

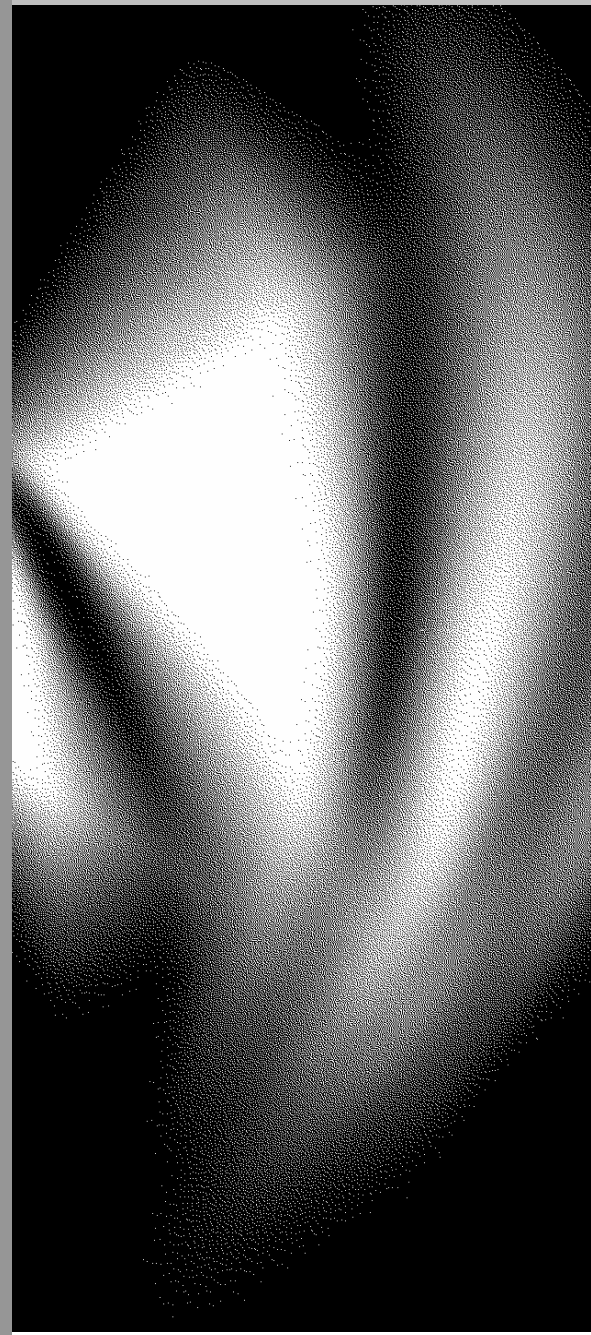


Australian Government
Productivity Commission

Standard Setting and Laboratory Accreditation

Productivity
Commission
Research Report
Overview

2 November 2006



OVERVIEW

Key points

- In general, Australia's standard setting and laboratory accreditation services are effective, but there is scope for improvement.
- The Australian Government should ensure both Standards Australia and the National Association of Testing Authorities (NATA) serve agreed public and national interest objectives by way of the Memoranda of Understanding, targeted funding, representation on governance bodies of both organisations and by recognising the special status of both bodies.

Standard setting

- Standards Australia should make the following improvements:
 - systematically consider costs and benefits before developing or revising a standard, and publish reasons for such decisions
 - ensure more balanced stakeholder representation
 - reduce barriers to volunteer and public participation
 - improve accessibility, transparency and timeliness, including an improved appeals and complaints mechanism.
- All government bodies should rigorously analyse impacts before making a standard mandatory by way of regulation and ensure it is the minimum necessary to achieve the policy objective. Each Australian Government agency should also provide the funding necessary to ensure free or low cost access to such standards, including Australian Standards.
- The Australian Government should continue to support Standards Australia's role in facilitating international standardisation activities.
- The Standards Accreditation Board should be renamed the Accreditation Board for Australian Standards to better reflect its role and should be recognised by the Australian Government.

Laboratory accreditation

- The Australian Government should continue to progress government-to-government mutual recognition of conformance assessment and NATA should continue to progress voluntary mutual recognition.
- The Australian Government should continue to support NATA's international roles.
- NATA's proficiency testing programs should not be funded by the Government unless there are net public benefits beyond those which the market would provide.
- NATA's prime role with regard to proficiency testing should be to set what is required for accreditation and to accredit proficiency testing bodies.
- Governments should only impose a mandatory requirement for NATA accreditation, if a comprehensive assessment demonstrates a net benefit to the community.

Overview

The Productivity Commission has been asked to review the Australian Government's relationship with both Standards Australia and the National Association of Testing Authorities (NATA). It was also asked, more broadly, to assess the efficiency and effectiveness of standard setting and laboratory accreditation services in Australia (see figure 1).

Standard setting

Standards affect nearly every facet of the modern world. They provide ways to approach problems or achieve objectives which are intended to be applied widely and repeatedly. They may be public or private, voluntary or regulatory and may focus on products, services, systems or processes. In line with the move from a product-dominated economy to one which is focused on producing services and managing processes, an increasing proportion of standards is being written for service and management requirements.

The use of standards is high and growing because:

- they play a pivotal role in facilitating market exchange: distant parties unknown to each other are able to share expectations on the qualities of products and processes, and ensure compatibility;
- international standards facilitate international trade, global transport, communication and technological innovation;
- they provide consumers with greater certainty about the quality and safety of products; and
- they are increasingly used by governments to address concerns about social issues and the environment.

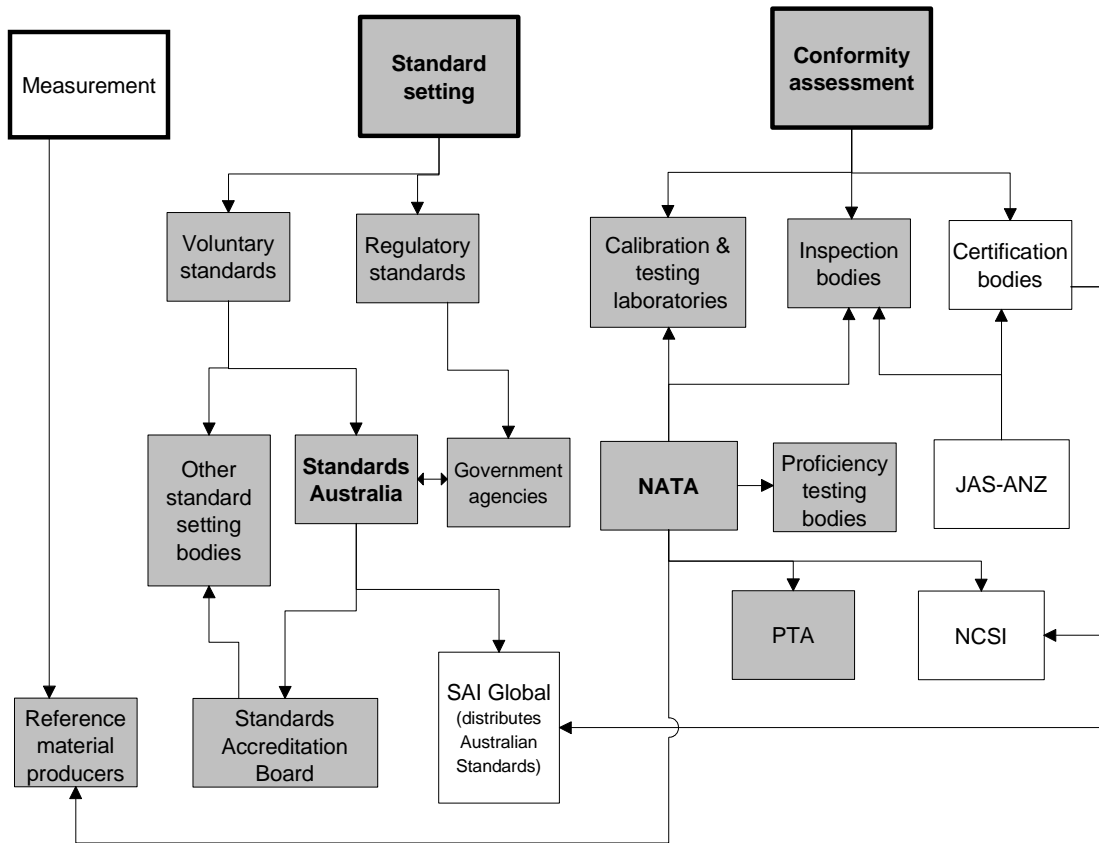
The assessment of the relationship between the Australian Government and Standards Australia (table 1) must be made in the context of the extensive international and domestic framework for standard setting.

In examining the efficiency and effectiveness of standard setting arrangements in Australia, the Commission considered a number of factors, including:

- the need to influence the development of international standards and avoid the creation of trade barriers;
- the risk that standards can be used inappropriately to limit competition among local producers resulting in net costs to the community;

- the extent to which private and public interests coincide in standard setting. While in most cases private interests may be fully aligned with public interests, they can diverge where, for example, there are spillover costs such as health, safety or environmental impacts which may require government involvement to ensure standards are written in the public interest; and
- the necessity for standards referenced in regulation to meet certain principles, including ensuring that they address what is the minimum necessary to achieve policy objectives and do not impose unnecessary compliance costs.

Figure 1 The standards and conformance infrastructure
(shaded areas are the main focus of this study)



Note: NCS International (NCSI) and Proficiency Testing Australia (PTA) are wholly owned subsidiaries of NATA.

While inevitable tensions exist between the private role and public interest functions of Standards Australia, the Commission considers that, on the available evidence, they do not require fundamental or structural reform. Rather, any conflicts should be capable of being addressed through enhancing the Memorandum of Understanding (MoU) with the Australian Government, increasing accountability and more clearly articulating the public interest role required of Standards Australia.

Table 1 Standards Australia: a snapshot

Current funding	<ul style="list-style-type: none">• Total budgeted operating expenditures in 2005–06 of \$15.9 million. Operating revenues of \$5.6 million (includes royalties on publications and government funding). Net investment revenues of \$11.1 million derived from funds received from SAI Global for the sale of its commercial operations.• Australian Government funding of \$2.1 million in 2005–06 to be expended on a range of designated activities, including membership of various international and regional standards fora, and for the operation of the Secretariat of the Standards Accreditation Board.
International standard setting	<ul style="list-style-type: none">• As Australia’s peak national standard setting body, Standards Australia represents Australia in some international fora, including the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the Asia–Pacific Economic Cooperation (APEC) Sub Committee on Standards and Conformance, the Association of Southeast Asian Nations/Closer Economic Relations of Australia and New Zealand (ASEAN/CER), and the Pacific Area Standards Congress. It participates in a range of ISO and IEC committees and working groups and provides the secretariats for 70 of these. It also chairs ISO and IEC technical committees in the areas of iron ore and direct iron sampling, uninterruptible power supplies, appliance couplers, equipment for explosive atmospheres, combustible dusts, detection of flammable gases, high voltage testing and common aspects of electro-medical equipment.
Number of standards	<ul style="list-style-type: none">• Currently 6750 standards are published.
Committees	<ul style="list-style-type: none">• Members of Standards Australia committees include representatives from commercial and retail interests; government (Australian, State and Territory and local governments); consumer and other end-user groups; trade unions; research, academic and testing organisations; professional bodies; manufacturers; and other industry interests.• Around 8200 experts on 1575 technical committees.
Sectors covered	<ul style="list-style-type: none">• Broad areas of standards development include: management and business; building and construction; electrotechnology; gas; communications, IT and e-commerce; food; and environment, safety and materials.

Standards Australia plays an important role in writing standards in Australia

Overall, Standards Australia provides industry with standards, effectively documenting technically relevant information for a wide range of products and services and ensuring compatibility where necessary. Of particular importance is its use of consensus in writing standards. This practice is adopted widely by national and international standard setting bodies and is considered to deliver better outcomes by balancing different interests. The relationships between Standards Australia and a range of Australian Government agencies are presented in box 1.

Box 1 Standards Australia and the Australian Government

Standards Australia is the predominant private standard writing body in Australia. A large number of Australian, State and Territory government agencies also write standards, primarily for regulatory purposes.

The Department of Industry, Tourism and Resources provides funding to Standards Australia and administers an overarching Memorandum of Understanding between the Australian Government and Standards Australia. In addition, many Australian Government agencies and intergovernmental bodies use Australian Standards in a variety of ways, impacting on a diverse range of regulations, including:

- building – the Australian Building Codes Board
- consumer product safety and adherence to the Trade Practices Act – the Australian Competition and Consumer Commission (ACCC)
- occupational health and safety – the Australian Safety and Compensation Council
- telecommunications – Department of Communications, Information Technology and the Arts
- energy efficiency labelling – Australian Greenhouse Office
- environmental standards – the Environment Protection and Heritage Council/the National Environment Protection Council
- deemed-to-comply solutions in the Australian Design Rules for motor vehicles - the Department of Transport and Regional Services
- financial risk management and corporate governance – the Australian Securities and Investment Commission.

Sometimes regulators simply adopt pre-existing Australian Standards. In other cases, regulators such as the ACCC ask Standards Australia to develop the standard and they contribute to the development process.

Some Australian Government bodies develop standards in-house, without the involvement of Standards Australia, for direct adoption in regulation. Examples include:

- the Therapeutic Goods Administration (TGA)
- the Office of the Gene Technology Regulator (OGTR).

It is common practice for Australian Government agencies to reference Australian Standards in regulation without payment to Standards Australia (but at cost to those wishing to access the standard), and for a significant number of State, Territory and Australian Government representatives to contribute to the development of Australian Standards at no cost to Standards Australia.

Australian Standards are usually voluntary and Standards Australia does not have a monopoly over standard writing

Even when Australian Standards are not made mandatory by way of regulation, there is a widespread misconception in industry and the community that these standards are a legal requirement. Also, while Standards Australia dominates the private standard-making sector, it does not have a legal mandate to be the sole writer. Indeed, there are numerous private standard writers, mostly industry associations.

As well as Australian Standards written by Standards Australia, some private sector associations partner with Standards Australia or are accredited by the Standards Accreditation Board (SAB) to write Australian Standards. Also, over the past decade access to, and use of, standards written overseas have increased.

Standards Australia and the Australian Government should continue to promote the accreditation of organisations to develop Australian Standards, providing they use procedural requirements substantially equivalent to Standards Australia's.

In the government sector, many Australian Government agencies, such as the Therapeutic Goods Administration and the Office of the Gene Technology Regulator, write their own regulatory standards. Also, many intergovernmental bodies write national standards, such as transport and food standards, for approval by Ministerial Councils.

Nevertheless, Standards Australia contributes to government regulation, mainly at the State, Territory and local government level. Often an existing Australian Standard is referenced without modification. Alternatively, government agencies work with Standards Australia to write standards under negotiated terms, specifying elements such as cost and qualities of the standards.

A growing trend is for a government agency to write the performance-based standard and rely on Standards Australia to provide optional, prescriptive 'deemed-to-comply' standards or supplementary standards which may assist in demonstrating compliance.

While there are advantages in avoiding duplication and inconsistency, contestability can improve outcomes

The costs of overlapping and inconsistent standards can be high. However, they are of much greater concern where they are reflected in regulatory standards. Inconsistencies between jurisdictions are an ongoing issue for Australia and

governments should actively encourage their agencies to avoid unjustified duplication and inconsistency.

Australian Standards have a special status in Australia. This enables Standards Australia to coordinate the writing of most national standards in Australia and thus reduce duplication of effort and overlapping or inconsistent standards. However, Standards Australia should not be granted a monopoly either to write standards or to accredit other standard writers which are not developing Australian Standards. This is because the potential for competition, from other standard writers, puts ongoing pressure on Standards Australia to deliver a good service.

Standards Australia plays a particularly important intermediary role in representing Australian interests overseas

Standards Australia has a long history and an established reputation in the international arena, which enhances Australia's ability to influence international standards and contributes to wider acceptance of Australian Standards. Its participation in a wide range of international fora also provides a direct link between national and international standardisation. Hence, a single national body which can competently represent Australian interests in these fora should be retained. Standards Australia should fulfil this role. In some other international fora, such as the Codex Alimentarius Commission and the World Organization for Animal Health, Australia is currently, and appropriately, represented directly by government officials.

Given the increasing complexity of issues and considerations that must be weighed to determine what is in Australia's national interest, it is important that the Australian Government has a greater input into Australia's international positions and generally ensures its effective representation overseas. There is also a need for enhanced consumer representation on the key international consumer committees.

Adopting international standards

Standards Australia should pay particular attention to facilitating international trade and providing the foundations for addressing barriers to trade which arise both within Australia and other countries. In general, there should be a preference for international standards because they will facilitate the importation of a wider range of goods to consumers and industry and ensure Australia fully participates in the global marketplace. Already more than 2600 Australian Standards are wholly or substantially based on international standards.

Nevertheless, international standards will not always be suitable for adoption in Australia, for example because they are inappropriate for Australian conditions, out of date, or not widely implemented around the world. Any decision to align with an international standard must be based on a case-by-case assessment of whether there are net benefits to the Australian community as a whole. Most importantly, as is the case with any other standard, regulatory impact analysis should be conducted before any international standard is referenced in regulation.

Concerns about standards development processes

Unless good processes are in place, there is the possibility that standards can be used by industry to restrict competition and trade. While the processes Standards Australia uses are generally sound, there is room for improvement in some areas and, in other cases, existing processes need to be applied more systematically and transparently. Performance appears to vary significantly between sectors and between technical committees. Major concerns raised in this study include:

- the absence of a systematic and transparent consideration of costs and benefits when considering the need for, and the priority of, standards development;
- the need for more rigorous impact assessment when standards are referenced in regulation;
- a lack of representational balance on some technical committees;
- perverse incentive effects arising from the legal relationship between Standards Australia and SAI Global;
- the accessibility, and in particular the cost, of Australian Standards;
- difficulties accessing suitable expertise on a volunteer basis to participate on standards writing committees;
- poor project management; and
- the need for a more formalised appeals and complaints mechanism.

Some of these concerns are longstanding, with many raised ten years ago in the Kean Report.¹ While some progress has been made, and Standards Australia has embarked on a significant plan to address key issues of concern, further improvements are required.

¹ *Report of the Committee of Inquiry into Australia's Standards and Conformance Infrastructure* (Chairman: Bruce R. Kean), Australian Government Publishing Service, 1995.

Ensuring balanced stakeholder representation

The Commission is concerned that industry tends to dominate the Council, the Board, the sector boards and the technical committees of Standards Australia. The Australian Government has limited representation on Standards Australia's governance bodies. Changes that would address these concerns include:

- appointing an Australian Government representative to the Board on an ex officio basis;
- ensuring all sector boards (which prioritise and supervise standards development for their industry sectors) have balanced representation, including representatives from small business and consumer associations;
- requiring Standards Australia to make public the company or organisation from which the members of sector boards come and the interest groups represented;
- empowering sector boards to be more rigorous in ensuring appropriately balanced representation on technical committees;
- ensuring the interests of users, exporters and importers are well represented on technical committees as a counter balance to domestically focused producers;
- requiring all technical committee membership lists to state publicly not only the name of the nominating organisation but also the name of the company or organisation from which members come; and
- strengthening complaints handling processes.

Improved justification before developing a standard

It is particularly difficult to discern the reasoning behind why some standards are developed and others are not. The Commission considers Standards Australia should: strengthen the justification process it uses prior to developing a standard to include more robust analysis; provide publicly available reasons for developing (or rejecting) a standard; and formalise rights of appeal by interested persons and improve related review processes.

It is imperative that governments rigorously analyse the impacts of a standard, whatever its source, before referencing it in regulation

Voluntary standards are developed to serve a variety of industry interests, such as supplying technical information and ensuring compatibilities, which do not necessarily serve regulatory purposes well. Hence, rigorous impact analysis should be conducted on voluntary standards before they are referenced in regulation. Further, regulators should give greater attention to ensuring only the most relevant

and ‘minimum necessary’ provisions of voluntary standards are made mandatory. As a general rule, standards made mandatory by way of regulation should be performance or outcomes-based while deemed-to-comply standards may be more prescriptive, such as occurs with the Building Code of Australia.

Some of the terms of the separation of Standards Australia and SAI Global constrain Standards Australia in making improvements

While the commercial agreement between Standards Australia and SAI Global has delivered significant financial benefits to both parties, it may constrain Standards Australia’s activities and possibly creates perverse incentives, including:

- reducing Standards Australia’s flexibility to deliver satisfactory access to, and promotion of, standards for clients due to SAI Global’s exclusive publishing and distribution rights to Australian Standards; and
- biasing Standards Australia towards delivering a quantum of standards rather than best meeting industry and community needs, due to the requirement to produce new standards material in any year that corresponds to 7 per cent of the stock of Australian Standards.

There are strong grounds to encourage Standards Australia to seek to renegotiate certain key terms of its agreement with SAI Global.

Access to standards

Another common complaint is the cost of accessing regulatory standards. This both increases the costs to business of complying with legal requirements and limits the capacity of consumers to keep track of their legal entitlements. As a general principle, the law of the land should be readily available to all citizens, and the Commission considers that whenever a government department or agency makes an Australian Standard mandatory by way of regulation that it should provide the funding necessary to ensure free or low-cost access. By bearing some of the costs of the standards, government bodies will have added incentives to fully assess the case for referencing them in regulation.

Declining volunteer participation on standards committees needs to be addressed

There has been a decline in volunteer participation on standards committees due to the costs of participation; changes in the imperatives facing business, academics, public servants and consumers; and some disaffection from seeing SAI Global and its shareholders profit from the intellectual property contributed by volunteers

(notwithstanding the upfront consideration paid by SAI Global to Standards Australia for the distribution rights).

In order to ensure comprehensive representation of all interests and attendance of technical experts, Standards Australia will have to reduce the barriers to participation. Options include: increasing use of technological solutions to reduce the number of face-to-face meetings; and paying the travel and accommodation costs of committee members, in particular consumers, small business and academic representatives, in the same way NATA compensates its assessors.

Using an independent expert to produce the initial drafts of the proposed standards or amendments may also help to concentrate the attention of committees and avoid ‘drafting by committee’, in the earliest stages, which seems inefficient and a cause of unnecessary time delays.

Improved appeals and complaints processes

Standards Australia needs to further improve its internal appeals and complaints handling processes. In particular, Standards Australia should provide and publicly disclose the right of an interested party to appeal against a decision to develop, or not develop, a new standard, or substantially modify an existing standard. Further, where there are grievances in relation to process or procedural matters, there needs to be a formal, robust and sufficiently independent internal complaints handling process in place.

Memorandum of Understanding (MoU), peak status and funding

The MoU between the Australian Government and Standards Australia warrants some modification, including a clearer statement of the Government’s objectives and definition of the public and national interest.

The Australian Government should, through the MoU, continue to recognise Standards Australia’s peak body status, as a way to promote sound processes in the writing of Australian Standards and their high recognition and acceptance both domestically and internationally, and to ensure Australia has a single authoritative national body to coordinate Australia’s participation in international standardisation where non-government representation is required or optimal.

Currently most Australian Government funding is directed towards covering the costs of overseas representation. This should continue, with some reallocation, at current or higher levels, via the Deed of Agreement between Standards Australia and the Department of Industry, Tourism and Resources.

Funding for domestic purposes should come directly from those government agencies using Australian Standards, in particular for:

- ensuring free or low cost access to Australian Standards made mandatory by way of regulation; and
- the development of regulatory standards, via ‘partnering’ or co-funding arrangements, on a case-by-case basis.

The Commission does not consider that continued funding for the SAB is warranted as the benefits for this function are derived by Standards Australia and the accredited SDOs.

Further, the Australian Government should require Standards Australia to report publicly on its performance against its MoU obligations at least annually, as well as maintain the current requirement to report quarterly to the Government under its Deed of Agreement.

Laboratory accreditation and conformity assessment

Conformity assessment is used to determine whether certain requirements (usually embodied in a standard) are fulfilled. Conformity assessment relates to both the direct assessment of goods and activities by way of testing, inspection, and certification (checking) and the indirect confirmation of capacities of bodies to perform these assessments by way of accreditation (checking the checkers).

Among the latter, laboratory accreditation has the longest tradition. It provides assurance that a laboratory is competent to perform nominated tests or calibrations. Laboratory accreditation plays an important role, including in: facilitating domestic and international trade; assisting in ensuring community health and safety in many areas, such as water quality and pathology; and generally checking compliance with regulations (box 2).

The Australian Government recognises NATA as the national authority for the accreditation of laboratories and certified reference material producers, and recognises its peak status for the accreditation of inspection bodies. It is also funded to represent Australian interests in a number of international fora and to provide some proficiency testing (table 2). Although NATA is a private body, the Australian Government is formally represented on its Council and currently holds two positions on its Board.

In reaching conclusions about the effectiveness and efficiency of laboratory accreditation services in Australia, and that of NATA in particular, the Commission took account of the following factors:

- laboratory accreditation can unnecessarily inhibit trade if importing countries do not recognise the conformity assessment conducted by accredited laboratories in the exporting country, thereby imposing extra costs (including uncertainty and delays) which are borne by suppliers and consumers;
- competition can be inhibited where prescriptive technical requirements favour one producer over another;
- establishing trust in the competence of foreign conformity assessment activities is essential to provide a ‘chain of confidence’ from the supplier in the exporting country to the buyer/government in the importing country; and
- self regulation, such as that undertaken by NATA, carries two potential risks: a reluctance to discipline poorly performing member laboratories; and the creation of unnecessary hurdles for new laboratories to receive accreditation, so as to lessen competitive pressures on the laboratories already accredited.

Box 2 NATA and laboratory accreditation services in Australia

NATA is by far the largest laboratory accreditor in Australia; currently more than 2800 facilities are NATA accredited. All of these facilities are members of NATA and, through representation on NATA’s Council, have some influence over the composition of NATA’s Board. Representatives from government, the professions, industry and other interested organisations are also members of the Council.

Laboratory accreditation gives users of testing services confidence in the accuracy of tests performed in those laboratories. Some Australian Government agencies (such as the Therapeutic Goods Administration, the Gene Technology Regulator and the Australian Quarantine and Inspection Service) accredit laboratories for specific purposes. The Australian Government is also a significant *user* of NATA accredited laboratories. It requires NATA accreditation for 19 different types of testing, including:

- pathology tests – Medicare Australia (previously the Health Insurance Commission)
- meat and live animals for export – Australian Quarantine and Inspection Service
- telecommunications equipment and electromagnetic compatibility and radiation – Australian Communications and Media Authority
- parentage testing – Attorney-General’s Department
- fuel quality – Department of the Environment and Heritage
- ambient air quality – National Environment Protection Council
- asbestos – Australian Safety and Compensation Council.

State and Territory governments also require NATA accredited testing in some areas, such as water quality testing.

Government employees comprise a large proportion of NATA’s volunteer technical assessors.

Table 2 National Association of Testing Authorities: a snapshot

Current funding	<ul style="list-style-type: none">• Total budgeted operating expenditure in 2005–06 of \$17.7 million. Operational income of \$17.1 million (includes fees for accreditation activity and government funding).• Australian Government funding of \$1.06 million for the 2005–06 financial year, representing 6.3 per cent of NATA’s budgeted revenue for that period.• Government funding is for a range of designated activities including: the provision of proficiency testing programs; participation in a number of international and regional fora; and facilitation of mutual recognition agreements with foreign laboratory accreditation bodies (to facilitate the acceptance of Australian test results overseas and vice versa).
Structure	<ul style="list-style-type: none">• NATA is an independent, not-for-profit company, owned by its members: over 2800 laboratories and facilities.• NCS International (NCSI) and Proficiency Testing Australia (PTA) are wholly owned subsidiaries of NATA.
International fora	<ul style="list-style-type: none">• NATA participates in a range of international fora: International Laboratory Accreditation Cooperation (ILAC) committees and working groups; the Asia Pacific Laboratory Accreditation Cooperation (APLAC); the OECD Panel on Good Laboratory Practice; and various committees of the International Organization for Standardization and the International Electrotechnical Commission.
Sectors covered	<ul style="list-style-type: none">• The areas in which NATA accredited laboratories and facilities operate include: metrology; construction materials testing; electrical testing; optics and radiometry; heat and temperature measurement; non-destructive testing; chemical testing; biological testing; acoustic and vibration measurement; medical testing; medical imaging; wool; mechanical testing; forensic testing; software and information technology; security testing; and veterinary testing.

Competition would be difficult to establish and is unlikely to produce net benefits

Economies of scale in laboratory accreditation in Australia make it unlikely that multiple accreditors would minimise costs. Obtaining a ‘critical mass’ of laboratories will be difficult for any potential competitor, given NATA’s good reputation and entrenched status. Further, the limited size of Australia’s economy and the amount of technical expertise available will probably limit the scope for competition to lower costs and improve quality. In addition to these scale issues, the emergence of multiple accreditors may erode confidence in Australian test results, and risk reductions in Australian exports. Overall, the benefits of a single national organisation for international trade purposes are likely to outweigh any efficiencies forgone from limited domestic competition. As a result, the Commission considers that the Australian Government should continue to recognise NATA as the national authority for the accreditation of laboratories and certified reference material producers and recognise its peak status as an accreditor of inspection bodies. This recognition should be contingent on NATA maintaining a high level of performance in promoting quality laboratory practices.

NATA's international work improves the quality of Australian laboratories ...

NATA is heavily involved in ensuring that laboratory accreditation arrangements do not act as trade barriers. Through international cooperatives, NATA has helped develop uniform laboratory standards, which give confidence to producers and consumers that all accredited laboratories (regardless of location) are of a similar, high quality.

Building on these standards, NATA has more recently negotiated voluntary mutual recognition arrangements which commit NATA, and other members, to recognise the results of each other's accredited laboratories, and to promote this equivalence in their own country. These arrangements have evolved from a few countries entering agreements ten years ago, to now involving accreditors in over 40 countries, covering 90 per cent of world GDP. Generically, these arrangements reduce the need for retesting, thus increasing the scope for trade and, in particular, they have contributed to increases in Australian exports of wine, olive oil and electrical products.

... yet the full benefits of mutual recognition are not being achieved

Notwithstanding the significant growth in mutual recognition arrangements, some participants were frustrated by the need to get products retested every time they cross an international border. Partly this is due to the voluntary nature of NATA's arrangements. NATA and its international peers can only promote the equivalence of accreditation marks; they cannot force purchasers or regulators to accept this equivalence.

An alternative approach involves the Australian Government concluding government-to-government mutual recognition agreements, which bind governments to accept each other's accredited test results for regulatory purposes. However, progress with these agreements is slow: they cover fewer countries than NATA's arrangements and sometimes they apply only to individual sectors.

Despite the frustrating progress with these government-to-government agreements on mutual recognition, the Commission considers that the Australian Government should continue to work to progress mutual recognition, particularly as part of its broader bilateral and multilateral trade negotiations. In addition, NATA's efforts remain an important vehicle for facilitating international trade. Regardless of the results of trade negotiations, or the responses of other countries, Australian governments should continue to accept the test results of suitably recognised overseas accredited laboratories, since there are benefits in permitting Australian businesses and consumers to buy products from their lowest cost source.

NATA's fees have recently risen

The majority of NATA's income is from the fees that it charges accredited laboratories. The Kean Report concluded that NATA's fees were among the lowest in the world in 1995. NATA's fees are now around the average of accreditation fees in other countries. Recent fee increases have occurred due to a number of factors influencing NATA's cost base. The Commission received a few complaints about NATA's fees, especially from smaller laboratories and particular sectors. The MoU should contain provisions for NATA to provide best practice accreditation services while minimising costs to industry.

There is merit in redefining NATA's role in proficiency testing

Although NATA's accreditation process relies heavily on biennial assessment, proficiency (or inter-laboratory) testing plays an important role in rapidly identifying the emergence of testing inaccuracies. The Commission received some complaints that proficiency testing costs too much, does not occur in 'real world' environments, and both that it is currently not undertaken frequently enough and that in other areas the requirements for such testing are too onerous for accreditation purposes. Such concerns are worrying, given that international evidence suggests that proficiency testing plays an important role in improving the performance of laboratories.

The Commission considers that there is merit in the facilitation of a more competitive proficiency testing market. Such a market would be facilitated if:

- NATA were to continue to set proficiency testing requirements for laboratory accreditation in greater consultation with stakeholders, including regulators and managers of government funding programs, but then allow all accredited proficiency testing bodies to compete to supply the testing;
- laboratories were to be explicitly required to pass on to NATA the results of a minimum number of proficiency tests (within an accreditation cycle) regardless of the provider used; and
- NATA were to ensure sufficient internal separation from the proficiency testing services provided by its subsidiary PTA.

Changes would need to reflect ongoing consultation with all stakeholders. In particular, there may be more scope for input into accreditation processes from the customers of laboratories. Further, there should be a strengthening of complaint handling processes to deal with grievances from laboratories and other proficiency testers in relation to NATA's conduct in these areas, including its accreditation requirements for proficiency testing.

There is a case for reviewing funding for NATA

Most of the benefits of NATA's activities flow to NATA's members or their customers. That said, at times the incentives of laboratories may not match those of the wider community. Specifically, although Australian laboratories have incentives to seek acceptance of their test results overseas, they may not have incentives to promote the recognition of overseas results in Australia. In addition, NATA undertakes some trade negotiating activities directly for the Australian Government. Accordingly, there is a case for funding NATA's international activities where they are in the public or national interest.

The Commission is proposing that the Australian Government:

- fully fund NATA's involvement in mutual recognition arrangements and its participation on the OECD Panel on Good Laboratory Practice;
- substantially fund the costs associated with NATA's participation in ILAC, APLAC and ISO/IEC committees, to the extent that contribution to these activities provides public benefits in excess of the private benefits going to the participants;
- provide case-by-case project funding to NATA for its involvement in trade negotiations or trade-agreement compliance procedures; and
- remove funding for proficiency testing programs, except where it can be demonstrated that there would be net public benefits beyond those which the market would provide.

Governmental requirements for bodies to have NATA accreditation should be carefully considered

Australian, State and Territory governments currently impose requirements for NATA accreditation in a wide range of regulation. In doing so, it is important to recognise that there are costs as well as benefits associated with accreditation. Consequently, governments should not impose a mandatory requirement for laboratory accreditation, unless a comprehensive review of the costs and benefits, as well as an assessment of alternative options, demonstrates that there would be a net benefit to the community. Governments should undertake the same analysis when reviewing existing statutory requirements for accreditation.

The Memorandum of Understanding is basically sound

The Commission considers that the MoU between NATA and the Australian Government is basically sound and is an appropriate vehicle to continue

government oversight of NATA's operations. That said, the Commission is proposing some changes, including:

- changes to reflect recommendations made in this report;
- more explicitly defining NATA's obligations and public and national interest activities; and
- requiring NATA to publicly report, on an annual basis, on its performance in meeting the MoU, as well as maintaining its requirement to report quarterly to the Government under the Deed of Agreement.

Recommendations

Standard setting

RECOMMENDATION 5.1

The Australian Government should maintain Standards Australia's status as Australia's peak non-government standards development body.

RECOMMENDATION 5.2

The Australian Government should continue to recognise the role of the Standards Accreditation Board in accrediting other standards development organisations to make Australian Standards, providing:

- *the Board has sufficient separation and autonomy from the other functions of Standards Australia; and*
- *requirements for accreditation are rigorous, transparent and consistently applied.*

The Board should be renamed the Accreditation Board for Australian Standards.

RECOMMENDATION 5.3

Standards Australia should seek to renegotiate key provisions of its Publishing Licence Agreement with SAI Global, including to ensure that:

- *there is no prescriptive requirement on the number of standards to be produced annually; and*
- *standards development organisations accredited to write Australian Standards and organisations with partnering relationships with Standards Australia can be guaranteed the right to distribute the standards they develop, at least to their members, at no or low cost.*

RECOMMENDATION 6.1

The Australian Government should, in conjunction with Standards Australia, improve the effectiveness of Australia's participation in international standard setting fora by more thoroughly canvassing and then more clearly articulating the national interest objectives to be pursued. Australia's future participation must be focused on those international standardisation activities with the potential for the greatest net benefits for the Australian community.

RECOMMENDATION 6.2

The Australian Government should, in consultation with Standards Australia, ensure the most appropriate expert representation in international standardisation activities and increase funding in order to address any financial barriers to such representation, where this is justified in terms of the expected net benefits to the Australian community.

RECOMMENDATION 6.3

Standards Australia should facilitate more direct participation by Australian consumer bodies on the ISO Committee on Consumer Policy and its working groups.

RECOMMENDATION 6.4

The Australian Government should, through the Memorandum of Understanding, continue to require that in the development of Australian Standards there is a presumption in favour of adopting international standards, and that Standards Australia should publish the compelling reasons where an Australian Standard departs from an equivalent international standard. However, the suitability of such standards should continue to be assessed on a case-by-case basis by Standards Australia and be assessed by governments through their regulatory impact analysis processes where the Standards are to be referenced in regulation.

RECOMMENDATION 7.1

Standards Australia's justification process for the development of new or amended standards and the setting of priorities should be made more transparent and robust including by the publication of reasons for decisions, the establishment of a more open formal appeals process, and ensuring that the primary decision criterion is a net benefit to the community as a whole.

RECOMMENDATION 7.2

For standards that are to be referenced in regulation, or for significant amendments to standards that are already referenced in regulation, rigorous impact analysis must be undertaken by the Australian Government and other governments in compliance with the requirements of the relevant jurisdiction (or COAG requirements for intergovernmental action). In order to best facilitate consideration of other regulatory and non-regulatory alternatives, impact analysis should be commenced at the earliest practicable opportunity.

Standards Australia should provide technical input and other information as required by government agencies for the impact analysis (typically in the form of a Regulation Impact Statement) and, where such input is substantial and additional to normal activities, be compensated accordingly.

RECOMMENDATION 7.3

Mindful of the fundamental principle of transparency and accessibility of legal requirements, the Australian Government and other governments (through their agencies) should fund free or low-cost access to Australian Standards made mandatory by way of regulation.

RECOMMENDATION 7.4

The Australian Government and other governments should seek to minimise the number of referenced standards and cross references to other standards which make it necessary to purchase multiple Australian Standards documents.

RECOMMENDATION 8.1

Standards Australia should do more to ensure adequate representation on all sector boards by all major stakeholder groups, including small business and consumer organisations. Details of sector board membership should be publicly available and should include at least the names of the companies or entities that employ the members.

RECOMMENDATION 8.2

The Australian Government should participate on Standards Australia's governance bodies and on technical committees developing Australian Standards to the extent necessary to ensure the standards will serve the public interest and not inhibit competition. Most importantly, a revised Memorandum of Understanding should include a commitment by Standards Australia and the Australian Government to ensure that the Government has permanent ex officio representation on the Board of Standards Australia. This would be appropriate so long as the Australian Government provides funding to Standards Australia and recognises its peak body status.

RECOMMENDATION 8.3

Standards Australia should improve the balance of interests represented on technical committees by:

- ***increasing the participation of small business, academic, consumer and other community interests;***

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- *ensuring a balance of industry interests are represented, including enterprises involved in overseas and interstate trade, wherever possible, as well as enterprises producing for the local market;*
 - *requiring sector boards to be more rigorous in ensuring appropriate balanced representation on technical committees, including by regular reviews of the composition of such committees;*
 - *requiring all committee membership lists to state publicly not only the names of the nominating organisations but also the names of the companies or entities that employ the members; and*
 - *improving complaint handling processes to deal with concerns about the lack of representational balance.*

RECOMMENDATION 8.4

Standards Australia should continue to apply the consensus decision making model for the development of Australian Standards. Standards Australia should make the standards development process more accessible to the general public, including by:

- *promoting and providing better opportunities for public comment and guaranteeing minimum time periods for consultation; and*
- *making all significant documents and other information readily accessible via the internet.*

RECOMMENDATION 8.5

Standards Australia should explore mechanisms for reducing the cost to volunteers of participation on technical committees, including specific measures to improve efficiency and timeliness (see recommendation 8.6).

RECOMMENDATION 8.6

Standards Australia should continue to improve the efficiency and timeliness of standards development, including by:

- *making greater use of independent experts to prepare early drafts of Australian Standards;*
- *reducing face-to-face meetings, including through better use of technology;*
- *increasing use of partnering arrangements; and*
- *improving project management.*

RECOMMENDATION 8.7

Standards Australia should strengthen its formal appeals and complaints handling processes. Such processes should be robust, transparent, independent and cover all aspects of the standards development process, including decisions about whether or not to develop or amend a standard.

RECOMMENDATION 9.1

The Australian Government should continue to support, with some reallocation of funding and possibly at an increased level overall, Australia's participation in international standardisation activities, including:

- *partial funding for Standards Australia's membership of, and participation in, ISO and IEC and regional standardisation activities;*
- *partial, but increased, funding for industry participation in ISO and IEC meetings;*
- *support for involvement in a broader range of specified international fora; and*
- *funding of the travel and accommodation costs for participation by consumer representatives in the ISO Committee on Consumer Policy.*

In addition, support should be provided, by the client government agency, for domestic standardisation activities, including:

- *on a case-by-case basis, funding for the development of regulatory standards and input from Standards Australia into the preparation of associated Regulation Impact Statements; and*
- *funding to enable free or low-cost access to standards made mandatory by way of regulation.*

The Standards Accreditation Board does not warrant future Government funding.

RECOMMENDATION 9.2

The Australian Government should continue to use the Memorandum of Understanding (MoU) as the most appropriate instrument for setting out its relationship with Standards Australia. While the terms of the current MoU generally remain appropriate, some changes are necessary, including to:

- *give effect to many of the specific recommendations in this report;*
- *improve the clarity of the Government's objectives, in particular by better defining public and national interest activities;*
- *deal with the special requirements of regulatory standards;*

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- *require public reporting on an annual basis of Standards Australia's performance against the MoU obligations;*
 - *more clearly define the nature of the information Standards Australia is required to include in a register of legal instruments referencing Australian Standards; and*
 - *update terminology to reflect recent developments.*

Laboratory accreditation

RECOMMENDATION 12.1

The Australian Government should continue to negotiate for the mutual recognition of conformity assessment as part of multilateral and bilateral trade negotiations. Similarly, NATA should continue to pursue and build on its voluntary mutual recognition arrangements.

RECOMMENDATION 12.2

Regardless of the actions of other countries, the Australian and State and Territory governments should recognise accredited overseas test results. Only when serious public health risks are involved or where clearly established concerns exist about a country's accreditation capacity, should the Australian and State and Territory governments rely exclusively on accreditation by NATA or designated government bodies.

RECOMMENDATION 12.3

NATA should ensure that the extent and design of proficiency testing requirements for accreditation are adequate, but not excessive, through more extensive consultation with all stakeholders, including customers of laboratory services. This may involve greater customer representation on NATA's Accreditation Advisory Committees.

RECOMMENDATION 12.4

In order to facilitate a more competitive proficiency testing services market, NATA should:

- *set the proficiency testing requirements for accreditation and allow any accredited body to undertake the testing;*
- *publicly detail the criteria for the selection of proficiency testing programs used for laboratory accreditation;*

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- *require accredited laboratories to inform NATA of the results of such specified tests in order to maintain accreditation; and*
 - *be able to demonstrate that its proficiency testing subsidiary is operated at arm's length and not favoured above competitors.*

RECOMMENDATION 12.5

NATA should strengthen, and make more accessible and transparent, its complaints handling process, including for complaints relating to accreditation and allied proficiency testing requirements.

RECOMMENDATION 12.6

As a general principle, the Australian Government and other governments should not impose a mandatory requirement for NATA accreditation until the case for doing so has been established through a comprehensive review of the costs and benefits, as well as an assessment of all alternatives.

RECOMMENDATION 13.1

The Australian Government should continue to recognise NATA as Australia's national authority for the accreditation of laboratories and certified reference material producers and recognise its peak status for the accreditation of inspection bodies.

RECOMMENDATION 13.2

The Australian Government should, prior to the negotiation of the next Memorandum of Understanding, review and clarify NATA's status relative to that of the Joint Accreditation System of Australia and New Zealand with regard to the accreditation of inspection bodies.

RECOMMENDATION 13.3

The Australian Government's funding to NATA should be allocated only to areas with clear public benefits. Future Australian Government grants should:

- *fully fund the costs of NATA's involvement in the OECD Panel on Good Laboratory Practice and its participation in mutual recognition evaluations;*
- *substantially fund the costs associated with NATA's involvement in ILAC, APLAC and relevant ISO/IEC committees; and*
- *provide funding for special projects which NATA undertakes directly for the Australian Government, such as involvement in international trade negotiations.*

The Australian Government should not underwrite proficiency testing programs conducted by NATA, or its subsidiary, unless it can be robustly demonstrated that they provide public benefits beyond those which the market would provide.

RECOMMENDATION 13.4

The Australian Government should continue to use the Memorandum of Understanding (MoU) as the principal means of setting out its relationship with NATA and, while it is basically sound, some changes are necessary to:

- *give effect to the specific recommendations in this report;*
- *improve the clarity of the Government's objectives, in particular by better defining public and national interest activities;*
- *clarify NATA's obligations, including requirements to keep laboratory standards high while minimising the fees it charges, maintain and publicise a list of proficiency testing providers and publicly report annually on its performance in meeting the MoU obligations; and*
- *reflect NATA's increasing role in service related industries, the establishment of the National Measurement Institute, the creation of a new NATA subsidiary (Proficiency Testing Australia), the correct terminology relating to certified reference material producers and changes in some standards.*

