

The Role of Technical Standards

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'Standard' – a definition

- Document, established by consensus, and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context
 - NOTE – Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits

ISO/IEC Guide 2: Definitions



Key elements of a standard

- Consensus,
- Approved by a recognised body,
- rules, guidelines or characteristics for activities or their results,
- achievement of the optimum degree of order in a given context
- based on the consolidated results of science, technology and experience, and
- aimed at the promotion of optimum community benefits



Consensus

- 1. general agreement of concord
- 2. majority of opinion

* MACQUARIE CONCISE
DICTIONARY, 4th Edition



Recognised body

- Public or private bodies who work on the basis of
 - Geographical/political affiliations (global, regional or national)
 - Professional competence (informatics, electrotechnology, health care)
- Who have established various means of co-operation
 - Direct reporting
 - Contractual agreements
 - Memoranda of understanding
- Non-profit organisations working on the basis of
 - Participation of interested parties
 - Transparency
- Competency is recognised by the government, regulatory bodies and the community



Recognised bodies

- ISO - International Organisation for Standardisation
- IEC - International Electro-technical Commission
- CEN - Comite' Europeen de Normalisation
- CENELEC - Comite' Europeen de Normalisation Electrotechnique
- ANSI - American National Standards Institute
- ASTM Int - American Society for Testing and Materials Int.
- AAMI - Association for the Advancement of Medical Instrumentation
- CLSI - Clinical and Laboratory Standards Institute

..... To name a few



And there are others

- BSI - British Standards Institution
- JIS - Nippon Kōgyō Kikaku (JIS Standards)
- NSAI - National Standards Authority of Ireland
- NZS - New Zealand Standards

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..... and





Transport and Logistics

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Australian Standards®



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Australian Standards in Legislation and Case Law

Current Projects

Drafts for Public Comment

Proposed Projects

Sector Updates

Standards Australia is recognised by the Government as Australia's peak Standards body. It coordinates standardisation activities, develops internationally aligned Australian Standards® that deliver Net Benefit to Australia, and facilitates the accreditation of other Standards Development Organisations. Through the Australian International Design Awards it promotes excellence in design and innovation.



First round of Standards development Prioritisation and Selection Process completed

Standards Australia has recently completed its assessment of the approximately 100 proposals received for consideration under the first round of the Prioritisation and Selection Process. Together these proposals included more than 300 projects.

Approved projects range across 11 of Standards Australia's 12 industry sectors and reflect the broad range of work undertaken everyday by Standards Australia. Work on all projects approved

Recognised bodies

- Standards development is now, very much an international process
- Two forms of Recognised Bodies
 - Developer's of Standards – ISO, IEC, CEN
 - Adopter's or 'taker's' of standards – SA, NZS, BSI

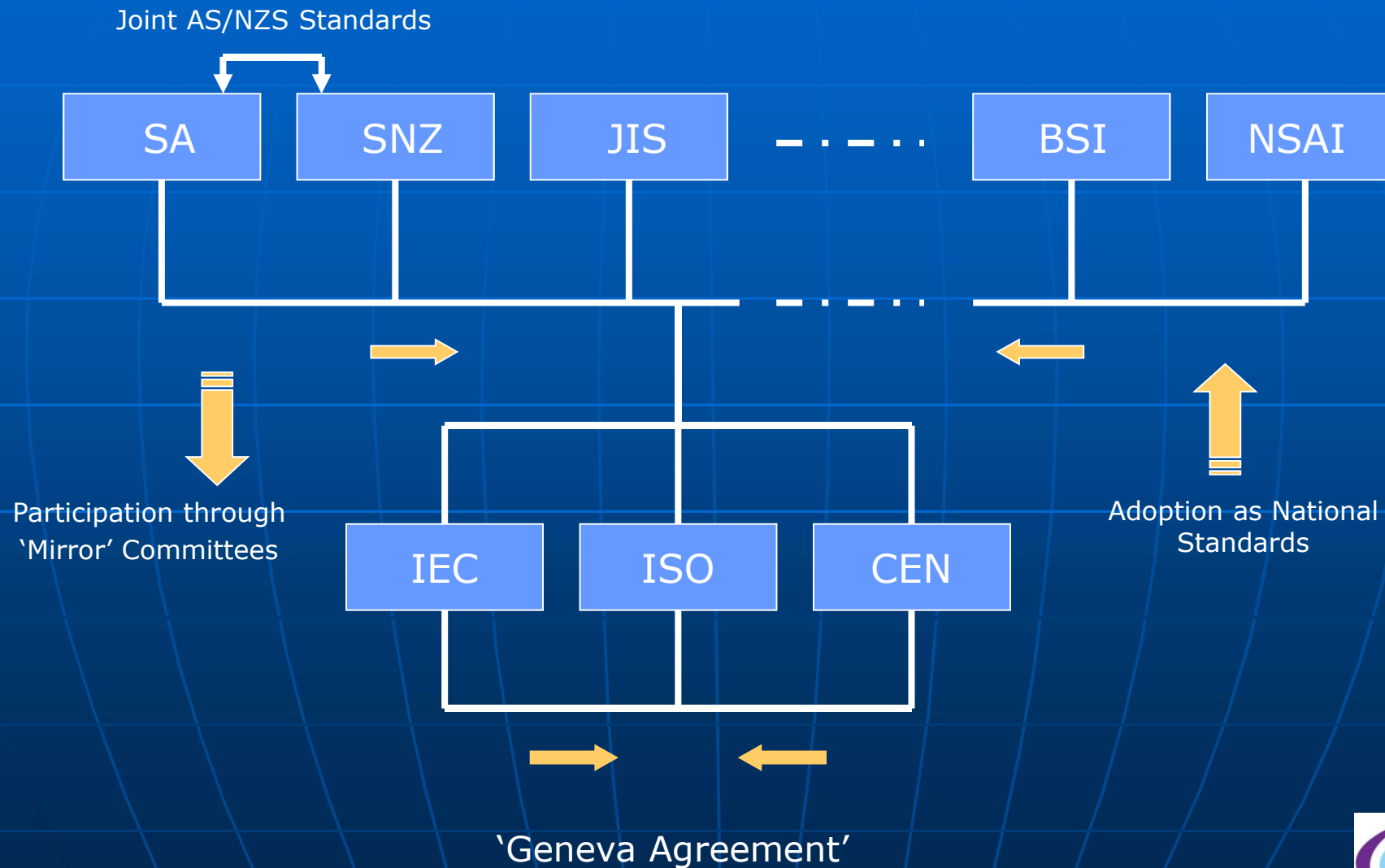


Strategic principles of Standards Australia

- Standards will benefit the Australian community;
- Australia will maximise use of prevailing international standards;
- Standards development will be driven by commitment of stakeholders; and
- Australian standards will only be produced where appropriate.



Standards Development Today



Legal Status of Standards

- None !!!

- Unless

- In contractual law – specification of products or services under contract
- In civil liability – compliance with requirements for safety
- In product regulation – compliance with the requirements for safety and appropriate performance



Standards

- Competition & Consumer Act 2010
 - Industry regulation, anti-competitive behaviour, industry codes, product labelling, price monitoring, **product safety**
 - Mandates compliance with some Australian Standards
 - Sunglasses
 - Fire safety of infant clothing
 - Infant car restraints
 - Bicycles





Mandatory standard—Prams and strollers

The mandatory standard for prams and strollers came into effect on 1 July 2008. It covers performance testing, design, construction, safety warnings and informative labels for prams and strollers.



Mandatory standard—Basketball rings and backboards

The mandatory standard for basketball rings and backboards came into effect on 11 October 2005. It covers specific safety marking requirements for basketball rings and backboards.



Mandatory standard—Elastic luggage straps

The mandatory standard came into effect on 10 July 1979. It covers specific safety markings and labelling requirements for elastic luggage straps.



Mandatory standard—Exercise cycles

The mandatory standard for exercise cycles came in to effect on 5 September 2007. It covers requirements including construction, design and instruction requirements.



Mandatory standard—Disposable cigarette lighters

This mandatory standard came into effect on 1 March 1997. It covers specific child resistance, labelling, testing, performance and compliance requirements for disposable cigarette lighters.



Mandatory standard—Trolley jacks

This mandatory standard came into effect on 2 August 2008. It covers a variety of requirements for trolley jacks, including design, construction, performance and packaging requirements.



Mandatory standard—Bunk beds

The mandatory standard for bunk beds came into effect on 7 April 2005. It covers specific construction, design and labelling requirements for bunk beds.



Mandatory standard—Vehicle jacks

This mandatory standard came into effect on 12 February 2010. Suppliers have until 30 June 2011 to adjust to the new requirements of this mandatory standard. It covers requirements for design, construction, performance and instructions for safe use for a variety of vehicle jacks.



Mandatory standard—Vehicle support stands

This mandatory standard came into effect on 25 November 2008. It includes design, construction, safety marking and packaging requirements for vehicle support stands.

Standards

- Competition & Consumer Act 2010
 - Mandatory reporting guidelines for product safety issues
 - Civil and criminal penalties for non-compliance
 - Can mandate product recalls and bans



Australia as Standards 'Takers'

- IEC60601.1:2005 + A1 and A2
- IEC 60601.1.3:2008
- IEC 60601.2.25:2011
- **AS/NZS IEC 60601.1:2015** - Medical electrical equipment General requirements for basic safety and essential performance
- **AS/NZS IEC 60601.1.3:2015** - Medical electrical equipment General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- **AS/NZS IEC 60601.2.25:2016** - Medical electrical equipment Particular requirements for the basic safety and essential performance of electrocardiographs
-**and 13 others**



STANDARDS



AS/NZS IEC 60601.1.3:2015

Medical electrical equipment General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment



GOST R IEC 60601-1-3:2013

Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard - Radiation Protection In Diagnostic X-Ray Equipment



NEN EN IEC 60601-1-3:2008

Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment



IEC 60601-1-3 Ed. 2.1

Medical electrical equipment Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment



KS C IEC 60601-1-3:2011

Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment



Australia as Standards 'Takers'

- Current Program –
 - Direct Text Adoption of 60601 and 80601 series
 - Next tranche of DTA of 25 IEC standards in progress
 - Blocks of 4 at a time
 - Published to HE-003 for consideration
 - Committee vote
 - Adoption as AS NZS IEC Standard



Australia as Standards 'Developers'

■ The Safety Triangle -

- AS NZS 2500:2004 – Guide to the safe use of electricity in patient care
- AS NZS 3003:2011 – Electrical Installations – Patient Areas
- AS NZS 3551:2012 – Management Programs for Medical Equipment

And let's not forget

- AS 2896:2011 - Medical gas systems - Installation and testing of non-flammable medical gas pipeline systems



AS NZS 3551:2012 – Management Programs for Medical Equipment

- Major re-write from 2008 'til publication in 2012
- Minor amendment in 2014
- Tidy up of technical detail and clarification of Touch Current Test in 2016
- Anticipated to be stable until projected review 10 years after initial publication

BUT.....

- Proposal by ACCI and MTAA to withdraw the Standard



AS NZS 3003:2011 – Electrical Installations – Patient Areas

- Currently under review and re-write
- Major issue of contention –
 - Patient areas in Nursing/aged care centres
 - Call for body protection
 - Objections from Nursing/aged care industry
- Watch this space



AS NZS 2500:2004 – Guide to the safe use of electricity in patient care

- 13 years since publication of last edition
- Delivery of health care and technologies has changed significantly in that time
- About to undergo review and major re-write



AS NZS 2500:2004 – Guide to the safe use of electricity in patient care

- HE-003 is about to form a sub-committee HE-003-XX
 - Tasked with reviewing and updating AS NZS 2500
- Looking for nominations of potential participants
 - Criteria
 - Practicing in the field.....BME, Nursing, Clinical.....
 - Competent and 'expert'
 - Nominated by appropriate organization
 - Nominees represent views of the profession, not their individual views
 - Participation is voluntary.....SA does not remunerate committee members

.....but you have the opportunity to make a lasting contribution to a safe healthcare environment



- If you are interested –
 - Discuss with SMBE(NSW) executive
 - They will be responsible for nominating (probably) up to 2 participants in the Committee

- Any thoughts or questions –
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 - M: 040 1147 605

