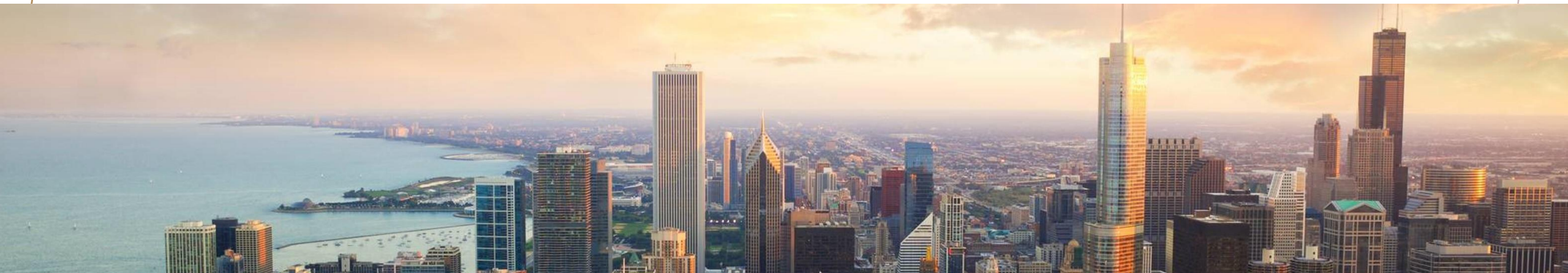


# *TECHNOLOGY CONVERGENCE AND STANDARDS READINESS*

## *TECHNOLOGY CONVERSION POINTS*

*LAURA LINDSAY  
STANDARDS STRATEGIST  
MICROSOFT*





With help from next-generation AI, Indian villagers gain easier access to government services




Taiwan brings in generative AI to help students learn English

**New Taipei City, TAIWAN** – Teachers often report that students learning English tend to read and write better than they speak, as shyness and a lack of practice can hinder the ability to converse. Now, a chatbot funded by Taiwan’s Ministry of Education and running on next-generation large language models offers a way for K-12 students to get that practice, and in a more engaging way than was previously possible.

Accelerating Sustainability with AI: A Playbook

Nov 16, 2023 | Brad Smith, Vice Chair and President, and Melanie Nakagawa, Chief Sustainability Officer

[f](#) [in](#) [t](#)



# The promises of AI



**Hack For '23 Public Good** Pair: AI writing assistant for public officials in Singapore

 **PRIME MINISTER OF AUSTRALIA**  
The Hon Anthony Albanese MP

Menu

Home / Media

Australian Government collaboration with Microsoft on artificial intelligence

## Australian Government collaboration with Microsoft on artificial intelligence

Media release

Thursday 16 November 2023

 Prime Minister



# Technology



Personal assistants like Siri, Google Now, Cortana use speech recognition to answer questions and perform simple tasks



AlphaGo beats professional Go player Lee Saedol 4-1

...

GPT 3

DALL-E

GPT 3.5

DALL-E 2



GPT 4

DALL-E 3

GPTs

GPT 4 Turbo

1950

...

2011 - 2014

2016

2017

2019

2021

2022

2023

...

2027

# Regulation & Governance

EU AI Act (draft)



Algorithmic Accountability Act (Proposed)



AI and Data Act

NIST AI Risk Management Framework



Executive Order on Safe, Secure, & Trustworthy AI



AI Safety Summit The Bletchley Dec



Hiroshima Process

EU AI Act (regulate)



# Standard

Establishment ISO/IEC JTC 1/SC 42

Foundational Standards

...

Data Quality Management

Risk Management

AI Management System

AI Impact Assessment

Requirements for Cert Bodies of AIMS

# Responsible AI

# *WHY DO WE NEED AI STANDARDS*

- Establishes global “rules of the road” based on input from civil society, academia, government and industry
- Enables global coherence between different regulatory regimes which is essential for industry
- Enables trust in organizations
- Enables responsible development and use of trustworthy AI systems
- Accountability and transparency
- Improve market adoption of technologies
- Support regulatory outcomes

# *AI STANDARDS NEEDED*

Terminology and concepts

Risk management

Governance implications of the use of AI

Data quality management

Quality models for AI systems

AI Management system

AI system impact assessment

Trustworthiness

- Unwanted bias
- Transparency
- Explainability
- Controllability
- Human oversight

Testing of AI systems

Best practices (data capture, privacy, transparency, confidentiality, etc.)

Application or Sector specific AI guidance

# *WHERE ARE AI STANDARDS AT*

- ISO/IEC have issued over 20 standards on terminology, risk framework, data management, AI Management Systems, and many more.
- ISO/IEC 42001 established the framework for quality models for AI systems with consistent terminology for specifying, measuring and evaluating system quality.
- ISO/IEC expects to publish ISO/IEC 42005 in 6-12 months. This will provide international standards for AI tailored to different domains and applications.



# *ISO/IEC 42001 AI MANAGEMENT SYSTEM*

## AIMS structure

### Management clauses

- Context of the organization
- Leadership
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement

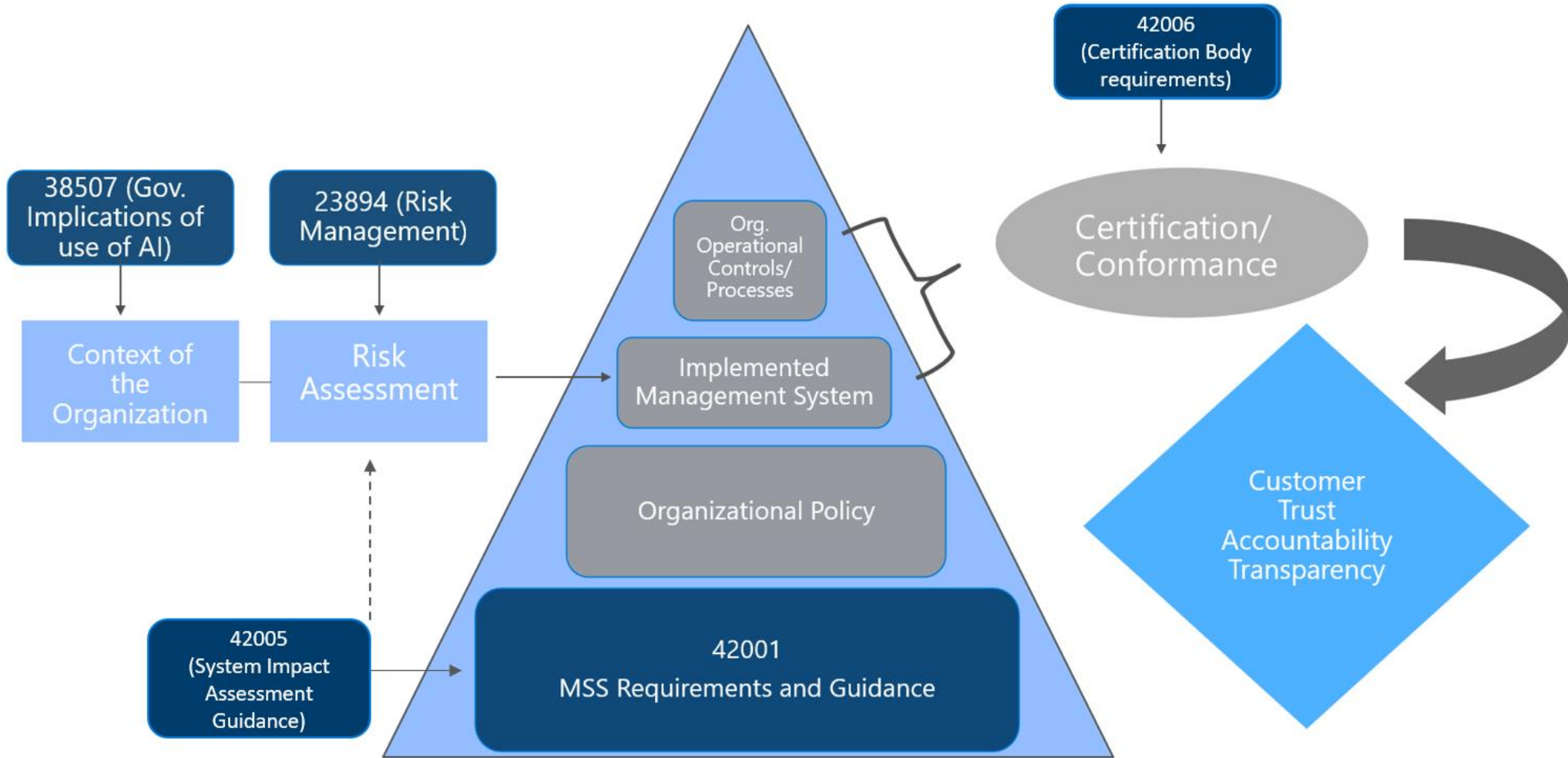
### Reference controls categories

- Policies related to AI
- Internal organization
- Resources for AI systems
- Assessing impacts of AI systems
- AI system life cycle
- Data for AI systems
- Information for interested parties of AI systems
- Use of AI systems
- Third-party and customer relationships

### AI related organizational objectives, risk sources and use of AIMS across sectors

- Organizational objectives
- Risk sources
- Integration of AIMS with other management system standards

# SUPPORTING STANDARDS IN THE FOUNDATIONAL AI ECOSYSTEM





*NEXT STEPS  
FOR AI  
STANDARDS:  
JOINT  
CERTIFICATION*



# *THE PROBLEM TODAY*

There is currently no ecosystem of conformity assessment for digital services (Like AI) that is \*equivalent\* to that of tangible/manufactured products

Testing and auditing methodologies for tangible products are very different, more robust, and more time consuming than current "digital services" focused audits

If regulators continue to insert these requirements without understanding the full conformity assessment ecosystem, the probability of inserting requirements that are impossible or extremely costly and difficult to fulfill (e.g., rebuilding controls and compliance programs from the ground up) is high

*IF IT  
DOESN'T  
CHANGE*

Existing certifications will not be scalable for organizations without an additional “product” component due to increasing regulatory expectations

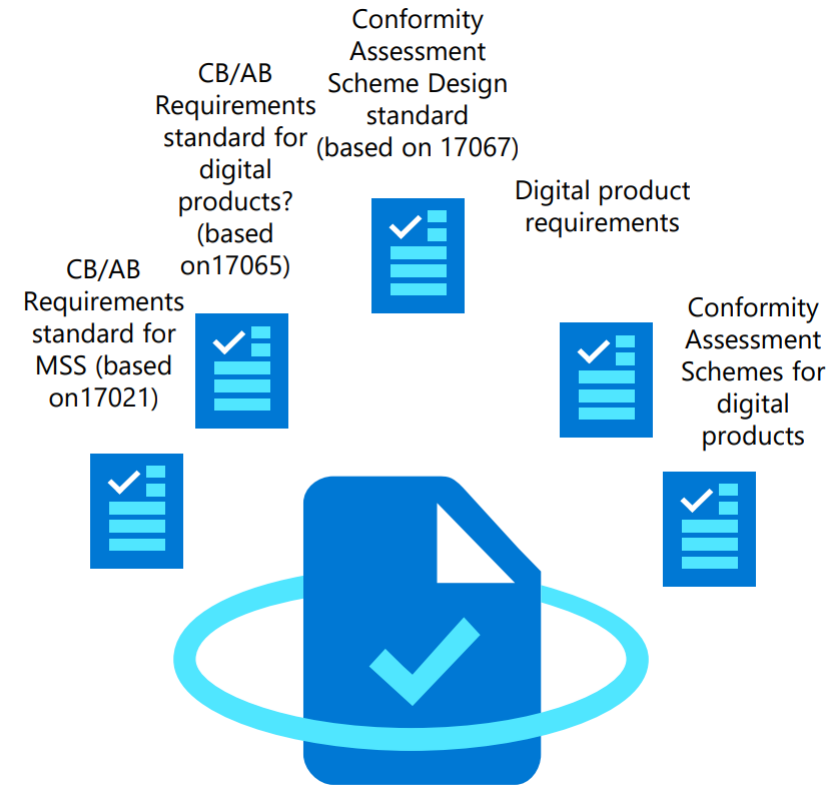
Proliferation of regional, sector-specific certifications in the absence of internationally recognized certifications for product-level assessment of digital services

Organizations faced with conformity assessment requirements they can't meet due to lack of frameworks available for digital services (e.g. schemes that can be used by certification bodies under ISO/IEC 17065 for digital services/non-tangible products)

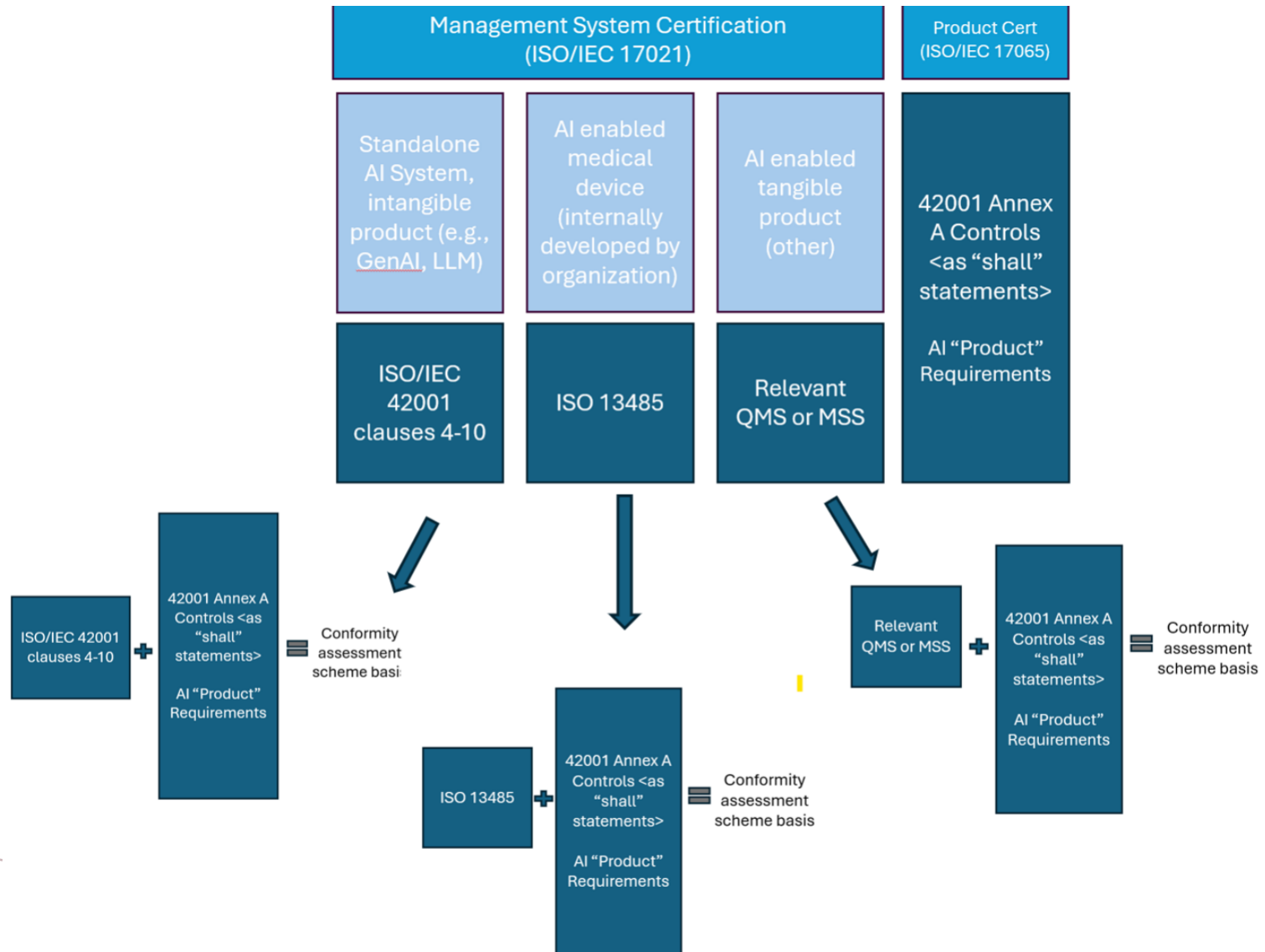
# ADDRESSING THE CONFORMITY ASSESSMENT PROBLEM

- Creating a CA ecosystem for digital products
- Within that ecosystem there need to be standards such as:
  - MSS CB requirements (e.g., 27706, 27006, 42006)
  - Digital product CB requirements (This would be new. )
  - Digital product conformity assessment scheme guidance

Within conformity assessment schemes, there is the concept of “certification of digital products leveraging management system standards” (such as 42001). This is what is informally known as “joint certification”



# CERTIFICATION OF DIGITAL PRODUCTS LEVERAGING MANAGEMENT SYSTEM STANDARDS : AIMS



## CONTEXT

An organization that manufactures Glucose Monitors aims to embed an AI algorithm to consistently alter insulin infusion to patients in the insulin pumps.

## TRIGGER

The MedTech firm plans to source AI components from a third-party provider, which would be just ISO/IEC 42001 certified

## KEY QUESTION

*Is there a scheme that can help MedTech organizations in streamlining audits for intangible digital services along with tangible products?*

## SOLUTION: JOINT CERTIFICATION SCHEME BY ABC CERTIFICATION BODY

ISO/IEC 42001 AI  
Joint Certification



AI Enabled  
medical  
device

ISO 13485 + Applicable  
product certification  
(FDA, CE, etc.)



- ✓ Integrated the control requirements mentioned in ISO/IEC 42001 controls with the mandates in AI regulatory act
- ✓ Combined the scheme (ISO/IEC 42001 + AI act integration) with their 13485 certifications

# *ADDITIONAL INFORMATION ON JOINT CERTIFICATION*

- How can the medical device industry seize the upside of changing AI regulatory requirements?  
(<https://www.linkedin.com/feed/update/urn:li:activity:7120772491618258944/>)
- A Joint certification approach to Digital Services  
(<https://www.linkedin.com/feed/update/urn:li:activity:6914989025967689728/>)

# *THANK YOU*

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