



**Submission to the Australian Commission
on Safety and Quality in Healthcare's
Discussion Paper on National Safety and
Quality Accreditation Standards**

22 March 2007

Executive Summary

This submission addresses several of the issues canvassed in the Australian Commission on Safety and Quality in Healthcare's Discussion Paper – National Safety and Quality Accreditation Standards, November 2006. The issues canvassed are those relating to standards and standards development - Standards Australia's core business and a domain in which our expertise is recognised internationally.

The Discussion Paper proposes a series of reforms and initiatives in relation to healthcare accreditation standards. Standards Australia is generally supportive of these although we consider that they are closely interlinked and that careful targeting will be required to maximise their collective return on investment.

Longstanding drivers for reforms to accreditation and standards include more consistent and comprehensive implementation of core standards that are widely perceived to be of critical importance to improving the safety and quality of healthcare, and reducing the burden of a proliferation of differing standards.

Accordingly, in terms of targeting, the Commission could initiate a process to build national consensus on those relatively few standards of critical importance nationally (e.g. clinical governance, open disclosure, credentialing, etc.) and undertake a meta-analysis to determine a superset of standards overarching the current accreditation standards, based on a national framework for safety and quality. These could then form the initial priorities for harmonisation, mapping (defining which accreditation standards relate to the core standards), registration, quality assurance and mutual recognition.

All of the proposed strategies are likely to be required to meet the twin goals described above, but without prioritising the standards of interest, each could be large, costly and time consuming.

Standards Australia's core business capacities include consensus building and the lifecycle management and metadata management of standards and related documents. Our business model embraces partnerships with external organisations, allowing them to focus on their core agendas while satisfying standards development needs. This approach is strongly supported by the Productivity Commission.

Accordingly, Standards Australia is well placed to assist the Commission in many of these endeavours if assistance is required. We have a long history in creating standards for the health sector, and our partnership with the National E-Health Transition Authority (NEHTA) demonstrates our capacity to assist an AHMAC-established agency to address a national interest area. In particular, we have extensive experience in:

- Building consensus amongst diverse players on standardization priorities, and rationalising existing standards and harmonising language in such priority areas;
- Managing standards registers and standards metadata at large scale, and accrediting standards developers; and
- Building the governance structures and frameworks for high quality standards development and mutual recognition.

We invite the Safety and Quality Commission to meet at any time with our senior personnel, including Chief Operating Officer, Craig Lauchlan, on any relevant matters where our experience, expertise and perspectives may be of use or of interest to the Commission.

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1 Introduction

This submission addresses several of the issues canvassed in the Australian Commission on Safety and Quality in Healthcare's Discussion Paper – National Safety and Quality Accreditation Standards, November 2006.

The issues canvassed are those relating to standards and standards development. This is Standards Australia's core business and is a domain in which our expertise is recognised nationally and internationally.

While Standards Australia has previously provided material to the Commission on frameworks for accreditation and conformity assessment¹, the application of these frameworks in the health sector lies outside our business domain. Accordingly, comments on accreditation issues canvassed in the Discussion Paper are limited to those areas inextricably linked with standards and standards development.

Section 2 of this submission highlights Standards Australia's roles and capacities, while Section 3 looks at the context for the Discussion Paper. Sections 4 to 8 outline Standards Australia's responses to specific references from the Discussion Paper. Section 9 discusses supplementary issues.

In addressing the issues raised in the Commission's paper, Standards Australia also indicates where its expertise and experience could be useful in implementing some of the foreshadowed reform strategies – should they be adopted. In doing so Standards Australia would only offer our services where our involvement was widely supported and added real value.

In our submission the over-arching test for any proposed action from the Discussion Paper must be – does it enhance and benefit the recipient of the health services.

2 Standards Australia

Standards Australia is an independent not-for-profit organisation. Standards Australia is recognised by the Australian Government, through an MOU, as the peak, non-government standards body in Australia. Standards Australia fulfils the following roles:

- **Co-ordinator and facilitator** of national and international voluntary standardization initiatives, knowledge and information exchange;
- **Accreditor** of organisations to develop Australian Standards through the autonomous Standards Accreditation Board;
- **Developer** of choice of national and internationally harmonized standards and other solutions;

¹ Standards Australia, Responses to questions from the Australian Commission on Safety and Quality in Healthcare, 23 August 2006.

- **Promoter** of excellence in design and innovation through the Australian design awards and other initiatives; and
- **Partner** with Governments, industry and community in the design, development, delivery and implementation of innovative solutions.

Standards Australia has **no** role or commercial interest in the business of accreditation or conformance assessment of organisations to Australian Standards. Standards Australia has **no** shares or ownership interest in the company that publishes our standards - SAI Global.

Standards Australia develops and maintains more than 7,000 Australian Standards and related publications that are prepared by 1,700 committees, sub-committees and working groups involving more than 9,000 committee members who span all sectors of the economy. These documents, used in countless daily business transactions, facilitate public safety, economic efficiency, better quality, and communication and trade between individuals, corporations and nations.

Standards Australia ensures the effective development of standards and recognition of other standardization bodies by providing an active forum for discussion, debate and consensus building. It uses facilitation processes based on transparency, consensus and stakeholder representation from interest groups including governments, industry bodies, trade and professional associations, academia and consumer groups.

Standards Australia is Australia's representative on the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the Pacific Area Standards Congress (PASC).

2.1 Experience in Health

Standards Australia has a long history in creating Standards for the health sector, from standards for products used to create the amalgam used in dental fillings to those for sterilization procedures utilised in office based practices, to those underpinning high tech health informatics.

The Therapeutic Goods Administration (TGA) uses Australian Standards to assist in the regulation of medical devices, to ensure the quality, safety and performance of medical devices.

Other Health Standards are used to regulate additional areas of the medical industry by the relevant professional body: for example the Australian Dental Association, Dental Industry Association and the Royal Australian College of General Practitioners which uses the AS/NZS 4815 Office based practice sterilization in its accreditation program.

We have previously provided a list of health organisations that have nominated contributors to both the national and international standards development areas.

The health committees are responsible for 300 Standards in total. A large proportion of these are ISO adoptions. Some of the more recognised standards include:

- AS/NZS 4187 Sterilization in Hospitals;

- AS/NZS 4815 Sterilization in Office Based Practice;
- AS/NZS 3200 Series – these pertain to requirements and safety for medical electrical equipment; and
- AS/NZS 3551. This Standard specifies procedures required to develop equipment management programs for medical devices. These include procedures for procurement, acceptance, fault management, routine testing and disposal of medical devices.

In addition to these more traditional areas of health standardization, Standards Australia established a health informatics committee (IT-014) in the early 1990s to develop information standards for the health sector. With the assistance of acceleration funding from the Australian Government, IT-014 will have published around 70 documents by mid 2007.

A complete listing of Australian healthcare standards and related documents has previously been provided to the Commission.

Currently, Standards Australia's traditional health committees and sub-committees are:

- HE-001 -- Medical, Diagnostic and Surgical Products
- HE-002 -- Medical and Surgical Equipment
- HE-003 -- Medical Electrical Equipment
- HE-003-00-02 -- Technical Assessment Group - Nuclear Medicine
- HE-003-00-05 -- Technical Assessment Group - Lithotripters
- HE-003-00-06 -- Technical Assessment Group - Ultrasound in Physiotherapy
- HE-003-00-07 -- Technical Assessment Group - Electromyography
- HE-003-01 -- General Safety Requirements
- HE-003-01-01 -- AS/NZS 3200 Series
- HE-003-01-02 -- AS/NZS 3551 Revision
- HE-003-02 -- High Frequency Equipment
- HE-003-03 -- Medical Ultrasound
- HE-003-04 -- Drug Infusion Pumps
- HE-003-05 -- Incubators and other Infant Care Units
- HE-003-06 -- Infant Apnoea Monitors
- HE-003-07 -- Patient Monitoring Equipment, Electroconvulsive Therapy Equipment and Defibrillators
- HE-003-08 -- Dialysis Equipment
- HE-003-09 -- Safe Use of Electricity in Patient Care Areas
- HE-003-10 -- Enuresis Alarms
- HE-003-11 -- Beauty Therapy Equipment
- HE-003-12 -- Lasers in Medical Procedures
- HE-003-15 -- Radiotherapy Equipment
- HE-004 -- Dentistry
- HE-005 -- Health Care Administration
- HE-006 -- Handling and Destruction of Drugs
- HE-007 -- Packaging of Infectious Material
- HE-008 -- Diagnostic Ionizing Imaging Equipment
- HE-009 -- Hypodermic Equipment - General Medical
- HE-010 -- Hypodermic Equipment - Insulin Injection

- HE-011 -- Safe Disposal of Sharps and Clinical Wastes
- HE-012 -- Surgical Implants
- HE-013 -- Surgical Apparel
- HE-013-00-01 -- Review of AS/NZS 4179:97 & AS/NZS 4011:97
- HE-014 -- Packaging - Sterile Goods
- HE-015 -- Packaging - Poisonous Substances
- HE-016 -- Packaging Systems and Devices - Child Resistant Chemicals
- HE-017 -- Medical Gas Systems
- HE-018 -- Resuscitators and Ventilators
- HE-019 -- Anaesthetic and Breathing Equipment
- HE-020 -- Medical Refrigeration
- HE-021 -- Transfusion Equipment
- HE-022 -- Sphygmomanometers
- HE-023 -- Processing of Medical and Surgical Instruments
- HE-023-00-01 -- Performance of Cleaning Products for Cleaning of Reusable Medical Devices & Equipment in Health Care
- HE-024 -- Personal Medical Information Devices
- HE-025 -- Medical Records
- HE-026 -- Hospital Emergency Procedures
- HE-026-00-01 -- Triage Tag System for Mass Casualty Incidents/Death Labels
- HE-027 -- Hospital Beds
- HE-027-00-01 -- Paediatric Hospital Beds
- HE-028 -- Quality Management and Corresponding General Aspects for Medical Devices
- HE-029 -- Clinical Laboratory Testing and In Vitro Diagnostic Test Systems

Current health informatics committees and sub-committees are:

- IT-014 -- Health Informatics
- IT-014-02 -- Health Concept Representation
- IT-014-02-01 -- Pharmacy Concept Representation
- IT-014-04 -- System and Data Security, Integrity and Privacy
- IT-014-06 -- Messaging and Communication
- IT-014-06-03 -- HL7 Messages
- IT-014-06-04 -- Prescription Messages
- IT-014-06-05 -- Diagnostics Messages Working Group
- IT-014-06-06 -- Collaborative Care Communications
- IT-014-09 -- Electronic Health Record Interoperability
- IT-014-10 -- Electronic Commerce
- IT-014-11 -- Financial Messages
- IT-014-12 -- Telehealth

The health sector is also heavily involved in international standardization. This is mainly due to the significant amount of medical equipment and health software that is made overseas.

We have a particularly close relationship with some of the ISO Technical Committees and have had the pleasure recently of hosting international meetings for delegates of the following committees:

- ISO TC 106 Dentistry
- ISO TC 198 Sterilization of health care products

- ISO TC 210 Quality management and corresponding general aspects for medical devices
- ISO TC 212 Clinical laboratory testing and in vitro diagnostic test systems
- ISO TC215 Health Informatics. This Committee will be hosted again in Brisbane in August this year.

In addition to the 4 committees listed above Australia also has international representation on the following:

- ISO TC 45 Rubber and Rubber Products
- ISO TC 48 Laboratory Equipment
- ISO TC 76 Transfusion, infusion and injection equipment for medical and pharmaceutical use
- ISO TC 84 Devices for administration of medicinal products and intravascular catheters
- ISO TC 121 Anaesthetic and respiratory equipment
- ISO TC 122 Packaging
- ISO TC 150 Implants for surgery
- IEC 62 A Common aspects of electrical equipment used in medical practice
- IEC 62 B Diagnostic imaging equipment
- IEC 62 D Electromedical equipment
- IEC 87 Ultrasonics
- IEC 76 Optical radiation safety and laser equipment
- ISO TC215 Health Informatics
- ISO TC215 WG1 Health Data Structures
- ISO TC215 WG2 Health Data Messaging
- ISO TC215 WG3 Health Concept Representation
- ISO TC215 WG4 Health Data Security
- ISO TC215 WG8 Electronic Health Records
- Health level 7 (HL7) – an international standards organisation specialising in technical standards for health information interchange. Australia co-chairs most of the HL7 technical committees and working groups concerned with clinical communications
- CEN TC251 Health Informatics

In recent times, as the national e-health agenda has accelerated under the guidance of the Australian Health Ministers' Advisory Council (AHMAC), Standards Australia has partnered with the National E-Health Transition Authority (NEHTA) to ensure a base of standards for health information interoperability. This partnership is now embodied in an agreement entitled Working Together. This document describes the operational relationship between NEHTA and Standards Australia and provides a model for other health-related partnerships.

2.2 Standards Accreditation Board

The Standards Accreditation Board is an autonomous Board reporting to the Council of Standards Australia, with the role of accrediting Standards Development Organisations that wish to develop a Standard(s) to be published as an Australian Standard.

The Standards Accreditation Board was established following a recommendation of the Kean Report on Australia's Technical Infrastructure². The Communications Alliance (formerly Australian Communications Industry Forum) and the Australian Forestry Standards Ltd are examples of currently accredited Standards Development Organisations.

The accreditation process determines the competency of an organisation to develop Australian Standards. While the organisation may use procedures not necessarily identical to Standards Australia's, it must ensure transparency and openness commensurate with good practice. This applies particularly to the manner in which decisions are reached.

Approval for the publication of documents as Australian Standards is the prerogative of Standards Australia and is normally exercised by the Standards Governance Boards. However, where a Standards Development Organisation has an equivalent balanced policy oversight structure, responsibility for process approval, as arranged by the Standards Accreditation Board, may be assigned as a part of the accreditation process.

2.3 Productivity Commission Research Report on Standards Setting and Laboratory Accreditation

On 2 November 2006, the Productivity Commission released a research report on its review of the Australian Government's relationship with Standards Australia and its assessment of the efficiency and effectiveness of both standards setting and laboratory accreditation services in Australia.

The report can be found on the Productivity Commission website at www.pc.gov.au. It recommends that the Australian Government should maintain Standards Australia's status as the Australia's peak non-government standards body. References are made to this report and the recommendations of the Productivity Commission in various parts of this submission.

3 Context for the Discussion Paper

Standards Australia's understanding of the context for the Discussion Paper may be summarised as follows.

The Australian Commission on Safety and Quality (the Commission) commenced on 1 January 2006 at the direction of Australian Health Ministers, following a review of governance arrangements for safety and quality in health care during 2005³. The Commission's functions include recommending nationally agreed standards for safety and quality improvement. The Report of the 2005 review indicates that these standards would be recommended by the Commission and, if accepted by Health

² Kean, B., 1995, Linking Industry Globally, Report of the Committee of Inquiry into the Standards and Conformance Infrastructure of Australia.

³ Paterson, R., National Arrangements for Safety and Quality of Health Care in Australia, The Report of the Review of Future Governance Arrangements for Safety and Quality in Health Care, 28 July 2005.

Ministers, implemented by jurisdictions and the Australian Government in partnership with private providers⁴.

The Review Team further proposed that Health Ministers be provided with a plan to transform accreditation arrangements, to enhance the role of accreditation in both quality improvement and in the implementation of agreed national standards⁵.

The Review Team noted that greater attention needed to be paid to implementation issues, (including the implementation of standards), leveraging strategic partnerships, and broadening the safety and quality focus beyond the (public) hospitals sector.

Whilst alluding to standards more generally, the Commission's Discussion Paper largely focuses on those standards that are used in health service accreditation processes to assess whether or not a service will be afforded accreditation.

However, it may be helpful to draw a distinction between:

- The Standards developed by healthcare accreditation (conformance assessment) bodies for assessing whether or not health services will receive accreditation; and
- Standards developed by (or at the request of) and endorsed by the Commission to encourage improved safety and quality, such as the Open Disclosure Standard⁶ and the Standard for Credentialing and Defining the Scope of Clinical Practice⁷, both developed by the former Australian Council for Safety and Quality in Healthcare. We assume that these latter examples are the types of standards the Review Team was referring to as agreed national standards, the implementation of which could be assisted by enhancing the role of accreditation.

The latter group are discussed further in Section 8 below.

4 Standards issues

The Discussion Paper raises a series of issues pertaining to standards development and poses a series of questions.

⁴ Ibid, Recommendation 6, page x.

⁵ Ibid, Recommendation 6, page viii.

⁶ Australian Council for Safety and Quality in Healthcare, Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals, Following an Adverse Event in Healthcare, July 2003.

⁷ Australian Council for Safety and Quality in Healthcare, Standard for Credentialing and Defining the Scope of Clinical Practice: A National Standard for Credentialing and Defining the Scope of Clinical Practice of Medical Practitioners, for use in Public and Private Hospitals, July 2004.

4.1 Proliferation of Standards

Question - What initiatives are required to coordinate and harmonise standards development?

Background

In highlighting stakeholder concerns with current accreditation processes, the former Council identified “considerable duplication of, and potential gaps in, standards” and the consequent requirement for many organizations to demonstrate compliance against multiple sets of standards that are directed at the same outcome. These concerns were reiterated in consultation processes undertaken by the Paterson Review Team⁸.

As depicted in Figure 1 below, this tends to originate from independent development of service quality and performance management standards by an array of organizations, and results in excess costs to the health system and potentially lack of clarity amongst the staff whose services are being assessed.

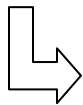
This problem is not unique to the health sector. In many sectors of the economy duplication and competing standards have been a challenge, particularly in areas of activity that are historically state based and/or regulated. As national organization acting in the national interest, Standards Australia has, in numerous cases, been able to facilitate a national approach overcoming state differences. Relevant cases studies can be discussed in detail at the Commission’s request.

Figure 1 – Limited cause and effect chain for differing standards

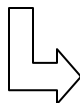
A lack of coordination and/or cooperation between:

- Accreditation programs and agencies; and
- Program based service initiatives accompanied by performance management frameworks;

... underpinned by differing professional or systems paradigms, and/or ignorance of other, pre-existing or planned standards



Similar but different standards against which conformance is assessed in the increasing number of agencies that provide multiple services/service types



- Excess standards development costs to the health system
- Excess compliance costs to services and the health system
- Drain on limited health staffing resources
- Potential lack of clarity in readiness and assessment processes.

⁸ Paterson, R., op cit, page 50.

Response

More formal root cause analysis would provide greater insight into the reasons for and impacts of this issue, but Figure 1 is sufficient to suggest that interventions are required at a number of levels in order to address the issue of proliferation of standards. These could include:

- At the points of origin of new standards:
 - Australian, State and Territory Governments committing to base all new performance management standards on common and complementary (i.e. reusable and extensible) safety and quality principles, measures and tools, irrespective of the funding programs from which they originate; and putting in place systems to support this commitment. Such systems would probably need to include:
 - Development of the overarching safety and quality performance management framework (consistent with and building upon AHMAC's existing health system performance framework);
 - A register of existing standards and measures and maintenance of a body of knowledge concerning their implementation;
 - Departmental policies requiring proposed new standards to be checked against existing ones and impact assessment where deviations are proposed; and
 - Audit and appeal mechanisms promoting policy compliance;
 - Accreditation agencies and other standards developers
 - Undertaking or being encouraged to undertake assessments of the impacts of proposed new standards. It is worth noting that the Productivity Commission report identified the need to have more rigour at the project initiation stage, and to this end Standards Australia has developed a Preliminary Impact Assessment document and also a document on Preparation of Standards for Legislative adoption; and
 - Providing mutual recognition of other existing or planned standards. This in turn would require a neutral forum in which to negotiate this recognition.
- Where there are already differing standards in existence, undertaking a mapping exercise to reverse engineer a higher level superset of common standards (consistent with the overarching framework above), mapping existing standards to the superset and cross-mapping existing standard sets against each other. Existing standards should populate the standards register during this process.
- At the point of impact (health services), encouraging a culture of constructive input into ongoing standards maintenance and development. Standards developers globally are tending to suffer from attrition of "volunteer" input into standards development processes, yet there seems little doubt that the input of those who bear the brunt of poorly developed or duplicative standards is

fundamental to ensuring that the standards developed are workable and that implementation costs are constrained. Provided that standards development processes conform to good practice (see 4.3 below), market feedback should encourage coordination and harmonization.

Health informatics provides a corollary

In the health informatics arena, which is another national focus area for standards development and implementation, a group of global standards development organizations (SDOs) have recently committed formally to collaboration and cooperation. Collaboration mechanisms that take into account the business models and imperatives of the SDOs are currently being developed and negotiated, and these may have some applicability to the safety and quality arena. Standards Australia is part of the leadership group developing this approach. A draft set of guidelines is expected to be available and can be discussed with the Commission in early April 2007 following the next ISO health informatics meeting.

4.2 Access to Standards

Question - What minimum information should be publicly available on accreditation standards?

In principle, it is difficult to argue that standards should be anything other than widely accessible and available. Consumer and other stakeholder confidence beyond a superficial level is dependent on knowing what standards the product or service under consideration conforms to.

In reality, however, consensus-based standards development is a labour intensive process that requires a sustainable funding stream, notwithstanding advances in telecommunications and other supporting technologies. The sale of standards is often a substantial component of those funding streams.

In the health informatics arena, Australian Governments have reduced or removed pricing barriers to the accessibility of standards by publicly subsidising them. Examples include:

- Block funding from the Department of Health and Ageing for electronic downloads of Australian health informatics Standards; and
- Purchase of a national license for the SNOMED⁹ standardised clinical terminology via the National E-Health Transition Authority.

In these cases standardisation has been seen as central to the achievement of e-health capability, and removal of potential access barriers has been seen as and is proving to be an effective encouragement strategy.

Differing levels of access to information about standards might involve different costs and support differing national objectives, as illustrated in Figure 2 below. Figure 2 illustrates three potential access levels but a continuum of other levels is feasible.

⁹ Systematised Nomenclature of Medicine.

Figure 2 – Public availability of standards

Public availability level	Associated information set	Purpose
Catalogue of standards.	Name of standard; Brief descriptor; Lifecycle status; Owner; Contact details.	To highlight the availability of existing standards, to encourage re-use. Marketing.
Register of standards.	As above, plus a summary of elements, key concepts and definitions, etc. and version control metadata that allows for clear identification of the scope, coverage, content and applicability of each standard.	To enable processes of rationalisation and mapping of standards.
Comprehensive metadata repository for safety and quality standards (analogous to METeOR, Australia’s repository for national data standards for health, housing and community services statistics and information, which is maintained by the Australian Institute for Health and Welfare. METeOR’s development was funded by the Australian Government).	Comprehensive descriptions of standards, the elements that comprise them and the relationships between them, potentially together with a (non-public) shared standards development infrastructure. Supported by powerful search capabilities.	To provide a toolset for standards developers that helps avoid resource wastage and promotes a common approach to specifications. To provide subscribers (whether free or paying) to a single electronic repository of nationally endorsed standards.

In summary, the extent of minimum information that should be publicly available will depend on the Commission’s strategic intent. This theme is further developed below.

However, it must also be noted that the real value of any catalogue, register or knowledgebase is also closely correlated with its currency, maintainability, accessibility and ease of use. Accordingly, such initiatives require a sustainable resourcing model and are best provided by organisations with substantial skills and experience in metadata and document management.

5 Process of developing standards

Question - What aspects of Australian health care standard development should be standardised for more streamlined, effective and efficient standards development?

The key issues arising here relate to involvement in standards development; transparency, effectiveness and efficiency of processes; and the styles, quality and consistency of the resulting outputs.

As described in the Discussion Paper, some standards developers such as ISQua, ISO and Standards Australia have best practice guidelines for standards development.

A Code of Good Practice for the Preparation, Adoption and Application of Standards is annexed to the World Trade Organization (WTO) Agreement on Technical Barriers to Trade. Australia is a signatory to this Agreement and its companion document, the WTO Agreement on Government Procurement. These Agreements require the Australian Government to encourage other Government and non-Government standardization bodies to comply with the Code of Good Practice.

Accordingly, the standardizations guides for national standards agencies such as Standards Australia describe how the Code of Good Practice will be met in a local context. These guides are available at <http://www.standards.org.au/cat.asp?catid=8>.

At a minimum, it would clearly be in the public and national interest to adopt a Code of Good Practice that is already well entrenched internationally and domain independent, and is endorsed by the Australian Government. Indeed, it may be interesting to question why any standards developer would not be prepared to adopt the Code.

Key elements of the Code of Good Practice include:

- Transparency, including publishing the standards development work program; and enabling all stakeholders to access and comment on standards developed – including via public comment periods of at least 60 days;
- Making “every effort” to achieve consensus, including clear processes for reconciling comments received;
- Coordination/harmonization of the work of national standardization bodies, to avoid duplication or conflict;
- Use of international standards, where they exist or their completion is imminent, in preference to local developments;
- Participating in the development of international standards, and not duplicating the work of other standards agencies;
- Focusing on specification of requirements based on performance rather than design or descriptive characteristics; and

- Prompt publication of and non-discriminatory charging for standards.

ISO's good practice procedures, which are expounded in greater detail in its Guide 59 - Code of good practice for standardization, supplement these principles. Key points are summarised below.

- Written procedures based on the consensus principle should govern the methods used for standards development. Copies of the procedures ... shall be available to interested parties in a reasonable and timely manner. Such written procedures should contain appeals mechanisms;
- Notification of standardization activity shall be made in suitable media as appropriate to afford interested persons or organizations an opportunity for meaningful contributions;
- Formal approval of standards should be based on evidence of consensus;
- Standards should be written to meet the needs of the market-place and should contribute to advancing free trade in the broadest possible geographic and economic contexts;
- When international standards exist or their completion is imminent, they, or their relevant parts, shall be used as the basis for corresponding national standards, except where such international standards or relevant parts would be ineffective or inappropriate, for instance because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems;
- Participation in standardization processes at all levels shall be accessible to materially and directly interested persons and organizations; and
- In order for standards to be mutually consistent and free from contradiction for the largest possible user communities, standardization activities should be actively, but voluntarily, coordinated at and between international and regional levels, and within each country.

A process of consensus building among the Australian safety and quality standards developers may be able to generate adoption of the Code of Good Practice as well as agreement on the major means of meeting its requirements. Although it relates to a regulatory rather than a self-regulatory framework, the Principles and Protocols for the Development of Food Regulation Policy Guidelines¹⁰ provide a pertinent example.

As another example, Standards Australia is currently in the process of finalising a Guideline for Data Development. This document addresses the health sector business problem that many people and organisations with varying levels of expertise tend to create data standards. This document demonstrates a health stakeholder community reaching a consensus position on what constitutes good practice in developing data standards.

¹⁰ Australia and New Zealand Food Regulation Ministerial Council, Principles and Protocols for the Development of Food Regulation Policy Guidelines, 31 March 2005.

Another relevant initiative from the health informatics domain is the inception of an E-Health Standards Coordination Group – a twice yearly forum of Australia's health information standards agencies that will ensure coordination and coherence of their work programs in the national interest and promote information sharing and a common platform of understanding about issues that are relevant to all of the groups represented. This Group, which will meet for the first time in April 2007, will be supported by NEHTA and the participants have nominated Standards Australia to provide the chair and secretariat.

Finally, supporting documentation can play an important role. Implementation guides accompanying standards have the potential to encourage more consistent adoption of standards or to bridge terminological differences between otherwise similar concepts.

5.1 Appropriateness of standards

Question - How do you ensure the standards being assessed are appropriate?

This issue pertains to the broad applicability of generic standards, particularly in light of the desire to implement standards beyond the realm of the (public) hospital sector.

However, the critical issue in addressing appropriateness is appropriateness for what? While this might seem trivial or pedantic, it is in fact a critical point. The ISO definition of a standard is a "document ... aimed at the achievement of the optimum degree of order in a given context". The fitness for purpose of a standard therefore cannot be assessed without explicit articulation of the:

- Purpose to which the standard is being put;
- Given context; and
- Optimum degree of order sought in that context.

At a national level, this articulation is likely to be the critical requirement that standards developers have of the Commission.

There are multiple aims of accreditation systems and standards, and the Commission may not be concerned with all of them, but it should clearly articulate those national safety and quality interests that it considers can be advanced via standards and accreditation systems at a national level, and the characteristics that it expects to be evident if implementation of the proposed standards is successful. Accordingly, articulation of the national performance management framework for safety and quality would be a substantial starting point – see 4.1 above.

Such a framework should take into account and articulate:

- Those aspects of the implementation of safety and quality policies and strategies that are most amenable to the use of standards as a policy implementation tool (as opposed to other tools such as education and advocacy, financial incentives and disincentives, etc); and

- The characteristics of effective standards (specific, unambiguously and objectively measurable, implementable without undue cost, etc.) for healthcare.

Existing and proposed standards could then be tested against a set of appropriateness and potential effectiveness criteria.

In terms of standards development processes, openness and transparency could be viewed as critical success factor for achieving appropriate standards.

6 Future Systems and Processes - Standards Reform Strategies

6.1 Registration of sets of health care standards

Question - What needs to be in place to make this feasible?

The feasibility of a registration scheme for healthcare standards is likely to depend on a range of factors, several of which have already been referred to above.

In the first instance, clear objectives, scope and coverage and use cases ("storyboards" that narrate how the register will be used to meet the specified objectives) will be required. These must articulate who the register applies to, in which contexts and in respect of what information, when, how and why. Business processes for populating and maintaining the register and the information sets required will flow from these and as a result of business and systems analysis.

The rationale for participation and in particular the consequences of non-participation will need to be clear and significant. This applies both to the suppliers of standards and potential users. As identified in 4.1 above, systematic processes will be required to ensure that service program developers access and use the register if objectives such as rationalisation are to be met.

A responsive and user-friendly register will also be a pre-requisite for success. However, effective, large-scale document and metadata management is a substantial, long-term endeavour requiring considerable (and standards-based) expertise in the area.

Accreditation of standards developers

While the Discussion Paper refers to registration of accrediting bodies, there is no mention of registration of safety and quality standards developers. However, not all standards developers are accreditors. In fact, it can be argued that separation of the two functions is desirable. As stated in part 2 Standards Australia is not an accreditor of standards.

It may be advantageous to register the standards developers, particularly if compliance with best practice in standards development is desired. The Discussion Paper notes that only those standards developed via best practice processes will be eligible for registration, but re-assessment of the development process for each and

every standard produced is likely to be both expensive and bureaucratic. As an alternative, accreditation of the standards developers is a normal industry practice and mechanisms already exist for this to happen. For example, Standards Australia's developer accreditation infrastructure could be readily adapted for this purpose even though it is currently geared to the production of Australian Standards.

In its recent research report of standards setting and accreditation, the Productivity Commission argues that there is a case for increased accreditation of standards development organisations through the existing Standards Accreditation Board¹¹.

Question - Which organisation is best placed to manage the longer-term register of standards?

The Discussion Paper notes that long-term implementation and management of a register such as this is outside the Commission's terms of reference. This seems appropriate, as an ongoing operational capacity could well distract the Commission from its more strategic endeavours.

Functions such as this, however, are core business to Standards Australia, which has a long history of excellence in and considerable infrastructure to support such large-scale document and metadata management. It should be noted that Standards Australia does not currently develop health service accreditation standards and has no aspirations to do so. On the other hand, Standards Australia does have considerable expertise in consensus building, which will be a critical success factor for this initiative.

Accordingly, Standards Australia's National Standards Office would be pleased to discuss this initiative further at the Commission's discretion.

6.2 Harmonization of health service standards

Question - What are the barriers to standardisation of language and definitions?

Barriers to standardising the language and definitions in healthcare standards (as opposed to the language of accreditation/conformity assessment, which has been canvassed in material previously sent to the Commission by Standards Australia) are likely to include:

- The extent of current usage;
- Association with professional paradigms (e.g. in relation to terms such as "patient" and "client");
- Protection of intellectual property by the standards developers; and
- Lack of documented evidence and/or appreciation of the business impacts of language and definitional mismatches.

¹¹ Productivity Commission 2006, Standard Setting and Laboratory Accreditation, Research Report, Productivity Commission, November.

Standardisation of language and definitions should be prioritised. Standardising language and definitions across the board would be a very large and long-term endeavour with diminishing marginal returns. However, selection of a subset of those critical to the Commission's strategic and national objectives would limit the scope of the task.

Question - Who needs to be involved in this standardisation process?

Standardisation processes require balanced participation by those interests that will be significantly affected by the results, in the form of representatives with expert technical understanding of the reasons for the existing wording and an ability to analyse the implications of changes. In the case of safety and quality standards these interests would include at least the standards developers, implementers (health services) and beneficiaries (patients, funders, etc.).

Expertise in facilitation and consensus building would also be critical, and Standards Australia has a strong track record in these areas. For example, an Australian Standard on The language of health concept representation (AS 5021–2005) was developed via the Health Informatics Technical Committee (IT-014) and published in 2005 to address comparable issues in that domain.

In the International Standards Development arena the vocabulary '*Risk Management - Vocabulary - Guidelines for use in standards*' (ISO/IEC Guide 73:2002) was developed by the International Organization of Standardization (ISO) working group on risk management, of which Australia holds the chair. The working group agreed that a vocabulary of terms was needed before the risk management standard could be developed. Both the vocabulary of terms and main standard have been developed from the very successful Australian/New Zealand standard AS/NZS 4360 *Risk Management*.

Standards Australia publishes in conjunction with the National Committee on Rationalised Building (NCRB) HB.50 '*Glossary of Building Terms*', which has 11,000 terms. This handbook includes General Terms, Terms from Australian Standards and Terms from the Building Code of Australia. This handbook is extensively used by the building industry to ensure national consistency with language.

As at 22 March 2007 Standards Australia has over 35 Standards setting out 'glossary of terms' for different industries or sectors.

6.3 Detailed mapping of standards

Question - Who needs to be involved in this mapping process?

Again, the mapping of standards at a detailed level (as would be required if this is to produce the desired benefits) is potentially a very large task and would benefit from prioritisation. It is also an ongoing task. Mappings require lifecycle management, since the source standards being mapped are dynamic.

As for the Register, this long-term role may be outside the Commission's scope and could detract from the Commission's strategic focus. Professional standards agencies are well placed for and highly experienced in this kind of work. Indeed, there are logical synergies in aligning this work with the development,

implementation and management of the Register, which would be required infrastructure for this task.

In terms of participation in the mapping processes, again this would require balanced participation by those interests that will be significantly affected by the results and with expert technical knowledge of the standards and their application.

6.4 Identification of core safety and quality areas

Question - What priority areas should be included in core safety and quality standards?

Articulation of the priorities is beyond Standards Australia's health domain expertise. However, Standards Australia routinely facilitates standards development work program planning and prioritising amongst and across very diverse interests, and has methodologies, toolsets, governance structures and skill sets that could be utilised for this purpose.

7 Mutual Recognition of Standards and Accreditation Processes

Question - What is required to implement mutual recognition of standards and accreditation processes in the Australian health care system?

Standards Australia has no comment on the mutual recognition of accreditation processes. However, mutual recognition of standards is an important mechanism internationally for ensuring free trade, and standards development organisations such as Standards Australia have expertise in the analysing and facilitating the analysis of candidate standards as well as the requisite consensus building capacities.

It should be noted that candidate standards for mutual recognition could be an output from the registration and mapping processes if they were designed with this in mind, and technical associated issues are highlighted in those sections (5.1 and 5.3) above. However, the primary non-technical issues concern the business models of the standards developers. As noted elsewhere in the Discussion Paper, there are an array of standards developers with disparate business models and policies (e.g. relating to intellectual property and copyright) that would need to be synchronised around mutual recognition.

Strategically, there are close connections between a range of the issues canvassed in the Discussion paper, and a roadmap will be required in order to ensure that capabilities built via shorter-term activities can be leveraged to meet longer-term needs. For example, the detail required in a Register of standards, the approach to accrediting standards developers and the nature of harmonisation and mapping tasks might vary significantly depending on whether mutual recognition is to be sought.

8 Accreditation Issues

As indicated above, Standards Australia does not wish to comment on accreditation issues in general. The following comments relate specifically to the standards underpinning accreditation.

8.1 Transparency

Question - What is essential to ensuring all accreditation processes are open and transparent?

Health service accreditation (or conformance assessment in the ISO parlance) concerns demonstrating and certifying that specified requirements relating to a product, process, system, person or body are fulfilled. This is relatively meaningless without knowledge of the requirements that are specified – the standards.

Accordingly, wide availability of accreditation standards is essential to ensuring that accreditation processes are open and transparent.

8.2 Governance

Question - What governance issues must be addressed by organisations setting standards, training surveyors or accrediting health services?

Governance issues critical to standards development include the following.

- In 'traditional' corporate governance, 'governance' is about the balance of control amongst owners, management and other stakeholders with some reasonably clear delineation between the members and interests of each. In the world of standard setting, however, stakeholders are cast as integral contributors to the business processes (e.g. through standards development committees), in monitoring and independent oversight roles and as implementers of standards. Accordingly, separation of the governance of the national strategic framework for safety and quality in healthcare from standards development governance may be sensible;
- Management of non-participants via external relationship management processes and structures is crucial. While balanced participation is the aim, it is often difficult as the technical and representational expertise required is at times in short supply (e.g. engaged in critical day-to-day health service delivery);
- Continuity and sustainability. Initial standards development is intensive but is merely the first step in a standards lifecycle. Bureaucratic structures and funding programs may come and go, but responsibility for the standards produced must be ongoing; and
- Legitimacy and credibility, including widely perceived neutrality are vitally important. It is for these reasons that Standards Australia:
 - Does not build internal expertise in specific standards domains (e.g. health, electronics), but rather brings in external expertise through technical

committees and instead builds internal expertise and infrastructure for consensus building; and

- Does not engage in activities such as the supporting the implementation of or certifying against standards.

9 Other Issues

As highlighted in Section 3 above, the initial impetus for the Discussion Paper appears to have arisen from the Paterson Review of Future Governance Arrangements for Safety and Quality in Health Care. While issues such as the burden of duplication and inconsistencies have carried through to the Discussion Paper (and have been responded to above), another major issue highlighted by the Paterson review was to examine the potential of accreditation systems to:

- Promote quality improvement (as opposed to other purposes such as public accountability for funding); and
- Support the implementation of nationally agreed standards (such as credentialing and open disclosure).

This latter point would seem to merit greater attention.

It is understood that various jurisdictions are continuing to develop statewide standards targeting a relatively small number of areas broadly agreed to be critical to enhancing safety and quality (such as clinical governance and complaints handling standards) and building on standards developed by the previous Council (e.g. correct site for surgery).

Obtaining consensus about relative priorities for these types of standards and developing/converting them into a relatively small core of nationally agreed standards may provide a worthwhile initial agenda. These standards are typically not "owned" by the commercial interests involved in accreditation. Activities such as standards mapping, registration and harmonisation and building consensus on mutual recognition could commence with these – i.e. processes could be initiated to scan the existing standards sets for any overlaps or relationships with the nationally agreed standards, and means devised to build these into accreditation processes to enhance their implementation.

In addition, maintaining existing standards such as the credentialing and open disclosure examples throughout their lifecycle (including decommissioning them if and when appropriate) is not mentioned in the Discussion Paper but is an important activity.

Standards Australia is well placed to undertake national standards development work on behalf of the Commission and its constituents.

10 Conclusion

The issues raised in the Discussion Paper are substantial and resolving them is potentially large, complex and costly. However, a highly strategic approach based around obtaining consensus about developing or obtaining national agreement to a relatively small number of standards that are widely considered to be crucial to safety and quality improvement seems manageable. Mapping these to existing standards and harmonising and registering them could provide substantial national benefit reasonably quickly.

Similarly, accrediting standards developers based on existing infrastructure such as the Standards Accreditation Board could have immediate benefits in terms of the quality of standards development.

Standards Australia's core business capacities include consensus building (about priorities and standards, but with wider applicability) and the lifecycle management and metadata management of standards and related documents. Our business model embraces partnerships with external organisations, allowing them to focus on their core agendas while satisfying standards development needs. This approach is strongly supported by the Productivity Commission.

Standards Australia therefore considers that we are well placed to support the Commission in its standards development, harmonisation and consensus building endeavours.

We believe there would be mutual benefit to have our Chief Operating Officer, Standards Development, meet with the Commission to provide general and technical information and explore ways in which we can further assist.

If you wish to discuss this submission, please do not hesitate to contact Adrian O'Connell, General Manager, Relationships and Partnering on 02 8206 6818 or at adrian.oconnell@standards.org.au