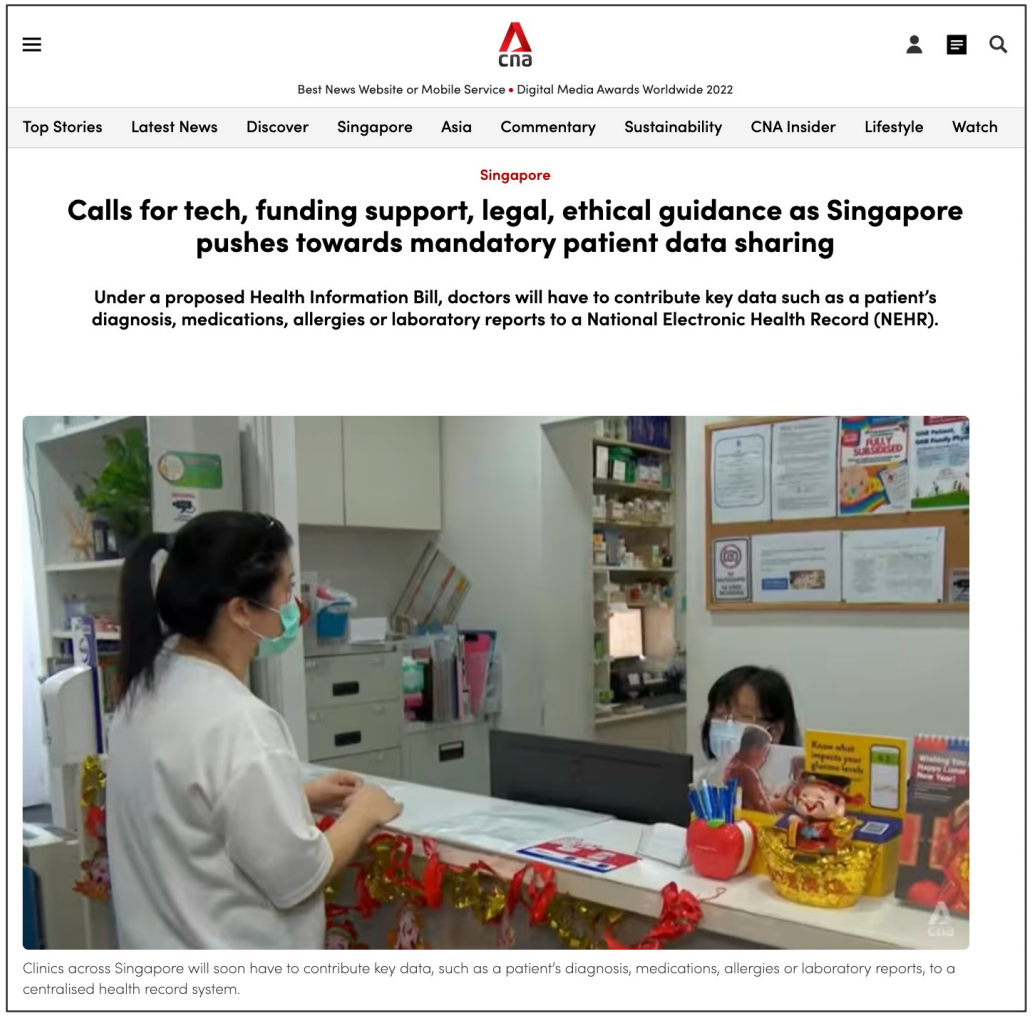
	Do you support the proposal and why?
	Do you oppose the proposal and why?

For information and discussion

Proposal for SS on Implementation Guideline for NEHR Data Standards

Proposed by Synapxe

Standard Demands from Industry and Government



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Singapore

Calls for tech, funding support, legal, ethical guidance as Singapore pushes towards mandatory patient data sharing

Under a proposed Health Information Bill, doctors will have to contribute key data such as a patient's diagnosis, medications, allergies or laboratory reports to a National Electronic Health Record (NEHR).

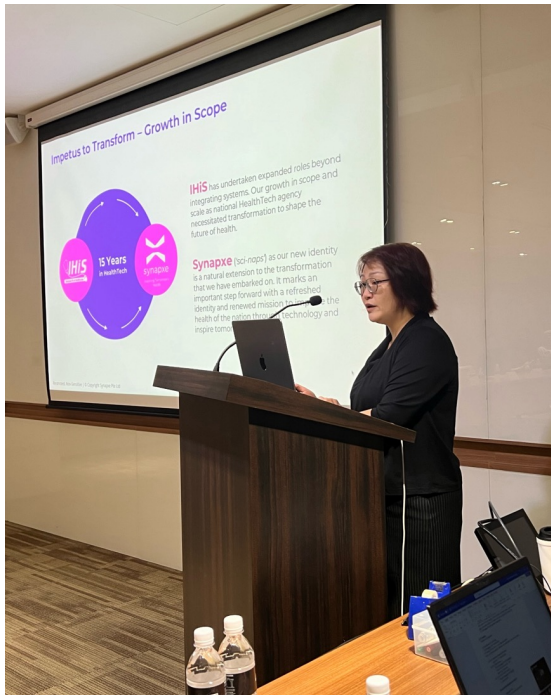
Clinics across Singapore will soon have to contribute key data, such as a patient's diagnosis, medications, allergies or laboratory reports, to a centralised health record system.

Background

Under a proposed Health Information Bill (HIB), all Healthcare Services Act (HCSA)-licensed healthcare providers, including clinics and laboratories, are mandated to contribute key data such as a patient's diagnosis, medications, allergies or laboratory reports to a centralised health record system, the National Electronic Health Record (NEHR). Such information sharing is also meant to go hand-in-hand with Singapore's national preventive care strategy, Healthier SG.

The Bill will be tabled for debate in parliament in the first half of this year.

New Proposal for Implementation Guideline on NEHR Data Standards by Synapxe



Ms Tan Hsiu-Li, Lead Informatics Specialist (Standards) at Synapxe, presents the proposal at the 12th BHSC meeting on 8 Nov 2024

Motivation

NEHR serves as a central patient data repository owned by MOH and managed by Synapxe, to support the "One Patient, One Health Record" initiative.

The data shared through NEHR will include diagnoses, medications, laboratory tests and patient demographics, using the following data standards:

- SNOMED CT[1] : for Diagnosis and Patient Problem List (clinical purpose),
- SDD[2] : for Prescribing and Dispensing Drug Identity,
- SMST[3] : for Supporting Drug Information (Route of Administration, Frequency, Dosage Form, Duration Units),
- LOINC[4] : for Laboratory Test Identity (including individual test identity for Panels), and
- NHDD[5] : for Patient Demographics.

[1] SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms
[2] SDD: Singapore Drug Dictionary
[3] SMST: Singapore Medicines Supporting Terminology
[4] LOINC: Logical Observation Identifiers Names and Codes
[5] NHDD: National Healthcare Data Dictionary

Data Standards throughout Patient's Journey

synapxe
Inspiring Tomorrow's Health

Patient's Journey Overview

NHDD

Ms Kim is having high fever, difficulty in breathing and vomited x 3, went to hospital for treatment.
Patient Demographic:
Ms Kim En En
NRIC: S1234567Z
Nationality: S'porean
Female, Chinese, 50 yrs, NKDA
Dr has accessed to NEHR:

- Problem list: DM & HTN
- Medication list: Metformin, Sitagliptin, Lorsatan, Etoricoxib
- Discharge Summary: Osteoarthritis, postop TKA done 4th Jul 2021, etc.

SNOMED

At A&E, Dr reviewed Ms Kim and ordered immediate test:
H/C, ABG (rm air)
Plan:
FBC, U/E/Cr, bld c/s, urine c/s
IV Clarithromycin, IV Insulin, IV Electrolytes
CXR, 12L ECG
Dx: Pneumonia, DKA
For ICU admission

LOINC

During ICU D3 stay, Ms Kim developed high fever (T 39.7°C), SOB
Assessment:
Vital signs taken (BP, HR, RR, Temp, POCT Gluc)
Plan:
Blood Test: Blood culture, U/E/Cr, FBC, ABG
Added new drug to further control her sugar: Dapagliflozin
Newly diagnosed: Fe deficiency
Few days later, Ms Kim was stabilized and transferred to General Ward

SDD & SMST

At GW, Dr seen Ms Kim and ready for home. The nurse prepared discharge documents, mc, medications, follow-up appointment with lab orders, etc.
Documentation by Dr:
Primary Diagnosis: Pneumonia, Diabetic ketoacidosis
Problem list: Diabetes Mellitus Type II, Hypertension, Iron Deficiency
Medications: Oral Clarithromycin 500mg q12h, Dapagliflozin 10mg OM
In NEHR, patient medical record will be displayed diagnosis, discharge summary, mc, meds orders, lab results, etc.

Objective and Content of the proposed SS

Objective

The goal is to set out a SS that consolidates NEHR-required data standards and provides their implementation guidelines to facilitate broader and more seamless adoption of NEHR across the healthcare sector.

Content

- Related MOH policy
- Purpose of use
- Terms of use for the data standards (e.g. Standards License Agreement requirements)
- Data standards definition, requirements, and specifications
- Access and implementation guidelines on data standards (e.g. implementation resources, NEHR onboarding processes, standards website, etc.)

Users and Working Group of the proposed SS

Users

All users enrolled to NEHR onboarding and contributing data to NEHR, including:

- 75 Service Providers (e.g. Private Acute Hospitals, GP/Specialist/Dentist, Clinical Labs, Radiological labs, Renal Dialysis Centres, Nursing Home, Hospices)
- 1577 End Users (e.g. Licensees from GP/Specialist/Dentist, Clinical Labs, Nursing Homes, and Hospices)

Working Group

- MOH Infocomm, Technology and Data group, National Chief Architect Office (NCAO)
- Synapxe NEHR Project Management team & NEHR Onboarding team
- Synapxe Standards team
- Additional WG members from industry, research, and education sectors?

Related international standards for comparison

ISO/TC 215 **N 4425**

ISO/TC 215 "Health informatics"
Secretariat: **ANSI**
Committee manager: **Hawthorne Rachel Ms**

CD2 TS 6201 Personalized Digital Health Framework

Document type	Related content	Document date	Expected action
Ballot / Reference document	Meeting: Arlington (United States) 7 Nov 2023 Project: ISO/CD TS 6201.2 Ballot: ISO/CD TS 6201.2 (restricted access)	2024-01-19	**COMMENT/REPLY** by 2024-03-21

Description

This CD is issued per the following resolution:

Resolution 2023-84: ISO/TC 215 agrees to distribute ISO/CD TS 6201 Health Informatics — Personalized Digital Health -Framework for 2nd CD commenting. The PL is requested to submit updated text and disposition of comments to the committee manager by 15 January 2024.

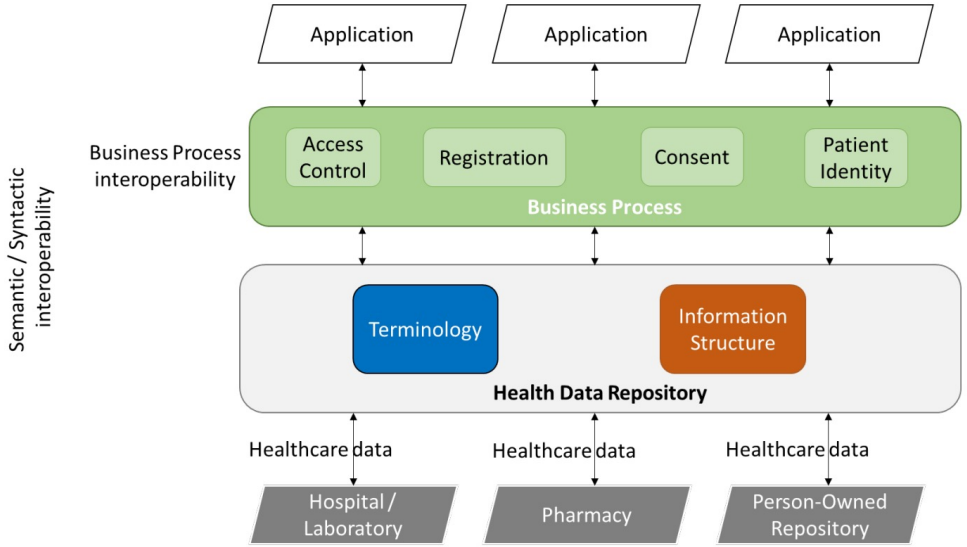


Figure 3 - Interoperability at different levels

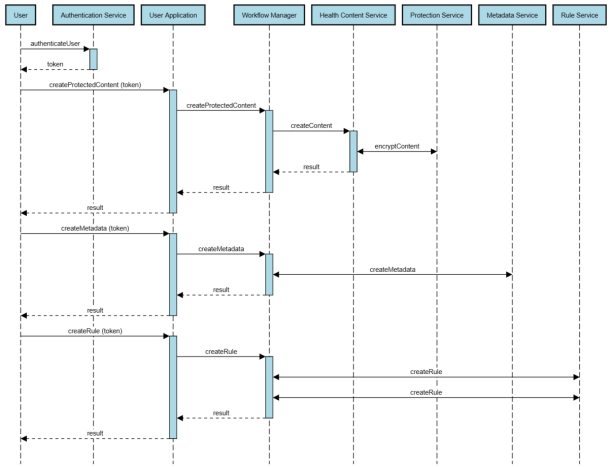


Figure A.3 - Protected registration use case

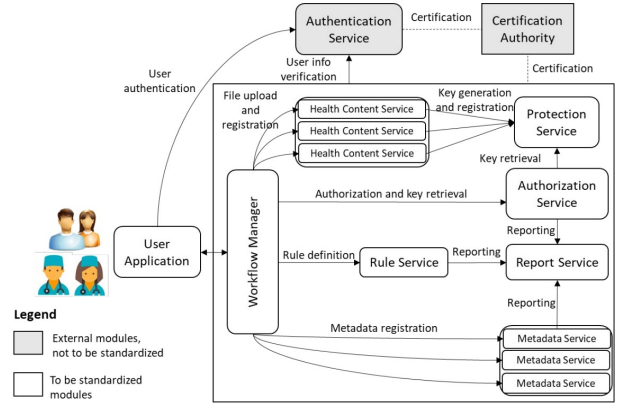


Figure 4 - A Reference architecture

Discussion on NEHR Data Standard Implementation Guide as Singapore Standard

Stage 0: Evaluation of the Work Item Proposal (WIP) ← Current

For Discussion:

	Do you support the proposal and why?
	Do you oppose the proposal and why?
	Recommend additional WG members from industry and research?

For information

Overall Strategy on New Standardisation Exploration

Ms Celine Tan

Deputy Director, Standards Division, Enterprise Singapore

SSC Strategic Plan 2025

GOAL

Fulfill national and industry standardisation needs in a timely manner

PRIORITIES

Support national and industry initiatives

- Industry and enterprise development [1]
- Research and innovation [2] (Emerging areas)
- Public health, safety and environment

Enhance standardisation value chain

- Identify market needs early
- Deliver quality standards on time
- Strengthen standards promotion & adoption

SUSTAINABILITY | **DIGITALISATION** | **RESILIENCE** | **NEW GROWTH CLUSTERS**

[1] This includes initiatives driven by the Future Economy Council, e.g. ITM 2.0
[2] This includes the Research, Innovation and Enterprise Plan 2025.

SSC key focus areas for 2H of strategic plan

SUSTAINABILITY

- Increasingly recognized as both a global priority and Singapore's national priority. E.g., Singapore Green Plan 2030.

DIGITALISATION

- Transforming the way we live and work with new technologies that are offering unprecedented opportunities for digitalisation, health services and collaboration. E.g. new technologies such as AI and metaverse

RESILIENCE

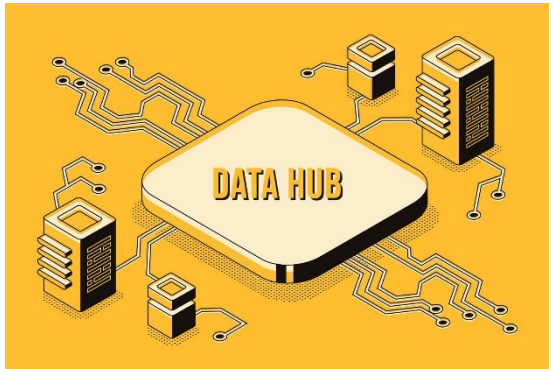
- Remains relevant as widespread disruption to our economy and supply chains due to West-China strategic competition, future pandemics, food shortages, social unrest, etc

NEW GROWTH CLUSTERS

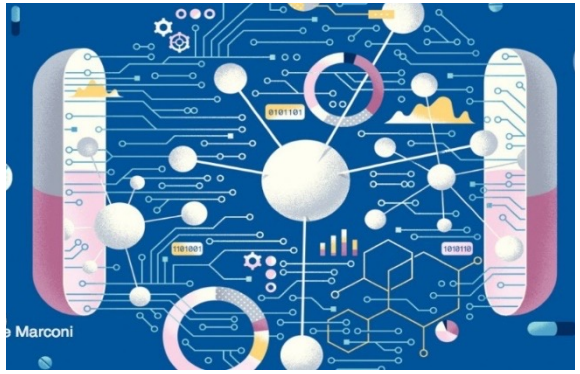
- Areas where SG has strong competitive advantage and global market potential.
  E.g. Offshore wind, Precision medicine

See Annex F for examples of standards to be developed

What will a complete Precision Medicine Ecosystem look like?

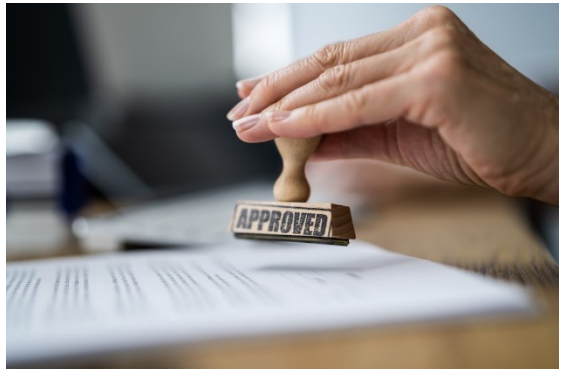


Data Hub
Convenient access to high quality, longitudinal data from disease cohorts across the Asian ethnic groups



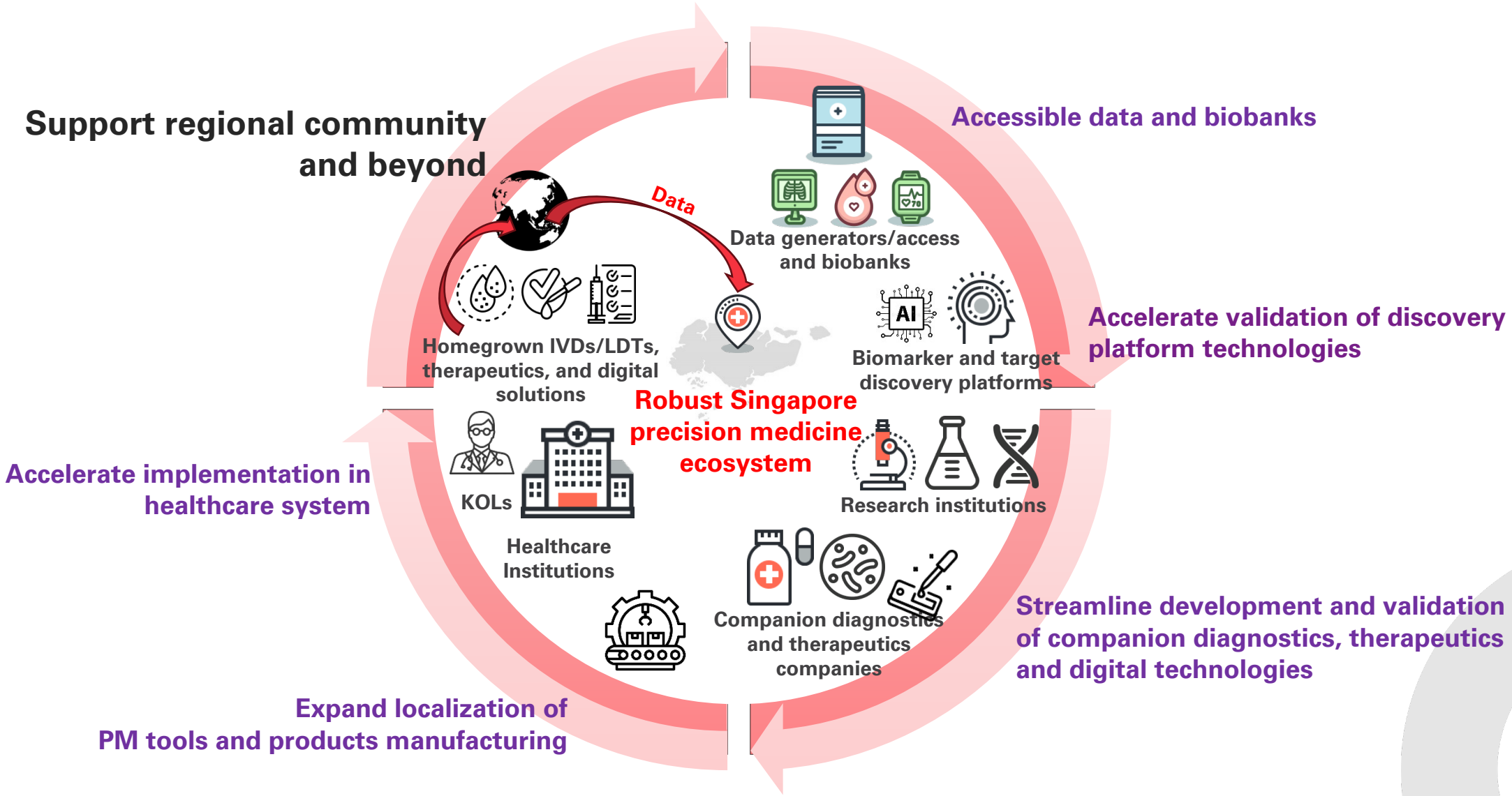
Innovation Hub
Strong therapeutics and diagnostics R&D with accelerated translation pathways

Manufacturing Hub
Design and production of multi-omics and other relevant technologies for the world



Effective implementation
Supportive governance frameworks with expedited regulatory clearances

Catalysing a virtuous cycle to build up the Singapore Precision Medicine ecosystem



Data is key to accelerate the growth of Precision Medicine in Singapore, and enabling access to data helps position Singapore as a Precision Medicine hub in the region

1. How important is it for companies / healthcare institutions to have data that is interoperable / harmonized / standardized, and why?
2. What are some specific regulatory compliance standards that need to be adhered to when collecting data? Are there any changes which you feel should be made to these standards?
3. *In what ways does data standardization enhance collaboration with external partners or integrate new technologies?*
4. How can national / international standards play a role in enabling access to data?

ISO TC 215: Health informatics

Overview of standards

1. Personal Digital Therapeutics
2. Personal Health device communication
3. Point-of-Care (PoC) communication
4. Electronic health record data archetype, data model and data communication
5. Communication Cybersecurity
6. NGS data elements and metadata for genomics applications, clinical sharing and EHR
7. Machine-readable and/or interoperable genomics data exchange
8. NGS quality control

- Standard “families” to consider:
- ISO 11073 (for PoC + Personal Health device communication and Cybersecurity)
- ISO 13606 (for EHR reference model, archetype, interface and security)

For information and discussion

New Standardisation for Healthcare Data Interoperability

By CoRE-SDO

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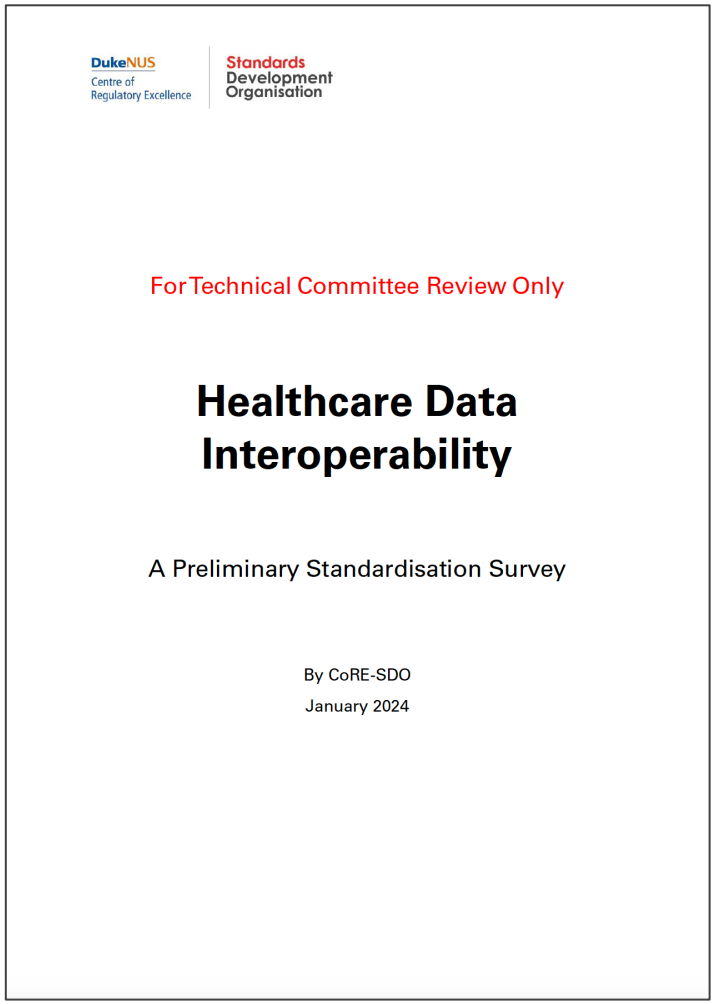
Standardisation Survey for Healthcare Data Interoperability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For Technical Committee Review Only

Healthcare Data Interoperability

A Preliminary Standardisation Survey

By CoRE-SDO

January 2024

The 3rd SPS Taskforce Meeting on 11 Jan 2024

Healthcare Data Interoperability has been identified by the Strategic Planning Session (SPS) Taskforce as as a key focus area for this TC to investigate new standardization initiatives. And CoRE-SDO has prepared a Preliminary Standardisation Survey under this topic for TC's reference.

International Standards to be Considered for Adoption

Regarding **Data Exchange Communication**

Number	Standard Title	Adopt?
ISO 21090:2011	Heath informatics - Harmonized data types for information interchange	
ISO 29585:2023	Health informatics - Framework for healthcare and related data reporting	
ISO/IEEE 11073 (all parts)	Health informatics - Personal health device communication	
ISO 10781:2023	Health informatics - HL7 Electronic Health Record-System Functional Model, Release 2.1 (EHR FM)	
ISO 12052:2017	Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management	
ISO 23903:2021	Health informatics - Interoperability and integration reference architecture - Model and framework	
ISO 13606:2019 (all parts)	Health informatics - Electronic health record communication	

International Standards to be Considered for Adoption

Regarding **Data Standards**

Number	Standard Title	Adopt?
ISO 28380:2014 (all parts)	Health informatics - IHE global standards adoption	
ISO/HL7 27932:2009	Data exchange Standards - HL7 Clinical Document Architecture, Release 2	
ISO/HL7 27931:2009	Data exchange Standards - Heath Level Seven Version 2.5 - An application protocol for electronic data exchange in healthcare environments	
ISO 17439:2022	Health informatics - Development of terms and definitions for health informatics glossaries	
ISO 22077:2022 (all parts)	Health informatics - Medical waveform format	

International Standards to be Considered for Adoption

Regarding **Health Informatics Guidance and Requirements**

Number	Standard Title	Adopt?
ISO/TS 14265:2024	Health informatics - Classification of purposes for processing personal health information	
ISO/TS 17975:2022	Health informatics - Principles and data requirements for consent in the collection, use or disclosure of personal health information	
ISO/TR 14639 (all parts)	Health informatics - Capacity-based eHealth architecture roadmap	
ISO 22600:2014 (all parts)	Health informatics - Privilege management and access control	
ISO 13131:2021	Health informatics - Telehealth services - Quality planning guidelines	
ISO 27269:2021	Health informatics - International patient summary	
ISO 18308:2011	Health informatics - Requirement for an electronic health record architecture	
ISO 13940:2015	Health informatics - System of concepts to support continuity of care	
ISO/AWI TR 24305	Health informatics - Guidelines for implementation of HL7/FHIR based on ISO 13940 and 13606	

International Standards to be Considered for Adoption

Regarding **Informatics Technology**

Number	Standard Title	Adopt?
ISO/IEC TS 19763-13:2016	Information technology - Metamodel framework for interoperability (MFI) - Part 13: Metamodel for form design registration	
ISO/IEC TS 19763-6:2015	Information technology - Metamodel framework for interoperability (MFI) - Part 6: Registry summary	

Regarding **Risk Management**

Number	Standard Title	Adopt?
ISO 27789:2021	Health informatics - Audit trails for electronic health records	
ISO 27799:2016	Health informatics - information security management in health using ISO/IEC 27002	

Evaluation Matrix to Consider Standards Adoption

Criteria \Action	Adoption	New Drafting	Disregard
Relevance to Singapore (e.g. local demands from industry and government bodies)	High	High	Low
Generality (e.g. general definition, method for formatting data exchange, and architectural structure)	High	Low	High or Low
Need for localisation (e.g. info related to local practices, including health insurance operations, reimbursement methods, regional clinical practices, etc.)	Low	High	Low or High

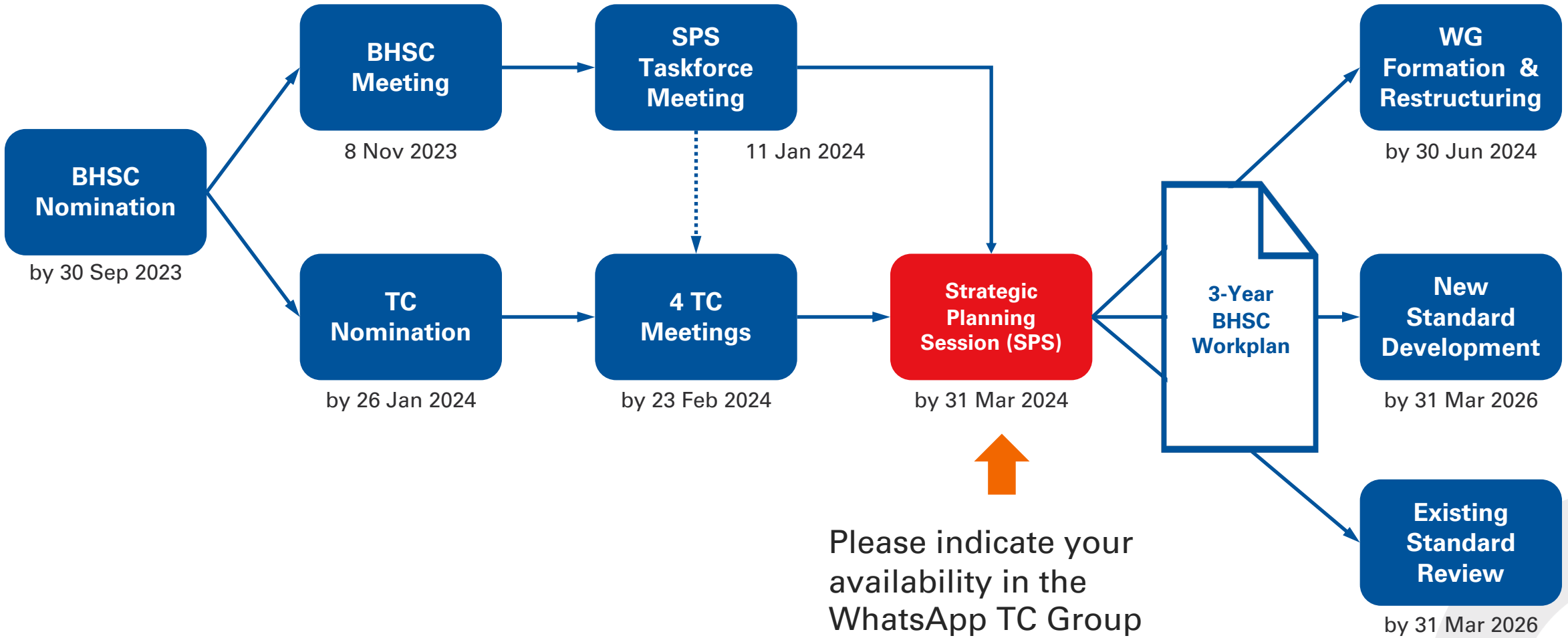
For Discussion:

- Which additional criteria should we take into consideration?
- What additional preparations that would best support your successful identification of standards for adoption?

For discussion

SPS Planning

Strategic Planning Session (SPS) Timeline



Please indicate your availability in the WhatsApp TC Group

SPS Objectives and Outcomes

1 Apr 2024 → 31 Mar 2027

Planning for the new 3-year BHSC Standardisation Workplan:

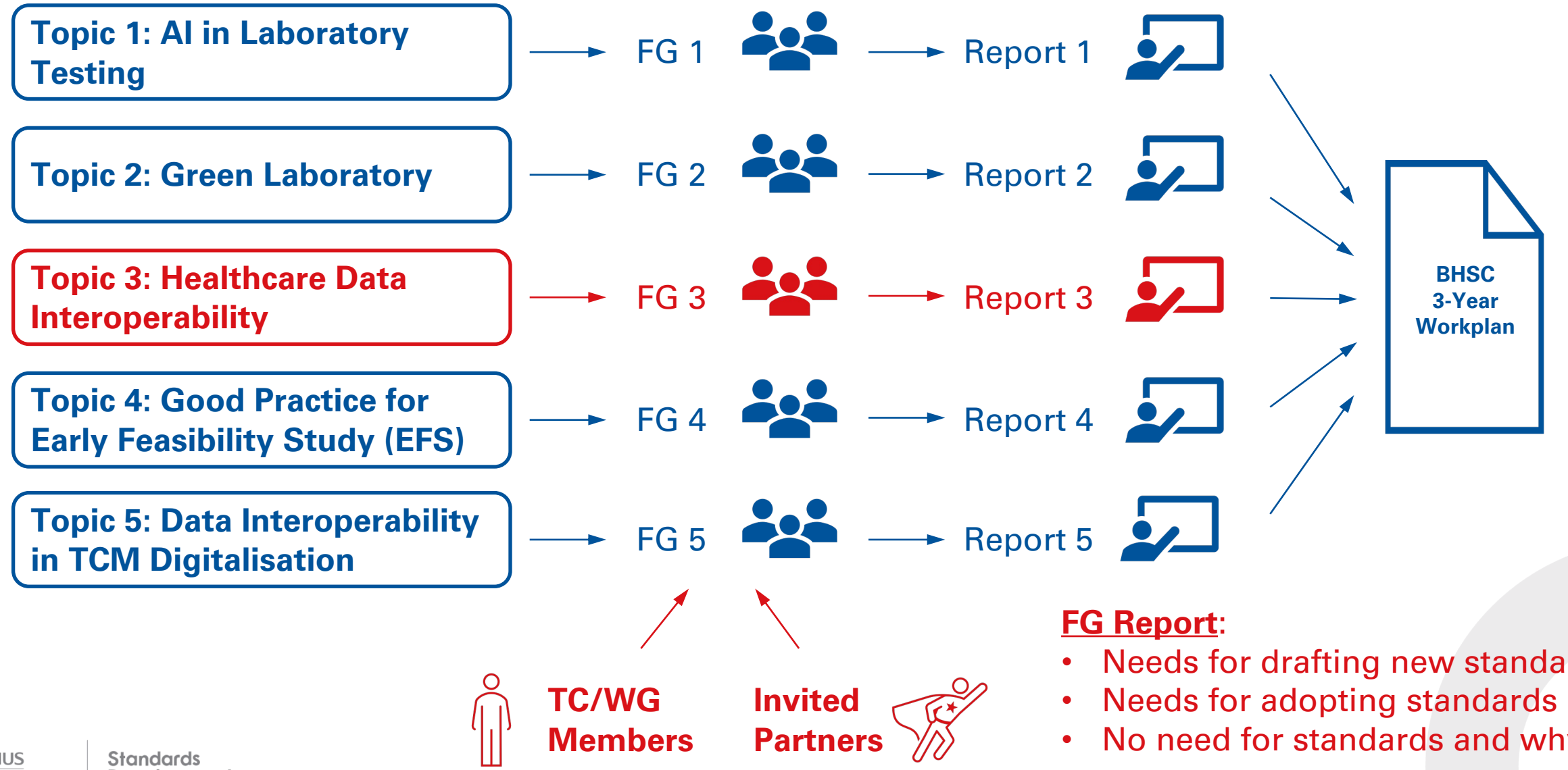
1. Identify new standardisation needs arising from industry, regulatory bodies, research and development, as well as government agencies that can result in new Singapore Standards (SSs) or Technical References (TRs)

2. Devise strategies for promoting national and international standards

Proposed Agenda for SPS in March

S/N	Item Description	Start Time	Duration	By
1	Registration	1:00 pm	30 mins	All
2	Welcome Address	1:30 pm	10 mins	BHSC Chair
3	Presentations (6x, 10 mins each)	1:40 pm	60 mins	Invited Speakers
4	Briefing for FG Breakout Discussion	2:40 pm	10 mins	Secretariat
5	FG Breakout Discussion (5x focus groups)	2:50 pm	90 mins	All in Groups
6	Report from FGs (10 mins each)	4:20 pm	60 mins	Facilitators
7	Summary	5:20 pm	10 mins	Secretariat
	Meeting Adjournment	5:30 pm		

SPS Focus Groups and Expected Outcomes



FG Report:

- Needs for drafting new standards
- Needs for adopting standards
- No need for standards and why

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Invited Speaker and Focus Group Composition

For Discussion:

Topic	Healthcare Data Interoperability
Facilitator	Dr Adam Chee
Speaker	Nominee from Synapxe

TC Members	WG Members	Guest Partners
All TC Members	WG Members relevant to this topic	Your nominations?

For discussion

ISO Membership and National Mirror Working Groups

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ISO/IEC Membership

BHSC currently oversees 9 P-Members and 6 O-Members

Aspect	P-member	O-member
Definition	Participating member (P): P-members actively participate by voting on the standard at various stages of its development.	Observing member (O): O-members observe the standards that are being developed, offering comments and advice.
Meeting Attendance	To contribute in meetings	To have the right to attend meetings
Voting	Obligation to vote on all questions formally submitted for voting within the technical committee or subcommittee, on new work item proposals, systematic review ballot, enquiry drafts and final draft International Standards	To have the right to submit comments

“P” and “O” Membership Consideration for this TC

Name	Scope	Current Status	For Discussion
ISO/TC 215 Health Informatics	Standardization in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.	• O-Member • TC is acting as the NMWG	• Shall we consider **P-membership** for deeper involvement and SG voice? • Should we establish a dedicated **NMWG** for it?
ISO/TC 304 Healthcare organization management **(e.g. ISO 7101)**	Standardization in the field of healthcare organization management comprising, terminology, nomenclature, recommendations and requirements for healthcare-specific management practices and metrics (e.g. patient-centered staffing, quality, facility-level infection control, pandemic management, hand hygiene) that comprise the non-clinical operations in healthcare entities.	• No membership or NMWG	• Shall we consider **P- or O-membership**? • If so, should we establish a dedicated **NMWG** for the new membership?

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THANK YOU