



The Importance of Standardisation in Digital Health

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Who Are Standards Australia...?



STANDARDS
Australia



Who Are Standards Australia...?



- Independent, not-for-profit, non-government
- Develop and adopt standards in the national interest
- Australian member of ISO & IEC
- A trusted partner of government, industry and the community
- Last year we celebrated our 100 year anniversary



Who Are Standards Australia...?

Our Work

6,314

Active committee members

2,216

Nominating Organisations

389

Active Technical Committees



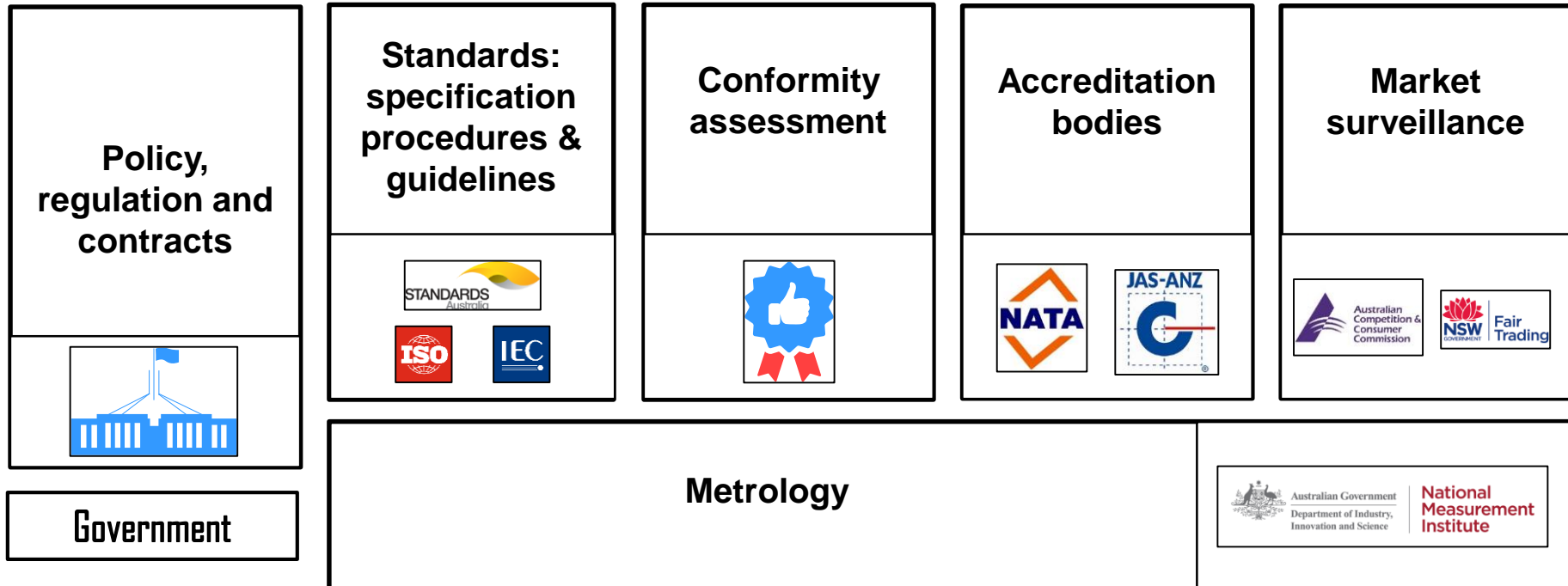
International participation



Standards Australia also Represents Australia at the ISO and IEC, providing Australia's official position on a global standards

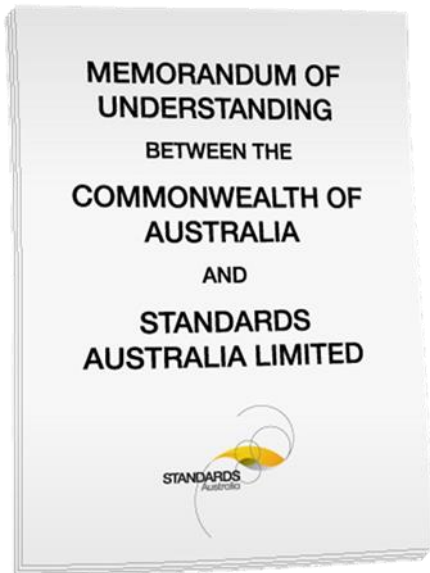


Our work fits into a much broader system





Who Are Standards Australia...?



Our role as the National Standards Body



A **broad** focus on government priorities



WTO TBT obligations



Compliance with best practice processes for regulatory compliance and standards development



Why Are Standards Important...?



- A set of available rules
- Define products, systems, processes – facilitating markets & interoperability
- Set out conformity (or testing) requirements
- Enable trade, measurement and quality

The Code of Hammurabi is the earliest known example of a written standard setting out 282 edicts in “if-then” form and dating back to 1750 BC



Why Are Standards Important...?



80% of world trade is affected by standards

Outsell Standards market sizing report 2018



Why Are Standards Important...?



Australia leads the world in a number of key areas of standards work,
with much more to be done



Why Are Standards Important...?



Within the ISO and IEC models, development of new standards must take into account the protections afforded under WTO Technical Barrier to Trade rules



The Challenges of Interoperability

- Technology is changing faster than ever
- Community expectations are rising as quickly
- Standards for innovative products and services are increasing in complexity
- New systems and products are coming to market all the time with significant convergence
- Different materials, design, operating and renewal methods are becoming mainstream
- The regulatory and standards systems and processes have been in place for many years





The Challenges of Interoperability



Everyone involved in the health sector wants products and services to:

- Be more inclusive and accessible
- Make better use of technology
- Support value chains
- Be open about risks and costs
- Support innovation to solve problems



The Challenges of Interoperability



New systems and products are coming to market all the time with significant convergence

The worst thing we can do is to do nothing

We need to focus on:

- Compromise and communication
- Flexibility in delivery
- Management of risk



How can Standards Australia help...?

Key areas where Standards and interoperability can help the industry (and patients):

- Telehealth
- Consistent capture, sharing and use of health records & information
- Safety, privacy and security of healthcare apps and devices
- Electronic Prescriptions
- Partnerships with industry, government and other standards developing organisations





How can Standards Australia help...?



- There is already so much content out there to increase interoperability in Digital Health
- Standards Australia are not the only source of Digital Health Standards
- We all have our part to play



How can Standards Australia help...?



- Raise awareness of current standards and work with industry, government and the community to understand them
- Facilitate collaboration between industry, government and the community to integrate into existing structures where applicable
- Volunteer our infrastructure to increase interoperability nationally and showcase your hard work and innovation globally



Key Australian Standards already in use



Standards in place:

AS ISO 13131:2022 Telehealth services — Quality planning guidelines

AS ISO 81001.1:2022 Health software and health IT systems safety, effectiveness and security, Part 1: Principles and concepts

SA TS ISO 21564:2022 Health Informatics — Terminology resource map quality measures (MapQual)

AS ISO 27269:2022 Health informatics - International patient summary



ISO Standards already in use

SA TS ISO 21526:2022 Health informatics — Metadata repository requirements (MetaRep)

ATS ISO 25237-2011 Pseudonymization

Australia could potentially adopt:

ISO TS 82304-2:2021 Health software - Part 2: Health and wellness apps - Quality and reliability

ISO 13940:2015 Health informatics — System of concepts to support continuity of care

Selected ISO/TC 215/SC 1 publications in the area of Genomics Informatics





Industry Partnerships

- Standards Australia have committed to working closely with the Australian Digital Health Agency as they execute their National Digital Health strategy
- We want to collaborate with other organisations who develop standards, who use standards, who simply want to be involved





How Can You Contribute?



Submit Proposals



Any member of the public can submit a proposal to create, revise or withdrawn an Australian Standard

Using our online portal and supported by our team, you will given all the tools to make you voice and idea heard



Become a Nominating Organisation



If you are part of a member based industry body, special interest group or volunteer association, you may meet the criteria to become a nominating organisation with Standards Australia

This would put your organisation in a position to be consulted on relevant proposals, take part in forums and have a regular presence in the standards development process both in Australia and Internationally



Join a National Technical Committee



Already part of a of a nominating organisation?

Speak to your Standards coordinator (we can always put you in touch if you're unsure) and ask to be kept in mind for any openings on our wide range of technical committees and international working groups



See a gap? Let us know



Is there an area where you feel Standards Australia could provide support?

Do you have an idea that could benefit from collaborating with us?

Have an idea for an app that could use funding?



Conclusion/Road Ahead



- Much of what the Digital Health industry needs to work together already exists
- Let's focus on coming together and collaborating on using what we already have to create the best outcomes for patients and practices
- Standards are just 1 piece of the puzzle – help us help you