National Association of Testing Authorities, Australia

Submission to the Productivity Commission

Study on Standards and Accreditation

April 2006

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Foreword

NATA welcomes this Research Study of its relationship with the Australian Government, particularly as it is 10 years since the comprehensive Kean Inquiry[1] into the whole of Australia's standards and conformance infrastructure.

While NATA's fundamental roles and ethos have not changed over that period, there have been significant developments and environmental changes, affecting both its operations and its delivery of unique accreditation services to the Australian community.

In NATA's view, the Study's Terms of Reference are both appropriate and timely. Efficiency and effectiveness are logical expectations for a national service. The appropriate roles of the Australian Government are of fundamental significance to many Australian stakeholders and the formal relationship between NATA and the Australian Government is an essential foundation for national and international understanding of the public interest functions which NATA's activities support.

A related issue for both NATA and the Government is the funding of activities deemed to be in the national interest. There is a need for a clearer elaboration of the elements of national and public interest served by NATA and the degree to which those interests are satisfied.

On this last point, NATA believes this current Study has a real opportunity to address a significant, unresolved issue from the Kean Inquiry. NATA sought from that inquiry an appropriate definition or description of the national interest elements for the whole Australian standards and conformity infrastructure. In the body of this current submission, NATA outlines its views on the national and public interest activities currently served by NATA itself (as one significant component of the infrastructure). In breadth and language they extend beyond the national interest elements described in NATA's current Memorandum of Understanding with the Commonwealth, and reflect NATA's view that its range of activities has a 'whole-of-society' impact in Australia.

While the focus of the Commission's Study is on the relationship between the Australian Government, Standards Australia and NATA, it is critical, in NATA's view, that the national and international significance of the whole of Australia's Standards and Conformance Infrastructure, and the interactions and interdependencies of the elements of that infrastructure, are understood and embraced in the considerations of this Study.

Before summarising NATA's views on the Study's terms, it is instructive to highlight the baseline of historical recognition of NATA's achievements and contributions to Australia, that have been acknowledged in previous Australian Government reviews. In particular:

- The *Report of the Committee of Review of Standards, Accreditation and Quality Control and Assurance 1987* (Foley Report) remarked,

  The Committee recognises the value placed by industry on the laboratory accreditation system operated by NATA. (p5)

  and went on to say

  …the overriding impression gained is that the system operates well and is highly regarded. On the information provided, NATA is well respected both in Australia and overseas….the present laboratory accreditation system is efficient and effective and should continue essentially unchanged. (p55)

[1] For further information refer to *Linking Industry Globally – Report of the Committee of Inquiry into Australia's Standards and Conformance Infrastructure, March 1995*

- *Linking Industry Globally – Report of the Committee of Inquiry into Australia's Standards and Conformance Infrastructure,* March 1995 (Kean Report) noted,

  By any measure, Australia's standards and conformance infrastructure is well developed. Our organisations have been prominent in international forums and enjoy high reputations. The infrastructure has successfully met the nation's needs in the past, and has the basic elements to meet the needs in the next century. (p vii)

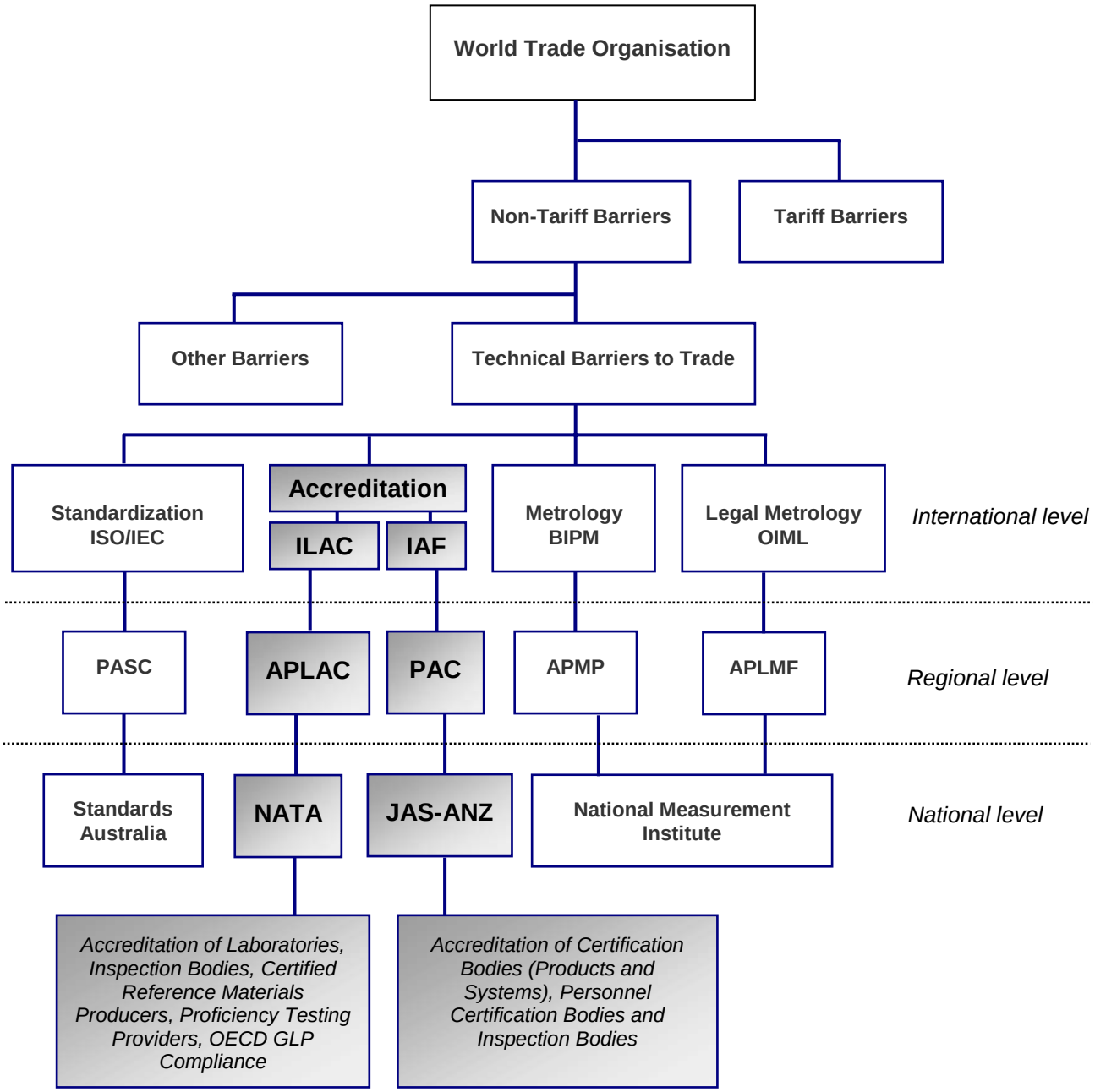
  It further noted:

  …the Committee was impressed by the high regard in which NATA is held in most quarters… (p115)

- The *Evaluation of the Australian Pathology Laboratory Accreditation Arrangements for the Commonwealth Department of Health and Ageing Vol 1*, 17 July 2002 said,

  The pathology laboratory accreditation arrangements are fundamentally compatible with modern approaches to health caments to meet the needs in the next century. (p vii)

Figure 1



To place NATA's submission in context, it is appropriate to describe and define the functions of 'conformity assessment' and 'accreditation'.

The World Trade Organization's (WTO) World Trade Report 2005, *II Trade, Standards and the WTO* (page 56) describes **Conformity Assessment** and its relevance in World Trade.

> *Exporters are often faced with having to test or certify their products in each of the countries to which they are exporting. Even if countries rely on internationally harmonized standards or accept as equivalent another country's standard, they may not rely on an exporting country's conformity assessment results. This can substantially increase costs of exports in a number of ways. First of all, exporters incur the costs of redundant testing and certification for each of the destination markets. Second, they face the risk of higher transportation costs if the goods are rejected by the importing country after shipment. Third, there is a cost in terms of time required for complying with administrative requirements and inspections by the importing country's authorities. For some time-sensitive products, such as textile and clothing, the time delays*

> *associated with product testing and certification in the importing country can severely impact on profitability and the ability to penetrate the market.*
>
> *In order to reduce such costs, a number of conformity assessment recognition agreements have been negotiated between and among countries bilaterally. Obviously, these agreements do not have an influence on the standards and technical regulations themselves. The impact of such agreements on the trade of participating countries is clearly positive due to a reduction in costs generated by the avoidance of duplicative tests, as well as lower transport and administrative costs, as handling time and uncertainty of delivery are reduced. Mutual recognition requires confidence in the competence of one another's conformity assessment bodies and in the methods employed to assess conformity. For this reason, agreements are often limited to accepting conformity assessment results from bodies that are recognised by the parties concerned, and do not extend to self-certification arrangements such as suppliers' declarations of conformity.*

As noted above, there needs to be "confidence in the competence of conformity assessment bodies", and this leads to the concept and role of **Accreditation**.

One relevant international definition of 'accreditation' is contained in ISO/IEC 17011:2004, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*. It reads as follows:

> *Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks*

The keywords in this definition are 'competence' and 'specific tasks'. The fundamental purpose of accreditation is to determine technical competence and to have such competence recognised for a *defined scope of activity*, rather than to provide blanket acceptance of capability.

For NATA, the primary accreditation roles are to formally recognise the competence of:

- Testing, measurement and calibration laboratories for specific tests or types of tests;
- Inspection bodies for specific inspection functions; and
- Producers of certified reference materials to assign 'certified' values to the specific materials or types of materials that they produce.

The major processes NATA uses to determine such competence is through the use of on-site assessment by appropriate technical experts (peer review) and, wherever appropriate and practicable, to complement such on-site assessment by proficiency testing (practical testing by inter-laboratory comparisons).

It also needs to be recognised that there are a number of interdependencies in conformity assessment activities, and particularly related to testing. For example, testing laboratories are dependent on calibration laboratories for appropriate reference values for their equipment and are also dependent on suppliers of certified reference materials and competent operators of proficiency testing programs for inputs to their testing processes.

Many inspection bodies also rely on laboratories for test data which form part of those bodies' judgement of compliance of a product, process or service with specified requirements.

Similarly, one other major group of conformity assessment bodies (product certification bodies) almost exclusively rely on test data to determine whether a product (or service) meets a specified Standard.

Thus NATA's accreditation roles often have a multiplier effect on confidence in various other groups of conformity assessment bodies.

The pervasive significance of accredited testing in the conformity assessment arena has again been acknowledged in the World Trade Organization's, World Trade Report 2005, *II Trade, Standards and the WTO*, where it states on page 100:

> *Accreditation of laboratories has the longest tradition, as the availability of objective and accurate test data is an essential element in compliance control that 'underpins much of the value of the other forms of conformity assessment'…*

3. NATA's Current Operating Environment

At the time of the Kean Inquiry there were a number of factors influencing not only NATA's activities, but also other bodies in Australia's standards and conformance infrastructure. In 1994-95 there was also some tension between Standards Australia and NATA. This led to that Inquiry considering whether it was in the national interest for laboratory accreditation to be performed by a single provider in Australia. The Inquiry strongly confirmed that a single provider model was appropriate, and reinforced it through a number of recommendations discouraging other forms of laboratory recognition. It was reinforced also through strengthening of the language in the Memorandum of Understanding between the Commonwealth and NATA.

At that time also, the other national accreditation body, JAS-ANZ, was relatively new and its charter of activities was refined. However, its charter continued to maintain one area of overlap with NATA's national roles: that of inspection body accreditation. In the 12 years since, JAS-ANZ has not accredited any inspection bodies in Australia but does currently have one accredited inspection body in New Zealand. NATA currently has accredited 88 inspection bodies.

The previous tension between Standards Australia and NATA no longer exists and all infrastructure bodies now enjoy a close working relationship.

After the Kean Inquiry, NATA restructured by separating its program of certification of quality systems into a wholly-owned subsidiary, NCS International Pty Ltd (NCSI). NCSI is now independently accredited by JAS-ANZ.

Additionally, from 1 January 2006, NATA was required to separate operation of its own proficiency testing programs into a wholly-owned subsidiary, Proficiency Testing Australia (PTA). The separation was necessary to meet the criteria for impartiality described in ISO/IEC 17011.

PTA has the same corporate status as NATA (a company limited by guarantee) and its objectives complement NATA's own public interest objectives. PTA has been independently accredited for its competence as a proficiency testing provider by the American Association for Laboratory Accreditation (A2LA).

Some of the factors evident at the time of the Kean Inquiry have evolved further, including the strong trend in globalisation of world trade. Technical barriers to trade have become more prominent as issues for resolution. Without such resolution, trade cannot be truly liberalised, and there is growing international pressure to harmonise practices in standards, testing, certification and technical regulations. During this period, Australia itself adopted a number of new strategies to support its trading relationships. These include: its engagement in Asia Pacific Economic Cooperation (APEC) related trade fora (including the APEC Subcommittee on Standards and Conformance and the APEC TEL MRA Task Force); and Australia's pursuit of bilateral trade arrangements such as the Free Trade Agreements (FTAs) with the United States of America (USA), Thailand, Singapore, and others currently under negotiation. NATA has worked closely with the Australian Government on these initiatives and NATA's processes have been used directly in government-to-government mutual recognition agreements on conformity assessment in some regulated sectors.

Australia has a large and growing stake in these developments. International trade has always been important, and over recent decades the share of trade in Australia's Gross Domestic Product has risen strongly. Increasingly, Australia is exporting highly transformed manufactured goods. Such goods are particularly susceptible to technical barriers to trade where quality is a key aspect of confidence. A standards and conformance infrastructure

that meets world best practice and retains, if possible, builds international confidence, is essential to the continued success of our exports in many areas.

NATA believes that if Australia wishes to be a significant trading nation, it has no realistic alternative other than to align its technical practices with those of its major trading partners.

The situation is compounded by the increasing technical complexity and the dangerous nature of many products. Customers are becoming more demanding, requiring more reliability, higher quality and better service. Products are also being specified in more technical terms. Even a commodity such as wool, which was traditionally sold on the basis of a subjective judgement, is now purchased almost entirely on the basis of objective measurement of attributes such as fineness and grease content. Similarly, wine is often regulated as a food with requirements for chemical composition. Hazardous substances and products are subject to quite extensive regulatory conformance regimes.

Resolution of these issues lies in greater uniformity of standards and regulations and the recognition of the mechanisms by which products can be demonstrated to conform to those standards – the so-called issue of transparency.

While the initiative for harmonisation may have come from an international trade perspective domestic considerations have added weight to the argument, particularly in a federation such as Australia where similar technical barriers have existed between the sovereign states.

NATA has striven to meet international expectations to a degree where its accreditation can be viewed by our trading partners as a sign of credibility for the data accompanying exported Australian goods and services. The most significant development to support this since the Kean Inquiry has been the finalisation (after 23 years of confidence building) of the International Laboratory Accreditation Cooperation's (ILAC) Mutual Recognition Arrangement (MRA), to which NATA is now one of 48 signatories. Concurrently there has been the formation of the complementary regional Mutual Recognition Arrangement of the Asia Pacific Laboratory Accreditation Cooperation (APLAC).

These multilateral MRAs have superseded the previous, less efficient bilateral MRAs which were the first phase of development of international confidence between economies' accreditation bodies.

The WTO's *World Trade Report 2005, II Trade, Standards and the WTO* notes on page 118:

> *A lot of international cooperation is taking place to establish confidence in the work of conformity assessment bodies in other countries. An efficient way forward seems to be the conclusion of mutual recognition agreements (MRAs) between accreditation bodies such that the results of any laboratory or other conformity assessment body accredited by one of the parties are accepted in any other country. In order for this to happen, it is important that common standards on best practices are adhered to, giving other parties confidence in the work of their partners.*

Other features of the environment for NATA's operations have changed over the past decade. In terms of new demands for its accreditation services much of the growth in NATA's client base has been in 'social testing' areas, rather than in more traditional 'product testing'. This 'social testing' has led to substantial growth in areas such as medical testing, forensic science, environmental monitoring (chemical, biological, noise etc), occupational health, and veterinary testing.

Some growth also resulted from deregulation where, in the absence of regulation, various parties have sought reassurance through the independent evaluation of competence that accreditation provides. Growth in NATA's inspection body program is of note over this period, with only eight inspection bodies accredited in 1996 compared to 88 in 2006.

Despite NATA's growth in non-product areas, Australian industry continues to be a major stakeholder in NATA's processes. Industry today must continue to operate within the constraints imposed by the external forces of governments and customers. NATA submits that industry wants low conformity costs, minimal duplication, and flexible and sensible regulatory regimes both in Australia and abroad. Industry also needs uniformity among Australian States and Territories and, in many sectors, a system that is internationally compatible and acceptable.

In today's environment, governments also continue to be major stakeholders in NATA's activities as described in detail in this submission. Australian governments need to ensure that the public interest is best met by a unified and integrated standards and conformance infrastructure and that such infrastructure achieves and maintains appropriate international respect.

4. Laboratory Accreditation in Australia – Main Features

A detailed history of Australia's national system of laboratory accreditation is provided in Annex B. A flowchart of the accreditation process is provided in Annex C.

Some main features of the Australian system and responses to specific background issues raised in the Productivity Commission's Issues Paper, are as follows:

(a) Accreditation Standards

NATA accredits laboratories in accordance with requirements of ISO/IEC 17025 - *General requirements for the competence of testing and calibration laboratories* and associated guidance for specific technologies defined in Field Application Documents prepared by Accreditation Advisory Committees (AACs). Medical laboratories are accredited to ISO 15189 - *Medical laboratories – Particular requirements for quality and competence*.

NATA accredits inspection bodies in accordance with requirements of ISO/IEC 17020 - *General criteria for the operation of various types of bodies performing inspection* and supplementary guidance prepared by NATA's Inspection AAC.

NATA accredits certified reference material providers to a combination of ISO Guide 34:2000 – *General requirements for the competence of reference material producers* and ILAC-G12:2000 - *Guidelines for the Requirements for the Competence of Reference Materials Producers*. These criteria are interpreted, as necessary, by NATA's Reference Materials AAC.

NATA accredits providers of proficiency testing to a combination of ISO/IEC Guide 43:1997 – *Proficiency testing by inter-laboratory comparisons* and ILAC-G13:2000 - *Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes*. Technical oversight is provided by NATA's Proficiency Testing Scheme Providers AAC.

(b) Other Services

NATA also recognises test facilities' compliance with the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice for the conduct of non-clinical health and safety studies. NATA is recognised by the Australian Government as Australia's monitoring authority for such compliance.

NATA provides training services for its cadre of voluntary assessors, and public training on topics related to good laboratory practices and management.

NATA provides a free public information service on the specific testing, measurement and inspection capabilities of 2,800 accredited Australian facilities.

NATA also provides some off-shore capacity building assistance and training of foreign accreditation personnel.

(c) International Compliance

NATA operates its accreditation program in compliance with ISO/IEC 17011 - *Conformity assessment: - General requirements for accreditation bodies accrediting conformity assessment bodies* and supplementary criteria defined by ILAC and APLAC.

A summary of NATA's international engagement is provided in Annex D.

(d) National Uniformity

PC Issues Paper Question 4 - Is there sufficient national uniformity in accreditation processes?

Generally, variation in accreditation processes has two components: variation resulting from differences *between* accreditation bodies, and variation resulting from differences *within* accreditation bodies.

In Australia, there are many accreditation bodies, but only one body involved in laboratory accreditation (NATA), and two accreditation bodies involved in inspection accreditation (NATA and JAS-ANZ). However, as JAS-ANZ has not yet accredited any inspection bodies in Australia, NATA is the only active accreditor for such bodies.

This means that for laboratory and inspection accreditation, one source of variation, that is, variation *between* accreditation bodies, is immediately eliminated, and hence uniformity is not compromised.

With regard to uniformity within NATA, this is reinforced through its operation as a national organisation with its own full time staff of 80 lead assessors. Lead assessors are NATA staff members responsible for leading teams of technical assessors undertaking assessments for the purpose of initial accreditation or continuance of accreditation of laboratories and inspection bodies. While there is potential for variability *within* NATA in the conduct of assessments, and the variability of conclusions reached, various mechanisms and processes are in place within NATA to minimise such variation.

First, all NATA assessments are based on the general requirements of ISO/IEC 17011, *Conformity assessment: - General requirements for accreditation bodies accrediting conformity assessment bodies* and the relevant specific standards related to each form of conformity assessment body, for example. ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*, ISO/IEC 17020 *General criteria for the operation of various types of bodies performing inspection*, and ISO 15189 *Medical laboratories – Particular requirements for quality and competence*.

Corrs Report

Recommendation 4.1 *That the NATA/RCPA accreditation assessment process is capable of reliably identifying laboratories that pose a significant threat to public health, and should continue to be the preferred mechanism by which such laboratories are identified for the purposes of the Health Insurance Commission initiating compliance measures.*

The process has shown that it can identify laboratories of concern and take timely action where the concern is perceived to be a threat to health. It continues to be the preferred mechanism by which those laboratories are identified.

Recommendation 4.2 *That the composition of NATA/RCPA accreditation teams continues to include NATA staff officers and peer assessors.*

The structure of NATA /RCPA accreditation teams has been maintained.

Recommendation 4.4 *That the maximum three year interval between accreditation assessments is maintained, but that NATA/RCPA continues to develop more efficient means of assessment, including greater use of desktop audits and a flexible approach to the composition of assessment teams and the scope of assessments in laboratories with a history of excellent compliance.*

The three year surveillance period is being sustained as required. Pathology laboratories are also required to participate regularly in extensive external quality assurance every year. A procedure for review of identified outliers in external quality assurance, and an associated early warning system, is also currently under development with the Royal College of Pathologists of Australasia in the areas of cytology and chemical pathology.

NATA also has an alternative surveillance program for pathology practices that can demonstrate consistent and acceptable performance at assessments over a number of years.

Practices that have large numbers of facilities under a common management structure and system are eligible to apply for this surveillance model. Since the Corrs inquiry, the numbers of practices involved has increased from four to six.

Moreover, NATA has a broader based alternative surveillance project under development that is examining other aspects of surveillance such as visits between full reassessments. Medical Testing is part of this process.

PC Issues Paper Question 36 - To what extent have previous recommendations improved the structure and process of accreditation?

Previous recommendations have had a substantial impact on the formal relationship between NATA and the Australian Government, NATA and its stakeholders, and NATA and its subsidiaries.

The MoU has improved the accreditation process as it has given a formal framework for NATA's interaction with the Australian Government. By being a party to the MoU the Commonwealth has recognised that encouraging competing authorities in the accreditation industry would be against the national interest. The MoU has been complemented by the signing of similar documents with some of the State and Territory Governments.

The establishment of NATA's certification services (NCSI) as a separate entity has led to a clear demarcation between the two activities of certification and accreditation, and a clarity of purpose from NATA's viewpoint, as the Association sees its accreditation activities as limited to matters of technical competence.

5. Trade Impacts of the Current System and Evolution of Mutual Recognition

PC Issues Paper Question 1 - Has export activity and access to imports been sufficiently supported by Australia's current standards and conformance infrastructure? If not, what reforms are required to facilitate trading opportunities?

The Australian standards and conformance infrastructure has a number of roles to play in support of both export and import activity. Broadly speaking, this support needs to be considered in two streams, namely, trade in sectors which are regulated by governments (both domestic and foreign) and trade in the voluntary (unregulated) sectors.

For trade in regulated sectors (typically those where products or services have an impact on such things as public health and safety, quarantine, public infrastructure compatibilities, and trade measurement devices) the standards and conformance infrastructure has existing roles or the potential to support governments in their relevant regulatory functions.

Regulatory Export/Import Support

NATA has worked very closely with the Australian Government over many years to provide the most effective mechanism possible to support each of the activities listed below. Many of those activities have been supported on a continuing basis as part of the national interest funding NATA receives from the Australian Government. Occasionally, the level of activity has increased dramatically to mirror specific trade and political initiatives of the Australian Government. For example, in the 1990s there was major development of regional infrastructure for accreditation of testing, measurement and inspection bodies in the Asia-Pacific region as part of the evolution of APEC and its objectives to reduce technical barriers to trade, as well as the development of the Mutual Recognition Agreement (MRA) between Australia and the European Union.

In the regulated sectors, the type of interaction between elements of the standards and conformance infrastructure, governments (both State and Federal) and importers/exporters include:

- Support for meeting Australia's international and regional trading obligations (such as the Technical Barriers to Trade (TBT) Agreement of the World Trade Organization (WTO); and Regional Agreements, such as the Asia Pacific Economic Cooperation (APEC) multilateral Mutual Recognition Agreements (MRAs) between governments for acceptance of products in specific regulated sectors);
- Support for the Australian Government's bilateral Mutual Recognition Agreements (such as those between the Australian Government and the European Union or Singapore);
- Support for dealing with technical barriers to trade components of Australia's Free Trade Agreements (FTAs);
- Support for Australian Government agencies' regulatory and trade support relationships with, and obligations to, foreign regulators and governments;
- Support for development of appropriate international and regional standards and codes of practice which may form part of the technical regulations and specifications impacting on Australian exports and imports; and
- Provision of information to Australian exporters and importers on relevant regulatory requirements of trading partners.

Elements of most relevance to NATA in the standards and conformance infrastructure include Australian testing, inspection and measurement resources and infrastructure supporting the credibility of domestic products and services or providing assurance of the integrity of imported products and services.

Specific examples of NATA's role in facilitating acceptance of Australian exports and access to imports include:-

Support of Australian commitments under the World Trade Organization (WTO) Agreements

The WTO Technical Barriers to Trade Agreement, has 15 articles which are binding on member governments. Five of those articles deal exclusively with conformity assessment procedures and Article 6.1 requires that member central government bodies:

> *…shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular:*
>
> *6.1.1 adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting members, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through* ***accreditation***[#]*, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;*
>
> *6.1.1 limitation of the acceptance of conformity assessment results to those produced by designated bodies in the exporting Member.*

Further in Article 6.3,

> *Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements of the* ***mutual recognition***[#] *or results of each other's conformity assessment procedures…*

While Article 6 deals with the responsibilities of central government bodies, Article 8 requires Member governments to,

> *..take such reasonable measures as may be available to them to ensure that non-governmental bodies within their territories (****such as NATA***[#]*) which operate conformity assessment procedures comply with the provisions of Articles 5 and 6 [of the TBT]…*

The mechanisms established in Australia by the Australian Government, largely through its recognition and support of NATA, meet both the intent and spirit of the WTO TBT Agreement as it applies to the acceptance of testing, measurement and inspection results (as major components of conformity assessment activity).

In particular, the Commonwealth (in its MoU with NATA):

1. Recognises NATA as the national authority for accreditation of laboratories and a peak authority for the accreditation of inspection bodies;

[#] NATA emphasis added

2. Requires NATA to maintain links with foreign national accreditation bodies and to develop and maintain mutual recognition arrangements with foreign accreditation systems. [NATA's achievement of this is reflected in it now being a signatory to the multilateral Mutual Recognition Arrangements of the ILAC and of APLAC. These MRAs provide a basis for recognition of NATA accredited laboratories in more than 40 of Australia's major trading partners].

3. Uses "to the maximum extent possible" both NATA accredited laboratories and "laboratories accredited by organisations with which NATA has a mutual recognition agreement" to "satisfy the Commonwealth's own testing needs"; and

4. Formally appoints NATA as its "designating authority" to underpin government-to-government mutual recognition agreements in some regulated sectors. [Designation may be used under Article 6.1.2 of the TBT Agreement].

Support of Australian commitments within the Asia Pacific Economic Cooperation (APEC)

In the context of support for Australian Government contributions to APEC's objectives to reduce technical barriers to trade and to facilitate trade, the following initiatives and mechanisms, (utilising NATA and its expertise) have been undertaken:

1. Capacity building of the accreditation infrastructure of many of the APEC economies. This involved multiple development projects funded by the Australian Government during the 1990s as part of the APEC Market Integration Program. NATA provided extensive consultancy, training and proficiency testing support to numerous accreditation bodies in the region and the Australian Government also facilitated the early development of the Asia Pacific Laboratory Accreditation Cooperation (APLAC). This subsequently led to the evolution of the APLAC MRA which now includes 23 accreditation bodies in 17 economies. [NATA continues to operate the secretariat of APLAC and currently holds the positions of Chair of APLAC and Chair of its Proficiency Testing Committee].

2. APEC itself, through its Subcommittee on Standards and Conformance, recognised the significant role of APLAC as one of its five Specialist Regional Bodies, and subsequently also funded some additional infrastructure development activities in the region with considerable NATA inputs;

3. The Australian Government has recognised NATA as a designating authority under the APEC (government-to-government) MRAs for Electrical and Electronic Goods, and Telecommunications Equipment (The July 2000 "*Report of the Senate Foreign Affairs, Defence and Trade References Committee on Australia and APEC – A Review of Asia Pacific Economic Cooperation*" made a total of eight recommendations. Of those, one specifically referred to NATA's constructive role and two other recommendations were relevant to the Australian Government's support for APEC development initiatives which have relevance to APLAC's supporting roles); and

4. NATA regularly hosts visits of foreign regulators and trade officials from the APEC region and beyond, often at the request of Australian Government agencies, to facilitate their understanding of Australia's testing and measurement resources and infrastructure. In the month of preparation of this submission NATA will host two such delegations.

Support of Australia's bilateral mutual recognition and trade agreements

NATA actively participated in the Australian Government's negotiation of the Mutual Recognition Agreements on Conformity Assessment with the European Union and also with Singapore.

For the European Union - Australia MRA, NATA is recognised by the Australian Government as its designating authority in five regulated sectors.

For the Singapore - Australia MRA NATA is recognised by the Australian Government as a Designating Authority under Article 6 of that MRA.

NATA has provided various inputs to the Australian Government's development of Free Trade Agreements, with particular emphasis on issues relevant to acceptance of Australian test, measurement and inspection data. These inputs include direct discussions with officials of the Department of Foreign Affairs and Trade, and Department of Industry Tourism and Resources and the conduct of surveys amongst NATA accredited facilities of specific cases where difficulties have been encountered with acceptance of data accompanying exported Australian products in the relevant markets.

Support for Australian Government regulators and trade facilitation agencies

NATA accreditation is specified as a requirement for support of export certification of various products and commodities. Significant examples include the specification by the Australian Quarantine and Inspection Service (AQIS) of export meat hygiene testing for the US and EU markets and for export certification of wine for the European Union under the auspices of the requirements of the Australian Wine and Brandy Corporation. In February 2006, AQIS signed a deed of agreement with NATA to use NATA's accreditation processes to support both the export of prescribed goods from Australia and foods imported into Australia.

Other examples include use of NATA accreditation to support the Australian Government's listing of competent laboratories for export testing of food and beverages for recognition by the Japanese Ministry of Health and Welfare and also for biological and chemical testing of seafood for recognition by the Korean Food and Drug Administration.

Support for acceptance of products imported into Australia is also provided on behalf of various government bodies. Such support includes NATA's maintenance of a list of Registered Testing Authorities (foreign accredited laboratories) on behalf of the Australian Communications and Media Authority (ACMA).

Support for development of appropriate international standards, and codes of practice relevant to Australian trade

NATA is a participant in more than 70 committees or subcommittees of Standards Australia dealing with various products and services that may have relevance to either Australian Standards or to Australian inputs to international standards. NATA also is specifically involved in the development of some international standards that may have a direct or indirect impact on acceptance of Australian products in foreign markets.

Of particular significance are the standards that apply to laboratories and other conformity assessment bodies. Such standards are increasingly being specified in both the voluntary and regulated sectors internationally as a pre-requisite for the acceptance of data.

Throughout its history NATA has been a leading contributor to the development of a number of key international standards that affect accreditation and conformity assessment bodies. (see Annex E for more details on NATA's contribution to international and domestic standards development). These include:

- ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*
- ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*
- ISO/IEC 17000:2004, *Conformity assessment – Vocabulary and general principles*
- ISO/IEC 17011:2004, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO/IEC Guide 43:1997, *Proficiency testing by inter-laboratory comparisons -*
  Part 1: Development and operation of proficiency testing schemes
  Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies
- ISO Guide 34:2000, *General requirements for the competence of reference material producers*
- ISO 15189:2003, *Medical laboratories – Particular requirements for quality and competence*
- OECD Principles of Good Laboratory Practice

The basic criteria for competence of laboratories now specified in ISO/IEC 17025, were previously addressed in ISO/IEC Guide 25. The criteria in that guide were based largely on requirements developed initially in Australia by NATA. Moreover, NATA chaired the ISO/CASCO Working Group that developed the current ISO/IEC Guide 43, and continues to play a leading role in international proficiency testing by chairing both the ILAC Proficiency Testing Consultative Group and the APLAC Proficiency Testing Committee.

NATA's participation in international standards committees has been essential to protect the interests of Australian laboratories, and other stakeholders from the development of impractical or onerous criteria which may inhibit business effectiveness or create unnecessary obstacles to trade. NATA considers its level of contribution to the development of these standards has been effective in preventing impractical elements being included. NATA's contribution has also ensured the technical and professional practice content of the standards reflect Australia's interests in setting benchmarks for international conformity assessment activities.

Apart from ISO committees, NATA has also been involved in various international fora of relevance to development of codes of practice in regulated sectors that are of significance in international trade. One such activity is NATA's participation in the OECD Working Group on Good Laboratory Practice (GLP) where NATA currently chairs the Working Group. NATA is formally recognised by the Australian Government as the national authority for monitoring compliance with the OECD Principles of Good laboratory Practice. The purpose of compliance with these Principles is to allow test data from non-clinical studies of the impacts of chemicals on human and animal health, and the environment to be recognised internationally.

In February 2006, NATA was also asked by the Australian Government's Department of Agriculture, Fisheries and Forestry to join the Australian delegation to the Codex Committee on Methods of Analysis and Samples (CCMAS).

Codex standards gained extra importance following the Agreement of the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). Both encourage the international harmonisation of food standards. The SPS Agreement cites Codex standards, guidelines and recommendations as the preferred

international measures for facilitating food trade. As such, Codex standards are the benchmarks used in cases of trade disputes before the World Trade Organisation (WTO).

The outputs of the Codex Alimentarius Commission (CAC) are achieved through the work of general subject committees such as CCMAS, commodity committees, regional coordinating committees and ad hoc inter-government task forces.

In issuing its invitation to NATA to participate, the Head of the Australian delegation advised:

> *Decisions made by CCMAS and ultimately the CAC can impact on the work required of laboratories in member countries. It is therefore important that such decisions are made in the light of considered scientific input from Australia's delegation. I believe NATA is well-positioned to provide excellent input to this process and assist Australia to develop national responses to such technical issues for presentation to CCMAS.*

At a State Government regulatory level, NATA is relevant to various import and export activities. One recent example of relevance for the protection of both domestic health and safety and vital export industries are the amendments to the NSW Government's *Stock Diseases Regulation 2004* – Clauses 10a and 10b. That regulation places strict conditions on testing for Bovine Spongiform Encephalopathy and Avian Influenza. The regulation requires that any testing must be carried out in a veterinary laboratory that has been accredited for such tests by NATA.

Provision of information to Australian exporters and importers on regulatory requirements of trading partners

NATA staff frequently provide Australian exporters and importers with details of the testing, inspection and accreditation requirements of foreign regulatory and specification bodies. Some of those inquiries also lead to requests from NATA to its Mutual Recognition Arrangement (MRA) partners to recommend acceptance of test results from NATA accredited laboratories in those markets.

Export/Import Support in the Voluntary Sector

Many of the mechanisms listed above are also of relevance to both import and export goods and services not covered by regulations.

NATA's accredited facilities operate in most economic sectors and include a broad spectrum of laboratories and inspection bodies that are operated directly by Australian manufacturers, commodity producers, trade groups or independent, commercial laboratories, as well as government laboratories. Some accredited government laboratories also provide testing support for clients involved in export/import testing in sectors not covered by regulation.

Internationally, Australia's laboratory accreditation system is the largest and most comprehensive in terms of breadth of coverage of industrial and scientific sectors. It provides Australian importers and exporters with an extensive pool of competent facilities to support the testing of their products, commodities and services.

Through its network of international MRA partners, NATA is able to promote the acceptability of Australian data in significant foreign markets. Many of the national accreditation bodies in foreign markets (in both developed and developing economies) were established with direct assistance from NATA. This has led to high recognition and positive awareness of NATA in such markets, and has created an environment where data from NATA accredited facilities is more easily accepted. Such awareness has been enhanced further by the prominence

Australia enjoys in ILAC and APLAC. For many years NATA has provided the Secretariats for both ILAC and APLAC, and has been an active contributor to their activities.

During the past decade NATA has received very few complaints from Australian importers or exporters about non-acceptance of test results from NATA accredited laboratories. Recent surveys by NATA in preparation for possible Australian Free Trade Agreements with the USA, Malaysia, Japan, China, ASEAN and the United Arab Emirates reported remarkably low evidence of non-acceptance of Australian test and inspection data in those markets.

A previous (1998) NATA survey of the use of its MRA network, also showed a low number of problems with acceptance of data, while highlighting a number of significant positive outcomes from the MRAs.

NATA submits it has provided a comprehensive set of effective mechanisms to facilitate export activity and access to imports in trade conducted in both the regulated and voluntary sectors.

For decades the Australian system for laboratory and inspection body accreditation has been assisting exporters with acceptance of their products and services overseas on the basis of Australian testing and inspection by accredited facilities.

Previously some overseas regulators and clients based their acceptance of testing on the presumption that tests were performed in a government laboratory. While there are still some regulators/clients that insist on this, NATA regularly assists exporters by promoting the view that NATA accreditation provides the necessary confidence. The emerging trend is for overseas regulators and clients to require testing to be done by an accredited laboratory. In these cases NATA accreditation often reduces or eliminates such potential technical barriers to trade.

Case Studies

Wine Exports to the European Union (EU)

EU regulations require that wine imports to the EU be accompanied by an official EU VI 1 Certificate of Analysis. The analyses must be done by “approved laboratories”. The Australian Wine and Brandy Corporation, a Commonwealth statutory authority, is responsible for issuing Australian VI 1 certificates. To satisfy the EU regarding competence of the testing, the AWBC has a list of "Approved Laboratories" each of which is required to be accredited by NATA.

Meat Exports to the USA

In 1996 the Food Safety Inspection Service (FSIS), the USA authority responsible for the safety of food imports, raised issues regarding the microbiological quality of Australian meat. The FSIS started a “Process Verification and Pathogen Reduction” program for US-listed abattoirs. To satisfy the FSIS that competent testing of meat carcasses was being undertaken, AQIS decided that all testing be done by NATA accredited laboratories. Many US-listed abattoirs gained NATA accreditation for their laboratories and the others now have the testing done by accredited commercial laboratories. This continues to be an AQIS requirement in order to maintain the USA market for Australian meat.

Olive Oil exports

Many olive oil merchants, particularly in Italy and Spain, insist on International Olive Oil Council (IOOC) certificates of chemical analysis and of taste (organoleptic assessment). The IOOC is a unique inter-government body that administers the International Olive Oil Agreement.

To obtain IOOC recognition a laboratory must be accredited for the chemical analyses by a national accreditation body and, to obtain recognition as an IOOC tasting panel, evidence supporting the panel's expertise must be provided. In addition, both testing laboratories and taste panels must participate in regular IOOC proficiency programs.

To assist Australian olive oil exporters, the NSW Department of Primary Industries' Wagga Wagga facility gained NATA accreditation for both chemical analysis and organoleptic classification. On this basis, plus participation in IOOC proficiency testing, the NSW DPI is an IOOC recognised testing laboratory and is seeking IOOC taste panel recognition.

Clipsal Australia Pty Ltd

Clipsal manufacture electrical accessories such as plugs, sockets, switches, conduit and dimmers for the Asia Pacific and South-East Asian markets. These products must meet the electrical safety regulatory requirements of each economy. For a number of countries such as Singapore, Malaysia and Hong Kong evidence of compliance must be provided on a test report issued by an accredited laboratory.

International Testing and Certification Services Pty Ltd is accredited by NATA for the testing involved. Clipsal issues a NATA endorsed report on compliance with the relevant local electrical safety standard. The Clipsal representatives in these economies are then able to register the products using the NATA endorsed test report.

Electrolux Home Products Ltd

Electrolux manufacture a range of domestic white goods for the Asia Pacific and South East Asian markets including washing machines, clothes dryers, dishwashers and ovens. These products must meet the electrical safety regulatory requirements of each country. For a number of economies, such as Singapore, Malaysia and Hong Kong, evidence of compliance must be provided on a test report issued by an accredited laboratory.

International Testing and Certification Services Pty Ltd is accredited by NATA for the testing involved. It issues Electrolux with an endorsed report on compliance with the relevant international standard plus compliance with any local deviations in the standards of the economies involved. The Electrolux agents in each country are then able to register the products using the NATA endorsed test report.

NATA accreditation as a trade facilitator

PC Issues Paper Question 43 - Do current accreditation arrangements and practices create barriers to trade?

Accreditation arrangements and practices in themselves do not create barriers to trade. Barriers to trade may occur when other parties, for example, governments or parties to a commercial transaction, exercise their rights to stipulate the need for results to come from accredited facilities, and there is a lack of access to accredited facilities or facilities cannot access a recognised accreditation system.

Over the last three decades, accreditation results and activities have been used by both public and private sectors as a trade facilitation tool. This has been particularly evident in the establishment of government-to-government agreements and voluntary mutual recognition arrangements (MRAs) on the acceptance of conformity assessment results.

In the context of government agreements, the WTO TBT Agreement states accreditation is one means of ensuring confidence in the continued reliability of conformity assessment results (clause 6.1.1). Accreditation has also been stipulated as an integral part of regional and bilateral trade discussions and agreements (for example the European Community - Australia MRA and Asia-Pacific Economic Cooperation (APEC) Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment).

In the context of voluntary arrangements which are applicable to laboratory accreditation in Australia, the two most important are the ILAC MRA and APLAC MRA. These arrangements establish commitments and obligations to accept and promote the accreditation results and activities of one signatory by all the signatories.

Regardless of whether the mutual recognition is by government or voluntary, the intent is generally the same - to enable the recognition results and activities of accredited facilities as being equivalent, and to avoid the need for retesting and/or recertification when goods and services are traded between parties.

> *A significant amount of international cooperation is taking place to establish confidence in the work of conformity assessment bodies in other countries and, in particular, on the conclusion of mutual recognition agreements (MRAs) between accreditation bodies. However, while MRAs may help purchasers to gain trust in the results of foreign bodies, it is not certain to what extent they are relied upon by government in regulated sectors.*
> *(World Trade Report 2005, pg 161.)*

Absence within an economy of an internationally recognised laboratory accreditation provider may mean domestic producers will face problems with market access. Exporters may be disadvantaged either when there is no domestic accreditation body or when the domestic accreditation body is not a signatory to an MRA. The domestic conformity assessment bodies must then seek accreditation from a foreign accreditation body. That adds to costs for the conformity assessment body.

For international recognition, as a signatory to an MRA, an accreditation body has to meet the impartiality and other requirements of ISO/IEC 17011. This can present a challenge in some economies where the provision of conformity assessment-related activities (including accreditation) by the same ownership (for example undertaken solely by government), or are discriminatory in terms of conformity assessment bodies that might be recognised (for example proprietary conformity assessment and accreditation frameworks). At present in Australia such difficulties are avoided as NATA is a signatory to the relevant voluntary MRAs and is often cited in government-to-government MRAs.

There is a great deal of effort being undertaken at regional and international levels to build accreditation capability to enable more economies to participate in mutual recognition arrangements.

Mutual recognition of test results and calibrations from accredited laboratories

PC Issues Paper Question 6 - How much progress has been made internationally with mutual recognition of conformance assessment across countries?

In the context of laboratory accreditation there has been significant progress.

NATA signed its first bilateral mutual recognition agreement (now called mutual recognition *arrangement*) with TELARC, New Zealand (now International Accreditation New Zealand (IANZ)) in 1981. Other bilateral agreements were signed in subsequent years with National Voluntary Laboratory Accreditation Program (NVLAP), USA; NAMAS, UK (now UKAS);

HOKLAS, Hong Kong China (now Hong Kong Accreditation Service (HKAS)); A2LA, USA; The Swedish Board for Accreditation and Conformity Assessment (SWEDAC), Sweden and Sterlab, Netherlands (now RVA). NATA's first multilateral arrangement was signed with EAL, (now European Cooperation on Accreditation (EA)) in 1994.

During the last decade there has been extensive growth in a global Mutual Recognition Arrangement (MRA) network. NATA was one of seven inaugural signatories to the regional APLAC MRA for testing and calibration in 1997, and was again one of four inaugural signatories to the extended APLAC MRA for inspection in 2003. There are now 23 signatories (from 16 APEC economies plus India) to the APLAC MRA, 10 of which are also signatories for inspection. APLAC is in the process of extending its MRA to include accreditation of Reference Material Producers. The extended MRA will be signed for the first time once four current signatories have been successfully evaluated. NATA intends to be evaluated for accreditation of Reference Material Producers in the first quarter of 2007.

In November 2000, the signatories to the EA and APLAC regional MRAs, and South African National Accreditation System (SANAS), South Africa became full members of ILAC (ie signatories to the became full members of ILAC (ie
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NATA submits these objectives are comprehensive and do not need refining at the present time. Clearly the objectives have evolved as the testing and broader community needs have changed. NATA re-examines its objectives regularly and, should they diverge from community expectations, would certainly respond and modify them in response.

NATA's current objectives

By analysis of the above, NATA's believes its current objectives correlate closely to society's and industry's requirements for laboratory accreditation services. NATA has three major sources of written specifications of the objectives for laboratory accreditation in Australia. They are:

a. Objectives set in NATA's Constitution as ratified by the NATA Council, who represent the diverse interests of NATA's stakeholders;

b. Objectives set in Memoranda of Understanding between NATA and the Commonwealth and some State and Territory Governments and various Commonwealth and State Government Departments and Agencies; and

c. Objectives set in various Mutual Recognition Arrangements (MRAs) between NATA and its overseas counterparts.

Objectives set by NATA's Constitution and NATA itself

The sources of NATA's own written objectives, apart from its Constitution, include NATA's Mission Statement, its Strategic Plan, and its Charter of Service.

The fundamental objectives of NATA are currently formally defined in Clause 3 of NATA's Constitution as follows:

> ***Objectives of the Association***
>
> *The objects for which the Association is established are:*
>
> *a. To promote and contribute to the quality of testing, inspection and related services in Australia.*
>
> *b. To promote national testing, inspection, calibration and related services to meet the needs of science, industry, trade, commerce, government and matters related to national interest.*
>
> *c. To promote the science and practice of testing, inspection, calibration and related services within Australia and internationally.*
>
> *d. To provide appropriate accreditation services to facilitate acceptance of Australian products and services within Australia and internationally.*
>
> *e. To provide international recognition of accredited laboratories' and accredited service facilities' reports and certificates through Mutual Recognition Agreements with appropriate bodies located in other countries.*

It should be noted the objectives are couched in terms of NATA's role in the national and public interest, rather than in terms of the interests of members of an association. The other objectives derived from agreements with Governments in Australia and those derived from NATA's international obligations are included in Annex F.

Efficiency

The Productivity Commission's Issues Paper makes the following statement in relation to efficiency:

> *In economics, the concepts of efficiency and effectiveness are closely related. Unlike engineering, they are not based solely on technical input-output terms but also allow for the influence of scarcities and preferences on choices made and methods used. At the broadest level, an economy is economically efficient if resources have been allocated in a way to maximise the welfare and living standards of the members of the society. An outcome is efficient if there are not alternative pursuits which would have produced greater value to citizens (allocative efficiency) and if the methods used are the least cost way of achieving the outcome (productive efficiency)…*
>
> *In the context of this review, to judge the efficiency of standards setting and laboratory accreditation services, it is necessary to evaluate:*
>
> - *whether society allocates an appropriate level of resources to standard setting and laboratory accreditation services; and*
> - *within this aggregate whether the mix of services is appropriate.*
>
> *This involves identifying possible market failures and examining, how well existing government interventions address the public interest. It is even possible for government interventions to reduce efficiency and community welfare, by distorting resource allocations or inhibiting competition without offsetting gains to community wellbeing.*
>
> *Productivity Commission Issues Paper, pg 10 and 11*

NATA believes the national system of laboratory accreditation it delivers is efficient. Reference to NATA's productive efficiency and dynamic efficiency are made throughout this submission.

Market failure

Potential market failure is generally considered to include:

- excessive transaction costs
- monopoly and market power
- externalities
- imperfect information

Transaction costs of conformance infrastructure to business and consumers

Transaction costs can affect economic efficiency. Transaction costs can be considered to include:

- search costs (the costs of locating information about opportunities for exchange)
- negotiation costs (costs of negotiating the terms of the exchange)
- enforcement costs (costs of enforcing the contract)

PC Issues Paper Question 3 - In what ways does the conformance infrastructure reduce and/or impose transaction costs on businesses and consumers?

Laboratory accreditation serves to reduce transaction costs (eg. search, negotiation and enforcement costs) for business and consumers.

In terms of search costs NATA provides a comprehensive publicly available directory of accredited facilities and the tests, calibrations and inspection activities that they are able to perform. The directory is updated on a daily basis and is available on the internet or by contacting NATA directly. The information contained in the directory reduces the costs to anyone with a need to identify an accredited laboratory or inspection body.

The consistent accreditation of facilities also reduces the cost of negotiation, because those who require testing can use accreditation as a 'screening' device – rather than conduct background research into a facility themselves, people can see what a facility is accredited to do, and have some idea of how well that facility can meet their needs. This benefit is present in domestic markets and international markets as a result of the MRA networks. Without the level of assurance provided through accreditation, parties may have protracted negotiations on testing, calibration or inspection requirements that may need to occur each time a new contract is negotiated or a new trading partner is identified.

Furthermore NATA maintains a comprehensive database of voluntary technical assessors that is updated and used by NATA secretariat staff to schedule and arrange assessment activities. This centralised system adds efficiency to the arranging and negotiating costs for assessments. Without such a centralised administrative system users of laboratories would find it difficult and costly to arrange their own assessors in order to be involved in assessment of technical capabilities.

Laboratory accreditation can support enforcement of economic transactions and act to reduce enforcement costs in some circumstances. Test data from an accredited facility can stand up to systematic scrutiny and can be a tool used in disputes and court proceedings to establish bona fides of a test result. For example, legislation under the Family Law Act requires that parentage testing results presented to the court be performed by a NATA accredited facility. The potential exists for test data from accredited facilities across all fields to minimise enforcement costs.

In defined circumstances, NATA may, and does, suspend the accreditation of a laboratory or inspection body for unsatisfactory performance. There is an administrative cost to NATA to suspend a facility but the benefit to society is a minimisation of incorrect test data.

In considering costs it is acknowledged that applicant and accredited facilities incur costs and expend time and effort in gaining and maintaining accreditation. These costs are considered to be direct rather than transactions costs.

Monopoly, market power and the degree of self-regulation

Is NATA a monopoly?

NATA holds a dominant position within Australia's economy as a provider of laboratory accreditation services, and has some characteristics off efficiency monopolies and natural monopolies. Under the MoU with the Commonwealth, the Government does provide a form of accreditation for a very specific sector related to therapeutic goods.

There are effectively no close substitutes[3] to laboratory accreditation.

NATA has developed a network of 3,000 voluntary assessors whose expertise NATA relies upon to undertake its accreditation activities.

Market power

Because of the potential for criticism of NATA's market position, it is cognisant of its responsibility to deliver its services in a way that provides optimal social and technical benefits. There are a number of factors that demonstrate NATA does not abuse this market position. They include:

Governance structure

As outlined in the following sector, the governance structure of NATA is robust and draws input and advice from the many stakeholders in laboratory accreditation.

Not-for-profit status and finance independence

NATA is a not-for-profit body with a Board that exercises prudence in its financial management. This requires NATA to maintain adequate reserves to maintain financial stability and to provide opportunities for investment of resources to meet new demands for services as they arise. For example, current policy is to maintain reserves to meet 30% of annual operational expenditure. This objective was achieved in 2004.

Appropriate pricing for services

The fee structure for NATA is fully transparent and listed publicly on NATA's website. The level of annual fees is dependent on the scope of accreditation of each facility. This is because the costs of establishing and maintaining accreditation varies with the breadth and technical complexity of the accreditation.

NATA is cautious in its pricing considerations. Later in this chapter there are some examples of the fee structures of other similar bodies in Australia and internationally. NATA's fees compare favourably and are appropriate to maintain the level of technical rigour needed to provide community confidence in its processes.

Cannot restrict supply

NATA accepts all bona fide applications for accreditation. That is, it does not in any way restrict supply of its accreditation services. This has always been NATA's *modus operandi* and this position is now a requirement in ISO/IEC 17011. This international standard for accreditation bodies requires non-discriminatory behaviour towards conformity assessment bodies.

Innovation in the services provided

In addition, ISO/IEC 17011 also requires that accreditation bodies have procedures for extending their activities and to react to demands of interested parties. NATA has done this since its inception and continues to be dynamic and responsive in its program development.

NATA is one of the leading accreditation bodies on the uptake of new accreditation programs where the need has been fully justified and necessary for the Australian community.

[3] The matter of close substitutes for laboratory accreditation, namely certification of a laboratory's quality management systems, was vigorously debated at the time of the Kean Inquiry. The Kean Report established a clear distinction between laboratory accreditation and certification. This latter found expression in the internationally accepted position on the difference between the two activities (see the joint statement *"Objectives and roles of "accreditation" and "certification" of laboratories"*, IAF-ILAF-ISO/CASCO Joint Working Group on Image and Integrity of Conformity Assessment, December 2002).

Is NATA self regulated?

PC Issues Paper Question 38 - Does "self-regulation" by NATA create conflicts of interest? Does this jeopardise the pursuit of the public interest?

NATA does not believe it is self regulating but is in fact regulated in the ways discussed above. Furthermore NATA believes the current arrangements in no way hinder delivery of pursuits in the public interest.

Factors affecting the regulation of NATA include:

- Accountability to its membership that is structured in the form of an association;
- The comprehensive and democratic nature of NATA's governing bodies, that includes all stakeholders, not just members;
- Accountability to the Australian Government, not only for contracted national interest activities, but also (through its MoU obligations), for all activities as Australia's laboratory accreditation authority; and
- Peer evaluation by international teams that results in international recognition.

NATA's activities are delivered in a balanced and transparent manner to its stakeholders.

'Regulation' of NATA by its members

NATA is an association of members, its members being the facilities that have been accredited through the accreditation system. These facilities come from a mixture of government, industry, research and commercial sectors.

The Association has a formal Constitution and set of Regulations set out in the *NATA Rules*. The Rules set out the rights, voting privileges, and obligations of the Association and its members. The governance and administrative structures and policies that apply are more complex and onerous than might normally be expected from such a document if NATA was an association focused solely on the provision of benefits to its membership. The *NATA Rules* reflect many of the external 'regulation' influences that NATA is peculiarly subject to, not least being the requirements set out in relevant international standards and guides for accreditation bodies.

It should be noted that the primary focus of NATA is to facilitate a national system of accreditation that is recognised both in Australia and abroad. Given the mix of stakeholders that support this system and their various origins (government and private) the association structure has proven to be an acceptable form of stewardship of the system over time.

Without the primary purpose of maintaining and developing the accreditation system it is arguable whether these diverse stakeholder interests would otherwise have formed a cohesive grouping.

In terms of specific structures, the NATA Council and NATA Board are explained below. However in relation to technical 'regulation' of NATA's accreditation programs there are a number of Accreditation Advisory Committees (AACs). Members on the AACs are appointed by the NATA Board, and are experts from relevant government, academic, professional and industry interests. In practice the AAC's advise the Board on the need and technical basis for accreditation programs in their discipline. In this way NATA is regulated at a grass roots level by the disciplines and industries it serves.

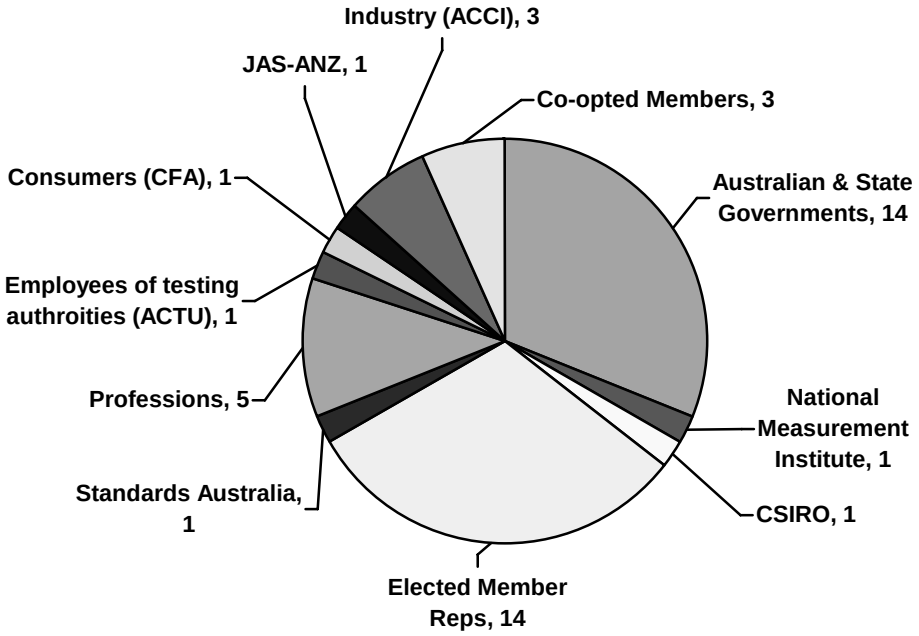
'Regulation' through NATA's governance structure

The governance structure and functions set out in the NATA Rules give NATA members and other stakeholders stewardship over the national system of accreditation that NATA provides. This is actioned through two principal governance bodies, the NATA Council and the NATA Board.

The NATA Council may consist of up to 46 representatives of stakeholders in the NATA system of accreditation. Currently NATA's Council consists of 45 representatives as illustrated in the following diagram.

Figure 2

Current Membership of the NATA Council (April 2006)



No specific group of stakeholders dominates, and the Australian Government, State and Territory Governments and agencies represent about one third of the NATA Council Membership.

The second governance body is the NATA Board. Presently the following individuals have been elected by the Council to be Directors on the Board.

Chairperson	Dr B Inglis	Chief Metrologist and CEO of the National Measurement Institute, Department of Industry, Tourism and Resources (DITR)
Deputy Chairman	P Duncan	Tarwyn Pty Ltd
Directors	M Callanan	pndt Pty Ltd
	T Mackey	Deputy Secretary, Department of Industry, Tourism and Resources (DITR)
	B McNair	Bryce McNair and Associates
	A Ross	Victoria Police
	D Turner	ENERGEX Limited

In both the Council and the Board there is a balance of interests, between members and other stakeholders, and between government and private representatives.

Each of these bodies monitors various aspects of NATA's operations and together they ensure that NATA is meeting the objectives of a laboratory accreditation organisation, established and operating for the purpose of meeting agreed national and public interest objectives.

In economic terms, these objectives must be met in a cost-effective manner. Operating as a not-for-profit association provides a constant focus on providing services within costs acceptable to the membership and stakeholders in the NATA system of accreditation.

In summary, NATA is governed by a Council with wide and varied representation, and a Board elected from that Council. Both bodies have representation from Government whose job includes ensuring NATA continues to operate in the public and national interest. NATA's members have a similar philosophy.

'Regulation' by government

Regulation by the Federal, State and Territory governments include the normal forms of corporate and taxation regulation that face any Australia organisation. In NATA's case its not-for-profit status means it has specific limitations on its purpose and its methods of operation, as well as, the distribution of any form of surplus generated by its activities. Effectively these limitations prevent NATA from pursuing normal commercial activities and paying dividends to its members. This reinforces the focus on the provision of an accreditation system that benefits all stakeholders including society at large.

Direct regulation is afforded through various Memoranda of Understanding and Deeds of Agreement that NATA has with the Australian Government, State and Territory governments and their agencies.

'Regulation' by international peers

NATA is subject to evaluations from its international peers every four years. In these evaluations NATA must demonstrate it is meeting the requirements of international standards and guidance related to the operation of laboratory accreditation services. These peer evaluations are significant and serious undertakings with evaluation teams being selected from senior personnel of foreign accreditation bodies. At stake is the continued recognition of NATA amongst its peers, and the continued recognition of the thousands of results from NATA accredited facilities that are necessary for Australian goods to be traded.

The evaluations usually take at least a week and end in formal reports that may contain nonconformities. NATA then has a specified time in order to adjust its performance and satisfy its international peers that the nonconformities have been resolved.

The requirements that NATA must comply with change over time, and hence within the four year cycle of formal peer evaluation there may be other occasions where NATA must demonstrate how it complies with changed requirements. Evaluations take place at both regional (APLAC) and international levels (ILAC).

In summary, NATA is not self regulated in the conventional sense. Its governance and operational framework is populated by NATA's membership and other stakeholders. This has proven to be an inclusive and responsive way to manage Australia's national laboratory accreditation system on behalf of the society it serves.

The prevalence of conflicts of interest

The degree of self regulation in NATA's case makes the linking of this concept with the prevalence of conflicts of interest a moot point. However conflicts of interest in laboratory accreditation are a significant and sensitive point which at times has involved NATA directly.

Perceived conflicts of interest at NATA are identified and managed from a number of standpoints.

NATA has specific policies and procedures for dealing with any conflicts of interest (Systems Manual 21.2) or undue influence (Systems Manual 21.4).

In response to specific requirements in ISO/IEC 17011:2004, NATA maintains statements on how it meets that standard's impartiality provisions and has complied with the structural requirements that prevent an accreditation body undertaking activities that it itself accredits (Systems Manual 3). In relation to this point NATA has recently separated the provision of proficiency testing services into a new wholly-owned subsidiary, Proficiency Testing Australia. While NATA does accredit other proficiency testing services providers it does not accredit Proficiency Testing Australia. Proficiency Testing Australia is accredited by USA-based A2LA.

The Kean Inquiry identified a perceived conflict of interest with NATA undertaking management system certification activities. The issue has been dealt with through the separation of those activities into another related body, NCS International Pty Ltd, which is not accredited by NATA, but by JAS-ANZ.

In discussions with the Commission in the lead up to NATA's submission, questions where raised over the degree of unfair advantage which might accrue to NCS International Pty Ltd by NATA fulfilling its mandate as Australia's national laboratory accreditation body. In the early days of establishment of a management system certification program within NATA many of the clients of the service were also NATA members.

This now has changed. The reasons are two fold. First, the conformity assessment community has drawn a greater distinction between the activities of quality management system certification and accreditation of laboratories which has had the effect that laboratories themselves make a clear distinction between these different forms of recognition. Second, with its independent Board and management, NCS International Pty Ltd has charted its own course and now has a majority of clients outside of the NATA membership.

Internationally, NCS International Pty Ltd has entered into agreements with service providers that are not in any way linked to NATA's international connections. NCS International Pty Ltd operates in countries where NATA itself has no direct involvement, and NATA officers do not undertake commercial activities on behalf of NCS International Pty Ltd when they are overseas on NATA duties.

Pursuit of the public interest

Given this self regulation and the extensive involvement of all stakeholders in the stewardship and management of NATA's accreditation system, there are clearly a range of opportunities and levels at which the public interest can be met.

In some many cases NATA provides services that would not be provided by the market, even though the NATA accreditation system may not cover the costs associated with those services, despite funding assistance from the Australian Government. NATA undertakes these activities because its members and stakeholders wish it to undertake various public interest activities.

For example, NATA's training services and the provision of proficiency testing services through its subsidiary are both loss making activities. Nevertheless, NATA undertakes these because they are important adjuncts to accreditation services, and are recognised as such by NATA's stakeholders. In regard to proficiency testing, it is unlikely that the market would undertake the number of programs that NATA's subsidiary current delivers as many of them will not be financially self-supporting.

NATA's accreditation activities are divided into 'fields', for example chemical testing, mechanical testing, medical testing. Some of these fields will not even in the long term, be financially self-supporting. The reason why such fields are defined and serviced is because NATA's stakeholders have over the years, been interested in providing a comprehensive national accreditation system that recognised the interdependencies of the testing disciplines. NATA has not pursued a 'cherry picking' strategy in terms of the coverage of its accreditation service.

Given the inclusion of Government, professional and private stakeholders in NATA's 'regulation', and that it provides Australia's national system of laboratory accreditation, NATA has an obligation not only to provide services for which it can recover costs. It must take on those services that the market would not otherwise provide. As proposed elsewhere in this submission, the efficiency and effectiveness of conducting the activities within one national framework outweigh the benefits of doing them in separate systems. The pursuit of the public interest is best served by using the current model.

Alternative provider for the national interest in laboratory accreditation?

PC Issues Paper Question 32 - Could other public or private bodies undertake such national interest activities? If so, should the government tender for the activities?

While it is possible for Government to specify the national interest activities currently provided by NATA, and to execute a tender process for delivery of such activities, NATA suggests this would have deleterious outcomes for the continued provision of accreditation services that are truly in the national interest.

Maintaining NATA as the service provider has the following advantages:

- Building on a successful track record over many years in delivering national interest outcomes in relation to laboratory accreditation matters.
- Continuation of the support and goodwill for the existing system of national accreditation by the voluntary technical assessors.
- Use of NATA's influence as one of the leaders in international laboratory accreditation.
- Use of NATA's depth of experience and respect as a laboratory accreditation authority that has been built over the past 60 years. Current staff have more than 1,100 person years of experience in the operation of a laboratory accreditation body, with 79 staff each having more than five years experience, 47 staff having more than 10 years experience, and 10 staff having more than 20 years experience. This level of experience cannot be matched by any other comprehensive laboratory accreditation body in the world.
- Use of NATA's comprehensive set of expert and political networks within the technical infrastructures of Australia, the Asia-Pacific area and internationally.
- Use of NATA's extensive track record, experience and goodwill in capacity building in laboratory accreditation with developing countries and Australia's significant trading partners.
- Use of NATA's extensive information and network of voluntary representations on many national and international standards committees and other similar fora.

Imperfect information

The potential cause for market failure that NATA primarily addresses is the problem of imperfect information, asymmetrical information. As noted in the Commission's Issues Paper, the standards and conformance infrastructure may be invisible to the community and does operate in a complex environment.

The problem of asymmetric information arises because quite often the testing facility has more knowledge of what it can do and how well it can do it than its potential customers. While its potential customers could obtain information about the testing facility, doing so may be overly complicated or expensive for one or more of the following reasons:

- It is expensive for users to conduct a background check on a testing facility;
- It is difficult and/or expensive to independently verify the results provided by a testing facility;
- For some testing that is time-critical, buyers of testing services do not have the time to investigate different suppliers;

By undertaking the responsibility for accrediting testing facilities, potential customers of testing facilities not only know whether or not a facility is able to perform the test they require, they may also know the standards the facility has had to meet to obtain accreditation.

This is because NATA operates transparently and in line with relevant international standards and in turn accredits facilities to other international standards and guides.

To assist the laboratory community, NATA has developed many documents to complement ISO/IEC 17025 and to assist in its application in each field of testing. Development of technical notes and availability of training programs are further examples of NATA's commitment to improving information availability.

NATA's recently upgraded website is a growing information source to the general public. It has a search facility that assists enquirers to locate accredited facilities in their area of interest. This is backed up by a telephone enquiry service where calls are answered by NATA's technical staff.

The availability of accreditation information is enhanced by the participation in assessments of laboratories by NATA's assessors. This gives rise to a large body of knowledge of the laboratory accreditation system and provides an excellent forum for the transfer of technical knowledge and good laboratory practices across Australian industry through the involvement of voluntary technical assessors.

Additionally, NATA directs resources to identifying fora to which to contribute its laboratory accreditation message and technical knowledge. This covers regional and international activities where the difficulties for exporters and importers to access technical and regulatory information relating to foreign markets are acknowledged.

Externalities

In economics, externalities are benefits or costs that accrue to stakeholders outside of the primary parties involved in the transaction. In the case of laboratory accreditation the direct beneficiaries is the laboratory, because a laboratory that is known to be accredited is likely to receive more custom than one that is not. However, a number of positive externalities, or indirect benefits, accrue to other stakeholders as well.

As discussed earlier, the potential customers of testing facilities benefit from knowing whether a particular facility is accredited or not. Both society and industry benefit through the added confidence and trust they can have in services and products that have been through testing or inspection by an accredited facility.

Also the assessment process exposes assessors and laboratories to best practices and innovations that can be adopted in other accredited facilities. By this method the whole testing, calibration and inspection infrastructure maintains a relevant and contemporary standard of excellence.

The results from NATA accredited facilities are recognised by many other trading partners and as such market access is enhanced for Australian goods and services.

All these positive externalities contribute to the general public and national interest.

Competition

NATA submits laboratory accreditation in Australia should not be subject to competition. NATA contends that the public and national interest are best served by upholding the single provider arrangement for laboratory accreditation services and that competition would be to the detriment of Australia's well refined and respected laboratory accreditation service. It does not believe that competition would produce a more efficient allocation of resources to society.

In 1995, in the Government's response to the Kean Report, stated:

> *The Government agrees with the Committee's view that opening laboratory accreditation to competition would not be in the national interest.*

The consistency of the Committee's view with the Hilmer principles[4] of competition was acknowledged in the Kean Report.

The laboratory accreditation landscape in 2006 is still very similar to that of the mid 1990s. The main difference is that new programs have been developed, and the international partnerships and MRAs have been further developed and cemented. With respect to competition, the reasons for not opening up laboratory accreditation still hold and are indeed strengthened by current international trends and new program developments.

NATA reaffirms its belief that the introduction of competition would be detrimental in the following ways:

Loss of single national focus

NATA believes competition would result in the loss of a single national voice on matters related to laboratory accreditation. Presently there is an efficiency of scale in terms of government and industry interfacing with the accredited laboratory community via NATA.

Competition would fracture the existing system and variations in the accreditation message are likely to occur. Should government and industry want to liaise, they may need to speak and coordinate with multiple providers perhaps at state and sector levels.

Loss of national identity

Competition for laboratory accreditation in Australia would, presumably, mean open competition. Under such an arrangement it is possible that foreign accreditation bodies

[4] See the *National Competition Policy, Report by the Independent Committee of Inquiry, August 1993.*

would enter the laboratory accreditation scene in Australia, as they have in many countries for quality systems certification. For the highly technical activity of laboratory accreditation and because of its strategic significance in underpinning trade and trade negotiations, NATA believes it is essential that Australia maintain its national sovereignty for this activity.

It would also send a signal to overseas counterparts that Australia has limited confidence in its own resources, which would undermine the reputation Australia has already gained as the international pioneer for the practice of laboratory accreditation.

Polarisation of scarce resources

Laboratory accreditation is a highly technical activity if conducted properly. As such it requires considerable technical input in terms of policy setting mechanisms, technical criteria development, technical assessors and for the design, development, implementation and analysis of proficiency testing programs. The Australian infrastructure has already invested a very considerable amount of intellectual and technical knowledge in the current NATA program. Polarisation amongst, and competition for, all these levels of voluntary input amongst multiple laboratory accreditation providers could lead to a costly dilution of the current technical support for the existing national accreditation system. If the same levels of technical input are not available to all possible providers of laboratory accreditation, the realistic outcome would be a steady but inevitable erosion of the standards of laboratory accreditation offered in Australia.

Loss of technology transfer

The strength of technology transfer, provided by a unified, single system of accreditation and its pool of leading edge laboratories and technical assessors, would be diluted considerably if these resources are split into separate families of multiple providers of accreditation. There would be less sharing of expertise and the potential payment of assessors will significantly alter their relationship with laboratories being assessed and add significantly to the direct costs.

Disruption and complication of international arrangements

Mutual recognition arrangements among national laboratory accreditation bodies are an appropriate way to establish international recognition of conformity assessment activities.

The global reach of NATA through its MRA network covers economies in Asia Pacific, Europe, the Middle East, Africa and the Americas. NATA is the Australian representative in these arrangements. Competition has the potential to disrupt this now extensive network with a subsequent disruption to trade in markets where confidence in test data has been sought via the MRA network.

Future arrangements should be facilitated by building on the confidence base already established. Fragmentation of the Australian representation would undoubtedly complicate future arrangements due to loss of national focus and general reluctance by overseas bodies to deal with multiple agencies in individual countries.

Lowest common denominator accreditations

The standard of laboratory accreditation offered by multiple providers may not be at consistent levels in all areas of technology needing to be serviced. It is possible that there would be some laboratories that would shop around for the easiest process available to achieve accreditation. The confidence given to users of accredited laboratories would be eroded in this process. The confidence will be reduced even more as competitive pressures lead to dilution of accreditation standards.

Cost rises

While there may be some initial reduction in charges by new providers of laboratory accreditation as they seek to gain market share, such savings cannot be guaranteed in the longer term.

- This will be due to competition for the scarce technical resources mentioned above leading to payment for previously volunteered services.

- The administrative cost of multiple providers will need to be recouped in the fees of those providers. These will aggregate to be more than the administrative component of NATA's fees under the current system, especially for facilities that have multiple fields of testing and calibration.

- Multiple providers of laboratory accreditation could lead to selective targeting of accreditation in those sectors of laboratories which are technically, geographically and administratively the easiest to service. This would leave the less attractive, but possibly significant laboratory sectors, either unserviced or under-serviced due to loss of the national perspective of the existing program and loss of economies of scale.

- Examination of most overseas national programs reveals that the smaller a program is, the more support it requires from government or the more costly it is in terms of fees to individual laboratories. Multiple, smaller programs in Australia will eventually lead to this outcome but obviously government support for multiple providers would be unworkable.

Additional level of administration

NATA's observation of economies with a multiple provider system is that an extra layer of bureaucracy is necessary to coordinate accreditation body activities. For example in Germany, Deutscher Akkreditierungsrat, German Accreditation Council (DAR) coordinates the activities of many accreditation bodies, only some of which are signatories to the ILAC MRA.

Regulatory efficiency

In considering efficiency, regulatory efficiency and how it can complement accreditation activities, should be examined.

In Australia, good regulatory practice is outlined in the *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*, originally published by the Council of Australian Governments in 1995 and subsequently updated in 2004.

These guidelines match contemporary works on the same topic in other countries, and at international levels (eg the OECD Reference Checklist for Regulatory Decision-Making (1995) and the APEC Information Notes on Good Practice Guidance for Technical Regulation (2000)).

Common in these documents is a stated preference for performance-based regulation.

> *Regulatory instruments should be performance-based, that is, they should focus on outcomes rather than inputs. 'Deemed to comply' provisions may be used in instances where certainty is needed. In such cases, regulations might reference a standard or a number of standards deemed to comply with the regulation. There should be no restrictions on the use of other standards as long as the objectives of the regulation are met.*
> *Council of Australian Governments (2004)*

This move away from prescriptive regulation, whereby the means of achieving the outcome was also stipulated, has provided opportunity for the market to be innovative in how it demonstrates its conformity. It has also led to a questioning of who should undertake the conformity assessment activity in relation to regulatory compliance. In many cases regulators have refocussed on the policy and regulatory specification part of the role, and effectively deregulated the implementation by conformity assessment to other providers of those services. Often cited benefits to this approach include greater cost effectiveness, lower conformity assessment fees, and the provision of a more immediate service.

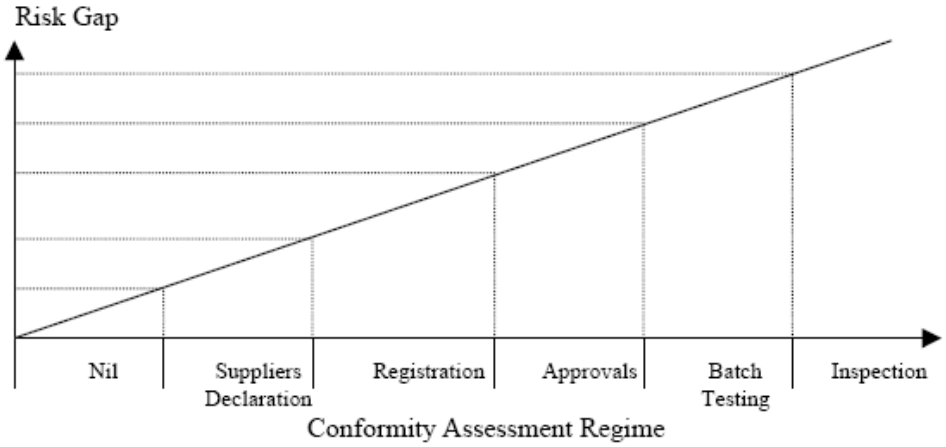
For industries where product innovation is critical, compliance costs are insignificant when compared to market costs. Approval processes that delay the products going to market are to be avoided. The emphasis should instead be placed on post-market surveillance.

The change to devolve implementation activities does rely on the new service providers being competent to undertake the testing, calibrations and inspection that were previously delivered by the regulator. Regulators maintain their confidence that this competence is available when those providers are independently assessed by NATA. In some cases they choose to stipulate that NATA accreditation is required by providers of those services.

Furthermore, regulators are also directed in the good regulatory practice documents to give careful consideration to the conformity assessment regime they select to demonstrate regulatory compliance.

> *"The choice of appropriate conformity assessment regime is dependent on the level of risk, or risk gap, that needs to be regulated and controlled. As depicted in Figure 3, for low level risk less invasive and more efficient conformity assessment regimes such as suppliers' declarations can be used. As the level of risk increases, then more invasive conformity assessment regimes such as approvals and inspections may need to be employed."*
>
> *APEC Information Notes on Good Practice Guidance for Technical Regulation (2000), pg. 31*

Figure 3



In Australia, NATA accreditation provides added confidence to all the conformity assessment regimes noted in the table above, and enables regulators to select conformity assessment types that are the most cost effective. This facilitating characteristic of accreditation is recognised in the recent APEC-*OECD Integrated Checklist on Regulatory Reform*, published in 2005.

Progress towards a more efficient system can also be made through the recognition of suppliers' declaration of conformity, unilateral recognition of conformity assessment results reported in other economies, or through voluntary arrangements between conformity assessment bodies in different economies. At the same time, governments should

encourage the development of domestic capacity for accreditation and ensure ease of access to the accreditation process for both foreign and domestic producers.

Case example 1 – Telecommunications and Radiocommunications Equipment

Telecommunications Act 1997 – Telecommunications Labelling (Customer Equipment and Customer Cabling) Notice

The Australian Communications and Media Authority (ACMA) have a graded approach to compliance verification based on risk. Types of telecommunication equipment are categorised in several levels, level 1 being the lowest risk and level 3 being the highest. All levels rely on self declaration, but at level 2 a test report from a NATA recognised testing authority is recommended, and at level 3 is mandatory.

In this case the regulator has determined that no specific investment needs to make by the government in direct conformity assessment. ACMA have come to this conclusion based on risk assessment. However for the products that do carry some risk, the regulator has sought some added confidence from the market in terms of the credibility of the testing. It has done this through a graduated referral for the test to come from a NATA accredited facility.

A similar approach is taken under the *Australian Radiocommunications Act 1992* Notices regarding electromagnetic compatibility (EMC) electromagnetic radiation (EMC) and radiocommunications transmitters.

Case example 2 – Appliance Energy Efficiency

The national equipment energy star ratings program allows suppliers to place items on the market with self declared ratings. The regulatory authority through the Energy Efficiency Team at the Australian Greenhouse Office then commissions NATA accredited laboratories to ensure the energy label and/or performance claims made by suppliers are valid.

Suppliers whose products fail check-testing review may be asked to ensure that future testing is conducted by a NATA accredited laboratory or a laboratory accredited by a body with a mutual recognition arrangement with NATA.

Specification by government of laboratory accreditation

Details of known cases of the specification of laboratory accreditation by Australian governments are listed on NATA's website at "Specification of NATA by Government Departments and Agencies". On the website there is an overall summary list together with more detailed lists for the Australian Government and each State and Territory.

The list of Australian Government regulations is attached as Annex G to this submission.

Redistribution

Redistribution of resources occurs within NATA. Redistributions are made with the objective of being able to fund and deliver as comprehensive an accreditation service as possible to deliver the maximum public benefit.

NATA provides accreditation services to laboratories and inspection bodies anywhere in Australia. It has a fee schedule whereby facilities' fees are indexed to their distance from a NATA office. This goes only part of the way to covering the higher costs of undertaking accreditation in remote areas.

Cross subsidisation and cross funding amongst laboratories

Within NATA, facilities belong to a 'field' of testing. Fields are arbitrary administrative divisions based on technical areas of testing. For example, laboratories performing human pathology tests fall into the medical testing field, laboratories performing veterinary pathology tests fall into the veterinary pathology field. Fields vary in their number of accredited facilities, technical complexity, location of facilities, risk profile and in the number of NATA secretariat staff allocated to the field. It has been suggested that large fields fund small fields but the matrix of field costs is clearly more complex.

PC Issues Paper Question 31 - Does NATA price its services so that cross subsidisation is occurring? Is this appropriate?

The term 'cross-subsidisation' often carries with it negative implications, and in the case of the national laboratory system it is more accurate to consider "cross-funding". This term better reflects the interdependencies between the testing and calibration activities within the fields. Use of the term "cross-subsidy" often reflects a difficulty in defining the true cost of running a field or activity. For example, in the case of the calibration field(s), it may appear that this is being subsidised by the more 'profitable' fields. However, without it, elements of calibration activities would need to be undertaken in support of testing in many of the other fields. So, instead of appearing that the 'poor cousin' is being subsidised and propped up by the "more profitable" fields it could be considered that there is a transfer of funding to cover the true costs of activities required by the other fields ie "cross-funding".

Cross funding happens within fields. As a national authority, NATA is required to offer accreditation to all relevant facilities. Such facilities may be in capital cities near a NATA office or in very remote locations. While NATA endeavours to provide fee equity according to geographical location, there is a limit to which this can be applied sensibly, before the cost of offering individual pricing becomes administratively more expensive than allowing some cross funding.

Cross funding happens across fields. This is an effective method of providing specialised activities, like calibration, at a critical mass that would not exist if each field had to provide such services within it. In addition such funding permits the establishment of new fledging fields of accreditation in response to market demand.

NATA's programs in personnel accreditation, accreditation of reference materials producers and proficiency testing providers, and recognition of laboratories performing tests and measurements in accordance with the OECD Principles of GLP are all small programs. None of these are financially self supporting and thus must be supported by the activities of the whole NATA economic entity.

There is also a recognition that the provision of voluntary resources to the technical assessor pool is not even across all NATA members. Some members release more technical staff than others to be part of NATA's teams.

NATA believes that some degree of cross funding, across all the boundaries mentioned above, is tolerable, especially where the cost to eliminate it would outweigh the benefits of such elimination.

As described in the competition section above, accreditation provides a good opportunity for technology transfer among technical experts and laboratories across the public and private sectors. This sharing and redistribution of knowledge is a valuable facet of accreditation.

Redistribution of resources to help developing countries

As a mature accreditation body NATA is willing to assist fledgling accreditation bodies in other economies and particularly in the APEC region. Whilst much of this is provided in formal ways NATA often assists in less formal ways by sharing its accreditation and technical infrastructure knowledge to less developed accreditation bodies. This includes hosting visits and attachment training for their representatives, assisting in benchmarking exercises and answering queries. Following due consideration, NATA's intellectual property may also be shared.

The current mix of public and private involvement in laboratory accreditation

PC Issues Paper Question 8 - Is the current mix of public and private involvement in laboratory accreditation efficient?

There is both public and private involvement in the stewardship and delivery of NATA's national system for laboratory accreditation in Australia. This is appropriate given the history and current coverage of the system that includes both Government and private facilities.

An organisation which spans both sectors allows technical resources to be pooled. This is especially so if the objectives of that organisation are in the public and national interest but to deliver on those objectives the private sector must be engaged.

Taking into account the objectives of laboratory accreditation, NATA considers the current system fulfils these objectives in an efficient manner, and represents an appropriate partnership between the private and public sectors which are embedded in NATA's activities.

Effectiveness

Effectiveness concerns the actual achievement of given objectives. When objectives have been achieved using methods which minimise costs, this is cost-effective.

When the objectives are those most desired by society, and they have been delivered to the optimal extent and pursued cost-effectively, this is also efficient.

In the context of this Study, the Productivity Commission has advised that effectiveness means:

- How well the service is delivering objectives.
- Whether cost-effective approaches are being used.

In terms of commenting on effectiveness NATA covers the following points:

- Delivery on society and industries objectives for laboratory accreditation.
- Existing funding and pricing arrangements.
- Cost-effectiveness.
- Other measures of effectiveness.

Are the existing objectives being met?

PC Issues Paper Question 10 - Are existing objectives being met? Are they being met cost effectively and are the best methods being used?

PC Issues Paper Question 11 - Participants are invited to comment on the role played by relevant bodies, in particular Standards Australia and NATA, in delivering services and meeting these objectives?

NATA has the responsibility in Australia for providing services that satisfy society's and industry's objectives for laboratory accreditation. NATA submits it can demonstrate that the trust placed in it to do this has been rewarded by performance demonstrated over decades of operation.

In particular, with respect to the objectives outlined in the efficiency section of this chapter:

Objective 1 – To provide high confidence in test, calibration and measurement data for use in decision making throughout the Australian community in both the public and private sectors.

There are numerous measures of community confidence in NATA's accreditation services in both the public and private sectors.

This includes the decisions of the Australian Government, two States and a Territory, through Memoranda of Understanding, to require the use of NATA accredited laboratories to satisfy their own testing needs, and to have their own laboratories accredited by NATA. Other State and Territory governments have also expressed strong confidence in NATA's laboratory accreditation activities.

Confidence in NATA accredited laboratories has also been expressed by numerous regulators who have legislated that testing be performed in NATA accredited laboratories.

More generally, independent market research, commissioned by NATA in 2005, of users of laboratory and inspection services, revealed that 61 per cent were required to use a NATA accredited laboratory for their latest test[5], and a further 32 per cent chose to use a NATA accredited laboratory even though they were not required to do so.

Objective 2 – To ensure the reliability and credibility of test data is itself underpinned by soundly-based data from demonstrably competent calibration laboratories.

Modern society comprehensively relies on competent testing and calibration. Failure to provide or use competent testing and calibration can be catastrophic. Historically, there are remarkably few cases in Australia of significant catastrophic failures based on poor testing.

Within NATA, each field of testing has clearly specified calibration requirements and intervals for equipment that can affect the quality of test results. As a national authority, NATA implements uniformity of requirements wherever possible, while at the same time recognising any special technical needs of a particular field.

Within the technical and conformance infrastructure, the interdependency of calibration, traceability and other forms of conformance assessment is also recognised. For example, the management systems standard ISO 9001:2000 says that:

> *Where necessary to ensure valid test results, measuring equipment shall be calibrated or verified … against measurement standards traceable to international or national measurement standards.*

[5] This includes requirements expressed in legislation and in other specifications.

JAS-ANZ Policy 3/04 clarifies this requirement for traceability by stating that:

> *An item of measuring equipment shall be deemed to have traceability to internationally or nationally recognised standards of measurement when it has been calibrated by one of the following bodies and is of appropriate accuracy for the measurement in question:*
>
> *National Measurement Institute, Australia (NMIA);*
>
> *[defined international equivalents];*
>
> *A metrology or calibration laboratory accredited, for the measurement in question, by one of the following national laboratory accreditation authorities:*
>
> *National Association of Testing Authorities, Australia (NATA)*
>
> *[defined international equivalents]*
>
> *The measurements must be reported on a certificate or report that contains the logo of one of the above-mentioned accreditation authorities; or*
>
> *A laboratory or facility recognised by the NMIA as a Verifying Authority for the particular calibration.*

Objective 3 - To ensure the technical breadth and rigor of the accreditation process provide assurance of impartial delivery, with accessibility on a truly national basis, while only recognising laboratories and related services meeting agreed national and international competence standards

NATA's requirements for accreditation are publicly available. Decisions to award or remove accreditation are made on the recommendation of peer technical experts but after review by more senior officers of NATA who have the impartiality to assess laboratory audit findings and to compare those findings with those from laboratories undertaking similar testing. This provides fairness and impartiality in the decision process.

Accreditation is only granted to laboratories that have been able to demonstrate to a team of NATA assessors their technical competence and ability to manage a testing or inspection facility. Accreditation is removed from any laboratory found at assessment or through other means to have lost such ability. It is not in NATA's interest as an accreditor, or in the interest of NATA members, for incompetent laboratories to remain accredited.

NATA uses two time intervals for reassessment. Accredited inspection services and laboratories, other than those testing for medical pathology and medical imaging, are reassessed every two years. These reassessments are augmented by participation in proficiency testing trials arranged by NATA and other providers.

Apart from these regular reassessment intervals, NATA's Rules allow for increased surveillance of laboratories that have failed to meet their accreditation requirements. This provision is used when necessary.

The geographical spread of NATA accredited laboratories across Australia including, for example, laboratories on Thursday Island and on off-shore oil platforms, demonstrates the accessibility of NATA accreditation where needed.

The willingness of NATA to work with technical experts to develop accreditation criteria when required by new circumstances has also been demonstrated eg, drug testing for the Olympics in Sydney in 2000, and testing for Cryptosporidium and Giardia in Sydney water.

Objective 4 – To ensure the outcomes of accreditation can be used appropriately and confidently by governments and the market to either support public interest needs (such as through regulatory intervention by governments) or through provision of accurate information, facilitation of transactions (and reductions in their costs) and through improvements to competitiveness.

The process and results of laboratory accreditation services are used by Government in a number of ways.

First, the mutual recognition arrangements negotiated between NATA and overseas laboratory accreditation organisations (the ILAC and APLAC MRAs) have helped to underpin the mutual recognition agreements negotiated between the Australian Government and other economies for the purposes of trade. These ILAC and APLAC MRAs have helped to prevent technical barriers to trade by ensuring that goods tested at an accredited laboratory in the country of origin are acceptable without further testing in the country of destination.

Second, through the provision of accredited laboratories, Australian Federal, State and Territory Governments have a mechanism for ensuring that reliable testing is available for specification in legislation. This is particularly important in matters concerning environment, health and safety, but also necessary in other contexts such as information security and parentage testing.

Occasionally, despite the availability of accredited testing services, governments have chosen to allow the market to decide whether to use such services, rather than legislate for their use. NATA believes that this trend could grow during an era of reduced market intervention by government. NATA submits that an emphasis on needs based on market failure should be balanced through judicious application of the precautionary principle: that legislation requiring accredited testing in areas where failure is intolerable is preferable to a free market able to choose not to use the most reliable testing services available.

In terms of broader utility in the market place NATA's role is to accredit competent facilities and to publish that accreditation. A free directory of NATA accredited facilities, updated daily, is available on NATA's website. It outlines precisely the terms under which each facility is accredited. In addition, NATA provides a telephone information service where callers unable or unwilling to undertake an on-line search are connected with a relevant NATA staff member who provides advice and/or undertakes that search on the caller's behalf.

NATA advertises these services and they are used extensively. NATA's website currently receives in excess of 55,000 visits each month, the directory being the most popular destination. A survey of NATA's telephone information service in 2004 indicated that NATA Sydney alone receives about 800 such calls each year.

Objective 5 – To maintain the direct costs of accreditation at levels sufficient to maintain the credibility, integrity and public reputations of both the accreditation process and its provider.

All stages involved in the initial assessments of laboratories (advisory visit, document review, on-site assessment and follow up) are charged at an hourly rate plus travel, accommodation and associated expenses. This ensures that the fees charged reflect the actual costs of providing the services.

Once a laboratory is accredited by NATA, it pays an annual fee that covers routine reassessments. These fees vary depending on the distance of the laboratory from the nearest capital city where NATA has an office, and the number of technical assessors required to undertake the assessment. These two variables provide a measure of fee equity without using a more exact, but administratively more intensive and expensive full, fee-for-service cost structure. The annual fee structure also provides fee predictability for laboratories.

For accredited laboratories, any additional services required beyond routine reassessments such as extensions of accreditation, or additional services that must be undertaken by NATA due to a failure of a laboratory to meet its accreditation requirements are charged on a fee-for-service basis - that is, an hourly fee plus any necessary travel, accommodation and associated expenses.

This system, which has operated for about seven years, has provided an enhanced level of fee equity.

Objective 6 – To provide mechanisms for the advancement of science, technology and standards including dissemination of relevant best practice.

NATA assessments are based on the use of peer technical experts. The interchange between these experts and the laboratories they are assessing means that technology and standards are discussed on a daily basis across Australia. These interchanges lead to questioning of current practices, and discussion and promotion of best practice.

Key technical issues that arise through assessments are discussed among members of NATA's Accreditation Advisory Committees and Technical Groups. This can also lead to recommendations for improving published standards and methods used in the laboratories.

NATA also has a direct influence on the content of published standards through its input to international standards writing committees and its membership of more than 70 standards writing committees of Standards Australia.

Objective 7 – To facilitate international acceptance of the process of laboratory accreditation as an effective mechanism to accept data across national boundaries, and to reduce non-acceptance of testing as a potential technical barrier to trade.

The objective that the process and results of laboratory accreditation services be recognised and utilised across national boundaries has been achieved through the establishment of government-to-government mutual recognition agreements which may include use of the ILAC and APLAC mutual recognition arrangements established between laboratory accreditation bodies. Additionally, the use of NATA's mutual recognition agreements is cited in various governments' specifications and regulations in Australia. These reduce technical barriers to trade.

Objective 8 – To ensure any concerns expressed about accreditation are dealt with expeditiously, with appropriate investigation and, if necessary, with required corrective actions.

Occasionally there are concerns raised regarding the provision of NATA's services or the capabilities of accredited bodies. There are provisions in the publicly available NATA Rules for dealing with all such complaints (Rule 55). These provisions are augmented by those outlined in NATA's operations manuals. Complaints are handled by NATA's Corporate Governance Manager.

There are also appeals processes for use when accredited facilities are not satisfied with NATA's decisions.

Objective 9 – To be responsive to new needs for accreditation with appropriate innovation and flexibility, while ensuring that such needs are driven by external stakeholders or potential users of new accreditation services.

NATA has a comprehensive history of developing new accreditation programs in response to need. Sometimes this need is first expressed by those outside NATA; at other times, NATA has identified areas that could benefit from the provision of appropriate accreditation services.

Examples of the former include accreditation in the areas of medical pathology, information security, forensic science including parentage testing, and wool sampling, testing and display for sale. Examples of the latter include accreditation in the areas of software testing, veterinary testing, and reference materials.

Apart from the development of entirely new programs or fields of accreditation, NATA and its accredited laboratories have reacted in a timely manner when extraordinary circumstances have arisen. For example, in 1998, the McClellan Inquiry into apparently high levels of Giardia and Cryptosporidium in the Sydney water supply, recommended that laboratories providing parasitic analysis should be accredited by NATA using an approach similar to that implemented by the US EPA. A panel of experts was then formed by NATA including overseas specialists and accreditation criteria were developed that embraced varying technologies and introduced a rigour and consistency of approach through extensive requirements for specialised proficiency testing.

On another occasion, immediately before the 2000 Olympic Games in Sydney, NATA was required to assess the testing for erythropoietin (a performance enhancing drug for which test methods were only then being developed). NATA was also required to accredit the test laboratory at the Games Village within a very short time frame to provide appropriate confidence in this high profile environment.

The achievement of these milestones was much appreciated by the regulators involved.

Objective 10 – To ensure the level of technical sophistication inherent in the accreditation process is matched to both the sector by sector needs of specific groups of laboratories and their end users' specific needs for assurance

While NATA uses generic standards applicable to all laboratories for its accreditation criteria, it needs to recognise the various individual technical and practical circumstances that apply in different sectors and technologies. These factors are considered by two main sources of technical input – the specialist experts on each of NATA's ACCs, who amplify the generic criteria to cover the needs of specific fields, and the peer technical assessors used to judge specific competence.

Current funding and pricing arrangements

NATA's current funding arrangements

A dissection of the major sources of NATA's operational income and expenditure for 2004-05 are shown below:

Figure 4

NATA Sources of Funds 2004-05 (Operational Income)

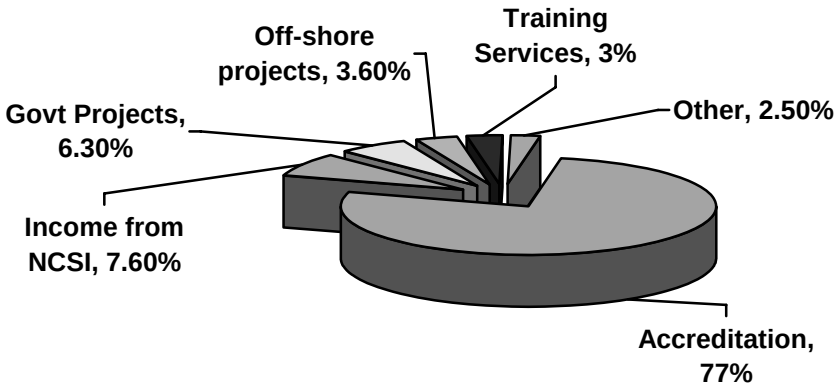
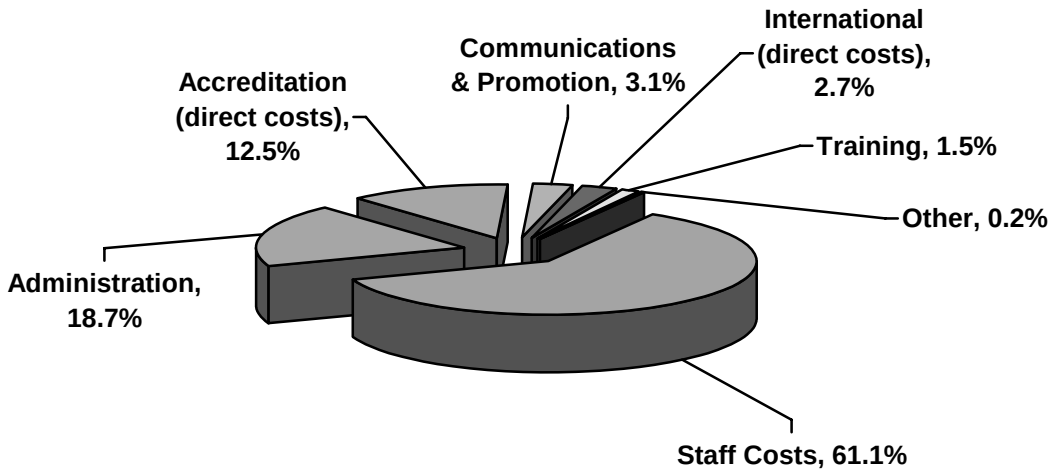


Figure 5

NATA Disbursement of Funds 2004-05 (Operational Expenditure)



In its budget, NATA needs to be conscious of *predictable* income sources. Accordingly, the annual fees from NATA's core accreditation activity are the predominant contribution to NATA's operational income. Income from the contributions of NATA's training services and its subsidiary (NCSI) are also reasonably predictable in a short term of 12 months. Other sources of income are less predictable, particularly from off-shore projects which may be of short duration and are often identified opportunistically at short notice. To some extent

government funding for national interest activities is also less predictable. While the amount of national interest funding has been steady for many years (approximately $1 million), it is not normally confirmed until after the start of the financial year.

The NATA Board's measure of financial stability is to establish sufficient reserves to meet 30 per cent of annual operational expenditure. This objective was only recently achieved in 2004.

Subsequently, with the assistance of the revenue provided by NATA's subsidiary during 2004-05, NATA was able to provide a rebate on the fees for accreditation for the financial year 2005-06.

NATA's fees

In establishing its fees for accreditation activities, NATA is conscious of a number of factors.

First, NATA is a not-for-profit organisation operating with an Australian Government mandate as the national authority for laboratory accreditation and for a number of other related roles.

Second, the provision of NATA's services is made possible by the voluntary contribution it receives from the Australian technical community.

Third, with its sole provider role, NATA is obliged to ensure it meets its charter to provide a comprehensive accreditation service for *all* of the testing and related services needs of Australian society. This means NATA regularly needs to develop accreditation criteria and resources to address new demands for accreditation of laboratories and related services' competence. In many cases the development costs and ongoing maintenance of such activities may never be recouped, but it is essential the service be established and maintained in order for NATA to provide a truly comprehensive national service.

Fourth, as NATA is a not-for-profit body, its Board needs to exercise prudence in its financial management of the Associations' affairs. This requires NATA to maintain adequate reserves to maintain financial stability and to provide opportunities for investment of resources to meet new demands for services as they arise.

NATA's fees are fully transparent and listed publicly on NATA's website. The level of annual fees is dependent on the scope of recognition of each accredited facility. This is because the costs of establishing and maintaining accreditation vary with their breadth and technical complexity.

NATA uses the concept of *technical units* as a measure of the assessment effort required to service an accredited facility per day. The number of technical units usually equates to the number of technical assessors required to cover the scope of accreditation per day of assessment. The annual fee is a combination of the fees per technical unit plus a base administration fee applicable to all facilities. The administration fee, broadly, covers the maintenance of general overheads across NATA (staffing, servicing technical committees, recruitment, assessor training, accommodation, promotional and information services, general administration for finance, human resources, IT and insurances, and representation of standards writing and other professional bodies, etc). As discussed earlier, there are also geographical surcharges added for remote facilities. For Australian-based facilities, the annual fee fully covers the direct costs of periodic on-site reassessments of accredited facilities. Any additional services provided to accredited facilities are costed on a user-pays basis charged at an hourly rate plus direct costs.

The total number of technical units covered by NATA's currently accredited facilities (at 28 March 2006) is 5,496 within 2,801 accredited facilities. Thus, the average size accredited facility is currently a two unit organisation. Some facilities are accredited for in excess of ten

Technical Units. NATA provides some discounts for linked accreditations and for corporate accreditations (multi-site or multi-field).

NATA's fees compare favourably and are appropriate to maintain the level of technical rigour needed to provide community confidence in its processes.

Comparisons of fees with other providers, including overseas laboratory accreditation bodies

It is difficult to make fee comparisons with other accreditation bodies. Each operates a different fee structure and fee amount. In addition, some are private companies only, some are partly government funded and others are solely government funded.

Within Australia the only organisation that NATA is aware of that has a reasonably similar accreditation process is the Therapeutic Goods Administration (TGA). The TGA licences contract testing laboratories and the TGA's fees and charges are listed on its website. These include an annual fee of $4,300 plus $440 per auditor hour (with 16 auditor hours in three financial years being included in the annual fees). These fees seem to be significantly higher than NATA's.

JAS-ANZ offers but has not undertaken inspection body accreditation in Australia. Its published fees are $5,000+GST per annum plus $800+GST for each auditor/expert day plus expenses.

The Australian Council on Healthcare Standards (ACHS) scheme is for accreditation of hospitals. An example of ACHS fees for a large two campus hospital is $14,000 p.a. including travel costs. Twenty two assessor days were involved in the four-yearly assessment/surveillance cycle. ACHS assessors are not paid and are usually from interstate.

The International Society for Quality in Healthcare operates from its secretariat in Melbourne. Certifiers of healthcare services such as general medical practices are accredited using assessors from outside the country. Annual accreditation fees are about $7,000 to $8,000 plus assessors travel costs for the four-yearly reassessment.

In relation to comparison of NATA's fees and charges with equivalent foreign accreditation bodies, NATA sought details of their fees and charges from a range of ILAC Arrangement partners. The comparisons are based on a laboratory requiring two technical experts on a reassessment team. The information provided is tabulated in Annex H. In the case of NATA, an all inclusive (travel and reimbursements) annual fee will vary from $4,321 to $5,205 plus GST, depending on the distance from the nearest NATA office. The UKAS, Japan Accreditation Board (JAB) and A2LA charges appear to be higher, mainly because they pay their assessors. The JAB fees listed are significantly higher.

Cost effectiveness

NATA endeavours to provide its services in a cost effective manner. This is achieved through:

- Careful cost control.
- Use of volunteer technical assessors.
- Strategic placement of Branch offices (increased in response to need).
- Being the single provider in Australia of laboratory accreditation, thus eliminating costly competition.

Cost control

Just about 60 per cent of NATA's costs are staff and salary related. NATA is conscious of the need to ensure staff productivity is maximised through employment of effective, adequate, but not excessive staff numbers, and the provision of resources, such as IT, which maximise staff effectiveness.

Direct costs of accreditation activities represent around 12.5 per cent of NATA's operational expenditure. NATA staff are conscious of these costs and endeavour to minimise them. For example, when interstate or intrastate travel is required to undertake an assessment, staff will try to arrange assessment activities in nearby locations so as to minimise the costs of travel to each assessed laboratory.

The cost per accredited technical unit is a financial measure in NATA's 2004-2008 Strategic Plan. NATA is attempting to hold that expenditure at or near the 2004 level so as to reduce the cost, in real terms, over the period of the plan.

The result of these and other measures has been that NATA has only needed modest fee increases over the years to meet its needs.

Figures 6, 7 and 8 show the increase in NATA's fees from 1995 to 2005. It can be seen that over this period, NATA's fees have generally risen in line with the rise in the Consumer Price Index which is also shown in the figures. This is a considerable achievement given the strong influence of salary costs on NATA's expenditure.

** Expected fee based on previous year plus CPI*

Figure 6: NATA Application Fee (1995-2005)

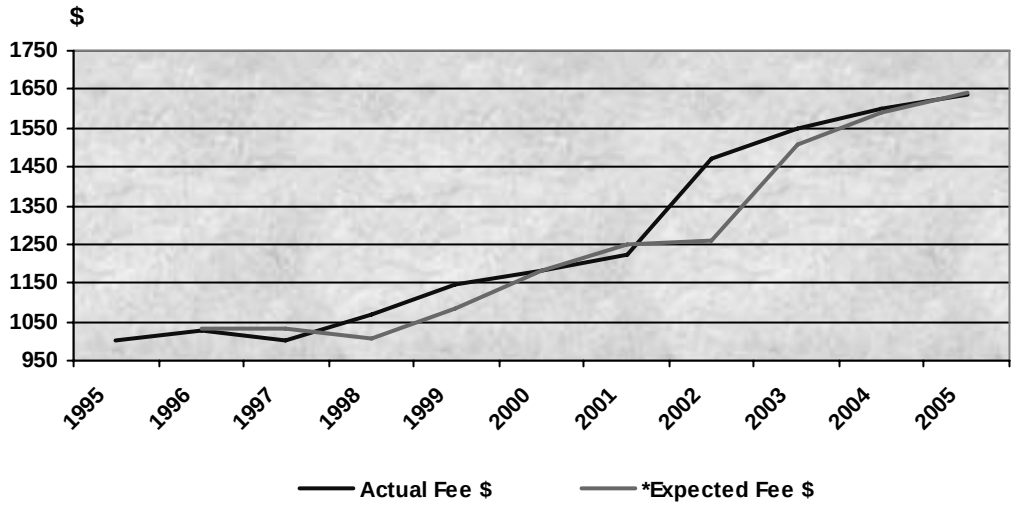


Figure 7: NATA Hourly Rate (1995-2005)

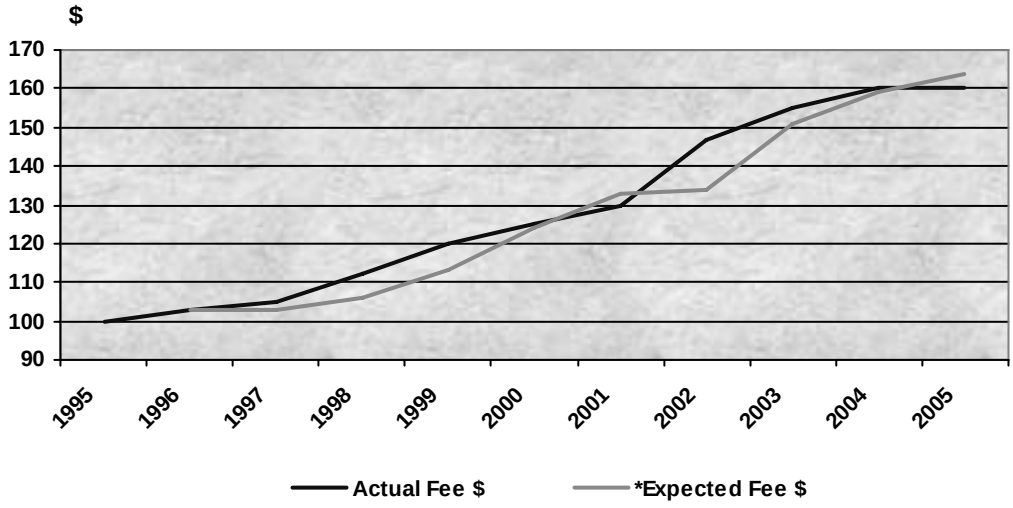
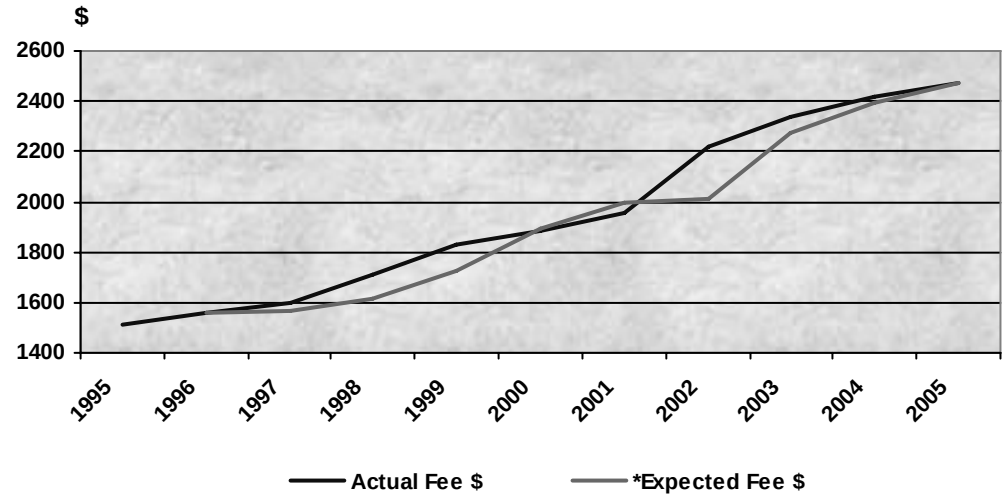


Figure 8: NATA Annual Membership Fee (1995-2005) for One Technical Unit Laboratory within 100km of a NATA Office.



Use of volunteer technical assessors

The national system of laboratory accreditation administered by NATA relies on volunteer technical assessors drawn from NATA members and other stakeholder groups. Facilities being assessed pay for the travel, food and accommodation expenses of such assessors but the labour is provided at no charge. Using NATA's existing charge out rate of $167/hour as a basis, this voluntary labour amounts to an estimated $13 million per annum.

This volunteer-based system reduces the direct costs of accreditation for laboratories. However, these costs are still incurred in part by the membership and other stakeholders as they invest their staff time in the system by allowing them to be volunteer assessors.

Should the volunteer system be abandoned, the fees for accreditation would need to at least double to take into account direct payment for technical assessor time.

Strategic placement and staffing of Branch offices

NATA is a growing organisation. Over time, NATA has responded to the geographical distribution of its accredited laboratories by opening branch offices. As well as its head office

in Sydney, NATA has offices in Brisbane, Melbourne, Adelaide and Perth. Each branch office is staffed at a level commensurate with the number of laboratories that need to be assessed in the region.

For this reason, offices have not yet been established in Tasmania, the Northern Territory or the Australian Capital Territory. These jurisdictions are usually serviced from Melbourne, Adelaide/Perth, and Sydney, respectively.

Cost effectiveness of being a sole provider

NATA is currently the sole accreditor of laboratories and inspection services in Australia. It can therefore take advantage of certain economies of scale for the benefit of its diverse stakeholders. Economies of scale apply not just in the provision of accreditation services where, for example, multiple assessments can often be arranged during a single trip. They also apply in spreading educational and administrative costs over the 2,800 facilities that NATA currently has accredited.

Are the best methods being used?

NATA has been refining its accreditation methods and its methods of operation for nearly 60 years, and continues to do so. Its basic model has been used by a number of other economies such as New Zealand, Hong Kong and Singapore. NATA continues to re-appraise its model and in recent years has made changes to its assessment schedules in response to improvement suggestions from staff and from members.

Indeed, one of the main strengths of NATA is that it is an association of members. This provides a constant feedback loop to NATA to ensure that its methods are meeting member needs while continuing to adhere to the standards required of it as a laboratory accreditation authority.

Other measures of effectiveness

NATA's view of the objectives required of a laboratory accreditation authority are set out earlier in this submission and NATA's satisfaction of these objectives is given above in response to Question 10 from the Productivity Commission. NATA believes it has delivered on all objectives.

NATA's view that it has met the requirements of a laboratory accreditation body is supported by comments from others, especially by government and by members.

In 2002, the current Minister for Industry, Tourism and Resources, the Hon. Ian MacFarlane, said:

> *NATA has an exceptional track record in terms of its performance but also its international acceptance*[6]

Apart from such endorsements of NATA by Government, NATA's accredited facilities have also recently strongly endorsed NATA's accreditation activities.

In 2005, NATA commissioned a survey of 369 of its members by an independent market research company, Catalyst Consultancy and Research.

[6] Source: CD, National Association of Testing Authorities, 27 September 2002

As part of this survey, members were asked to identify the main benefits of NATA accreditation. Members advised that NATA accreditation:

- Provided a useful check-up and kept facilities operating well or provided confidence to the laboratory or their customers;
- Provided a marketing advantage or gave them credibility and prestige;
- Allowed them to bid on work that required such third party endorsement (not all members test in areas where such endorsement is necessary); and
- Gave them access to advice and information and allowed them to discuss issues with their peers.

Members were asked how likely they were to recommend NATA accreditation to a colleague in a similar situation. Seventy-three percent said they were extremely likely or very likely to make such a recommendation.

More specifically, members were asked to comment on the overall quality of NATA's people, products and services. Ninety-three percent rated NATA's quality as good, very good or excellent, with 62 per cent rating it excellent or very good.

Members were also asked to consider the overall quality of NATA in relation to its pricing, and hence rate the overall value provided by NATA. Seventy-seven percent rated NATA's overall value as good, very good or excellent, with 31 per cent rating it excellent or very good. This is a four per cent improvement on the result in a similar survey conducted in 2002.

NATA members pay for some services at an hourly rate, rather than through an annual fee. Surveyed members were asked to rate the value provided by these paid services. Seventy-five percent of members rated them as good, very good or excellent, with 24 per cent rating them as excellent or very good. This is a seven per cent improvement on the result in a similar survey conducted in 2002.

In the independent 2005 market research conducted among 369 accredited facilities, the facilities were asked to clarify why they rated NATA highly on quality. These answers provide NATA with an indication of what is important to their customers and the behaviours of NATA that should be continued and reinforced. Statements from the facilities were generally supportive as the following examples illustrate.

Consistency of service

> *We've dealt with them for many years and they're consistently good. We always get good service. Knowledge and their people are good – NSW/ACT, Electrical*
>
> *I have been dealing with NATA for 20 years. From a technical point of view they cannot be faulted. They controlled the laboratory systems – Vic/Tas, Heat and Temp*
>
> *I find them always acting professionally. Hard working. Always ensure the labs are working correctly – NSW/ACT, Medical*

Technical expertise

> *Their office is always very professional and prompt with call backs. They take their job seriously and they're well trained, efficient and know their stuff – NSW/ACT, Medical*
>
> *Conduct a professional, well structured operation. They're a good source of industry based information. They have a good reputation – Qld, Construction*

It's just the way they conduct themselves and their professionalism. When they come out for the audit they're very knowledgeable and it's always a positive experience – NSW/ACT, Mechanical

Well recognised in technical community

I know quite a few people who are associated with NATA and they've all achieved a higher standard all the time, so NATA has been a good basis for quality. If we didn't have it, Australia would be in a lot of trouble – Vic/Tas, Metrology

They have a high reputation around. People ask me if I am NATA certified which gives the perception of excellence – NSW/ACT, Inspection

They are recognised throughout Australia. They answer our needs. They're very helpful over the telephone. You can understand their work, haven't had any problems with them – SA/NT, Biology

Fairness of assessment

In medical testing they are very fair in their approach. It's a peer approach assessment involving practitioners in the field. They will take pathologists as well as medical scientists for assessment. They do not jump to conclusions, they invite different medical opinions on contentious issues, and there is little ambiguity in their procedures – SA/NT, Medical

Thorough

I am a new metrologist, I haven't been assessed yet so I haven't had too much experience, all I can go by is the thoroughness of the accreditation requirements – Vic/Tas, Metrology

Just extremely thorough and professional to deal with – Vic/Tas, NDT

They've been very helpful, very direct, positive in most ways. Over the years, going through audit in the way it was carried out was very thorough. In any areas that were borderline they were helpful in ways for correcting or assisting us to get back on track – WA, Inspection

They are thorough and rigorous and concerned with fulfilling the charter and that we are doing our job properly – Vic/Tas, Chemical

Ethical

Quality is excellent. Go through every issue in the lab, try to find out lapses that may occur, helps to keep high standard of quality, also very strict regulation of quality requirement. Don't compromise – NSW/ACT, Chemical

The managers that we deal with are professional, unbiased and capable. Responsive to requests and always ready with advice – Qld, Forensic

Helpfulness of assessment report

The report for our assessment is very relevant to the work we have been doing, the follow-up was excellent too, it wasn't too finicky – WA, Metrology

As well as commissioning a survey of its members in 2005, NATA commissioned a survey by Catalyst Consultancy and Research of 249 users of laboratory and inspection services. These are the customers and potential customers of NATA members. Satisfaction by this group indicates that NATA accreditation is providing a useful role for the end-users of laboratory services, as much as for the laboratories themselves.

A majority of the users said that NATA accredited facilities, when compared with unaccredited facilities, provided:

- better value;
- better availability and customer service;
- greater reputation and expertise;
- better quality system and output; and
- were considered more ethical and trustworthy.

On the question of value provided by NATA accredited facilities, 74 per cent of users surveyed said that they expect to pay more for a NATA endorsed test report (such reports can only be issued by laboratories accredited by NATA for the tests reported thereon). Clearly, as users, they are seeing value for which they are willing to pay.

NATA-accredited facilities, when compared with unaccredited facilities, were also seen by a majority of users as:

- having a greater reputation for technical competence;
- being easier to deal with;
- having staff who were more skilled; and
- being more service focused.

Users were asked why they specified NATA accreditation. Answers included:

> *All labs should be and we presume they do the right thing because they are accredited – SA/NT, CMT*
>
> *It's a benchmark that we can trust – WA, Electrical*
>
> *I'd say it's the reputation of NATA, and it is recognised generally as being the standard in laboratories – NSW/ACT, Biology.*

PC Issues Paper Question 9 – Are there market failures or weaknesses in laboratory accreditation services that justify government involvement?

NATA considers that there are no significant market failures at present in the provision of laboratory accreditation services in Australia that would justify government intervention. What is appropriate is for Government to continue to provide existing support and funding in the national and public interest and act as a channel for cooperative dialogue. (Further commentary on what NATA considers to be an appropriate role of government and of government funding is provided in the following chapters).

It is recognised that competition is not a characteristic of the current national accreditation system. However, NATA considers the existing model for laboratory accreditation in Australia does indeed provide an efficient and effective service to Australian society and industry. NATA believes that it is responsible in its behaviour as a single provider. The checks and balances that cover all aspects of NATA's governance and operation guard against any misuse or abuse of market power. Indeed, Government provides some of the checks and balances, especially in governance through NATA's Board and Council and in review of national interest funding to NATA. Again government support facilitates NATA's activities and assists in providing a comprehensive, well regarded, and above all, efficient service to the community.

Within any system there will always be room for improvement and NATA has a track record of seeking to improve its administration and service over time. It is sufficiently flexible and innovative to change with the times and to address new demands as they arise.

7. Appropriate Role for the Australian Government in Relation to Laboratory Accreditation

Role of Government in the National Conformity Infrastructure

There is no universally agreed position on the appropriate role for government in providing a national conformity infrastructure. Within the industrialised economies, the minimalist position would be that of the United States, while countries such as Japan and China have a policy of wide ranging government intervention. The roles of government in many economies with infrastructures matching Australia's are similar to the current Australian arrangements. Annex H describes NATA's understanding of the range of arrangements that exist in a number of relevant overseas countries. Policy proposals in the European Union are described in the boxed text below.

Within the menu of elements comprising conformity assessment, governments almost always accept responsibility for national systems for legal metrology, provision of physical standards of measurement and accreditation services. Even where commercial services may deliver some or all of a particular service, governments must accept the responsibility for the efficacy of the delivery of the service. These services can rarely be commercial and often require government financial support. They always require some form of government imprimatur; this is particularly evident in the current policy discussion in the European Union.

Standardisation, while rarely being commercial across the spectrum of work necessary to service a nation's industrial interests, is usually left to the private sector. Governments, however, have an interest to ensure that the process is efficient and that standards are not used as trade barriers or in ways contrary to either government policy or the national interest. Governments usually financially support organisations producing standards and always provide technical input and support through the committee processes.

Testing, calibration, inspection and certification are usually regarded as commercial activities although, in some technically esoteric areas, governments will support laboratories for strategic reasons. Nevertheless, in some countries, governments take the view that the national interest is best served by direct government ownership of the major testing laboratories and inspection and certification bodies.

Traditionally Australian governments have been very forward thinking in the provision of various services. The National Measurement Laboratory (now within the National Measurement Institute) was established for strategic reasons and is regarded as being in the first rank of physical standards laboratories; NATA was the first comprehensive laboratory accreditation body in the world; and the National Standards Commission and the National Measurement Act were pace-setting internationally.

Case example - European View on the Role of Government

It is of interest to note the European Commission's current view on the role of its member states with respect to accreditation.

The European Commission (DG Enterprise) has been developing its policy on accreditation in conjunction with its revision of its "New Approach" to European Community regulations. This is to ensure that accreditation can effectively support the Community's internal market and external trade policies.

The latest Commission document on this subject is Draft CERTIF 2005-12. This proposal defines accreditation as a service of general interest deriving its authority from the national governments.

If accepted, the proposal would formally establish the non-competitive nature of accreditation within the EU.

Draft CERTIF 2005-12 contains the following statements:

> *"Accreditation may be operated by a private law body, provided that the public authorities maintain a certain influence and the overall political responsibility, so that the body can be considered to operate under their authority."*
>
> *"Member States should organise accreditation free from commercial competition through the entrustment of accreditation to a single national accreditation body or system of single (sectoral) accreditation bodies."*
>
> *"These principles shall apply irrespective of whether accreditation services are provided to support conformity assessment in the regulatory and/or non-regulatory spheres, and irrespective of the legal status of the accreditation body."*

Having established such facilities, the Australian Government tended to leave the bodies to their own devices with little or no supervision or policy direction. However this has changed since the late 1980s with MoUs being maintained with NATA and SAI, NML and NSC being brought into a new National Measurement Institute within the DITR and JAS-ANZ being created as a treaty organisation with New Zealand. This has been appropriate because standardisation, physical standards, testing and certification issues are becoming significant in trade. As a consequence governments must understand the policy implications, have confidence in the technical competence of the operators, know that the Australian system is internationally acceptable and ensure that the system is working in the national interest.

The Kean Inquiry in 1995 considered the role of government and advised in its report:

> *The Committee considered that the role of government should be to ensure that the system is functional, efficient and has strategic direction. In a complex framework of Commonwealth, State and Territory governments, the mechanisms to coordinate the needs of business, consumers, regulators and science are diverse and difficult. There is a demonstrated requirement for coherence and strategic direction at all levels. Oversight and leadership were required to ensure that national interest activities, including effective pursuit of Australian interests internationally were given appropriate emphasis.*
>
> *In making its recommendations, the Committee was concerned that it provided government with the flexibility to introduce and manage the checks and balances required to ensure the national interest was enhanced, while ensuring that government did not constrain the commercial activities of the private sector bodies, nor inadvertently encroach into the delivery of services which are provided more appropriately by the private sector.*

In summary, in a modern trading system governments have a significant role in the national conformity infrastructure, particularly with respect to trade in goods subject to regulation either at home or abroad. Governments cannot adopt a purely hands-off approach.

Role of the Australian Government in the Accreditation Process

PC Issues Paper Question 14 - What is the appropriate role of the Australian Government within the current accreditation process?

NATA believes that the Australian Government's current roles within the Australian laboratory accreditation process are comprehensive. They are also fundamental to both the domestic and international effectiveness and credibility of Australia's system.

While some of the Government's roles may need greater utilisation, as discussed elsewhere in this submission, NATA considers that the current roles do remain appropriate.

The Australian Government has a number of both direct and indirect roles in the NATA accreditation process and has been constantly involved since the Government itself was instrumental in NATA's establishment in 1947.

Direct Roles

The following are some of the principal, direct roles which the Australian Government has in the NATA process:

Corporate Governance

- The Australian Government has provision for six representatives on NATA's Council, which is more than any of the other specified representations in NATA's Constitution (Rules). Other Australian Government officials may also, from time to time, occupy other specified representations on NATA Council (such as representing Commonwealth Scientific and Industrial Research Organisation (CSIRO), National Measurement Institute (NMI), professional bodies, accredited facilities etc);

- From NATA's inception to the present, the Australian Government has traditionally also been represented on NATA's Board and the Board's predecessors (such as the previous Executive Committee of NATA's Council); and

- The Australian Government also oversees the funding of NATA's national interest activities through formal, annual funding deeds, which include mutually-agreed objectives and outputs for each year. The Government receives quarterly reports and an annual summary of achievement of agreed objectives.

Technical Governance

- The Australian Government's departments and agencies are comprehensively represented on such bodies as NATA's Accreditation Advisory Committees and Technical Groups, which play fundamental roles in the development of NATA's technical and other accreditation criteria. Committee members also have direct involvement in the accreditation decisions made by NATA.

- The Australian Government's scientists, engineers and technologists are strongly represented in the panel of voluntary assessors used in NATA's on-site assessment process and in provision of other technical advice for the accreditation process.

The Australian Government's commitment to such comprehensive involvement in the NATA accreditation process, is specified in Article 5.3 of the MoU between the Commonwealth and NATA, which reads as follows:

> *5.3 The Commonwealth and its agencies will, to the maximum extent possible, participate on NATA Technical Committees and Council. Where Commonwealth officers assist NATA in furtherance of its work as members of Council, its committees or as assessors, no recovery will be sought for the salary and salary-related costs involved. The use of Commonwealth officers in assisting any other NATA activity shall require further agreement with the Commonwealth.*

Indirect Roles

In addition to its direct roles in Australia's current laboratory accreditation processes, the Australian Government has a number of other indirect roles. These include:

- *As a client of NATA accreditation services*
  The Australian Government's own laboratories are major clients of NATA accreditation. This not only provides a comprehensive and continuous awareness of NATA's activities and processes by a broad spectrum of government departments and agencies, but also provides the clients of government laboratories and the public at large with reassurance that the Government's own testing and measurement capabilities are *independently* evaluated and recognised for their technical competence.
  This involvement in NATA and the support for the Government's commitment to accreditation of its own laboratories, is formalised in the Commonwealth's MoU with NATA in Article 5.6, which states:

  > *5.6 All Commonwealth laboratories whose principal function is to provide calibration, measurement, testing or related services to either Government or outside agencies will, as appropriate, obtain and maintain accreditation by NATA.*

- *As a user and/or purchaser of services from NATA accredited facilities*
  The Australian Government is also a significant user of non-government laboratory services and, here again, it commits to using laboratories that have had independent assessment of their competence through the NATA accreditation process. This commitment is formalised in Article 5.4 of its MoU with NATA as follows:

  > *5.4 To the maximum extent possible the Commonwealth shall, to satisfy its own testing needs, use NATA accredited laboratories or laboratories accredited by organisations with which NATA has a mutual recognition agreement.*
  >
  > *6.1 The commonwealth and NATA will, where appropriate, encourage service providers in all sectors of the Australian community to adhere to the principles of good laboratory practice embodied in NATA's criteria for accreditation, to have such adherence recognised through NATA accreditation and as necessary to incorporate use of accredited laboratories in appropriate purchasing decisions, regulations, quality assurance requirements and operational procedures.*

- *As a specifier of testing and measurement services*
  The Australian Government's departments and agencies specify the use of NATA accredited facilities. Reference to NATA accredited facilities can be found in public policy, government specifications and regulations. Examples include specification of NATA accreditation in pathology testing in relation to Medicare, support for AQIS export certification and parentage testing under the Family Law Act. (see also further examples of Australian Government references in Annex G.

- *For underpinning government-to-government mutual recognition agreements (MRAs) for conformity assessment activities*
  As detailed previously, the Australian Government has recognised NATA as its designating authority under the Australian Government's MRAs with the European Union and Singapore.

- *Liaison on trade and technical barriers to trade*
  Historically, the Australian Government has engaged with NATA at various levels of formality in negotiation of trade and technical barriers to trade issues with foreign governments. This is clearly the role of Government, but there is great value in using NATA's inputs from a practical working perspective. This has proven effective in the

past. The "partnership" value of this relationship is currently captured in Article 4.20 of the MoU between NATA and the Commonwealth, which states:

4.20 NATA will work with APLAC and other regional for a to ensure that the national interest priorities of the Commonwealth and Australian industry are taken into account in APEC, the WTO, Asean Free Trade Area (AFTA)/ Closer Economic Relations (CER) and other trade agreements and arrangements.

Government Influence on the Work of NATA

PC Issues Paper Question 15 - What difference would it make if the Government had no influence on the work of NATA?

If the Australian Government had no influence on the work of NATA, there could be adverse impacts on the operations, community recognition, international acceptance and the public interest ethos of Australia's laboratory accreditation system.

Some specifics are:

- NATA must comply with the International Standard ISO/IEC 17011 to satisfy and to maintain international recognition through the ILAC and APLAC MRAs. This Standard requires NATA to maintain a balanced representation of interested parties for developing and maintaining the principles and major policies of operation of the accreditation body together with providing opportunity for effective involvement of such interested parties. Clearly, the Australian Government represents a significant interested party. Its withdrawal from influence could seriously compromise the ability of the Australian accreditation system to meet international requirements and expectations;

- If the Government had no significant involvement in, or influence on, the work of NATA it could lose the ability to be directly involved in the policy formulation and strategic development of the accreditation body, including its maintenance of appropriate awareness of national and public interest issues; and

- Loss of a *whole of government* opportunity to be engaged in NATA's work would potentially lead to development of fragmented relationships between NATA and various departments. This would also foster a non-uniform approach to use of laboratory accreditation by Government as a supporting mechanism for its regulations and its other needs for confidence in testing and measurement.

Use by Government of accredited facilities

PC Issues Paper Question 22 - Should regulatory bodies be able to make greater use of non-NATA accredited laboratories?

Decisions on whether the use of NATA accredited laboratories should be mandated are made by regulators and legislators after due consideration of the alternatives. Such decisions are not made by NATA.

A succession of MoUs between the Commonwealth Government and NATA have expressed the view of the Australian Government that, to satisfy its own testing needs, and to the maximum extent possible, the Australian Government shall use NATA accredited laboratories or laboratories accredited by organisations with which NATA has a mutual recognition arrangement. In the MoU, the Commonwealth Government has also undertaken to encourage Australian Governments and instrumentalities to adopt a similar approach.

To date, similar memoranda have been signed between NATA, Victoria, Tasmania and the Australian Capital Territory. There are similar undertakings in these memoranda for specification of laboratories accredited by NATA or by organisations with which NATA has a mutual recognition arrangement.

In an interview on NATA's activities, the Federal Minister for Industry, Tourism and Resources, the Hon Ian MacFarlane, made the following comments:

> *We would like to see a position reached in Australia where NATA is actually the accreditation agency for all laboratories, both government and non government right across Australia. That ensures that we have consistency between States and between laboratories.*
>
> *What we would like to see encouraged is that people using products or using services supplied by laboratories in Australia only use those laboratories who are NATA accredited.*[7]

There are a number of risks associated with using non-accredited facilities. These include:

(a) A lack of assurance that:

- The facility is managed in a way that ensures consistency in testing results;
- Appropriate test methods are selected and performed correctly;
- The people undertaking the activities at the facility are competent to do so;
- Equipment used in testing is calibrated at appropriate intervals;
- The test results are indeed an accurate determination and are fit-for-purpose in terms of being the basis for determining regulatory compliance and subsequent decision making;

(b) The absence of a complaints and appeals framework to address poor service and/or technical results.

Should regulators not rely on the NATA system, they would need to develop and invest in alternative criteria and methods of demonstrating satisfactory assurance and dealing with complaints. This may not result in the most economically efficient form of market intervention.

The undertakings by the Australian Government, two States and a Territory to use laboratories accredited by NATA were made in the light of the national competition policy. Specifying the use of NATA accredited laboratories does not necessarily reduce competitive functioning of the testing services market. It simply establishes a base line above which competition can take place amongst testing providers in compliance with international criteria. For each of the technical units covered in the NATA system a vast majority have more than one accredited provider. The customer therefore has choice as to which NATA-accredited facility to use.

NATA always has been prepared to accredit laboratories in new disciplines to meet regulatory needs for reliable testing. However, there have, been instances where regulatory demand has preceded the availability of accredited laboratories leading to either delays in full implementation of the regulatory requirement or to the regulator having to accept tests from unaccredited laboratories as an interim measure. The most recent case has been with the Australian Greenhouse Office, in conjunction with State regulators, introducing Minimum Energy Performance Standards for a number of appliances and electrical equipment. NATA has made a significant effort to be responsive to laboratories wishing to gain accreditation for the testing of newly regulated products such as three phase electric motors, and very recently, the testing of plug-pack type power supplies.

[7] Source: Promotional CD, National Association of Testing Authorities, 27 September 2002

While it may initially appear desirable that there be a free choice for regulators as to whether to specify NATA accredited laboratories or not, Australian Government, State and Territory Governments have all determined that there are clear advantages in specifying the use of NATA accredited laboratories to the maximum extent possible.

Should Government or the private market perform laboratory accreditation functions?

PC Issues Paper Question 16 - Should any of the current functions of laboratory accreditation bodies be performed directly by government or solely by the private market?

In the Australian context, where there are multiple government jurisdictions (Federal, State and Territory), the complexity of potential government delivery of accreditation services, meeting the needs of all jurisdictions and non-government stakeholders, is a pertinent consideration.

Additionally, a scenario of sharing *some* of the functions of laboratory accreditation between government and other providers would lead to a dilution or duplication of expertise in operation of such activities, potential competition for scarce technical resources, potential loss of the highly valuable input of voluntary experts, and multiplication or duplication of international linkages and recognition (with considerable additional costs).

Historically, the Government has withdrawn from such activities seeing value in a unified, centralised system for laboratory accreditation. This was highlighted in the 1987 Foley *Report of the Committee of Review of Standards, Accreditation and Quality Control and Assurance*, which noted:

> *The Committee's attention was drawn to the number of accreditation schemes in existence which serve similar purposes. There was concern at the resultant duplication and the need for some companies to be accredited separately against similar criteria by different accrediting bodies…*

In the United Kingdom, during the 1980s, a similar need to centralise multiple government and other bodies' programs led to the formation of the National Testing Laboratory Accreditation Scheme (NATLAS).

NATLAS itself was later merged with the government operated British Calibration Service, to form a totally centralised laboratory accreditation system (NAMAS). It later became the current United Kingdom Accreditation Service (UKAS). UKAS itself was later moved out of government, and now has the same type of corporate status as NATA, a company limited by guarantee.

To a limited degree, the Australian Government now provides a form of laboratory recognition through the activities of the Therapeutic Goods Administration (TGA) as part of its Good Manufacturing Practice requirements. There is some overlap between NATA and TGA activities for various types of laboratories which are assessed by both NATA and TGA.

For the most part, the laboratories covered by TGA inspections are not also covered by NATA accreditation. There are, however, some medical and consulting laboratories which are subject to accreditation by NATA and evaluation by TGA for at least part of their activities. The degree to which this duplication affects such laboratories, and the potential inefficiencies arising, could perhaps best be answered by the laboratories themselves, rather than NATA. However, NATA submits that scope exists for the TGA to take account of NATA's relevant accreditation assessments, as do other regulators in Australia. NATA also submits it is very amenable to the conduct of joint assessments with TGA. This would reduce the time impact on affected laboratories and could reduce, or eliminate, any

differences in findings or interpretations that might arise from two bodies conducting very similar assessments.

NATA is of the view that the Government is already closely involved in its accreditation process as described in detail elsewhere in this submission, with various types of accountability by NATA to the Government. In that sense, NATA does not consider it is operating its accreditation activities in a solely private market.

8. Appropriate Terms for Memorandum of Understanding between the Australian Government and NATA

The current Memorandum of Understanding (MoU)

Background

The current MoU represents a formalisation of the 60 year relationship between the Government and NATA. The Kean Report (1995) noted:

> *The Committee has recommended that DIST renegotiate the MoUs with Standards Australia and NATA. The original agreements were comprehensive in detailing the areas for which the Commonwealth and the two agencies agreed that they would accept responsibility. (Kean 1995, pg 203)*

Subsequently, the Government renewed the MoU with NATA and included more detail on reporting and the obligations of the parties. For NATA, the MoU is important as the instrument by which Government provides NATA with national recognition and makes a commitment to fund NATA for its national interest activities. For Government, NATA considers the MoU sets out NATA's responsibilities to Government, including acceptance of Government involvement in NATA's governance, strategy setting and an obligation to report on operational issues that impact on the national interest. Kean (1995) noted that the MoU did constitute a significant instrument of Government in terms of technical infrastructure policy, and enabled Government to use NATA as a tool to achieve policy outcomes in this area.

Performance of the parties under the current MoU

The current MoU is attached in Annex J. It is expected to be reviewed and renegotiated with Government in 2007 for a further period, starting in 2008.

The Commission has asked a number of specific questions about the operation and appropriateness of the current MoU. NATA provides its response to these questions below. This section addresses the performance of the parties under the current MoU including NATA's international performance, the importance to NATA of Government recognition through the MoU, and details the current checks and balances in place to ensure that NATA delivers appropriately on the national interest outcomes which are identified by Government from time to time.

PC Issues Paper Question 18 - How well have the parties performed in meeting their responsibilities and specific undertakings under the MoUs?

NATA's Undertakings under the MoU

NATA considers it meets its responsibilities under the MoU with the Commonwealth. However, the degree to which this is possible in some cases is confined by the degree of consultation that is possible with relevant stakeholders, access to government policy and information, and available resources.

NATA's obligations are contained in article 4 of the MoU. Information throughout this submission provides details of how NATA is achieving these obligations. One obligation, (Article 4.15) is dealt with in detail below. Article 4.15 states:

> *NATA will develop plans to increase the involvement of industry in its laboratory accreditation scheme, to encourage all laboratories (including Commonwealth and State) to be accredited and to promote recognition of the scheme by all users of test and measurement data.*

Industry involvement

Industry is involved in various ways in NATA's laboratory accreditation scheme. The Australian Chamber of Commerce and Industry has three representatives on NATA Council, and two further bodies whose members are heavily involved in industry, The Institution of Engineers, Australia and The Royal Australian Chemical Institute also have representatives on NATA Council. NATA relies on these members to bring forward matters of industry concern. NATA also relies on the two representatives from the Department of Industry, Tourism and Resources, both of whom are also on NATA's Board, to raise matters of industry concern with NATA.

Apart from these members, the NATA Accreditation Advisory Committees contain representatives from industry who are able to inform NATA about matters related to accreditation criteria and testing performance of laboratories.

Encouraging all laboratories to be accredited

NATA attempts to encourage all laboratories to be accredited by print, exhibition and internet advertising, sponsorships of relevant conferences and events, presentations at conferences and educational institutions, representation on relevant committees, media releases and personal visits to laboratories.

One of the difficulties faced by NATA in meeting the requirements of this article is that there is no publicly available list of all laboratories in Australia. While NATA does not believe that all laboratories would necessarily need from accreditation, it would nevertheless be useful to know the contact details of all laboratories so that they can be made aware of NATA's requirements.

Apart from helping NATA to meet its undertaking in Article 4.15 of the MoU, having access to this information would also assist in the Joint Undertaking of NATA and the Commonwealth under Article 6.1 of the MoU:

> *The Commonwealth and NATA will, where appropriate, encourage service providers in all sectors of the Australian community to adhere to the principles of good laboratory practice embodied in NATA's criteria for accreditation, to have such adherence recognised through NATA accreditation and as necessary to incorporate use of accredited laboratories in appropriate purchasing decisions, regulations, quality assurance requirements and operational procedures.*

Furthermore, under Article 5.4 of the MoU, the Commonwealth has undertaken, to the maximum extent possible, to satisfy its own testing needs by using NATA accredited laboratories. If the Australian Government is to be provided with the maximum choice of laboratories, which would also be in accord with competition policy, it is advantageous to the Australian Government for NATA to have access to contact information on testing services so that they can be offered the opportunity of accreditation and hence consideration for use by the Australian Government.

The information required is available in the Australian Business Register which is administered by the Australian Taxation Office. However it is non-public information.

Promotion of NATA laboratory accreditation to all users of test and measurement data

As noted previously, NATA undertakes promotion of its accreditation service and its accredited laboratories through many channels.

In 2005, NATA commissioned independent market research on 249 users of laboratory and inspection services involved in all disciplines in which NATA has accredited laboratories.

The results showed 95 per cent of those surveyed were aware of NATA, and 93 per cent were either obliged through legislation or contract specification to use a NATA accredited service for their latest testing or inspection, or chose to do so. This demonstrates the general awareness of NATA, which can in part be due to NATA's own promotional efforts.

Commonwealth undertakings under the MoU

NATA is pleased with the support provided to it by the Australian Government through its participation on NATA Council, NATA technical committees and as technical assessors. The undertaking by the Commonwealth to do this is given in Article 5.3 of the MoU.

Article 5.4 of the MoU states that:

> *To the maximum extent possible, the Commonwealth shall, to satisfy its own testing needs, use NATA accredited laboratories or laboratories accredited by organisations with which NATA has a mutual recognition agreement.*

NATA has no objective data from the Commonwealth as to its use of NATA accredited laboratories.

Article 5.5 of the MoU states that:

> *The Commonwealth will encourage other Australian governments and instrumentalities to adopt a similar approach to that indicated in Article 5.4.*

NATA understands that the Commonwealth wrote to State and Territory Governments and instrumentalities following the Kean Report (1995).

Article 5.6 of the MoU states that:

> *All Commonwealth laboratories whose principal function is to provide calibration, measurement or testing or related services to either Government or outside agencies will, as appropriate, obtain and maintain accreditation by NATA.*

NATA is not aware of any ongoing Commonwealth process for this.

Article 5.8 of the MoU states that:

> *The Commonwealth will, where appropriate, invite NATA to participate in national, regional and intergovernmental discussions involving the standards and conformance infrastructure, unless there are reasons of confidentiality for not doing so. Where such discussions may give rise to intergovernmental agreements, the Commonwealth will, as appropriate, take into account NATA's views on how best to implement such agreements.*

NATA's input was sought and provided recently during discussions surrounding the US Free Trade Agreement. However, NATA has noticed a general decline in occasions on which its input has been sought compared with previous practice. This may be due to there being fewer such national, regional and intergovernmental discussions, or the opportunity to involve NATA has not been utilised.

In summary, NATA submits it is meeting its requirements under the MoU. NATA has little objective evidence to determine whether Commonwealth undertakings have been met. NATA and the Australian Government could be assisted in their undertakings by having access to non-public contact details for laboratories in Australia.

International performance

PC Issues Paper Question 20 – Are the current arrangements between the Australian Government and NATA in relation to representation at international fora effective in facilitating Australia's international competitiveness?

As described elsewhere in this submission NATA's formal representations in international fora are detailed in the MoU between the Commonwealth and NATA. In particular, they include NATA's involvement in ILAC, APLAC, OECD, and ISO (for relevant activities) and in various trade related fora, such as APEC and AFTA/CER. NATA itself is not qualified to measure 'international competitiveness', but believes it has been highly successful in establishment of its recognition by counterpart bodies and various foreign regulators, thus providing vehicles for greater acceptance of Australian data accompanying traded goods and services.

Case examples of NATA's facilitation of international competitiveness

Marand Precision Engineering

In 2005 Marand Precision Engineering developed a unique engine installation and removal trailer for the Joint Strike Fighter. The trailer now forms a pivotal part of the US$300 billion program.

The fighters will be based in many parts of the world. As the trailers will be operated in Europe they must be European Conformity (CE) marked to signify that they comply with the essential safety requirements of the European Machinery Directive.

Marand were able to CE mark the trailer based on a conformity assessment undertaken by Risk-Plant Consultants Pty Ltd. Risk Plant are accredited to assess compliance with the European Machinery Directive under NATA's Inspection program and are therefore designated by NATA for the Machinery Directive under the European Community – Australia mutual recognition agreement on conformity assessment.

Holden Ltd

In 2001 Holden Ltd entered into negotiations with the technical authority in South Africa regarding the export of their Holden Commodore range of vehicles. Representatives of the authority, the South African Bureau of Standards, visited to Australia and studied the Australian automotive type-approval/certification system. As a result South Africa now conditionally accepts vehicles certified under the Australian system that have technical equivalency in the required regulations. One of the conditions is that the testing involved is done by NATA accredited laboratories. Accredited testing thus became a cornerstone for the export of these vehicles.

Subsequently, Holden Ltd negotiated with the UK authority, the Vehicle Certification Agency, for export of vehicles. Again Holden Ltd was able to utilise NATA accredited testing to avoid the expense and complications of testing being undertaken overseas.

In terms of qualitative measures, the establishment of the ILAC Arrangement and the APLAC MRA during the past decade has reduced significantly the number of inquiries NATA receives from laboratories seeking assistance with acceptance of their data in foreign markets. Similarly, the remarkably few areas of difficulty in acceptance of data in selected foreign markets, revealed during NATA's recent surveys of Australian laboratories as

background information for Australia's negotiation of Free Trade Agreements, appears to illustrate a generally positive environment for acceptance of Australian data internationally.

One of the challenges faced by NATA in recent years is to maintain its links with Australian trade officials in Canberra and overseas. In response to changes in various agencies' staff NATA needs to constantly renew its high level relationships and to assist officials in understanding how technical infrastructure matters affect trade policy. This is important at a time of emphasis on bilateral trade agreements, and renewed interest in conformity assessment options in the WTO TBT and SPS committees. Without appropriate briefing and technical support from NATA such negotiations and discussions may be skewed towards other models which could cause problems for market access of Australian products and their international competitiveness.

Recognition of NATA by the Government

The Commission's Issues Paper states:

> *The special recognition by the Australian Government through MoUs, affords Standards Australia and NATA privileged status and considerable power and authority.*

In relation to this statement NATA makes the following points:

- NATA and its national system of accreditation are not distinct from its members and stakeholders that oversee both the technical and administrative management of the system. These members and stakeholders are diverse and come from Government, industry, professions, consumers, and employees. They work collaboratively to ensure NATA's system of accreditation benefits Australia, and any power or authority that might be manifest in the NATA system is actually derived from the power or authority inherent in those stakeholders and members. Such power and authority is directed to meeting their interests, interests that include the public interest and the national interest.

- NATA's system of accreditation is the oldest of its kind in the world, being established in 1947. Its current status and authority have been built mostly by the thousands of voluntary government and private experts who have contributed to the accreditation system's evolution over the years by being its technical and governing bodies, and by being technical assessors. This represents an acknowledgement by the Australian technical community that NATA's system has value for them and for Australia's society in general.

- NATA has been fortunate in receiving ongoing government recognition, especially for its international activities. In the area of international laboratory accreditation NATA is recognised as a major player, and has been an architect of mutual recognition and capacity building amongst its peers in other countries. This considered use of one source of authority has led to several 'firsts' in market access for Australian produce to Europe, the USA and other major markets.

- Ongoing government recognition is necessary as one source of authority that allows the NATA system of national accreditation to be economically efficient, and to deliver outputs that meet public and national interests.

PC Issues Paper Question 23 - Is it appropriate that NATA is accorded recognition as a 'peak' body within the Memorandum of Understanding that it has with the Australian Government? Is the public interest best served by this special recognition?

Appropriateness of status

In response to the Kean Report (1995), the Government decided that NATA should be recognised as the national authority for laboratory accreditation, rather than a peak body, to remove any possibility of confusion as to the role of NATA in the technical infrastructure[8].

This was confirmed in the MoU between the Commonwealth Government and NATA which *inter alia* states that:

> *Except with respect to therapeutic goods (as defined by the Therapeutic Goods Act 1989 (Cwlth)) the Commonwealth recognises NATA as the national authority for accreditation of laboratories conducting tests and measurements in all technical fields and including laboratories performing tests and studies in accordance with the OECD Principles of Good Laboratory Practice and for the accreditation of suppliers of certified reference materials.*

The Government also undertook to inform other governments, relevant international organisations, the laboratory community and users that NATA is the only nationally recognised laboratory accreditation body[9].

NATA also is recognised in the MoU with the Commonwealth as a peak authority, rather than the national authority, for the accreditation of inspection bodies. The reason for this is that the Australian Government also recognises JAS-ANZ (Joint Accreditation System of Australia and New Zealand) as an accreditor of inspection bodies.

The Australian Government has been of the view that NATA has demonstrated over the course of its history that it has the capability to offer a laboratory accreditation service that meets Australia's public and national interests.

In 2001, Senator the Hon. Nick Minchin, then Minister for Industry, Science and Resources, described NATA as the *oldest, largest and most highly respected laboratory accreditation body in the world*[10]. With such a resource available in Australia, NATA's recognition as the national authority in the area of laboratory accreditation and associated areas seems appropriate.

NATA submits that its recognition as a peak body for inspection accreditation is appropriate. Should JAS-ANZ decide not to remain an available accreditor in this area, it may be advantageous to Australia's public and national interest that NATA be accorded national authority status in the area of inspection accreditation also.

Public interest in NATA retaining its current status

NATA believes public interest is best served by an accreditation body that meets the agreed public interest objectives of such an organisation, NATA has explained elsewhere the various mechanisms by which it meets the objectives of society and industry with respect to laboratory accreditation.

Accordingly, special recognition as a 'peak' body by Government provides assurance to the Australian community as well as reassuring our trading partners, that the national laboratory

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8 Ref. letter, Hon. Peter McGauran, Minister for Science and Technology, to John Gilmour, then Chief Executive NATA, and subsequent MoU between the Commonwealth Government and NATA.

9 ibid

10 Senator the Hon. Nick Minchin, (then) Minister for Industry, Science and Resources, published in *Australia's Technical Infrastructure – Standards and Conformance* (2001).

accreditation program is operating in close alignment with the Government's national interest expectations for this activity.

The situation in 2006 has not changed significantly since it was last discussed in the 1995 Kean Inquiry, which confirmed it was in the national interest for NATA to continue as the national laboratory accreditation body.

PC Issues Paper Question 41 - Is the current general practice of specifying NATA as the only recognised body for conducting accreditation appropriate?

As this submission notes, there are relatively few cases where NATA is specified exclusively for conducting laboratory accreditation, despite the Australian Government's preference to date for such a position[11].

Nevertheless, where any specification is made in regard to laboratory accreditation, NATA accreditation is often specified at least as one of the alternatives.

The appropriateness of such specification was investigated most recently through the Kean Inquiry (1995) and as a result of that extensive investigation, the Australian Government resolved that:

- NATA should continue its status as Australia's laboratory accreditation authority.
- The Australian Government would use NATA accredited laboratories wherever practicable.
- The Australian Government would encourage the State Governments to do likewise.
- The Australian Government would have its own laboratories accredited by NATA.

NATA believes such specification is appropriate. It provides integrity in laboratory accreditation as such services are provided through a single supplier that has been recognised among its international peers in ILAC, and APLAC, as a world leader in its field.

Checks and balances

PC Issues Paper Question 25 - To what extent do the current checks and balances provided to the Australian Government in relation to the activities of NATA produce an appropriate balance between the national interest and the need for NATA to have some degree of operational autonomy?

NATA is very mindful of its national interest responsibilities and is monitored through several mechanisms by the Australian Government. Within those boundaries, NATA believes that it has sufficient scope to remain a dynamic organisation that seeks continuously to improve its operational performance.

NATA also believes the checks and balances available to the Australian Government in regard to NATA's operations can provide confidence in the activities undertaken by NATA in the public and national interest.

These checks and balances are provided through the representation of the Government on NATA's Board and Council, through the Memoranda of Understanding with the Commonwealth and with Departments, and through the annual Deed of Agreement between the Commonwealth and NATA.

[11] Ref. Memorandum of Understanding between the Commonwealth of Australia and NATA, and statements from the Minister for Industry, Trade and Resources, quoted herein.

There are two senior members of the Department of Industry, Tourism and Resources (DITR) on NATA's Board. The Board is chaired by Dr Barry Inglis, CEO National Measurement Institute, DITR and Australia's Chief Metrologist. Mr Tim Mackey, Deputy Secretary, DITR is also a member of NATA's Board.

Apart from these DITR representatives, the Australian Government has four further Departments represented on NATA Council: Defence, Foreign Affairs and Trade, Health and Ageing, and Agriculture, Fisheries and Forestry.

The Government's expectations of NATA are set out in the Memorandum of Understanding (MoU) between the Commonwealth Government and NATA. In that MoU, there are 22 Articles of undertakings expected from NATA.

There are also MoUs between NATA and particular Departments and Agencies such as the MoU between AQIS and NATA and the MoU between the ACMA and NATA. NATA also has an agreement with the Health Insurance Commission (now Medicare Australia) with regard to NATA's accreditation activities in medical pathology. NATA also has responsibilities on behalf of the Australian Government as a designating authority for the European Community Mutual Recognition Agreement on Conformity Assessment, and as a designating authority for the Asia Pacific Economic Community (APEC) Mutual Recognition Agreement for Electrical and Electronic Equipment. These responsibilities as a designating authority are outlined in separate MoUs.

In addition, there is an annual Deed of Agreement signed between the Commonwealth and NATA. This agreement sets out the national interest activities that NATA is to undertake on behalf of the Australian Government, and the funding that the Australian Government will provide for this undertaking. NATA is required to report quarterly on the achievement of goals specified in the Deed of Agreement.

This combination of MoUs, Deeds of Agreement and representation by the Australian Government on NATA's Board and Council helps ensure that the Australian Government is closely in touch with NATA's operations on a regular and frequent basis. NATA believes that this provides adequate checks and balances by the Australian Government while allowing NATA sufficient operational autonomy to meet its requirements as a laboratory accreditation organisation and an association of accredited members.

Confirming the Roles of Government and NATA

The role of government in laboratory accreditation is addressed elsewhere in this submission. However NATA makes the following responses to Commission questions to confirm the roles of government and NATA in future versions of the MoU.

The relationship between NATA and Government

PC Issues Paper Question 33 - What have been the significant impacts of major changes on the relationship between the Australian Government and NATA across time, particularly since the Kean report in 1995?

The most significant change for NATA has been the formalising of the level of accountability, and the strengthening of that arrangement through various deeds of agreement including the Memorandum of Understanding with the Commonwealth Government.

For NATA, these agreements clearly set out the roles for the Association and remove areas of contention (such as the perception by some in past years that NATA should be a regulator). The recognition of NATA's work and its unique role has done much to underpin

the Association's ability to promulgate proactively the benefits of accreditation to government and non-government laboratories.

Historically, NATA has seen a steady decline in Government financial support for accreditation activities, resulting in increasing reliance on members' fees. Government support has declined from nearly 100 per cent in 1947 to just over six per cent at the time of writing. Although NATA is in a pre-eminent position regarding accreditation in Australia, it has to be said that fees compare very favourably with those of the Association's counterparts overseas. NATA has not only adapted to declining government funding, but has done so efficiently and economically.

Defining the national interest

PC Issues Paper Question 19 - Is 'national interest' well and/or appropriately defined? Are accreditation services sufficiently independent of business interests to adequately take into account the national interest and more generally the public interest?

In its Issues Paper of March 2006, the Productivity Commission notes the concepts of *public interest* and *national interest* are treated as equivalent in an economic framework, but may be used in slightly different contexts. In this regard *national interest* is usually applied in an international context, while *public interest* relates to the well-being of the whole community.

Both of these concepts of *national interest* and *public interest* are fundamental to NATA's raison d'être. However, they have only been broadly described (in terms of relevance to NATA) in a few public documents.

The first document is NATA's own Constitution, where the Objectives of NATA are defined as:

> ***Objectives of the Association***
>
> *The objects for which the Association is established are:*
>
> *a. To promote and contribute to the quality of testing, inspection and related services in Australia.*
>
> *b. To promote national testing, inspection, calibration and related services to meet the needs of science, industry, trade, commerce, government and matters related to national interest.*
>
> *c. To promote the science and practice of testing, inspection, calibration and related services within Australia and internationally.*
>
> *d. To provide appropriate accreditation services to facilitate acceptance of Australian products and services within Australia and internationally.*
>
> *e. To provide international recognition of accredited laboratories' and accredited service facilities' reports and certificates through Mutual Recognition Agreements with appropriate bodies located in other countries.*

The second document is NATA's Mission Statement, where the first plank of that Mission is:

> *Provide, in the national interest, accreditation and supporting services that meet the needs of stakeholders and facilitate the domestic and international recognition and acceptance of their products and services.*

The third document is the March 1995 report of the Kean Inquiry, which makes the following observations (pp 201-202) on aspects of the national interest relevant to the standards and conformance infrastructure and government's support for its component parts:

> *…National interest activities have been defined for funding purposes as those:*
>
> - *where benefits exceed their costs; and*
> - *where providers of services cannot recoup the costs from the parties that benefit.*
>
> *There are clearly some activities that under this definition would not be provided by the private sector, suggesting the following roles for the Commonwealth Government, in addition to its role in protecting the health and safety of the community and the environment:*
>
> - *provision of a national system of measurement standards*
> - *ensuring traceability in measurement made for legal purposes*
> - *provision of support for the peak standards body to pursue the national interest*
> - *endorsement and provision of support for accreditation bodies*
> - *assisting the participation of Australian bodies in international organisations and influencing the direction and performance of bodies that are given special responsibilities.*

The fourth document is the MoU between NATA and the Commonwealth, which makes the following pertinent references, but does not provide an overarching definition of *national interest* or *public interest*:

> *4.1 NATA will provide national leadership in establishing standards of good laboratory practice, in accrediting testing laboratories, inspection bodies and suppliers of certified reference materials thereby providing a network of competent accredited service providers **to meet national needs** as identified by governments or industry groups.*
>
> *4.2 NATA will prepare, publish and, where appropriate, review and revise its procedures and standards to ensure that these will:*
>
> *4.2.1 conform with international standards;*
>
> *4.2.2 meet national interest requirements;*
>
> *4.2.3 facilitate international trade;*
>
> *4.2.4 satisfy the requirements for public health, safety and environmental protection;*
>
> *4.2.5 enhance quality and performance of products, materials and related services;*
>
> *4.2.6 be suitable for uniform reference in Australian governments' laws, regulations and public purchasing contracts; and*
>
> *4.2.7 provide the laboratory testing, measurement and calibration basis for certification systems.*
>
> *4.7 NATA, in developing and implementing its corporate objectives, will seek to assist industry to improve its competitive advantage by providing a world class testing and measurement system and through this, **promote community benefits**. It will evaluate ways in which its services can be provided more efficiently and, consistent with international standards, apply innovative techniques to its accreditation process.*
>
> *4.9 In its role as Australia's representative **NATA will act in the national interest** identified by the Commonwealth and take into account the priorities of Australian industry.*

*4.11 NATA will develop and maintain links with foreign national accreditation bodies responsible for accredited service providers and maintain its operations in harmony with those foreign accreditation systems considered appropriate for development of reciprocal recognition agreements, bilateral or multilateral, which are considered **in the national interest**. In developing such reciprocal agreements, NATA will consult with the Commonwealth on the relevance of each agreement to **the national interest** or to the support of business efficiency and competitiveness and trade opportunities for Australian industry and services.*

*4.14 NATA will promote an awareness of the importance of its work to quality and **the national interest**, in educational institutions, industry and the general community.*

*4.20 NATA will work with APLAC and other regional for a to ensure that the **national interest priorities** of the Commonwealth and Australian industry are taken into account in APEC, the WTO, AFTA/CER and other trade agreements and arrangements.*

*5.1 The Commonwealth may, through a grant-in-aid, provide financial assistance in relation to activities assessed as being **in the national interest** which will be addressed in detail in the annual Deed of Agreement between the Parties.*

In terms of accreditation services being "sufficiently independent of business interests to adequately take into account the national interest and more generally the public interest", NATA makes the following observations:

- NATA's fundamental objectives as stated in its Constitution are directed at the national interest and those objectives do not state any "benefit to members" component;
- In regard to NATA's corporate governance, "business" interests are only one of a balanced set of representations on NATA's Council. The Australian Chamber of Commerce and Industry (ACCI) has three nominated representatives on a Council comprising more than 40 stakeholders. In contrast, the public sector has six Australian Government representatives, plus a total of eight representatives of the State and Territory Governments;
- In technical inputs to NATA through bodies such as its Accreditation Advisory Committees and technical assessor panels, an appropriate balance of public and private sector representatives is also maintained; and
- NATA extends its accreditation services to cover new technical fields as required. NATA absorbs all attendant development costs irrespective of whether the new fields will be financially self supporting. NATA considers its privileged position, as the government recognised national provider, requires it to address all areas of need for its services.

Removal of special recognition by Government

PC Issues Paper Question 24 - What would be the consequences if government removed the special peak status of NATA?

Removal of the Government's imprimatur of NATA as Australia's laboratory accreditation authority would be unlikely to affect NATA's long-term viability though it would obviously cause disquiet in the domestic and international markets given the strong government support that NATA has been given for many decades. While it is likely that NATA would continue to exist, removal of government recognition may ultimately result in competing laboratory accreditation businesses being established in Australia.

Not only would the effect on the public and on Australia's trading partners of removal of government imprimatur be severe, but the establishment of a new administration, at considerable cost and little benefit, could occur.

This was recognised in the Kean Report (1995), page 120:

> *The Committee was not persuaded by all the arguments advanced for retention of a monopoly in laboratory accreditation. Nevertheless, it considers that there are compelling reasons for concluding that opening laboratory accreditation to competition is not in the public interest.*

At present, the public, industry and others with a need for testing have a single, recognisable source for information about testing and testers, as well as for accreditation of these services. This would not be the case in a competitive laboratory accreditation environment. Accessing such information would become more time consuming and the answers could be inconsistent due to differences between accreditation bodies.

The international audience would become confused if there were multiple providers of laboratory accreditation services. Which one has the information they require? Which can be relied on to provide accreditation services? Which can they trust?

International counterparts find it easier to meet their own due diligence requirements when dealing with a single, national accreditor that has government imprimatur.

Trade negotiations and government-to-government mutual recognition agreements would become more difficult if there was not a single, national laboratory accreditation authority. It is for this reason that in 2002, the Hon. Ian MacFarlane, Minister for Industry, Tourism and Resources, said:

> *What I would say to laboratories in Australia is if you all accept one accreditation process, if you all accept NATA as the accreditation process because it is already internationally recognised, when we do a trade deal with a foreign country and they see NATA as the accrediting agency of the laboratory that is doing the testing, they are immediately comfortable.*[12]

Should the Australian Government remove such recognition, it would need to assure the Australian public, and Australia's trading partners, that they could have confidence in alternative providers. To give such assurance, there may be need for a government to assume the role of accreditation regulator to determine whether the different laboratory accreditation bodies were meeting the needs of the public, industry and the government. NATA submits that it is difficult to see that such a system would be more effective or efficient than the current model.

Indeed, the Australian Government has already studied this scenario through the Kean Inquiry (1995). It was concluded then that there is no nett benefit to Australia to have multiple providers of laboratory accreditation. In the previous MoU between the Commonwealth and NATA, the Australian Government undertook to "make efforts to discourage the offering by other conformity assessment bodies of programs purporting to be equivalent to NATA accreditation"[13]. This provision was in response to the establishment of a conformity assessment system for laboratories that suggested it was equivalent to laboratory accreditation. The Kean Inquiry determined that this was not in Australia's national interest, and the Government endorsed that recommendation.

As a result, the provider of this alternative system willingly divested itself of this service and it was therefore unnecessary for this provision to be included in the current MoU between the Commonwealth and NATA.

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12 Source: Promotional CD, National Association of Testing Authorities, 27 September 2002

13 MoU between the Commonwealth and NATA, signed on 25 February 1998. (The current MoU between the Commonwealth and NATA was signed on 14 February 2003).

In summary, while NATA might survive as a laboratory accreditation and national testing information service if government imprimatur was removed the potential costs outweigh the potential benefits. If government imprimatur was removed the potential costs are disruption caused to the domestic and international markets, potential loss of accreditation services to regional Australia, the resulting loss of confidence from a removal of the current single comprehensive system, and the probable increase in total accreditation costs for Australia due to having multiple accreditation providers.

Confirmation of the roles of NATA and Government

NATA's response to the question on what should be the role of Government in laboratory accreditation (PC Issues Paper Question 14) is included in the previous Chapter.

The Kean Report included findings on the role of government, and confirmed that the Government could rely on the existing bodies to undertake activities within the technical infrastructure. In the case of NATA this was to continue to provide its system of national accreditation. The Kean Report also recognised the national interest in such activities and confirmed that the Government should seek to formalise the delivery of such national interest activities through the continuance of MoUs between the Commonwealth Government and the four peak standards and conformance bodies, namely the NML, Standards Australia, NATA and JAS-ANZ, and funding as necessary.

In addition the Kean Report recommended that the Government, through the then Department of Industry, Science and Technology (now the Department of Industry, Tourism and Resources) maintain a coordinating and policy role for the technical infrastructure and act as the conduit between the technical infrastructure bodies and other parts of Government.

NATA considers these roles defined by the Kean Report remain relevant in today's environment, and that their reflection in the current MoU should be carried over to any renewed MoU between the Government and NATA.

The MoU identifies the interface between the Government's role (motivated by public/national interest and as a recipient of NATA services) and NATA's role in supporting laboratory accreditation in Australia. It also identifies the roles of the two parties in terms of representing Australian interests internationally on matters that pertain to laboratory accreditation.

Suggested Amendments to the MoU

PC Issues Paper Question 17 - Are the current terms of the MoU with the Australian Government and its agencies, including the objectives and the undertakings of the parties appropriate?

PC Issues Paper Question 26 - Are there additional matters currently not addressed that should be included in the MoUs or are there some currently included that are inappropriate?

Given the public and national interest in a recognised national laboratory accreditation system it is appropriate that there be some formal instrument between it and Government. This was first recognised in the Foley Inquiry (1987) which recommended that a formal Memorandum of Understanding (MoU) be established between Government and NATA.

Generally speaking NATA considers the current terms of the MoU with the Australian Government to be appropriate and necessary in order for both Government and NATA to meet society's and industry's objectives for laboratory accreditation.

In terms of changes to the current MoU, NATA makes the following general and specific suggestions.

General suggestions

Since the Kean Inquiry NATA has established new accreditation programs in response to society's needs. Rather than only use in industry, the results from these accredited programs are used increasingly for public health, safety and environmental purposes. This broadening of direct beneficiaries to include the public in general should now be reflected in the wording of a renewed MoU.

NATA submits that the MoU should also reflect that the NATA national accreditation system is in the public interest in addition to the national interest, particularly as described in the Commission's Issues Paper.

Deliberate articulation of the public interest and national interest in NATA's national accreditation system may also prove beneficial. At present references to the national interest are scattered throughout the text without any specific description of the national and public interest.

Specific suggestions

Preamble

The preamble in Clauses A and B could be expanded to include the general suggestions made above, and particularly in regard to the relevance of accreditation to the whole of society.

Article 1 Definitions

Article 1 should be updated to reference the recent replacement of ISO/IEC Guide 2, which is ISO/IEC 17000.

Article 2 General Provisions

The General Provisions could be expanded to include NATA's status as the national authority for the accreditation of proficiency testing providers. The term of 5 years should be retained.

Article 3 Recognition

There is a public and national interest in NATA's laboratory accreditation system. The system's efficiency and effectiveness is maximised when it is provided by a single national provider. Subject to suitable checks and balances for this single provider position, the existing recognition in the MoU should be retained.

At present there are two peak bodies for accreditation of inspection bodies in Australia, NATA and JAS-ANZ. To date in Australia this has not led to any conflict between the two accreditation bodies because in practice NATA is the sole provider of accreditation in Australia. However in New Zealand there has been open competition between JAS-ANZ and NATA's equivalent, International Accreditation New Zealand. It is understood that the New Zealand government is currently seeking to clarify this situation. NATA does not believe the most efficient economic outcome will be achieved through competition at the accreditation level of the technical infrastructure – and as such suggests the process of renewing the MoU can provide an opportunity for a clear mandate on a single national provider of accreditation

of inspection bodies in Australia, and would seek the Australian Government's support to negotiate such an outcome with JAS-ANZ.

Article 4 NATA Undertakings

Article 4.1

NATA would like to see the Australian Government include NATA's national leadership in accreditation of proficiency testing providers. This is a non-commercial public interest activity for which there was no national service at the time of the Kean Inquiry. NATA is the sole Australian provider for this new service and is Australia's representative in ILAC's Proficiency Testing Consultative Group.

Article 4.4

NATA proposes deletion of reference to:

> *…the National Standards Commission… and*
>
> *…Australian Government Analytical Laboratories…*

As these entities have been absorbed into the new National Measurement Institute, whose name should replace National Measurement Laboratory in this Article.

Article 4.6.2

Replace 'National Measurement Laboratory' by 'National Measurement Institute'.

Article 4.6.3 and 4.6.4

Combine these two sub-articles into a new 4.6.3 to read "collaborate with the National Measurement Institute in matters pertaining to legal, physical, chemical and biological metrology".

Article 4.1.8

Amend slightly to read 'NATA will continue to ensure there is adequate separation from its commercial subsidiary, NCS International Pty Ltd, and from its public interest subsidiary, Proficiency Testing Australia".

Article 5 Commonwealth Undertakings

Funding

Presently Article 5 provides for a grant-in-aid on an annual basis for national interest activities. Using the definitions in the Commission's Issue Paper NATA would suggest this be broadened to include relevant activities that are provided in the public interest as well.

Where identified public or national interests are ongoing or are for projects that take place over several years, the funding mechanism should be flexible enough to provide secure funding for as long as that interest remains valid. This would permit proper planning, resource allocation and scheduling to be undertaken in advance.

It is possible that the current source of funding for NATA's national interest activities, that is the Support for Industry Service Organisations Program, may in itself not be adequate to cover funding for all public and national interest activities that NATA undertakes. NATA notes that some of its overseas counterparts are supported by specific government funding.

In making these suggestions NATA acknowledges the funding it has received from Government for national interest outcomes to date. It considers the annual monitoring of any government derived funding through identified goals, measurable objectives and outcomes, as in the current annual Deeds of Agreement, should be retained.

Whole-of-government approach

NATA seeks the possible strengthening of the role of the MoU's implementing Department (DITR) to facilitate a whole-of-government approach to awareness and use of the national accreditation system for laboratories and related services. In the past NATA has experienced challenges in engaging with other parts of Government with a lack of awareness of the existing accreditation system. Similarly, a clearer whole-of-government profile would enable NATA to respond more broadly to Government's needs, and to assist in delivery of Government's public policy and regulatory outcomes in an efficient manner.

Article 6 Joint Undertakings

No change to Article is requested.

Articles 7 – 9

No changes to these Articles are requested.

9. Government Funding of NATA for National Interest Activities

In its Issues Paper, the Productivity Commission notes that in an economic framework, the concepts of national interest and public interest are treated as being equivalent, but can be used in slightly different contexts.

In this Study, the Commission has advised that national interest may refer to Australia's position relative to other countries, while public interest relates to the wellbeing of the whole community. The Commission has also noted that Australia's national interest is generally best served when community wellbeing is maximised – in other words, that there is some merging of public and national interest.

The Commission has posed a number of specific questions in regard to Government funding of activities of national and public interest. NATA's responses can be found at the end of this chapter.

The following material provides background information to those answers.

Activities undertaken by NATA in the national/public interest

NATA has commented in Chapter 8 of this submission on the need to more adequately define the national and public interest in laboratory accreditation (see NATA's response to the PC Issues Paper Question 19).

The Government funded national and public interest activities undertaken by NATA over recent decades have primarily been directed at:

(a) NATA's continued membership of ILAC and APLAC;

(b) NATA's participation in the key policy and technical fora of ILAC, APLAC and the OECD Working Group on Good Laboratory Practice;

(c) NATA's inputs to the relevant ISO Committees affecting NATA's national accreditation roles and the criteria used internationally for such activities;

(d) NATA's participation in evaluation of compliance of its counterparts in the ILAC Arrangement and the APLAC MRA and the OECD Mutual Acceptance of Data Protocol, together with NATA's own demonstration of compliance with MRA criteria; and

(e) Partial support for the operation of domestic proficiency testing programs.

All of the above activities are sought by NATA to be continued to be funded in the national interest, as they are essential to Australia's maintenance of both international and domestic credibility in underpinning trade facilitation and business competitiveness.

The following aspects are not currently funded by the Government:

- Coverage of annual shortfalls in the costs for (a) to (e) above. These have ranged from $170,000 to $460,000 per annum over the past four years.

- Facilitating equitable access to accreditation by remote facilities by removal of the geographical premiums placed on the fees for such facilities. This is currently costed at approximately $300,000 per annum.

- Shortfalls in the provision of national training programs on good laboratory practices and laboratory management.

- Supporting the maintenance of the national information service on Australia's accredited testing and measurement capability.

Some background on various activities (in additional to (a) to (d) above), which NATA considers to be in the national and public interest, are described below.

Liaison with Government agencies to ensure there are accredited testing services to meet Governments' needs

One of NATA's objectives is to provide accreditation of testing services to meet the needs of Government. To help ensure this objective is met, NATA maintains ongoing contact with relevant departments and agencies, and where appropriate, enters into deeds of agreement or other instruments.

For example, currently there are specific deeds of agreement with Australian Government agencies, such as with Medicare Australia (through its predecessor, the Health Insurance Commission), regarding pathology laboratories, and one with AQIS regarding testing for export of prescribed goods and for foods imported into Australia.

There is also a Memorandum of Understanding with the Victorian Department of Human Services regarding pathology laboratories.

In addition to these specific agreements, examples of close liaison with departments and agencies may involve keeping them up to date on relevant accreditations – for example the Australian Government Attorney-General's Department regarding parentage testing, the Victorian WorkCover Authority regarding asbestos testing, and the Victorian Department of Human Services regarding testing of drinking water.

Other examples of close liaison include:

- The Australian Greenhouse Office regarding energy efficient equipment;
- The Australian Communications and Media Authority regarding a range of telecommunications and electromagnetic emission and compatibility issues;
- DAFF regarding its National Residue Survey and Codex Alimentarius;
- The National Institute of Forensic Science;
- The National Measurement Institute regarding verifying authorities;
- The Defence Signals Directorate regarding the Australasian Information Security Evaluation Programme;
- DOTARS Vehicle Safety Standards regarding testing of motor vehicles; and
- State and Territory road construction, environment protection and electrical safety authorities.

Policy research for Government Departments

NATA is always willing to undertake research and participate in policy discussions to assist government departments and agencies. This provides Government with expert advice on matters concerning testing and inspection, including advice from NATA's members, when

appropriate. An example is the research done to assist in the negotiation of the Australia-European Community mutual recognition agreement on conformity assessment.

As a result of this research, participation in the European Commission (EC) MRA negotiations, and subsequent Joint Committee meetings, NATA is the main contact for government and industry on European Union's mark for regulated products, ie the CE mark.

Another example has been the surveys of NATA members' experiences to assist DITR and Department of Foreign Affairs and Trade (DFAT) in the negotiation of free trade agreements, particularly those with the USA and China.

A third example is the input provided to DFAT as requested on triennial reviews of the WTO Agreement on Technical Barriers to Trade.

A fourth example is work with the DITR on Australia's commitments within APEC Standards and Conformance Sub-Committee in relation to its Collective and Individual Action Plans.

Provision of a directory of NATA accredited facilities, including their scopes of accreditation

NATA provides a detailed, on-line directory of NATA accredited laboratories, free of charge to anyone with internet access. The directory has extensive electronic search capabilities, and is updated on a daily basis.

Web usage statistics show that the NATA website currently receives about 55,000 visits per month. This indicates that it is of considerable public interest. It is also of national interest as it signals to the world the extensive capabilities of accredited laboratories in Australia, and allows overseas economies to check whether test laboratories in Australia are actually accredited for the tests appearing on test reports.

The directory, and website on which it resides, were significantly upgraded by NATA in March 2006. The upgrading allows laboratories to place their own commentary on their activities in addition to the accreditation details which are provided by NATA.

This directory is the only free-to-public listing of accredited laboratories in Australia.

Provision of training courses

NATA and the Commonwealth agreed in the MoU to promote understanding and awareness of principles of good laboratory practices and the objectives and mechanisms of laboratory accreditation. NATA fulfils its role in this undertaking through the provision of training by the NATA Training Services Group.

NATA's Training Services Group was established in 1987 to fill the need within Australia for training courses related specifically to laboratory management. The Training Services Group provides public and in-company management system training courses for laboratories, inspection bodies and other facilities. The courses cover the interpretation and application of the relevant national and international standards, the establishment and implementation of effective management systems, and the internal and external auditing of such systems.

The specific courses offered are:

- Documenting and Implementing your Laboratory Management System
- Understanding NATA's ISO/IEC 17025 Requirements

- Understanding ISO 15189 - Accreditation Requirements for Medical Laboratories
- Internal Audits
- Quality Management in the Laboratory
- OECD Principles of Good Laboratory Practice
- Quality Control in the Microbiological Laboratory
- Laboratory Assessor/Lead Assessor Training

All courses are presented by experienced trainers who retain the currency of their practical experience through frequent involvement in NATA's laboratory accreditation assessments.

NATA Training Services has become a well-respected training organisation within the Asia-Pacific region and beyond, and actively conducts training courses in all capital cities and regional centres of Australia. Courses are also conducted within the Asia-Pacific region, including on-going annual programs in some countries. Further afield, NATA has conducted training courses in Sweden, Finland, Mexico and the United States.

While NATA aims to recover costs from its national and international training courses in the longer term, they are currently loss making activities. There are currently increased demands to provide national training in regional centres with fewer laboratories, and if this need is met, deficits from training services will increase.

Provision of proficiency testing services

NATA's domestic proficiency testing programs have been the major domestic national interest activity of NATA funded by the Australian Government over the past decade.

Proficiency testing programs involve inter-laboratory tests (or practical tests, such as measurement audits) to assess the performance of individual accredited laboratories. As such, they complement the major evaluation tool used for accreditation ie, on-site peer evaluation by teams of NATA staff and technical assessors. Previous inquiries into Australia's technical infrastructure have recognised the importance of proficiency testing as a tool to ensure the reliability of Australia's network of accredited laboratories.

Australia's laboratory accreditation system is the most comprehensive national program in operation. The diverse range of tests and measurements performed by NATA accredited laboratories makes it impractical to design and operate proficiency testing programs across all areas of testing and measurement. NATA, therefore, needs to set priorities for its operation of proficiency testing based on advice from its external technical committees regarding areas where the most critical reassurance of technical competence of accredited laboratories is needed, or where there are other significant side-benefits to the Australian community resulting from proficiency testing programs. Some of these side-benefits include development of precision information for standard test methods, improvements in testing and measurement procedures, and assignment of reference values to certified reference materials.

Historically, the ability of NATA to operate comprehensive proficiency testing across the broad spectrum of its activities has been made possible by the Australian Government's funding support. This has enabled NATA to cover complex areas of technology, where limited participation of laboratories would prevent their conduct on the basis of costs, while blending these proficiency testing activities with other programs which are more self-supporting. While some laboratories may never be involved in proficiency testing, all accredited laboratories benefit from the extra credibility provided by NATA's proficiency testing activities.

Benefits derived from Government funded proficiency testing

In summary the benefits of NATA's proficiency testing programs are:

(a) Achieving and maintaining NATA's network of Mutual Recognition Arrangements with its counterparts in overseas markets. It is now even more critical for NATA to maintain its access to proficiency testing activities to comply with the policy adopted by APLAC for its MRA signatories for defined participation rates by accredited laboratories;

(b) The range and frequency of proficiency testing used by NATA has allowed for the operation of a cost effective program of on-site surveillance assessments of accredited laboratories. Many of NATA's overseas counterparts, without comprehensive proficiency testing programs, need to conduct such visits at twice the frequency of NATA's program. This has resulted in considerable cost savings in NATA's operations and thus in the accreditation fees charged to all laboratories; and

(c) Many of those domestic proficiency testing programs are operated in Australia's key export sectors and provide additional reassurance to specifiers and regulators in major trading partners that testing performed by NATA accredited laboratories is reliable and access to their markets is facilitated by products having been tested by our accredited laboratories.

The international dimension

While proficiency testing is principally a domestic national interest activity, it also continues to be a critical feature in establishing the credibility of testing in a range of sectors with international trading significance, and of particular significance in the Australian economy. For example, major trading partners (such as the European Union for Australian wine imports, the USA for meat products, Japan and others for dairy and other food products, South Korea for seafood and multiple markets for coal) require reassurance about the testing of such commodities and products. All of the areas cited here are the subject of regular proficiency testing programs historically operated by NATA, and now continued through its subsidiary, PTA.

Additionally, there are new demands being placed on laboratory accreditation bodies to make greater use of proficiency testing to meet commitments for maintaining signatory approval in multilateral Mutual Recognition Arrangements (MRAs). It is now the policy of APLAC for all signatories to its MRA to undertake at least one proficiency test in all areas of accreditation over a four-year cycle. This policy is also expected to be adopted by ILAC for its global Arrangement. The availability of a comprehensive suite of proficiency testing programs is now even more essential in order for NATA to meet its international commitments.

NATA's accreditation of proficiency testing providers

Over recent years, NATA also operated an approvals scheme for other operators of proficiency testing schemes both in Australia and internationally. To date, 16 Australian operators and one foreign operator have been accredited under this scheme. NATA's rationale for operation of such a scheme was to provide an extended base for accessing credible proficiency testing data which could assist NATA in its accreditation decisions while also providing additional credibility for such programs. In 2003, NATA's Board converted this scheme into an accreditation program for external proficiency testing providers. There is no specific government funding for this.

Proficiency Testing Australia (PTA)

The importance of NATA's continuing role as an operator of proficiency testing, while continuing also to accredit external providers, was highlighted in the findings of the APLAC/ILAC re-evaluation of NATA for continuation of NATA's signatory status in the ILAC Arrangement and APLAC MRA. Their report noted NATA's strength in its proficiency testing activities, and its pivotal role in APLAC's regional proficiency testing activities, and that NATA had in place arrangements to reconcile any apparent conflicts of interest in being both a provider of proficiency testing activities and an accreditor of such services. They also noted the probability that any withdrawal of NATA from operation of its proficiency testing activities would lead to operation of only "*commercially viable"* programs in Australia.

Part of the arrangements put in place by NATA to manage this apparent conflict of interest was to have NATA's own proficiency testing activities independently accredited by one of its international counterparts. This was achieved in the latter part of 2004 when A2LA from the USA accredited NATA's proficiency testing service.

During 2005-2006 the NATA Board examined further measures to manage any perceptions of a conflict of interest in NATA's continuing provision of its own proficiency testing activities while also accrediting other providers of proficiency testing.

The new International Standard ISO/IEC 17011 *Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*, makes provision for an accreditation body to continue accrediting conformity assessment activities if it also conducts those activities through a "related body". NATA was expected to comply with ISO/IEC 17011 in full by 1 January 2006. The NATA Board therefore agreed that NATA's existing proficiency testing activities would be undertaken by a new, wholly-owned subsidiary.

Annex K contains a communication from NATA to its members about launching the new PTA subsidiary. It is expected NATA's peers will evaluate NATA's management of this perceived conflict of interest in May 2006 and again in a full APLAC/ILAC peer evaluation in 2007.

The separation of NATA's proficiency testing activities into a subsidiary company is in line with NATA's MoU with the Commonwealth which acknowledges, in Article 3.4, that *"The Commonwealth recognises that NATA needs to enter into complementary business activities to enable it to support the full range of its accreditation activities and to be a primary source of information on laboratory accreditation in Australia*".

In this case, the activity is not new; the novelty is only in the structure through which the activity is delivered.

Capacity building projects in overseas economies

NATA has a long history of providing assistance in capacity building for new and developing accreditation bodies, and in the development of technical infrastructure.

As well as helping the overseas economies, this assistance enhances the recognition of Australia as a leader in laboratory accreditation which, in turn, reinforces the credibility of Australian testing in matters of international trade. It also builds up goodwill and relationships with all of NATA's counterparts overseas that can then form the basis for tackling market access or other issues as they may arise in the future.

Key projects undertaken by NATA since 1990 have covered a variety of clients including national governments in economies in the Asia-Pacific region, the Americas, the Middle East and Africa. These projects, of varied duration, have included:

- A review of the Standards, Quality Assurance, Accreditation and Metrology (SQAM) infrastructure in South Africa;
- Assistance in the establishment and development of national accreditation bodies;
- Ongoing support and assistance to Papua New Guinea Laboratory Accreditation Scheme (PNGLAS), Papua New Guinea;
- A survey of APLAC member needs to assist in their becoming signatories to the APLAC MRA;
- Assistance in identifying metrology needs in a developing economy and in designing mechanisms to meet those needs;
- Provision of 'train the trainer' courses, covering accreditation and related issues, in the Asia-Pacific region;
- Assistance in the establishment of specialist accreditation programs, eg, for medical laboratories and inspection bodies;
- Building proficiency testing and measurement audit capacity;
- Accreditation service for key government medical laboratories and associated training in an APEC economy;
- Promotion of voluntary sector MRAs to APEC regulators; and
- Provision of "attachment" training for staff from developing accreditation bodies.

These activities were carried out with funding from a number of sources including the Australian Government's Grant-in-Aid, the APEC Market Integration Program (MIP) fund, AusAid, the World Bank and the United Nations.

Hosting of national and international delegations

NATA regularly hosts groups of international delegations seeking knowledge of Australia's testing and accreditation capabilities and their support of export and import credibility. Hosting of many of these visits is conducted on behalf of Australian Government departments.

Provision of secretariats for international laboratory accreditation cooperations

NATA is a founding member of both the International Laboratory Accreditation Cooperation (ILAC) and the Asia-Pacific Laboratory Accreditation Cooperation (APLAC).

Prior to 1996, there was no fixed ILAC secretariat. The ILAC member providing the Chair of each ILAC committee provided secretariat support for that committee. NATA provided the Chair for various committees over time and, thus, also provided the secretariat for that committee.

Since 1996, ILAC has had a dedicated secretariat that has been provided by NATA but funded through ILAC membership fees. ILAC has signed a Deed of Agreement with NATA for the provision of the secretariat and has detailed a statement of duties for the secretariat against which NATA staff who provide the secretariat are reviewed annually.

The current agreement with ILAC is to the end of 2006 but it is likely that NATA will be approved to provide the secretariat for at least a further 2 years.

APLAC was formally established in 1995 with the signing of an MoU among accreditation bodies in the APEC region, but considerable work had been done in the years prior to 1995 to achieve the MoU. The APLAC secretariat has existed since 1992 and has always been provided by NATA.

Funding for the secretariat was initially provided by the Australian Government through APEC Market Integration Program (MIP) funding. Since 1998, the secretariat has been funded through APLAC membership fees. APLAC has also signed a Deed of Agreement with NATA for the provision of the secretariat and has also detailed a statement of duties against which the NATA staff who provide the secretariat are reviewed annually. NATA currently provides the secretariat until at least the end of 2008, with the option to seek an extension.

NATA continues to receive compliments from the ILAC and APLAC membership on the professionalism and efficiency of the ILAC and APLAC secretariats.

Membership of national and international standards committees

There are advantages for Australia's national and public interest in having laboratory accreditation authority representation on national and international standards committees, not the least of which is the knowledge and experience that NATA brings to those committees and the fact that the interests of Australia, and the interests of the Australian laboratories, cannot then be ignored.

NATA provides members on more than 70 Standards Australia committees and sub-committees. These committees and sub-committees cover a wide range of disciplines that are of interest to NATA and its accredited facilities (see Annex E for further details)

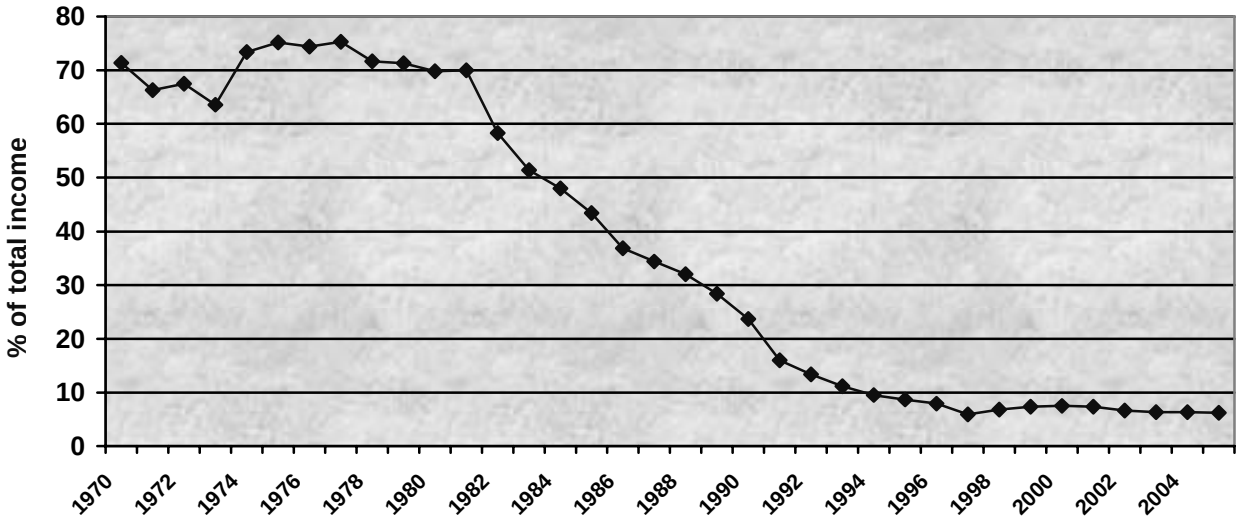
Government Funding

The funding of NATA and its current fee policy was described in Chapter 6.

Government funding over time

Government funding as a proportion of NATA's overall funding has declined dramatically over the past 35 years, as shown in the figure below.

Figure 9



Current Government funding

Currently the Australian Government provide approximately $1.1 million in funding through a formal Grant-in-Aid from the Support for Industry Service Organisations Program, administered by DITR. This equates to approximately six per cent of NATA's total annual funding.

The current funding for NATA's national interest activities is determined each year through a formal submission to DITR. The template used for such funding is the current Memorandum of Understanding between NATA and the Australian Government and the subsets of funding are related to specific activities identified in that MoU. Progress in meeting the objectives and outputs for each subset are reported quarterly and an annual summary report and independent audit of outlays is also provided to the Australian Government. The specific activities funded are formalised in a deed between the Australian Government and NATA (through DITR). NATA has provided the Productivity Commission with its latest submission for funding for 2005-06, which describes in detail the background for seeking funds for each identified activity.

Future issues in terms of funding and fees

The reduction in government funding (as a percentage) has had some impact on NATA's pricing structure for its core activity. The major impact was NATA's need to introduce a fee surcharge for laboratories that are geographically remote from NATA's offices (in five state capitals). The surcharge ranges from five per cent (for facilities within 100-200km) to 20 per cent (for facilities more than 1,500km). The additional quantum of fees raised through these geographical surcharges for 2005-06 was $286,000. Previously, when Government funding was a major component of NATA's income, a uniform fee scale was applied nationally, irrespective of distance from NATA offices.

In terms of this current Productivity Commission Study, the question arises whether it is in the public interest to have no geographical surcharge for laboratories, and whether government funding might assist to provide equal costs for accessibility. This would be commensurate with the founding concept for NATA to provide a truly national network of competent testing and measurement facilities to serve Australia's interests.

NATA also estimates the additional contributions which NATA itself makes for the national interest activities contained each year in the deed between NATA and the Australian Government. Over the past four years NATA's additional contributions have been in the order of:

2004-05	$270,000
2003-04	$460,000
2002-03	$270,000
2001-02	$170,000

In this context it should be noted that the national interest activities currently funded are a subset only of the total public interest activities NATA considers it supports. Some of those additional activities are discussed elsewhere in this submission, including some estimates of their value.

Criteria for continued government funding

PC Issues Paper Question 27 - What criteria should be used for determining when or which of the activities of NATA should be funded by government or alternatively by industry?

NATA submits that Government could fund NATA activities to an amount that is commensurate with the levels of national and public interest inherent in those activities. It is recognised that identifying and calculating this amount with precision is difficult, especially when an activity has direct and secondary benefits to both the public and other interests involved in the activity.

Having considered the market failure material in the economic efficiency and effectiveness chapter in this submission, and material from a number of overseas publications (including *Guidelines for Contracting with Non-Government Organisations for Services Sought by the Crown (2003)* published by the New Zealand Treasury, and work by HM Treasury entitled *Guidance to Funders - Improving funding relationships for voluntary and community organizations (2003))* NATA suggests that the following criteria may be considered when determining an appropriate amount of government funding:

- The extent to which the identified activity has a public or national interest benefit, especially in terms of:
  - Facilitating international trade;
  - Satisfying requirements for public health, safety and environmental protection;
  - Enhancing quality and performance of products, materials and related services;
  - Supporting government's laws, regulations and public purchasing contracts;
  - Provision of proficiency testing to support the national accreditation system; and
  - Provision of the testing, measurement and calibration base for certification systems.
- The extent to which the activity is in response to a perceived or actual market failure, for example:
  - Providing appropriate institutional support to the Australian economy;
  - Provision of appropriate institutional support for general market access for Australia's exports and imports;
  - Ensuring appropriate information and assurance of claims to underpin decision making and transactions;

  - Positive or negative externalities; and
  - The activity fulfils the objectives of society and industry of laboratory accreditation, but in the absence of government funding that activity would not be undertaken by the market.
- The degree of importance the Government places on the activity due to political, international and other commitments;
- The extent to which benefits of the activity are focused toward a specific group of interest or are dispersed across society as a whole;
- Whether the activities have already been agreed to between NATA and Government;
- The extent to which the funding provided meets the requirements and obligations of specific international agreements (eg. WTO Agreements, obligations from multilateral, regional or bilateral trade agreements or mutual recognition arrangements); and
- The immediacy of the need for funding, especially in times of emergency where public safety, security or other national interest interests are at stake, or there are significant synergies in making funding available a short notice.

The appropriate extent and amount of Government funding

PC Issues Paper Question 28 - Should funding be restricted to national interest activities, or also extended to those activities which NATA undertakes to address market failures?

NATA believes Government funding should not be restricted to narrowly defined national interest activities. As noted by the Commission in the Issues Paper, the concepts of national interest and public interest are equivalent. What matters is to whom the benefits of laboratory accreditation accrue.

The beneficiaries of laboratory accreditation are both the public and private interests. The Government could therefore fund NATA activities to levels commensurate with the degree of national and public interest in those activities.

PC Issues Paper Question 29 - Is government funding sufficient to cover the costs of activities undertaken by Standards Australia and NATA on behalf of the Government?

The amount of current Government funding for services provided by NATA in the national interest and public interest does not fully cover the costs to NATA of providing those services. The estimated shortfall in funding over and above the current $1.1 million funding that NATA receives ranges from a further $170,000 to $460,000 per annum. This shortfall is likely to increase in the future as NATA responds to the growing needs of the Australian community.

In response to limited Government funding NATA has had to introduce a geographically-based surcharge in its fee setting which equates approximately to $300,000 per annum.

NATA would like the Government to increase its annual funding to more accurately meet NATA's costs in providing services that provide public and national benefit.

NATA considers it is appropriate for funding to consist of a base annual figure with further funding provided on a project by project basis. Project based funding should be confirmed for the entirety of the project when the project is scheduled to operate over several years.

In terms of future public and national interest funding it would assist NATA's forward planning greatly if the approximate amount of base annual funding was made known in advance for, say, a rolling three year period.

NATA considers that it can increase the amount of benefit to the public and national interests if more Government funding was made available.

Checks and balances in relation to Government funding

PC Issues Paper Question 30 - What checks and balances should be established to ensure these funds are used optimally to cater for the public or the national interest?

NATA considers the existing checks and balances inherent in the current funding process are appropriate (see NATA's response to PC Issues Paper Question 25 in the previous Chapter).

Funding support would presumably continue to be on the basis of predefined objectives and expected outputs, along with estimates for each activity's direct costs and personnel needs. As currently managed, the funding Department would continue to receive quarterly progress reports along with a final annual report and independently audited financial summary of expenditure. The current format of annual deeds between NATA and the Australian Government continue, in NATA's view, to be appropriate for this form of funding.

For the second type of funding (special projects), NATA believes that the following checks and balances are sufficient to ensure optimal use of funds during the three stages of a project: application, implementation and completion.

Prior to project commencement - application

- Clear specification of the need and its relevance to public or national interest.
- Clear description of the expected outcomes and deliverables if work to address the need is funded.
- Clear description of the resources/methods/process proposed to address the need.
- Clear milestones in achieving outcomes – to indicate progress and that funds are being spent appropriately.
- Approval by a government officer with the authority to negotiate and make changes as required.

During project implementation

- Simple reporting mechanism that satisfies the funding body without imposing unnecessary burden on NATA – reporting frequency to be aligned with major milestones rather than on a time eg, quarterly, basis. Report writing to be a funded activity as part of the project.

- Flexibility to withdraw funding if milestones are not achieved, or for NATA to withdraw from the project, if milestones are not achievable or desirable due to changed circumstances. This must be balanced with coverage for financial obligations already entered into.

After completion

- Final report available publicly except where contraindicated by commercial, trade, or other considerations agreed between the funding body and NATA.

10. Future Issues and Challenges

NATA has identified a number of issues and challenges which will affect its work in future years in assisting the government with its public policy goals, regulatory efficiency and deregulation. NATA advises it is always amenable to offer additional services identified by government which fall within NATA's scope of expertise.

PC Issues Paper Question 12 - What changes to current arrangements might improve the effectiveness of the standards and conformance infrastructure?

NATA's commentary below covers the current status of various arrangements and, where needed, changes which might improve the effectiveness of the standards and conformance infrastructure.

Compliance with International Obligations:

Current status

To NATA's knowledge all of the existing bodies in Australia's infrastructure meet their individual international obligations.

In NATA's case:

- NATA is a founding signatory of the ILAC Arrangement for *testing* and *calibration*. NATA must demonstrate compliance *with AS ISO/IEC 17011:2005 – Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies* to maintain such recognition, along with other international criteria set by ILAC. NATA's ongoing compliance is regularly evaluated by multinational teams of its international peers;

- NATA is a founding signatory of the APLAC MRA for *testing* laboratories, *calibration* laboratories and *inspection* bodies. NATA is also an applicant to become one of the founding signatories for the new APLAC MRA for bodies accrediting producers of certified reference materials. NATA's compliance is also regularly evaluated by APLAC.

- NATA's role as the national authority for monitoring compliance with the OECD Principles of Good Laboratory Practice, is also periodically evaluated by multinational teams of OECD compliance monitoring authorities. NATA has continuously met those international expectations.

There are also other Australian and international obligations which NATA's accreditation system supports. As described elsewhere in this submission, the availability of NATA's accreditation program assists Australia's compliance with the World Trade Organisation's Technical Barriers to Trade Agreement, and the Australian Government's obligations under its own mutual recognition agreements with the EU, Singapore and within APEC.

Future opportunities to enhance effectiveness

NATA considers it could provide enhanced assistance to the Australian Government's trade negotiations (WTO TBT, FTA's, etc), if there was additional and programmed briefing of the standards and conformance infrastructure bodies by relevant departments such as DFAT and DITR on emerging priority areas for trade or regulation. This could facilitate better awareness on the part of the infrastructure bodies. This issue also seems to be cyclical in

nature. Throughout much of the 1990s there were constant requests for NATA to have inputs to Australian Government position papers relevant to the TBT issues, including Australian initiatives, and included direct participation by NATA personnel in some Government delegations.

It could also be of value for the standards and conformity infrastructure bodies themselves to provide programmed briefing to relevant Government Departments on emerging international issues and trends in standards and conformity activities. This could include refreshing Governments' awareness of the current levels of international recognition and influence that the Australian bodies have in international fora. Government agencies such as Austrade and AusAID might also benefit from such regular awareness initiatives.

Interaction and Collaboration of the Infrastructure Elements

Current status

There are various types of formal and informal interaction between the elements of the infrastructure. For both NATA and Standards Australia, the organisations' Councils have formal representations by two of the other bodies (JAS-ANZ and NMI).

There are also annual working meetings of the Chief Executives of the bodies to identify issues of common or complementary interest.

Additionally, both NMI and NATA have multiple representations on Standards Australia Committees and Subcommittees.

NMI is also comprehensively involved in NATA's accreditation process at a technical level. Officers of the NMI, for example, are currently represented on seven of NATA's 18 Accreditation Advisory Committees and they Chair four of those committees. They also provide many technical assessors across a broad range of the fields in which NATA operates.

To NATA's knowledge there is only one area of overlap between the bodies: both NATA and JAS-ANZ are recognised by the Australian Government as peak bodies for accreditation of inspection bodies.

There is also considerable liaison with Australian Government departments and agencies. NATA's work increasingly impacts upon trade as the arrangements it enters into with other economies for mutual recognition of accreditation programs take on increasing prominence. Australian exporters are advantaged by these arrangements providing them with a competitive edge when exporting materials, goods and services based on testing data from accredited facilities. As outlined, elsewhere, NATA is a signatory to two major international multi-lateral recognition arrangements administered by ILAC and APLAC. These arrangements encompass more than 40 economies including all of Australia's significant trading partners. This involves interaction and collaboration with DITR and DFAT.

Additionally, much of NATA's relationship with Government is predicated upon the MoU. The scope of NATA's activities with the Australian Government currently covers, for example, the Attorney General's Department, Australian Pesticides and Veterinary Medicines Authority, the Australian Quarantine and Inspection Agency, the Australian Building Codes Board, the Australian Communications and Media Authority, the Australian Customs Service, the Department of Environment and Heritage, the Department of Transport and Regional Services, Medicare Australia, the National Appliance and Equipment Energy Efficiency Committee, the National Environment Protection Council, and the National Residue Survey.

Future opportunities to enhance effectiveness

Due to the largely complementary nature of the interactions between the standards and conformance infrastructure, NATA believes the elements do currently work effectively and allow their concentration on the key skills and supportive networks the individual bodies need to perform their roles.

The only grey area relates to the dual Government recognition of NATA and JAS-ANZ as peak bodies for inspection body accreditations. This is a theoretical issue while NATA is the only body currently actively involved, but there could be some national disadvantages should the activity be viewed as a competitive market. There is already unwillingness in Europe, for example, to recognise more than one national accreditor in each country under the Mutual Recognition Agreements of the European Cooperation for Accreditation (EA).

Additionally, under a competitive model for inspection body accreditation, there is a high risk that the currently voluntary technical assessors and specialist Accreditation Advisory Committee members would not be available to multiple providers. This would ultimately lead to considerably higher costs for this service, and might also seriously undermine the voluntary component of the laboratory accreditation program. Clearly, this could be an issue of sensitivity for JAS-ANZ, and NATA would be keen to ensure that negotiation of this issue did not impede the good working relationship it enjoys with JAS-ANZ.

In relation to international arrangements, NATA would benefit from regular briefings by DFAT, DITR and other relevant agencies so that it can best focus its international efforts in areas deemed to be of current priority for the Australian Government. This may be particularly relevant in the context of WTO and trade agreement discussions and in the context of good regulatory practice.

In relation to liaison and collaboration with Australian Government departments and agencies on a domestic level, NATA believes that the MoU's objectives could be achieved more efficiently if Government were to take steps to ensure that all levels of government were aware of the MoU and its purposes. Resources and authority should be provided to the DITR in order for them, with the assistance of NATA, to educate and influence other departments and agencies to understand and specify testing and services from accredited facilities. Furthermore, it may be appropriate to include consideration of accredited conformity assessment as a cost-effective implementation tool when preparing regulatory impact statements for the Office of Regulation Review.

Governance and Process

Current status

NATA's governance structure has changed in line with the changing environment and allows for inputs from various stakeholders, including Governments and NATA's international peers.

NATA has given corporate governance a high priority in its own management structure, with one of the senior organisational positions being Manager, Corporate Governance. This role includes constant review of NATA's Constitution and Regulations to ensure the organisation meets current community expectations and best governance practices.

The dynamic nature of NATA's governance is reflected in the periodic changes to its own Constitution since the Kean Inquiry. The Constitution underwent major changes following the separation of NATA's quality systems certification activity into a separately-named and managed subsidiary.

Other changes have been influenced by the results of other Government reviews, most recently by the Australian Government Department of Health and Ageing's 2002 Evaluation of the Australian Pathology Laboratory Accreditation Arrangements. This led to a streamlining of the appeals process embodied in NATA's Constitution.

NATA's governance is also highly sensitive to perceived or potential conflicts of interest. NATA has checks and balances in its formal governance and its operating practices to ensure it can act objectively and impartially.

NATA has also acted to address conflicts in its own practices as they arise. The most recent significant example of this was NATA's separation of its proficiency testing activities into a new subsidiary, Proficiency Testing Australia.

The objectives of NATA's constitution are not membership-benefit based, but community-interest based. Moreover, the peak of NATA's governance derives from its Council which contains a balance of community interests, including the governments, consumers and professional bodies, many of which are end-users of accredited facilities rather than being clients for accreditation. Accredited facilities themselves have a direct interest in NATA maintaining an objective and impartial system to ensure that the integrity of the total system is not brought into disrepute and the value of their own accreditation status is not undermined or under-valued.

Future opportunities to enhance effectiveness

NATA considers its existing governance and management of potential conflicts of interest will continue to be effective in the future.

Consultation with and Accountability to Stakeholders

Current status

NATA has a broad spectrum of stakeholders, including:

- The Governments in Australia
- Accredited facilities
- Voluntary experts (NATA's assessors and committees)
- International peers
- End users (including the public at large)
- Industry
- Professional bodies

Consultation with, and accountability to, stakeholders take various forms.

As a continuing source of consultation, NATA has available to it the NATA Council. The Council's composition is meant to reflect appropriate representation of the various stakeholder groups, covering all of the above-listed sectors, except NATA's international peers. NATA is also accountable to that Council, including the NATA Board, which itself is elected from the Council. At its peak the NATA Chair is subject to re-election each year, and the Council is kept fully informed of the Board's activities throughout the year. Each year the Chairs of NATA's 18 Accreditation Advisory Committees are invited to participate in the

Council's meeting, so there is a full appreciation of administration, policy and technical issues amongst all the stakeholders' representatives.

NATA also has periodic meetings at 18 month intervals of NATA-accredited facilities and voluntary NATA assessors in most State and Territory capitals. These provide an open forum for both consultation with NATA's direct clients and its panel of voluntary experts, and also provide an opportunity for NATA to keep them informed of emerging issues.

For consultation with NATA's international MRA partners, NATA is involved in a broad range of the policy, technical and communications committees of ILAC and APLAC, and is represented also on appropriate ISO Committees. NATA also chairs the OECD Good Laboratory Practice Working Group and is a participant in the evaluations of the competence of other economies' OECD GLP compliance monitoring authorities.

NATA is also accountable to its international peers, in that it is subject to periodic re-evaluation of its compliance with the criteria for maintenance of signatory status of the ILAC Arrangement and APLAC MRA and as a compliant body under the OECD's Mutual Acceptance of Data Protocol.

Future opportunities to enhance effectiveness

NATA's Board recently agreed to a review of the representations on NATA's Council, to ensure that all stakeholders (such as the professional bodies represented on Council) are appropriate for the range of activities NATA now undertakes.

Additionally, NATA management has started one-on-one consultation with appropriate stakeholders on NATA Council. The first phase of that consultation was initiated in November 2005 for the elected representatives of accredited facilities on NATA's Council.

Transparency and Responsiveness of Processes

Current status

All of NATA's criteria for accreditation and its mode of conduct of accreditation are fully transparent and publicly available. NATA's ability to respond to accreditation needs is partly dependent on the availability of information from client facilities, and identification and availability of appropriate technical expertise to conduct assessments of competence, and the ability to match that expertise to specific clients' needs. Geography may also play a role in terms of responsiveness. Many of NATA's accredited facilities are remote from NATA offices (in five state capitals) and from convenient forms of transport. Nevertheless NATA attempts to respond within appropriate time frames (as detailed in a Charter of Service) and in as cost effective a way as possible for transport and related costs.

Future opportunities to enhance effectiveness

NATA is currently reviewing its mode and frequency of on-site assessments. This should lead to some opportunities for enhanced responsiveness. Additionally, NATA is in the process of merging five measurement fields to provide better service to facilities which are multi-disciplinary in nature.

Use and Availability of Technical Expertise

Current status

NATA has access to some 3,000 external technical experts, in addition to its own technical staff. NATA relies on access to this technical expertise at all levels of its operations.

Technical expertise is required at Board level in order to understand and direct the affairs of the Association. NATA is fortunate in having Australia's Chief Metrologist, Dr Barry Inglis, as its Board Chair. Dr Inglis is also the Chief Executive of the National Measurement Institute (NMI). Like NATA, NMI is one of the key groups in Australia's technical and conformance infrastructure.

NATA has technical as well as other expertise available on its Council. Technical organisations represented on the NATA Council include the Australian Institute of Physics; the Commonwealth Scientific and Industrial Research Organisation (CSIRO); the National Measurement Institute (NMI); The Institution of Engineers, Australia; The Royal Australian Chemical Institute; the Royal Australian and New Zealand College of Radiologists (RANZCR); and the Royal College of Pathologists of Australasia (RCPA).

NATA operates 18 Accreditation Advisory Committees and eight technical groups. All contain technical experts in their fields.

Every assessment undertaken by NATA requires access to technical expertise. This is provided firstly by NATA's Lead Assessors (NATA staff), most of whom are graduates from technical disciplines aligned with the fields in which they accredit.

These Lead Assessors are supported by volunteer technical assessors drawn from public and private testing facilities, research organisations and academia.

Reference has been made above to the voluntary nature of the activities of peer technical assessors. That is, they are generally not paid for their work for NATA though the cost of all transport, accommodation and meals for these technical assessors is met by NATA.

In 2002, assessors were asked, in independent market research conducted on behalf of NATA, whether they believed they should be paid for their efforts as technical assessors. About 60 per cent of assessors interviewed said NATA should not pay technical assessors.

Technical assessors are motivated by the value they provide to an assessment, the opportunity to meet professional colleagues working in similar technical areas, to discuss common areas of interest, and to share their expertise for the betterment of testing operations.

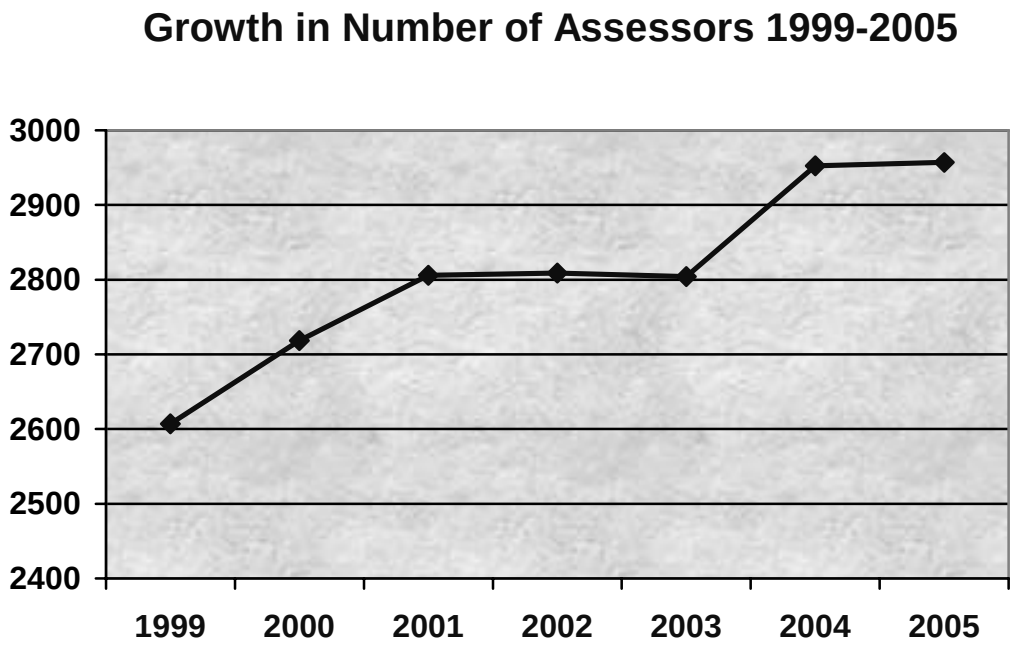
Mindful of this valuable, volunteer service, NATA is continuously seeking mechanisms to minimise the disruption caused to technical assessors' normal routines. There is a limit to this however, as NATA believes that technical assessors must be present at all assessments during which the technical competence of testing facilities is being assessed.

Concern about the reduced availability of technical expertise has been expressed in many technical fora, and by professional associations such as the Royal Australian Chemical Institute and the Institution of Engineers, Australia. From time to time, NATA has also faced difficulty in attracting sufficient technical expertise in esoteric areas of science. However, this has not yet become an endemic problem where assessments have had to be cancelled due to a lack of technical assessors. On some occasions assessors have been drawn from overseas but at present nearly all the necessary resources are available in Australia.

NATA technical assessors are required to be more than technical experts: they must also demonstrate auditing skills and people handling skills. NATA conducts Assessor Development Courses across Australia. These are free to assessors and are designed to assist them in honing their skills in these areas.

The availability of technical expertise (or its convenient availability) does vary. However, the assessor pool has grown over recent years as shown in the chart below.

Figure 10



Future opportunities to enhance effectiveness

NATA believes that the current arrangements for attracting, training and retaining technical experts in the scientific disciplines and in the roles required are effective in maintaining the cadre of technical experts required for NATA's operations.

Review and Continual Improvement of Processes and Services

Current status

NATA has a number of mechanisms for review and continual improvement. One such mechanism is NATA's own quality management system which includes comprehensive internal audit and periodic management review components. NATA's highly developed complaint handling system is also a source of identification of improvement needs or opportunities. Consideration of such complaints is also one element of senior management review of NATA's processes, policies and service delivery.

NATA conducts triennial, independent market research of accredited facilities' satisfaction with NATA's services. The results are fed into NATA's strategic planning and development initiatives.

A third mechanism is the opportunities for improvement that are identified during NATA's evaluation by its international peers, as part of NATA's maintenance of signatory status in the ILAC Arrangement and APLAC MRA.

Fourthly, the meetings of the NATA Council and Board also provide a significant opportunity for input and comment on NATA's processes and services from the stakeholders.

Future opportunities to enhance effectiveness

Each of the mechanisms described above provide appropriate and ongoing opportunities for review and improvement of NATA's processes and services.

Appropriateness and Quality of Accreditation

Current status

The acceptance and demand for laboratory accreditation are both very strong in Australia.

Measures of this include the fact that NATA has been asked regularly to address new areas of accreditation for laboratories as new community needs arise. Of the 18 fields of accreditation in which NATA now operates, six of those fields have been introduced in the past 15 years.

Establishing new accreditation programs is a complex task. An Accreditation Advisory Committee must be established, technical documents prepared, and volunteer assessors identified. The process typically takes at least six months to one year to establish.

Apart from accreditation in the pharmaceutical, cosmetics, and related sectors, which are covered separately by the regulatory inspections of the Therapeutic Goods Administration (TGA), NATA is not aware of any significant gaps in the scope of accreditation available to Australian laboratories. One emerging area of interest, however, is accreditation of research laboratories, and NATA has developed new criteria and approaches to address that potential need. A pilot program has recently been completed and the first accreditation granted.

Another measure of the demand for NATA's accreditation services is the fact that NATA is still the largest comprehensive laboratory accreditation body internationally.

The current distribution of accredited facilities is shown in the accompanying table. There is also continuing, strong demand for the service with an additional 195 applicants currently being processed.

Field	Total*
Acoustics and Vibration Measurement	22
Biological Testing	157
Chemical Testing	469
Construction Materials Testing	590
Electrical Testing	112
Forensic Science	72
Good Laboratory Practice^	24
Heat and Temperature Measurement	42
Information Technology	9
Inspection	88
Mechanical Testing	330
Medical Testing	564
Medical Imaging	9
Non-destructive Testing	111
Optics and Radiometry	18
Physical and Dimensional Metrology	130
Proficiency Testing Scheme Providers	17
Reference Material Producers	9
Veterinary Testing	27
Total	**2,800**

^ This field is not considered an 'accreditation' field, rather it is a compliance recognition program
* *totals as at 24/3/06*

Future opportunities to enhance effectiveness

NATA's forward planning on the issue of new accreditation fields would be greatly enhanced if there was some mechanism whereby Government could alert NATA well in advance of the potential need for a new accreditation field, and recognise that such programs may take many months to implement.

NATA is investigating new approaches to administration of accreditation across multiple disciplines and multiple sites. These initiatives may actually reduce the raw numbers of accreditations by combining existing accreditations, but should provide operational and administrative benefits for both the organisations affected and NATA. These initiatives are also leading to some reductions in fees for the affected facilities.

Accessibility – Cost of Accreditation Services

Current status

The costs of accreditation services potentially have two dimensions. The first is the direct costs (fees) for accreditation. The second dimension is the costs of meeting accreditation criteria.

In relation to the first dimension NATA maintains some cross-funding of the cost of accrediting facilities in remote locations to make the costs of accreditation programs as equitable as possible. However, a geographically-based surcharge on accreditation fees has been unavoidable.

The second dimension has two components. The first is the investment in staff, equipment, testing environment, quality assurance, calibration, and supporting management systems. NATA's view is that this component is not a cost of accreditation – it is the internationally agreed set of resources that laboratories should maintain, irrespective of accreditation. The other component is the time spent by laboratory staff in communicating with the accreditation body and their on-site time in hosting NATA assessment teams and performing in specified proficiency testing programs.

The international report attached to this submission (Annex H) contains a table of the different fee elements of a number of NATA's counterpart bodies abroad.

Future opportunities to enhance effectiveness

NATA believes a more equitable approach would be a return to the previous situation where the Government's national interest funding met the cost differential between performing city and remote location accreditation assessments.

NATA has embarked on a number of changes to its administration of accreditation, including the forthcoming merger of five measurement fields and the growing number of corporate accreditations in the NATA system. The latter accreditations receive a five per cent discount and some fee reductions are expected also for laboratories affected by the merger.

Additionally, NATA recently negotiated with representatives of the insurance industry to provide an opportunity for accredited laboratories to receive favourable pricing treatment due to the reduced risk they should provide. This has already provided some major cost-savings to laboratories pursuing this opportunity. One laboratory has reported that its saving in annual insurance costs is more than double its NATA accreditation fee. Another accredited laboratory recently advised that its annual insurance costs had been reduced from $115,000 to around $78,000.

Annex A - Cross reference table of Productivity Commission Questions in the Issues Paper and NATA's Response

No.	Question	Page
Future Challenges [p7]		
1	Has export activity and access to imports been sufficiently supported by Australia's current standards and conformance infrastructure? If not, what reforms are required to facilitate trading opportunities?	25
2	Do the current standard setting and accreditation arrangements and processes best serve Australia's public interest and are they appropriate to meet future domestic and international challenges including the increasing globalisation of markets?	*No response provided*
3	In what ways do the standards and conformance infrastructure reduce and/or impose transactions costs on businesses and consumers?	40
4	Is there sufficient national uniformity in standard setting and accreditation processes?	20
5	What impacts do current arrangements have on: • competition, innovation and international trade; • the quality, safety and performance of products, materials and related services; and • public health, safety and environmental protection?	21
6	How much progress has been made internationally with mutual recognition of standards and of conformance assessment across countries?	33
Four specific areas for Analysis [p8] The efficiency and effectiveness of standards setting and laboratory accreditation services in Australia [p9] Efficiency [p9]		
7	Participants may wish to nominate what they currently consider to be society's and industries' objectives for standards setting and laboratory accreditation services. Should these objectives be changed?	37
8	Is the current mix of public and private involvement in standard setting and laboratory accreditation efficient?	54
9	Are there market failures or weaknesses in standard setting and laboratory accreditation services that justify government involvement?	68
Effectiveness [p10]		
10	Are existing objectives being met? Are they being met cost effectively and are the best methods being used?	55
11	Participants are invited to comment on the role played by relevant bodies, in particular Standards Australia and NATA, in delivering services and meeting these objectives.	55

No.	Question	Page
12	What changes to current arrangements might improve the effectiveness of the standards and conformance infrastructure? Participants may wish to group their comments around the following considerations: • Compliance with international obligations • Interaction and collaboration with other elements of the standards and conformance infrastructure • Governance and process • governance structures; • conflicts of interest; • consultation with and accountability to stakeholders; • transparency and responsiveness of processes; • use and availability of technical expertise; • review and continual improvement of processes and services. • Appropriateness and quality of standards and accreditation • acceptance/demand for standards and laboratory accreditation • Accessibility • cost of access to voluntary and mandatory standards; • cost of accreditation services; • effectiveness of communication; • interdependence of standards (ie not all the essential information is contained in a single referenced document)?	105
13	Participants may wish to comment on whether the concerns about standards processes noted above also apply in other sectors. How much do practices and effectiveness vary between committees and sectors? How do other standard-writing bodies or processes compare?	*No response provided*
The appropriate role of the Australian Government [p12]		
14	What is the appropriate role of the Australian Government within current standard setting and accreditation processes?	70
15	What difference would it make if the Government had no influence on the work of Standards Australia and NATA?	73
16	Should any of the current functions of standard setting and laboratory accreditation bodies be performed directly by government or solely by the private market?	75
Appropriate terms for Memoranda of Understanding (MoU) between the Australian Government and Standards Australia and NATA [p12]		
17	Are the current terms of the MoUs, with the Australian Government and its agencies, including the objectives and the undertakings of the parties, appropriate?	89
18	How well have the parties performed in meeting their responsibilities and specific undertakings under the MoUs?	77
19	Is 'national interest' well and/or appropriately defined? Are standard setting and accreditation services sufficiently independent of business interests to adequately take into account the national interest and more generally the public interest?	85
20	Are the current arrangements between the Australian Government, Standards Australia and NATA in relation to representation at international fora effective in facilitating Australia's international competitiveness?	80
21	Does Standards Australia undertake, document and distribute the assessments (risk and cost benefit analysis) required by the MoU where appropriate? At what point in standards development should a Regulation Impact Statement be prepared if they are going to be referenced in regulation? What role should Standards Australia play?	*No response provided*
22	Should regulatory bodies be able to make greater use of non-NATA accredited laboratories?	73
23	Is it appropriate that Standards Australia and NATA are accorded recognition as 'peak' bodies within the Memoranda of Understanding that each organisation has with the Australian Government? Is the public interest best served by this special recognition?	82
24	What would be the consequences if government removed the special peak status of Standards Australia and NATA?	87

No.	Question	Page
25	To what extent do the current checks and balances provided to the Australian Government in relation to the activities of Standards Australia and NATA produce an appropriate balance between the national interest and the need for these organisations to have some degree of operational autonomy?	83
26	Are there additional matters currently not addressed that should be included in the MoUs or are there some currently included that are inappropriate?	89
Appropriate means of funding the activities of Standards Australia and NATA which are deemed to be in the national interest [p16]		
27	What criteria should be used for determining when or which of the activities of Standards Australia and NATA should be funded by government or alternatively by industry?	102
28	Should government funding be restricted to national interest activities in international fora? Should other public interest activities, such as writing standards to enable market failures to be regulated, also be funded?	103
29	Is government funding sufficient to cover the costs of activities undertaken by Standards Australia and NATA on behalf of the Government?	103
30	What checks and balances should be established to ensure these funds are used optimally to cater for the public or the national interest?	104
31	Do Standards Australia and/or NATA price their services so that cross subsidisation is occurring? Is this appropriate?	53
32	Could other public or private bodies undertake such national interest activities? If so, should the government tender for the activities?	47
Additional issues [p17] History of the relationship between the Australian Government, Standards Australia and NATA [p18]		
33	What have been significant impacts of major changes in the relationship between the Australian Government and Standards Australia and/or NATA across time, particularly since the Kean Report in 1995?	84
34	How are the current operations and future development of these organisations influenced, and potentially constrained, by the past relationship with the Australian Government?	*No response provided*
35	Are there other reviews of the Australian standards and accreditation systems that are relevant to the conduct of the present study?	22
36	To what extent have the recommendations of the past reviews listed above, and any other relevant reviews, been implemented? To what extent has the implementation of these recommendations resulted in improvements in the structure and processes for standards development and accreditation?	23-24
Costs and benefits [p19]		
37	Should voluntary standards be seen as industry self-regulation and beyond the interest of governments? Should there be criteria to determine when a voluntary standard should be developed or should this be solely a matter for the private sector? Is there a need for more rigorous cost benefit analysis prior to the development of standards — mandatory and/or voluntary? If so, how should this be facilitated?	*No response provided*
38	Does 'self-regulation' by NATA create conflicts of interest? Does this jeopardise the pursuit of the public interest?	42
39	Is the current adoption of standards developed by Standards Australia in regulation appropriate? Does the use of these standards place any special pressure on the standards development process? If so, should this be the case?	*No response provided*
40	Do the incentives provided by the current system lead to too many or too few standards being developed?	*No response provided*
41	Is the current general practice of specifying NATA as the only recognised body for conducting accreditation appropriate?	83
42	Do any current Australian voluntary or mandatory standards act as trade barriers?	*No response provided*
43	Do current accreditation arrangements and practices create barriers to trade?	32
Overseas models [p20]		
44	How do other countries manage the relationship between government and standard setting and accreditation? Which models used in other countries would provide useful lessons — both those to be adopted and pitfalls to avoid — for this review?	150

Annex B - The History of the National Association of Testing Authorities, Australia

Beginnings in national development and security

NATA was born of necessity in the Second World War when Australia was cut off from any means of ensuring the munitions it was manufacturing were of the standard demanded by modern weapons. The notion of ensuring testing standards were themselves subject to examination was then a novel one - NATA was a unique organisation. Today, the pioneering work of NATA has led to similar organisations being set up in all the world's major economies. And yet, despite being the oldest such organisation in the world, NATA very much remains on the leading edge in terms of efficiency, responsiveness and innovation.

For almost 60 years the NATA has promoted the use of competent testing, measurement and calibration for the benefit of Australian industry, government and community. The changing needs of these sectors have had a major influence on NATA's development, yet NATA's primary mission has remained unchallenged.

NATA is internationally recognised and respected for its role as a world leader in laboratory accreditation, as well as its continuing contribution to testing, measurement and accreditation practices world-wide. But how did it evolve into the dynamic organisation it is today?

The history and development of NATA reflects Australia's growing shift from an agrarian to an industrialised economy last century.

Before the Second World War, Australia's economic focus was on agriculture. Yet even then, during the 1930s, the Australian government was beginning to consider the implications and requirements of developing a strong secondary industry.

During the 30s, the Federal Government set up a committee to advise it on issues related to testing and research in secondary industry. The committee's report highlighted the lack of sound technical and scientific infrastructure in Australia - crucial to supporting serious industrial development. It made recommendations which essentially outlined the structure for a national testing, measurement and calibration system.

These recommendations led to the creation of the National Measurement Laboratory and NATA. However, prior to the Second World War, the envisaged system was based around the use of government and university operated laboratories.

The idea was transformed into a laboratory approval scheme during the Second World War by government laboratories' inability to meet Australia's war effort demands.

The 'Approved Wartime Test House Scheme' as it was known, laid the foundations for accepting the testing conducted in non-government laboratories based on a demonstration of their testing competence. The scheme was widely regarded as a success at the end of the war, and showed that testing competence is determined by technical factors rather than by ownership.

From those successes the possibility emerged of a similar program providing accreditation for industrial and commercial laboratories, as well as those operated by the government in a peace-time environment.

1947: the creation of NATA

In late 1945 a conference on the coordination of testing services was attended by representatives of all State and Federal governments. The conference led to the formation of the National Association of Testing Authorities a little more than a year later. The new association was to provide a national testing service to Australia and would span across all technical, industrial and geographical areas of the country.

Not only was such a scheme a world first but its means of operation – relying on a vast pool of volunteers who would provide a 'peer-review' basis of accreditation – remains to this day a pivotal facet of the NATA structure.

NATA has always maintained that these unsung volunteers - voluntary technical experts who assess the testing competence of facilities on behalf of NATA – are the underlying reason for NATA's reputation.

This approach, combined with the use of technical advisory committees and industry-derived evaluation criteria, helped ensure the future success and continued relevance of NATA in the years ahead.

Following the creation of an advisory council, executive committee and various state and registration advisory committees during 1947, NATA set about deciding on the basis by which laboratories were accepted as members of the new association.

This was no easy task. There were no other models from laboratory accreditation systems anywhere else in the world at the time: NATA was working this out from scratch, so principles as well as practices needed to be established. Eventually, procedures for assessing laboratory compliance with those criteria were developed and trialed on selected laboratories operated by the Defence Department.

The success of these trials allayed the early concerns of the Registration Advisory Committees. Those concerns had to some extent slowed the implementation of the accreditation programs. In fact, the initial slow progress of the committees caused considerable dissatisfaction and loss of support form various professional and industrial groups.

This was probably the most vulnerable period for NATA, as its future depended very much on the interest in and acceptance of its role as a broadly based accreditation system. Fortunately, support outweighed dissension and NATA gained the acceptance necessary to pursue its objectives.

Within the next five years more than 60 laboratories had been registered in one or more of the eight fields of testing then available. These fields very much reflected the focus of government and industry in the immediate post-war period. Of course, since then NATA has substantially expanded and modified its fields of testing to suit changing demands. The initial emphasis was on testing associated with engineering disciplines with somewhat lesser importance given to the physical, chemical and biological sciences. This pattern of NATA services reflecting the demands of the time is evident right up to the present. And is probably one of the key elements in the success of laboratory accreditation in this country.

1950-1960s: Growing acceptance

During the 1950s NATA's Council expanded to include representation from key industry and professional bodies including the Royal Australian Chemical Institute, the Institute of Physics and the Institution of Engineers Australia. Most importantly, previously severed links with the Associated Chamber of Manufactures Australia (ACMA) were restored, and several ACMA

representatives were appointed to Council. By 1957, the Council membership had stabilised and the decision was taken to incorporate NATA.

Incorporation provided a sense of formality to the organisation, which by this time had grown to a membership of more than 200 laboratories with another hundred applications seeking registration. By the mid 1960s, this membership had more than doubled: NATA had registered laboratories in nine fields of testing (the newest field being Acoustic and Vibration Measurement, established in 1963).

During this time, the main demand for accreditation was from laboratories engaged in either chemical or mechanical testing. By 1967, three quarters of all registered facilities were testing in either of these areas. And by 1970 about one third of all chemical and mechanical laboratories in Australia held NATA registration. In other fields, with the exception of Biological and Electrical Testing, the number of accredited laboratories was about 75 per cent of all Australian laboratories operating in these fields.

1970s: A time for consolidation

Celebrating 25 years of service in 1972, NATA noted it had received 1234 applications and had granted 1000 registrations. Of these, about 700 registrations were granted to laboratories operating in industry. Government owned laboratories accounted for another 200 registrations and tertiary institutions represented a further 70 registrations.

This contrasted markedly to the early 1950s when the majority of registrations were held by government sector laboratories. During this same period, the introduction of annual membership fees saw NATA start to take financial responsibility for its future, with government funding dropping from 100 per cent of NATA income, to about 70 per cent by 1972. The figure now stands at little more than six per cent.

The 1970s was not so much a period of bold new directions for NATA, but an opportunity to consolidate and build upon its achievements to date. Nonetheless, the 70s were a particularly significant era for NATA in that several emerging opportunities would stimulate the foundations for future programs and endeavours. The medical program, the proficiency testing scheme, the development of NATA's training resources as well as NATA's international role during the following decade can all trace their roots back to this period.

The 70s began with a complete review of NATA's Rules in an effort to enhance efficiency, facilitate its future development and improve contact with its members. The revision was completed, with some difficulty due to the complexity of Company law, by mid 1974. NATA also organised a series of symposia and seminars on laboratory management and related topics throughout Australia, which proved not only to be very popular, but a means of disseminating NATA's philosophies and building relationships with its members.

The topics for seminars were later expanded during the mid 70s but their presentation was never formalised in the style of training courses offered today.

In 1972 – some 26 years after NATA's birth, Telarc was established in New Zealand as only the second national laboratory accreditation system in the world. Denmark was the next country to establish a national scheme in 1973. Very soon after this, other countries seriously started to look at establishing their own national accreditation systems. NATA began to receive inquiries and visitors for several national measurement bodies from the United States and Europe, who were keen to understand the role and operation of NATA in Australia. This interest continued to grow throughout the mid 1970s and eventually led to the first International Laboratory Accreditation Conference (ILAC) held in Copenhagen in 1977.

The Australian Government also had an increasing interest in NATA during the 70s. NATA representatives were invited to Canberra on a number of occasions to present the concept and objectives of NATA to politicians, senior public servants and business groups. The State and Federal governments showed their support, both directly by insisting on NATA endorsed reports for certain activities, and indirectly through legislation in areas such as air quality, water resources, industrial noise and motor vehicle safety.

Following the Birch report in 1977, the Australian Government changed its relationship with NATA and the CSIRO so that NATA would communicate directly with the government through the then Department of Science rather than via the CSIRO. This ended an arrangement that had existed since NATA's creation 30 years before, although the relationship in technical areas continued to flourish.

Another government initiative that called on NATA's expertise was the establishment of a working party by the Department of Health in 1974 to examine the accreditation of pathology facilities throughout Australia. NATA offered its services to the Department of act as the accreditation agency for this program. However, the Department of Health baulked at the proposal: it was another eight years until the Royal College of Pathologists of Australasia (RCPA) took up the proposal.

This period also saw interest and support develop for NATA from particular industrial sectors such as the food industry, which eventually translated into the registration of many laboratories in these sectors. At different times, surges of registrations occurred in areas such as pollution control, motor vehicle testing, clean room and air balancing and mineral resources exploration and mining.

During this decade initiatives were taken by NATA to improve communications with its members. Notably, several publications for members were born or came of age including *NATA News*, the *Annual Directory* and the publication of the first *Technical Notes*. These publications were designed to improve member awareness about technical issues and the Association's affairs, and to increase community awareness about NATA registered laboratories.

In 1976 this approach was further expanded when NATA started using advertising in trade and professional publications to promote its members.

Towards the end of the decade, NATA began to sponsor and organise inter-laboratory testing programs as an additional quality assurance tool in its surveillance program. This would be formalised in the early 1980s as NATA's proficiency testing scheme, which was to become one of the great strengths of NATA's accreditation system.

At the end of the 70s, NATA significantly restructured its Registration Advisory Committees. This review also saw the emergence of the first technical groups, created to provide specialist advice of particular technical issues.

As the decade closed the world's major trading nations were seriously considering how to overcome impediments to trade. In this climate, an international forum was convened in 1977 to examine trade barriers related to testing.

1980s: The international horizon emerges

The International Laboratory Accreditation Conference (ILAC) brought together laboratory accreditation bodies and other interested parties from around the world to contribute their ideas and support for the forum.

In 1979, the third ILAC conference was hosted in Australia by NATA, at what was a critical time in the development of international cooperation. In the decade that followed, NATA was to become one of the world's leading contributors to the development of an international community of national accreditation organisations. This involvement in ILAC was reinforced by the establishment of a series of bilateral mutual recognition agreements with national bodies in Australia's overseas markets.

The first agreement was with New Zealand (Telarc) on 1981, followed by the USA (NVLAP) in 1983, the UK (NAMAS) in 1986 and Hong Kong (HOKLAS) in 1989. Agreements were later established with A2LA in the United States as well as several European accreditation bodies and regional cooperations. These agreements were central to the acceptance of Australian test results overseas, and were further supported throughout the 1980s by NATA consultancies to assist the development of national accreditation systems in Papua New Guinea, Hong Kong, Brazil and other economies.

NATA training courses were also conducted in many Asian and European countries as well as in the USA during this period. Training of overseas personnel was also conducted by NATA in Australia.

Before 1980 there were only a handful of national accreditation bodies worldwide. By 1984 seventeen such organisations had been established, and 21 by 1987, many with NATA assistance. NATA also began accrediting several overseas laboratories, who sought NATA registration for trade or other reasons. The first of these laboratories was in Singapore, which achieved registration in 1988.

On the home front, Australia was focussing on the development of its rich resource base. In the early 1980s there was a surge in the registration of laboratories involved in the mineral resources area. Many of these laboratories were located in remote regions, and NATA had to work out new procedures to deal with these remote registrations. Both financially and functionally, the accreditation of these facilities presented problems due to their location and modes of operation.

The early 1980 also saw the formalisation of NATA's proficiency testing scheme, created to supplement its accreditation program. Launched in 1981, the scheme soon expanded to offer programs across almost the full spectrum of testing and measurement activities.

Proficiency testing played an important role in two key health areas during the 1980s – pesticide residues in meat (organised in conjunction with the Australian Government Analytical Laboratories and the Australian Quarantine and Inspection Service) and the estimation of airborne asbestos dust (in conjunction with Worksafe Australia).

These collaborations between NATA and government authorities helped strengthen NATA's ties with the Australian Government. Those ties were further strengthened during the decade with the outcomes of two key Government inquiries into testing practices, standards and accreditation in Australia.

The first inquiry was conducted under the chairmanship of Professor IG Ross in 1983 and examined the role of Australian Government laboratories. Ten of its recommendations related to NATA and four key recommendations pertaining to the Association were accepted by the Australian Government in 1986. These recommendations specified the NATA registration of Australian Government laboratories, as well as non-government laboratories seeking to do business with the Australian Government. The recommendations also specified that NATA endorsed reports be used as the basis for certification of goods to Australian Standards, and that the Australian Government's grant to NATA should be maintained.

In 1986, the committee of review of standards, accreditation and quality control and assurance was established under the chairmanship of Dr KJ Foley. The report from this committee presented to the government the following year, recognised the significant contribution made by NATA to laboratory accreditation in Australia, and the wider impact of NATA's achievement in terms of the national good.

The eventual outcome of this report was the establishment of a Memorandum of Understanding with the Commonwealth in 1988, which formally recognised NATA as Australia's national provider of laboratory accreditation services.

Two significant programs were launched during the 1980s in response to approaches from the medical community and the wool industry. In 1983, NATA established its medical testing program to accredit pathology facilities in response to a request from the Royal College of Pathologists of Australasia. This Australia-wide program was to be administered by the Australian Government as well as State governments of NSW and Victoria, with NATA acting as the accreditation agency. For NATA, the medical program presented both problems and opportunities.

An initial delay, followed by a shortfall in applications from medical laboratories placed a severe financial burden on NATA in the mid to late 1980s. The eventual swell of medical applications also stretched logistical resources to their limits. In one 12 month period 340 applications were received for medical testing registration. Despite these hurdles, the medical testing program was to prove successful with more than 300 medical facilities accredited within the next few years.

The Australian Wool Surveillance Authority was established in 1988, following an approach by the Australian Wool Corporation for NATA to accept a leading role in the surveillance of wool display, sampling and testing facilities throughout Australia. Wool facilities accreditation by NATA was aimed at enhancing international confidence in Australia's system of sampling testing and showing greasy wool for export.

This mandatory program saw the processing and registration of more than 200 applicant wool organisations during Australian Wool Surveillance Authority's first full year of operation: a remarkable achievement indicative of the high level of cooperation between NATA and the wool industry.

Other landmarks in NATA's growth during the 80s included the establishment of branch offices in Perth (1984) Brisbane (1986) and Adelaide (1989) to better service the needs of clients and the community.

Moreover, NATA started comprehensive training programs for its assessors (1985) laboratory managers (1987) and quality practitioners (1989/90). These courses were created to cater for training needs not satisfied by other courses then available. NATA's training courses were immensely popular both domestically and internationally and have since been further expanded to meet demand.

Internally, NATA had to adjust not only to a rapidly increasing membership (more than 2000 facilities were registered by 1990 - the figure in 2006 was just under 3000) but also to increased staff resources spread around the continent and to new technologies available for the processing of its registered laboratories and applicants. Operating procedures, policies and registration criteria all had to be reviewed and amended where necessary.

The 1980s also saw the development and implementation of a new corporate plan which set objectives for the surveillance programs, goals for corporate development and plans for NATA's interaction with other industry and government bodies. The plan was subsequently reviewed and updated in 1989. The late 1980s also saw a full revision of NATA's Rules which was completed by 1990 and published shortly thereafter. The new rules provided a

clearer definition of criteria for registration and provided greater flexibility for members to certify their conformance with their customers' expectations

1990s: A decade of challenge and confirmation

Undoubtedly, the most important influence on NATA's development in the 1990s was the tide of quality awareness that immersed Australia and the world. The quality movement in Australia started gaining momentum in the mid to late 1980s and NATA had already recognised this in its dealings with registered laboratories. In 1987 NATA introduced the concept of quality systems documentation to Australian laboratories by requiring the development and use of laboratory quality manuals. By the close of the decade NATA members were already approaching NATA to expand its accreditation activities to include quality systems certification.

In 1990, NATA started offering certification to national and international quality management standards. At first, this was directed at member laboratories, but soon organisations that had no involvement with testing and no previous association with NATA, were seeking certification. The growth in this program was phenomenal and exceeded the growth rates experienced in the wool and medical programs in the 1980s.

Within four years of its start more than 400 organisations had achieved certification – NATA's staff resources in this area increased tenfold during the same period. Overseas interest in NATA quality systems certification was high with certifications in New Zealand and Fiji. Opportunities for cooperation with South East Asia were also identified during 1994.

The certification program was formally recognised in 1993 by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ), the first such recognition in Australia. During the year, NATA also responded to the quality needs of small business by launching the Q-Base program. This program, tailored to the specific needs of smaller companies, had been successfully operated in New Zealand for several years. NATA started operating Q-Base in Australia under licence from Telarc (New Zealand) and received up to 100 enquires per week from interested companies.

Various industry sectors requiring the development of specific programs saw NATA activities expand considerably during the first half of the 1990s.

These activities included new accreditation programs for inspection services and forensic sciences (both launched in 1992) and personnel certification in the construction materials industry (launched in 1993 with first certifications in 1994). The programs involved considerable collaboration between NATA and specific industry and professional bodies both within Australia and overseas.

NATA's traditional accreditation fields also adapted to changing industry demands, new laws and government policies. In October 1990 the Agreement of Standards, Accreditation and Quality (ASAQ) was signed between the Australian Government, State and Territory Governments and the New Zealand Government. The agreement was brought about to provide a way of eliminating inefficiencies caused by the inconsistent use of standards and accreditation systems by government.

NATA was appointed as one of the organisations involved in the ASAQ Monitoring Committee. The agreement supported NATA's MoU with the Commonwealth as well as NATA's mutual recognition agreement with Telarc New Zealand.

The following year saw an increase in the registration of laboratories involved in environmental testing. These accreditations, for activities such as soil and water testing, air monitoring and the analysis of stack gas omissions were incorporated under the Chemical

Testing and Biological testing fields. NATA started offering accreditation to Calibration Systems Standards in 1993. In addition, following a specific number of recommendations in the Foley Committee report, NATA was appointed as the National Authority in Australia for monitoring compliance with the OECD Principles of GLP, and undertook the first recognition in this area in 1991.

NATA was also engaged in 1991 by AQIS to help meet the requirements of the USA Food and Drug Administration to assist with the assessment of shellfish imported from Australia by the United States. These and other collaborations presented vital opportunities to further promote the international acceptance of Australian test data.

To this end further mutual recognition agreements were made with the United States the Netherlands and Sweden. In 1994 agreement was reached with the Western European Laboratory Accreditation Cooperation to enter into a mutual recognition agreement with NATA.

The agreement, now with the European cooperation for Accreditation (EA), includes national bodies from an ever-increasing number of major European nations. This emerging international profile continued to grow strongly throughout the 90s and into the next decade, spurred on by NATA's active involvement in ILAC and the continuing use of NATA's training courses by overseas organisations.

Also helping develop this international recognition were developments in 1992 which saw a regional cooperation of national accreditation bodies established. Currently chaired by NATA's Chief Executive, the cooperation known as APLAC includes many of Australia's principal trading partners in South East Asia, the Americas and the Pacific. NATA actively contributes both support and resources to help develop this regional forum which, like ILAC, does much to assist with the elimination of trade barriers related to testing in the region.

NATA was inaugural signatory to the APLAC MRA in 1997.

International criteria for accreditation were incorporated into NATA's own laboratory registration procedures with the review of its criteria in early 1991 and the publication of its new General Requirements for Registration in 1992. These and the associated field-specific Supplementary Requirements for Registration were based on the revised guidelines which have been adopted by many national systems around the globe. This ensured that NATA's criteria remained in harmony with those of other accreditation bodies, and were not the source of problems in the international acceptance of test results.

NATA requirements also did much to develop the quality systems approach within laboratories, including documentation control, corrective action procedures and quality auditing. The review of criteria for laboratory accreditation has also been accompanied by changes in the accreditation process to allow for more efficient assessments of applicant and member laboratories.

The only major area of accreditation to be significantly affected by altered customer demands was the Wool Surveillance Program. In 1991, a major restructuring of the wool industry began in an effort to revitalise Australia's wool exports. The Australian Wool Exchange assumed responsibility for the registration of sampling sites and show floors.

Paradoxically, while NATA was expanding its activities, government funding for them was dropping sharply away. The then NATA Chair, Cliff Baker, noted in one annual report that government support was dropping away so sharply that the 'Association must develop a reserve of members' funds which allows it to consolidate its existing activities and invest in new processes.' Baker noted that funding, once almost 100 per cent of NATA's income, had dropped away to 16 per cent in the early 1990s. His hopes for restitution were unfounded: by 2006, funding had dropped much further to just above six per cent.

In 1992, NATA's Sydney headquarters moved from Chatswood to Rhodes. Rapid expansion, consolidation of a somewhat precarious financial position and communication were issues high on the agenda. National interest functions included the national calibration services and implementation of government initiatives which involved testing and certification requirements, and the need to ensure NATA could respond rapidly to any national need in those areas. That year also saw the Asia Pacific Laboratory Accreditation Cooperation established.

'Simmering debate' on the issue of accreditation versus certification as the measure of laboratory competence was the hallmark of 1994. Baker, in his annual report for the year, said 'there is strong divergence of opinion between NATA and Standards Australia on the subject'.

The Kean Inquiry of the Standards and Conformance Infrastructure set up the subsequent year found the government supportive of NATA's role in the technical infrastructure, particularly with regard to its role as the national provider of laboratory accreditation.

The subsequent recommendations were that ISO 9000 certification practices be split from NATA: In 1997, NCS International Pty Ltd (NCSI), a wholly-owned subsidiary – was created in response to the recommendations.

The late 90s saw an explosive growth in NCSI activities, and increasing awareness by NATA that its success was predicated on its responsiveness to the ever changing technical environment.

In 1998 NATA Chair Mike Gledden noted "Because of the invaluable and unique input from NATA's accreditation Advisory Committees, NATA members can be confident that the evolving technical standards expected of laboratories and inspection bodies will be carefully monitored. What is also needed is for the accreditation process itself to be allowed and encouraged to evolve. For instance, the right balance must be struck for the frequency at which laboratories are audited. NCSI performs beyond expectations".

Increasing demands and increasing demands on limited revenue streams - a NATA perennial - saw a slippage in the so-called surveillance interval, the average period between successive reassessments. Much greater demands than ever before were being placed on NATA, especially in 1999 with NATA's role in providing support for international government trade initiatives.

NATA had come a long way. As Gledden noted in one annual report, "Accreditation in general and NATA in particular is seen as an instrument of modern trade policy.'

The new millennium

Significant features of NATA's activities and profile in the years from 2000 to the present include:

- Maturation of the global ILAC Mutual Recognition Arrangement (*the ILAC Arrangement*) which was inaugurated in 2000 after a 23 year history of confidence building. The ILAC Arrangement has since been growing steadily as the number of economies which have developed national capabilities for accreditation has also increased;

- Investment by NATA in significant enhancement of its own technical staff resources to address both growth in demand and to redress some previous reductions in surveillance activity;

- Development of closer links with State and Territory governments to mirror NATA's relationship with the Australian Government and to recognise their roles and needs as major stakeholders in NATA's activities;

- Renewal of the MoU with the Commonwealth in 2003 and refinement of the format of submissions for Government funding to reflect in more detail the expected objectives and outcomes from the Government's financial support; and

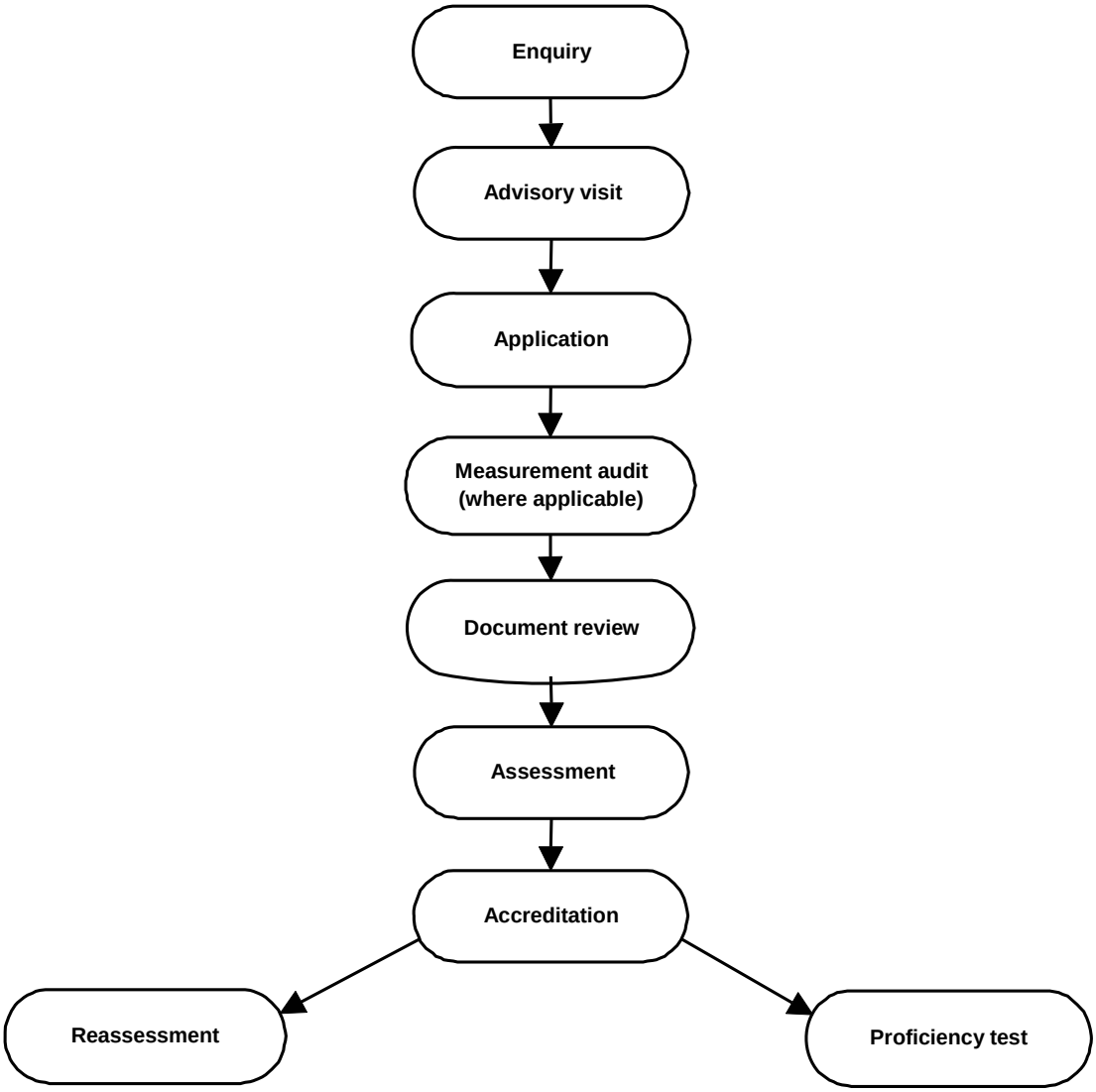
- Participation in the 2002 review conducted on behalf of the Department of Health and Ageing of Australia's Pathology laboratory accreditation arrangements

That 2002 review coincided with comprehensive national media publicity, following NATA's refusal to grant or maintain accreditation for three pathology laboratories. This crystallised the need for greater community awareness of the distinction between the role of governments as regulators and the supporting functions that accreditation can provide to assist in regulatory decisions. The review also led to a more detailed expectation of the Government's requirements for NATA's supporting roles to be incorporated in a deed of agreement with the Heath Insurance Commission (now Medicare Australia). Moreover, it led to some streamlining of NATA's formal appeals process for laboratories affected by suspension or cancellation of their accreditation.

Along with the above influences, the growth in NATA's accreditation services closely reflected the changes in the Australian economy, with more growth evident in service sectors than traditional product or commodity related testing.

In 2007, both laboratory accreditation and NATA achieve the landmark of 60 years of operation. It is fitting, also, that NATA as the pioneer of laboratory accreditation will be hosting the 2007 annual meetings of ILAC, which itself turns 30 in that year.

Annex C – Flowchart of the Accreditation Process



Annex D - NATA's International Activities

NATA's international activities fall into the following categories:

- representation and promotion of Australia's interests, particularly in the area of conformity assessment
- capacity building, especially in the APEC region

NATA's participation in ILAC and APLAC activities, in ISO/CASCO and ISO/REMCO committees and working groups and on the OECD Working Group on GLP have been essential for the protection of the interests of Australia's laboratories and other stakeholders. This participation has helped ensure that the various criteria documents prepared by these groups do not place impractical or onerous requirements on the Australian conformity assessment infrastructure.

NATA was a founding member of both ILAC and APLAC and provides the secretariats for both cooperations. NATA has provided, in the past, the Chair of ILAC and APLAC and of various ILAC and APLAC committees. Currently the Chief Executive of NATA is the Chair of APLAC, and a member of the ILAC Executive and APLAC Board of Management. NATA staff have active involvement in the following ILAC and APLAC committees:

- ILAC Arrangement Committee
- ILAC Arrangement Issues Committee (and various Working Groups)
- ILAC Marketing and Communications Committee
- ILAC PT Providers Consultative Group
- ILAC/IAF Joint Development Support Committee
- APLAC Proficiency Testing Committee
- APLAC Technical Committee
- APLAC Training Committee

Allied to NATA's active participation in the various ILAC and APLAC committees is NATA's position as a signatory to both the APLAC regional Mutual Recognition Arrangement (MRA) for testing, calibration and inspection and the ILAC Arrangement for testing and calibration (there is, as yet, no global MRA for inspection). NATA was an inaugural signatory to both arrangements. As a signatory to the two arrangements, NATA has certain obligations to meet. These obligations include the provision of peer evaluators for the APLAC and ILAC evaluation processes. Currently NATA provides ten peer evaluators, six of whom are lead evaluators. Participation in evaluations is one way in which NATA can benchmark its processes and procedures against those of other accreditation bodies.

NATA has been a leading contributor to the development of a number of key standards relating to conformity assessment, including the current standards ISO/IEC 17025 (requirements for the competence of laboratories), the standard NATA applies to laboratories, and ISO/IEC 17011 (requirements for accreditation bodies), the standard applied to NATA by its MRA partners.

NATA has represented Australia on the OECD Working Group on GLP since its inception and has actively contributed to the development of the Principles of Good Laboratory Practice, the standard applied by NATA in its role as Australia's GLP compliance monitoring authority. NATA's representative to the Working Group is currently its Chair, the first Chair from outside Europe or the USA.

A list of other international fora in which NATA represents Australia's interests are given elsewhere in this submission but, indirectly, NATA has representation on other fora as a representative of either APLAC or ILAC. These include:

- APEC TEL MRA Task Force (currently the Chair)
- BIPM's Joint Committee on Traceability in Laboratory Medicine
- Joint ILAC and IEC Technical Panel
- Joint Committee on Coordination of Technical Assistance on Metrology, Accreditation and Standardisation

Objectives set for NATA by the Governments of Australia

This group of objectives are described in various Memoranda of Understanding (MoUs) between NATA and the Australian Government, State and Territories and specific government departments or agencies.

The most significant of these MoUs is the current whole of Government MoU between the Commonwealth of Australia and NATA. Its content forms one of the terms of reference for this current Productivity Commission Research Study.

The primary objectives set for NATA by the Commonwealth in that MoU are to:

- provide national leadership in establishing standards of good laboratory practice, in accrediting testing laboratories, inspection bodies and suppliers of certified reference materials and providing a network of competent service providers to meet national needs as identified by governments or industry groups;
- prepare, publish and review its procedures and standards to ensure they conform with international standards; meet national interest requirements; facilitate international trade; satisfy requirements for public health, safety and environmental protection; enhance quality and performance of products, materials and related services; be suitable for reference in Australian governments' laws, regulations and public purchasing contracts; and provide the testing, measurement and calibration base for certification systems;
- ensure NATA and its committees develop practices in harmony with international standards for good laboratory practice and operation of laboratory and related accreditation systems;
- recognise and cooperate with other key standards and conformance infrastructure bodies;
- seek a fair and reasonable balance of interests in developing international compatibility and uniformity of testing, measurement and calibration throughout Australia;
- assist the Australian Government in attaining the objectives of the National Measurement Act 1960;
- provide a world class testing and measurement system, and evaluate means for providing services more efficiently and consistent with international standards including application of innovative techniques to its accreditation process;
- represent Australia in the International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC), the OECD Panel on Good Laboratory Practice and other agreed fora, taking into account national interest identified by the Australian Government and the priorities of Australian industry and consult with industry, government, other infrastructure bodies and consumer organisations in such representation;
- develop and maintain links with foreign national accreditation bodies, maintain harmony with foreign accreditation systems and develop appropriate, reciprocal recognition agreements in the national interest;
- be the national authority for monitoring compliance with the OECD Principles of Good Laboratory Practice;
- provide a national database of accredited service providers in Australia;
- promote awareness in educational institutions, industry and the general community, and develop plans to increase involvement of industry, Australian Government and State Governments' laboratories and promote recognition by all users of test and measurement data;

- encourage accredited service providers to identify the specific needs of industry;
- ensure proficiency testing at an appropriate level is an integral part of the laboratory accreditation program;
- ensure adequate separation from NATA's subsidiary (NCS International Pty Ltd);
- work with APLAC, APEC, the WTO, AFTA/CER and other trade agreements and arrangements taking into account national interest priorities of the Australian Government and Australian industry;
- advise the Department of Industry, Tourism and Resources of details of agreements with Australian Government agencies to ensure consistency with the MoU between NATA and the Commonwealth; and
- respond with timely feedback to concerns raised by Australian Government agencies in respect to performance or competence of NATA accredited laboratories or those accredited by NATA's MRA partners.

Objectives set for NATA by its International MRA obligations

The two principal international Mutual Recognition Arrangements (MRAs) which NATA has with its international counterparts are the MRAs of ILAC and APLAC.

The objectives and obligations placed by those MRAs on signatories such as NATA include:

- recognition of the equivalence of accreditation of laboratories (and inspection bodies for APLAC) of MRA partners;
- acceptance of reports (e.g. calibration reports) from laboratories accredited by MRA partners;
- recommending and promoting acceptance in Australia of reports covered by accreditation by MRA partners; and
- investigation of complaints about Australian accredited facilities initiated by MRA partners.

To achieve and maintain signatory status in these MRAs NATA must:

- itself maintain compliance with relevant ISO/IEC Standards (such as ISO/IEC 17011) and also the additional requirements (both technical and administrative) specified by APLAC and ILAC
- use agreed international standards as the basis for accreditation of laboratories and inspection bodies (ISO/IEC 17025; ISO/IEC 17020; ISO 15189);
- maintain an appropriate level of proficiency testing as an input to the accreditation process; and
- be subject to periodic evaluation of compliance with the above criteria by multi-national teams of APLAC and ILAC member bodies.

Annex G – List of Australian Government law and regulation referring to NATA

This Annex provides details of the use of NATA by the following Australian Government agencies:

- Attorney General's Department
- APVMA - Australian Pesticides and Veterinary Medicines Authority
- AQIS - Australian Quarantine and Inspection Agency
- Australian Building Codes Board
- Australian Communications and Media Authority
- Australian Customs Service
- Department of Environment and Heritage
- Department of Transport and Regional Services – Vehicle Safety Standards
- Medicare Australia
- National Appliance and Equipment Energy Efficiency Committee
- National Environment Protection Council
- National Residue Survey

Jurisdiction: Commonwealth (Last update 1 March 2006)

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
Agency: Attorney – General's Department			
Parentage Testing Australian Family Law Act 1975 Family Law Regulations	Regulation 21D Compliance with regulations "A parentage testing procedure is taken to be carried out in accordance with these Regulations if: it is carried out: (ii) at a laboratory that is accredited by NATA for the purpose of carrying out parentage testing procedures; and"	Family Law and Legal Assistance Division Attorney General's Department Arts House Macquarie St BARTON ACT 2600	NATA maintains a list of parentage testing laboratories for the Attorney General and the Family Court.
Agency: Australian Pesticides and Veterinary Medicines Authority (APVMA) *(formerly National Registration Authority (for Agricultural and Veterinary Chemicals)*			
Agricultural and Veterinary Chemicals 1. Analysis of Chemical Products Agricultural and Veterinary Chemicals Code Regulations 1995.	"56 Analysis at an accredited laboratory For the purposes of paragraph 99 (4) (c) of the Code (which deals with requirements for analysis), a prescribed laboratory, in relation to the analysis of a substance or mixture of substances, is a laboratory accredited by NATA, or approved by the NRA, to carry out an analysis of that kind."	APVMA PO Box E240 Kingston ACT 2604 contact@apvma.gov.au www.apvma.gov.au Phone: 02 6272 5852 Fax: 02 6272 4753	The APVMA operates the Australian system which evaluates, registers and regulates agricultural and veterinary chemicals. Before an agricultural or veterinary chemical product can enter the Australian market, it must go through the APVMA's rigorous assessment process to ensure that it meets high standards of safety and effectiveness.

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
OECD Principles of GLP NRA Requirements and Guidelines for registering agricultural and veterinary chemicals.	Veterinary Requirements Series - Part 5A Residues 5A-2.1 Residue Data (updated 28/11/2002) includes the same provisions as 'Agricultural Requirements' and Agricultural Requirements Series - part 5A Residues 5A-21 Residue Data (updated 28/11/2002). 'Both field and laboratory phases of residue studies conducted in Australia, and used to support the establishment of MRLs in food and feed commodities, must be generated in accordance with the OECD Principles of GLP.' 'The National Association of Testing Authorities (NATA) is the sole Australian organisation responsible for monitoring compliance with the OECD Principles of GLP'. NRA Gazette No. 3, 5 March 2002 page 36. "2. For a study conducted in Australia to be GLP-compliant it must be undertaken by facilities that are accredited and within the Australian GLP compliance monitoring program. The National Association of Testing Authorities (NATA) is the sole Australian organisation responsible for monitoring compliance with the OECD Principles of GLP. Overseas studies must be conducted by facilities covered by that country's GLP compliance monitoring program."	Contact details: see above	Under the OECD Council Decision of the Mutual Acceptance of Data in the Assessment of Chemicals (MAD) "data generated in the test of chemicals in an OECD member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment" [C(81)30(Final)] That is, data from non-clinical environmental health and safety studies conducted by facilities that are recognised by the compliance monitoring authority of an OECD Member country, eg NATA in Australia), should be accepted by regulatory authorities in other OECD Member countries.
Agency: Australian Quarantine and Inspection Agency (AQIS)			
1. Live Animal Export Testing AQIS Approval of Veterinary laboratories – Information Sheet Issue 1 (2003?)	"Criteria for AQIS approval" 1.NATA accreditation for veterinary laboratory service. - must cover all fields of testing offered for export purposes.	Live Animal Exports AQIS GPO Box 858 Canberra Act 2601 www.affa.gov.au	

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
2. Imported Food Imported Food Control Act 1992 Food - List of Food Testing Laboratories (Appointed Analysts)	To analyse food inspected by AQIS a laboratory must be appointed as an analyst under Section 34 of the Act.	Food and Agricultural Products - Import Clearance AQIS GPO Box 858 Canberra Act 2601 Phone: 02 6272 5447 importweb.aqis.gov.au	NATA accreditation for the particular analyses undertaken is required.
3. Counting and Organism specific testing of Food for Export Website document: "Certification for importing countries - what you need to know to export processed foods	"Some analyses results may be required from a NATA approved laboratory."	Export Facilitation AQIS exportfac.aqis.gov.au	AQIS can provide certificates to satisfy specific importing country requirements.
4. Meat for Export Various AQIS Meat Notices e.g. Meat 2003/6 and 2005/16	"AQIS requires meat establishments to have testing conducted in NATA accredited laboratories using AQIS approved methods that are included in the laboratories' NATA accreditation" (2005/16)	Meat Program Phone: 02 6272 4535	Notices cover microbiological and chemical tests, including E.coli testing at abattoirs. NATA and AQIS signed a deed of agreement on 03/02/06 regarding testing for export of prescribed goods and for foods imported into Australia. Currently the schedule to the deed covers meat (including game, rabbit and poultry).
Agency: Australian Building Codes Board			
Construction of Buildings Building Code of Australia (2005) The BCA is called up in the building legislation of the States and Territories	BCA Clause A2.2 – Evidence of suitability. Suitable evidence includes among a number of items a report issued by a Registered Testing Authority which is defined as: the CSIRO Division of Manufacturing Infrastructure Technology; or an authority registered by the National Association of Testing Authorities (NATA) to test in the relevant field; or an organisation outside Australia recognised by NATA through a mutual recognition agreement.	ABCB GPO Box 9839 Canberra 2601 Phone: 1300 857 522 Fax: 02 6213 7287 ABCB.offfice@abcb.gov.au www.abcb.gov.au	The ABCB is a joint initiative of all levels of government in cooperation with the building industry. The Board reports directly to Commonwealth, State and Territory ministers. NATA maintains a copy of the BCA in its Melbourne office (contact Rob Oke).

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
Agency: Australian Communications and Media Authority			
Telecommunications Equipment Telecommunications Act 1997. Telecommunications Labelling (Customer Equipment and Customer Cabling) Notice.	Labelling Notice For Compliance level 3: "….. a test report by a recognised testing authority …..". A recognised testing authority means: "a specified person that is determined by an accreditation body".	Regulation and Compliance Branch Standards Section Australian Communications and Media Authority PO Box 13122 Law Courts Melbourne VIC 8010 Australia Comply.label@acma.gov.au http://www.acma.gov.au Phone: 03 9963 6873 Fax: 03 9963 6970	There is a graded approach to compliance. Level 1 in the lowest and Level 3 the highest. Level 3 requires a test report from a NATA determined recognised testing authority (RTA). The list of RTAs is maintained on the NATA website.

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
Electromagnetic Compatibility (EMC) Australian Radiocommunications Act 1992 Radiocommunications (Compliance Labelling – Incidental Emissions) Notice 1998	In 1998 Notice: For compliance Level 3: "(i) tests under the section 17 by an accredited testing body; or a technical assessment under Division 5 of Part 3". Accredited testing body means: "NATA; or a body that has entered into a mutual recognition agreement: with NATA; or under the Agreement on Mutual Recognition on Conformity Assessment Certification and Marking between Australia and the European Community signed on 24 June 1998". (For technical assessments – see comments). Notice: 2 (1) In this notice, unless the contrary intention appears: accrediting body means: NATA: or A body that has entered into mutual recognition agreement with NATA. "If you require the highest level of confidence the ACMA recommends using a NATA accredited organisation to assess radiofrequency field strengths."	See above	Compliance with the mandated standards of the EMC scheme may be demonstrated by a test report or a technical construction file (TCF). To use the TCF route a technical assessment from a NATA determined competent body is required (accredited with NATA's Inspection program).
Radiocommunications Transmitters Australian Radiocommunications Act 1992 Radiocommunication Devices (Compliance Labelling) Notice		See above	

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
Electromagnetic Radiation (EMR) Radiocommunications Licence Conditions (Apparatus Licence) Determination 2003 EMR Question and Answer Sheet		See above	Limits have been set for exposure to EMR. NOTE: The Mobile Carriers Forum's EME Regulatory Compliance Strategy (17/01/05) requires the Site Compliance Certificate to be issued by a NATA accredited organisation.
Agency: Australian Customs Service			
Imported Products (Main example is ceramic surfaces) Customs (Prohibited Imports) Regulations 1956 Regulation 4E – Glazed ceramic ware Specific Administrative Requirements under 4E.	The Specific Administrative Requirements state: 'NATA is recognised by the Australian government as the national authority for accreditation of laboratories. Formal agreements exist between NATA and other national laboratory accreditation organisations for recognition of test and measurement results from accredited laboratories. A Certificate may only be accepted from a laboratory that states that it belongs to its national accreditation organisation."	Mr Martin Davies Community Protection Policy Australian Customs Service 5 Constitution Avenue Canberra City 2601 Phone: 02 6275 5963 martin.davies@customs.gov.au www.customs.gov.au	Australian Customs Service is the enforcement agency. The Safety Policy Unit of the Consumers Affairs Division within Treasury provides Customs with policy advice and direction. Schedule 7 of Regulation 4E calls up testing to BS 4860 1972 for lead and cadmium.

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
Agency: Department of Environment and Heritage			
1. Fuel Quality Testing Fuel Quality Standard Act 2000 Fuel Quality Standards Regulations 2001 Reg 21	1. Act - Section 58B Signing of Certificate In any offence proceedings a certificate signed by an authorised person in relation to an accredited laboratory is admissible as prima facia evidence …… 2. Regulations Accredited Laboratories see comments column (3) For item 1 of the table to subregulation (1): (a) the criteria must be verified by a laboratory accredited, by the national laboratory accreditation body operating in the country where the laboratory is located, to perform the tests mentioned in the criteria; See comments	Clean Fuels and Vehicles DEH GPO Box 787 Canberra ACT 2601 Phone: 1800 803 772 fuel.quality@deh.gov.au www.deh.gov.au	Accredited Laboratories "(1) For subsection 58B (8) of the Act, the following are accredited laboratories: (a) a laboratory in Australia that is accredited by NATA; (b) a laboratory in another country that is accredited by the national laboratory accreditation body operating in the country where the laboratory is located; (c) an organisation of more than 1 laboratory or similar undertaking that uses their joint resources and is accredited by NATA; (2) For paragraph (1) (b), a national accreditation body must: (a) be a member of ILAC; and (b) accept the accreditation standards of that Corporation; and (c) comply with ISO/IEC Guide 58:1993 *Calibration and testing laboratory accreditation systems - general requirements for operation and recognition*, first edition, published by the International Organization for Standardization, Geneva." (4) For paragraph (3) a, a national laboratory accreditation body must: (a) have a mutual recognition agreement with the National Association of Testing Authorities, Australia; and (b) comply with *ISO/IEC*
2. Used Oil Recycling Product Stewardship (Oil Regulations 2000 (No 1)		Environment Standards Branch As above Phone: 1800 982 006 oilrecycling@deh.gov.au	*Guide 58 Calibration and testing laboratory accreditation systems - General requirements for operation and recognition*, first edition 1993, published by the International Organization for Standardization, Geneva." Note: this relates to oil for which a product stewardship benefit is payable.

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
3. PCB – containing capacitors An information booklet for electricians and electrical contractors 1997 (Revised 2005)	3. Identification If there is any doubt as to whether the equipment contains PCBs or not, submit a sample to a laboratory (listed as Appendix 1) that is NATA registered for PCB analysis."	DEH As above Phone: 02 6274 1111	Booklet prepared on behalf of the Australian and New Zealand Environment and Conservation Council, as part of the National Strategy for the Management of Schedule Waste.
Agency: Department of Transport and Regional Services – Vehicle Safety Standards			
Vehicle Safety Motor Vehicles Standards Act 1989 Administrator's Circular 0-12-0 "Test Facility Inspection"	Section 4 Circular 0-12-0 "In Australia NATA registration of a test facility for a particular ADR test will be accepted by the Administrator as an acceptable standard of 'fitness to test'. When such registrations are held, regular inspections will not normally be conducted. "Consideration may also be given to acceptance of accreditation of overseas test facilities by overseas national test facility accreditation agencies, where such accreditation is given for testing to ADR requirements".	Bob Seow Principal Engineer Vehicle Safety Standards Department of Transport and Regional Services GPO Box 594 Canberra 2601 Standards@dotrs.gov.au www.dotrs.gov.au/land/index.htm Phone: 02 6274 7504 Fax: 02 6274 6013	Vehicle type approval for compliance with relevant Australian Design Rules (ADRs) is required before supply to the market for first use in transport. Tests must be conducted by a laboratory that is part of the DOTRS Test Facility Inspection scheme. It is not mandatory to be accredited to be a TFI facility. TFIs are subject to audit by DOTRS.
Agency: Medicare Australia *(formerly the Health Insurance Commission)*			
Health Insurance Act 1973 Health Insurance (Accredited Pathology Laboratories - Approval) Principles 2002	Sub-Section 23 DN(1) of the Act allows the Minister to determine eligibility for premises to be approved as an accredited laboratory. In the Principles 2002 "assessment report means a report provided by an independent body or a special adviser in accordance with section 9." "independent body means: (a) NATA; and (b) in relation to a category M laboratory - any other organisation approved under subsection (2) by the Minister."	Manager Pathology Section Medicare Australia PO Box 1001 Tuggeranong DC ACT 2901 Phone: 02 6124 6182 www.medicareaustralia.gov.au	The Medicare Australia has an agreement with NATA, for NATA to undertake accreditation inspections of Medicare Pathology Laboratories.

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
Agency: National Appliance and Equipment Energy Efficiency Committee			
Appliances and Equipment Appliance and Equipment Energy Efficiency Program. Mandatory Labelling and Minimum Energy Performance Standards for Appliances. Administrative Guidelines Agreed by all Australian Regulators Edition 5 – as at 5 June 2005. Available at: www.greenhouse.gov.au/ energyefficiency/admin_ guidelines.html Click pdf link at bottom of page.	See Guidelines Clauses 4.5, 4.6, 4.7 and 4.8 "4.5 Withdrawal of approval to conduct testing "Applicants that use laboratories for registration testing whose products subsequently fail check- testing review may be asked to ensure that future testing conducted in relation to their products is undertaken by a NATA accredited laboratory or a laboratory accredited by a body with a mutual recognition agreement with NATA." 4.6 Compliance monitoring through laboratory check testing "Regulatory authorities will commission NATA accredited laboratories (not associated with the registration holder) to check test selected models to ensure that the energy label and/or performance claims made by suppliers are valid."	Shane Holt Energy Efficiency Team Australian Greenhouse Office GPO Box 621 CANBERRA ACT 2601 www.greenhouse.gov.au Phone: (02) 6274 1825 Fax: (02) 6274 1884	NAEEEC operates under the authority of the Australian and New Zeland Minerals and Energy Council (ANZMEC) through its Energy Management Task Force (EMTF). NZMEC is made up of ministers from the various State, Territory, Commonwealth and New Zealand Governments. The Australian Greenhouse Office provides support for NAEEEC's activities. An AGO Officer is the chair of NAEEEC. AAEEEC guidelines are implemented through State and Territory legislation (see separate entries).
Agency: National Environment Protection Council			
1. **Ambient Air Quality** National Environment Protection May 2003 (Ambient Air Quality) Measure	12. Accreditation of performance monitoring 1) Subject to subclause (2) the operator of a performance monitoring station must be accredited by the National Association of Testing Authorities. 2) The operator may apply an equivalent system for ensuring adequate monitoring, quality assurance, and validation procedures. 3.3 Quality Control and Quality Assurance	NEPC Service Corporation Level 5 81 Flinders Street Adelaide SA 5000 Australia www.ephc.gov.au Phone: 08 8419 1200 Fax: 08 8224 0912	The National Environment Protection Council is a statutory body with law making powers established under the National Environment Protection Council Act 1994 (Commonwealth), and corresponding legislation in the other jurisdictions. The NEPC operates under the umbrella of the Environment Protection and Heritage Council (EPHC)

USE OF NATA BY GOVERNMENT AGENCIES			
Legislation, regulation, code of practice, Guide, etc.	**Relevant clauses which reference NATA**	**Agency contact details** *(person, address, phone, fax, email, web)*	**Comments**
2. Assessment of site contamination National Environment Protection (Assessment of Site Contamination) Measure 1999 Schedule B(8) Guidelines of Laboratory Analysis of Potentially Contaminated Soils	Laboratories undertaking analysis of potentially contaminated soils for the purpose of assessment of site contamination should be accredited by the National Association of Testing Authorities (NATA) in the test methods and matrix for the analytes of concern.		
Agency: National Residue Survey			
Chemical Residue in Agricultural Products National Residue Survey Annual Report 2004-2005	Page 37 "NATA accreditation of contract laboratories All NRS-contracted laboratories must achieve and maintain NATA (or equivalent) accreditation and operate within a comprehensive quality assurance/quality control system."	National Residue Survey Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601 Phone: 02 6272 3446 nrs@daff.gov.au www.daff.gov.au/urs	The primary purpose of NRS is to facilitate key export and domestic market access for participating industries by maintaining consumer confidence in Australian food commodities covered by NRS projects.

Annex H – Overseas Accreditation Models

This Annex contains some comparative data and commentary on overseas accreditation structures and bodies that are signatories to the ILAC Arrangement.

Comparative Table – NATA and Some Other Accreditation Bodies

Name	NATA	IANZ	UKAS	IAJapan	JAB	SANAS	A2LA
Economy	Australia	New Zealand	UK	Japan	Japan	South Africa	USA
Model *(see note 1 below)*	A	A	C	C	C	C	D
Governance	independent private not-for-profit company, operating as an association	Autonomous Crown Entity, operating under the Crown Entities Act 2004; govt. owned, not-for-profit, non-tax paying	non-profit distributing company, limited by guarantee, having Members rather than shareholders; set up by UK govt. in 1996 as an independent agency	govt. accreditation body established within National Institute of Technology and Evaluation (NITE) that is itself an Incorporated Administrative Agency	private non-profit organisation supported by 35 industrial organisations under the auspices of the Japan Federation of Economic Organisations	section 21 organisation under the Company Act of South Africa; non-profit-distributing company but after enactment of Accreditation Act (see below) will become a public entity	registered in District of Columbia as a non-profit, tax exempt organisation under Internal Revenue Service Code section 501(c)3 for scientific, educational and charitable organisations
Govt. designated	MoU with govt. (through DITR)	MoU with govt. (through MED)	MoU with govt. (through DTI); recognised as sole national accreditation body	government accreditation body	Letter of authorisation from AIST dept. of MITI (now METI) issued Nov. 1996 to allow expansion into accreditation of laboratories	Accreditation Act to be presented to parliament end of 2006. SANAS to be sole accreditation body for conformity assessment	No whole of govt. designation but some govt. agencies accept A2LA accreditation among accreditation by other US accreditation bodies
Govt. funding **(see note 2 below)**	funding for designated activities, agreed annually	none	for international activities; promotion of accreditation; "as needs" for new programs to meet govt. request	95% of operating budget provided by govt.	none	govt. funding to subsidise programs identified by the govt. as being "strategic" for industry in South Africa	none

Name	NATA	IANZ	UKAS	IAJapan	JAB	SANAS	A2LA
Income sources	accreditation fees; training; special projects; "tied" govt. funding	accreditation fees	accreditation fees; "tied" govt. funding	govt. funding; accreditation fees	accreditation fees	accreditation fees; training; special projects; "tied" govt. funding	accreditation fees; training; membership fees (membership is optional)
Financial turnover (last year available)	2004-2005 year; revenue AUD 17.15 M; expenditure AUD 16.44 M	2004-2005 year; revenue NZD 8.80 M; expenditure NZD 8.71 M	2004-2005 year; turnover £10.39 M; expenditure £ 9.92M	not available	2004-2005 year; revenue JPY 1,199.62 M; expenditure JPY 1,167.84 M	2004-2005 year; revenue ZAR 20.86 M; expenditure ZAR 18.99 M	2004 year; revenue USD 7.80 M; expenditure USD 7.22 M
Accredited lab. input into fees (see note 3 below)	via Board representation	via Board representation	via Board representation		via Board of Trustees representation	via Board representation	via Board representation
Typical fees for a laboratory requiring 2 technical experts on the team (see note 4 below)	appl: AUD 1636+GST; annual fee: AUD 3928 – AUD 4731+ GST (depending on distance from nearest NATA office); initial asst: AUD 160+GST per hour per person plus expenses at cost; reasst: covered by annual fee for routine reassessment	appl: NZD 800+GST; annual admin. fee: NZD 500+GST; initial asst: NZD 160+GST per hour per person plus expenses at cost; reasst: as for initial assessment	appl: £1200+VAT; annual admin. fee: £150+VAT; initial asst: £795 per person per day plus expenses at cost; reasst: £600 per person per day plus expenses at cost	appl: JPY 180,000 160,000; annual fee: none; initial asst: covered by appl. fee; reasst: JPY 440,000 Note: fees vary from program to program so this is just an example	appl: USD 1800; annual fee: USD 5400 x total technical assessment person days; initial asst: USD 180 per person per hour plus expenses at cost; reasst: as for initial assessment	appl: ZAR 4000; annual fee: ZAR 14,900; initial asst: ZAR 14,900 plus expenses at cost; reasst: covered by annual fee but expenses charged at cost	appl: USD 600; annual fee: USD 1200; initial asst: USD 960 per person per 8 hour day plus expenses at cost; reasst: as for initial assessment
Payment to external experts	none but travel, etc. expenses covered	none but travel, etc. expenses covered	various, depending on expertise, etc; averages £400.00 per day	JPY 96,000 – 144,000 per assessment, depending upon expertise, etc.	USD 85.00 per hour	ZAR1970 per day (lead assessor); ZAR1470 per day (technical assessor)	USD 500 –700 per day, depending upon expertise

appl – application
asst – assessment
reasst - reassessment

Notes on table above

1. Models
   - A - secretariat staff who are always the lead assessor, supported by unpaid external technical experts
   - B - secretariat staff who are always the lead assessor, supported by paid external technical experts
   - C - secretariat staff as lead assessor or external contracted lead assessor, supported by paid external technical experts
   - D- contracted external lead assessor, supported by paid external technical experts; secretariat staff are not involved in assessment teams

2. Globally the national structure, governance and funding of laboratory accreditation bodies vary. In most instances some government funding is provided for at least national interest activities.

3. ISO/IEC 17011, the international Standard with which accreditation bodies must comply, requires an accreditation body to ensure that it has a structure that provides opportunity for effective involvement by interested parties, and that the representation of interested parties is balanced with no single party predominating. "Interested parties" would include accredited facilities.

4. In general, the size of the annual fee depends on whether or not that fee covers routine reassessment costs (eg NATA) or is only an administration fee (eg IANZ) with re-assessments being charged in the same way as initial assessments. It is difficult to put a total figure on some activities that are charged by the hour as it is difficult to estimate the total time needed, ie for pre- and post- assessment activities plus on-site time.

PC Issues Paper Question 44 - How do other countries manage the relationship between government and standard setting and accreditation? Which models used in other countries would provide useful lessons — both those to be adopted and pitfalls to avoid — for this review?

Europe

The creation of a single market within Europe in 1993 was the impetus for increased harmonisation and regionalisation of, among other things, conformity assessment processes under the New Approach to Standardisation and Harmonisation ("the New Approach"). This led to most EU members restructuring accreditation activities to create a single integrated national accreditation body (covering laboratories, inspection bodies and certification bodies) in each economy. For example, in the UK NAMAS merged with NACCB to form UKAS.

In 1999 the European Commission (EC) signed a Memorandum of Understanding with EA (European cooperation for Accreditation) that formalised a level of support for the organisation of accreditation activities within Europe. Currently there are discussions between EA and the EC's DG Enterprise as part of a revision of the New Approach.

The EC's proposal is that accreditation be defined as a service of public interest deriving its authority from national governments. It has been stated by the EC that it is necessary for accreditation bodies to be independent of commercial conformity assessment activities and that there should not be competition among accreditation bodies. EA supports the view of the EC.

A recent DTI policy document states that UKAS's status as the sole national accreditation body has advantages for the UK, including that accreditation is done consistently and authoritatively, that UKAS accreditation is recognised nationally and internationally, that there are economies of scale, and a single UK representative at international accreditation fora. The DTI document also reinforces the EC view that national accreditation bodies should, among other things, operate under the aegis of government and not compete with each other.

Germany is the major exception in Europe in that there are numerous accreditation bodies, some covering the regulated sectors and others the voluntary sectors, some competing with each other. Belgium and Italy also have multiple accreditation bodies but in both economies the division is in terms of accreditation of testing laboratories, of calibration laboratories and of certification. The situation in Belgium and Italy is, thus, comparable to that in Australia (NATA and JAS-ANZ).

Because of the complex situation in Germany, a study was recently undertaken by the German Federal institute BAM (Bundesanstalt für Materialforschung und–prüfung, Federal Institute for Materials Research and Testing) to examine the structure of accreditation bodies in Europe and other parts of the world, with aim of establishing what improvements could be made to the German system.

Within Germany, Deutscher Akkreditierungsrat, German Accreditation Council (DAR) is a coordinating body for accreditation activities. Not all German accreditation bodies, however, especially in the voluntary sector are members of DAR. Membership of DAR by the German accreditation bodies is currently voluntary. The study report, available only in German from the DAR website (http://www.dar.bam.de), notes in part that

> *the system is difficult to assess (NATA's translation)*

The German study examined the accreditation systems in 37 economies in Europe, the Asia-Pacific, the Americas, Israel and South Africa. The report noted:

- Twenty five of the economies have either an accreditation law or accreditation regulations
- In 27 of the economies the accreditation body is either a government or public authority
- In 16 of the economies the accreditation body is a private authority with some form of mandate from government
- The accreditation bodies are not-for-profit and in most cases have some government funding, particularly to support international representational activities
- Only in Germany and the USA are there numerous public (i.e. government, either federal or state) and private accreditation bodies in competition with each other
- Within the German system, particularly in the regulated sector, a conformity assessment body may need multiple accreditations depending upon the breadth of its operations.

Asia Pacific Region

Within the Asia Pacific region, in general, there is only one (integrated) accreditation body for each economy, although in some economies (Australia, India, Japan, Korea, New Zealand, Thailand) there are separate accreditation bodies for accreditation of laboratories and of certification bodies. This was also the case in the People's Republic of China until very recently but CNAL and CNAB have now merged to form an integrated accreditation body, CNAS. This mirrors the regional situation with APLAC covering accreditors of laboratories and PAC covering the accreditors of certification bodies. In some economies, namely Japan, Thailand and the USA, there are multiple accreditors of laboratories.

In Japan there is a mix of both government, International Accreditation Japan (IAJapan) and private (JAB, JCLA, VLAC) accreditation bodies. JAB, JCLA and VLAC are strongly based on industry, with the latter two being sector specific.

IAJapan, as a government accreditation body, does not intervene in areas where accreditation is provided by private accreditation bodies and thus limits its activities to the areas where accreditation is necessary to meet legislative and regulatory requirements. The 3 private accreditation bodies are able to accredit laboratories in any areas, including in those areas covered by legislation but the accreditations in those areas have no legal effect. There is competition to some extent among the Japanese accreditation bodies, particularly between JAB and the two private sector-specific bodies.

A coordination body, JLAC (Japan Laboratory Accreditation Cooperation), whose secretariat is within IAJapan, has been set up to coordinate activities. To date there has been only limited coordination covering such matters as promotion of accreditation, holding of seminars for stakeholders, issuing publicity material. JLAC intends to extend its activities to include cooperation on proficiency testing and assessor training.

In Thailand all three laboratory accreditation bodies (TLAS, DMSc, DSS) are government bodies, the latter two parts of government departments. There is some overlap in the the scopes of accreditation activities, especially between TLAS and DSS. NAC has a coordinating role in Thailand.

The arrangements in the USA for laboratory accreditation are confused and fragmented. Within government there is a multiplicity of “accreditation systems” at both the federal and state level, many of which do not use ISO/IEC 17025 as the basis for the “accreditation” and that do not themselves meet the requirements of ISO/IEC 17011. There is little consistency among the government accreditation programs and, as in Germany, a laboratory may need multiple accreditations to meet various government requirements. There are also several private sector accreditation bodies in competition with each other, most of which are for-profit organisations. Only three USA laboratory accreditation bodies have international recognition (all are signatories to the APLAC MRA and the ILAC Arrangement): A2LA, IAS, NVLAP.

A2LA is a not-for-profit, tax exempt organisation registered in the District of Columbia. It offers accreditation in a wide scope for both testing and calibration. IAS is also a not-for-profit organisation, fully owned by the International Code Council and offers accreditation mainly in the area of building materials and structures. NVLAP is a government accreditation body being a department within the National Institute of Standards and Technology (NIST).

In February 1996 the National Technology Transfer and Advancement Act (NTTAA, Public Law 104-113) was enacted by the US Congress. Section 12 of NTTAA requires NIST to coordinate conformity assessment activities (including accreditation activities) of US Federal, state and local entities with private sector activities with the aim of eliminating unnecessary duplication of conformity assessment activities. There has been little change in the US conformity assessment infrastructure in the ensuing 10 years. An attempt to establish a coordinating body was made in 1998 with the establishment of NACLA (National Cooperation for Laboratory accreditation), a private not-for-profit cooperation with representation from industry, government, laboratories and accreditation bodies. Membership of NACLA, as with DAR, is voluntary. To date there are only six accreditation bodies “recognised” by NACLA, out of the more than a hundred accreditation bodies operating within the US. A seventh accreditation body was recognised but it withdraw from NACLA as, being already internationally recognised through the APLAC MRA and ILAC Arrangement, it found little benefit from the NACLA recognition process.

Annex J – MoU between the Commonwealth and NATA

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

COMMONWEALTH OF AUSTRALIA

AND THE

NATIONAL ASSOCIATION OF TESTING AUTHORITIES, AUSTRALIA

ABN 59 004 379 748

This *MEMORANDUM OF UNDERSTANDING* is made

this day of

2003 **BETWEEN**

The *COMMONWEALTH OF AUSTRALIA* represented for the purposes of this Memorandum by its Commonwealth Department of Industry, Tourism and Resources,

AND

THE NATIONAL ASSOCIATION OF TESTING AUTHORITIES, AUSTRALIA (ABN 59 004 379 748) (NATA), a company incorporated in Victoria limited by guarantee, having its Head Office at 7 Leeds Street, Rhodes, NSW 2138.

WHEREAS:

A. The Commonwealth and NATA, in partnership, desire to assist industry by strengthening the measurement and product and material testing system in Australia and to ensure that an appropriate level of accreditation of the various elements of the system is available. They also recognise that this system, amongst many other community benefits, provides an important mechanism for improving business efficiency and competitiveness of Australian industry in international and national markets

B. The Commonwealth:

(i) aims to promote an appropriate, internationally recognised infrastructure for inspection, testing, measurement and certification, based on accreditation;

(ii) has adopted a strategy of encouraging further development and strengthening of that infrastructure;

(iii) through the reforms arising out of the Committee of Inquiry into Australia's Standards and Conformance Infrastructure, expects that the appropriate infrastructure organisations will meet the changing needs of industry and consumers for these purposes;

(iv) looks to organisations within that infrastructure, such as NATA, to provide leadership and guidance; and

(v) recognises NATA as the key organisation in Australia's standards and conformance infrastructure in developing knowledge, international experience and recognition in accreditation of inspection bodies, testing and measurement laboratories.

IT IS HEREBY A GREED as follows:

Article 1 Definitions

1.1 General terms used in this Memorandum shall have the meaning given in the definitions contained in the current version of ISO/IEC Guide *2* "General terms and their definitions concerning standardization and related activities" unless the context otherwise requires.

1.2 The following terms and their definitions shall apply for the purpose of this Agreement:

'Laboratory' means a facility engaged in calibration, measurement, testing or related services.

'Reference Material' means an artefact or substance that enables the transfer of values of measured or assigned quantities between laboratories both domestically and internationally.

'Inspection Body' means a body carrying out inspection services.

'Accredited Service Provider'

means a Laboratory, a supplier of certified Reference Materials or an Inspection Body.

Article 2 General Provisions

2.1 The Memorandum encompasses the accreditation of laboratories, inspection bodies and suppliers of certified reference materials by NATA. It also encompasses the activities of NATA in participation in international and regional fora.

2.2 The Memorandum has effect for a period of five (5) years from the date of its execution.

2.3 After four (4) years from the date of its execution the Parties will review the performance of this Memorandum with particular reference to "national interest" activities as set out in an annual exchange of letters between the Parties.

Article 3 Recognition

3.1 Except with respect to therapeutic goods (as defined by the *Therapeutic Goods Act 1989* (Cth)) the Commonwealth:

3.1.1 recognises NATA as the national authority for accreditation of laboratories conducting tests and measurements in all technical fields and including laboratories performing tests and studies in accordance with the OECD Principles of Good Laboratory Practice and for accreditation of suppliers of certified reference materials.

3.1.2 recognises NATA as a peak authority for the accreditation of inspection bodies.

3.2 This Memorandum recognises the close relationship that exists between NATA and its New Zealand counterpart organisation, International Accreditation New Zealand (IANZ).

3.3 The Commonwealth recognises NATA as the Australian member of the International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the OECD Panel on Good Laboratory Practice.

3.4 The Commonwealth recognises that NATA needs to enter into complementary business activities to enable it to support the full range of its accreditation activities and to be a primary source of information on laboratory accreditation in Australia.

Article 4 NATA Undertakings

4.1 NATA will provide national leadership in establishing standards of good laboratory practice, in accrediting testing laboratories, inspection bodies and suppliers of certified reference materials thereby providing a network of competent accredited service providers to meet national needs as identified by governments or industry groups.

4.2 NATA will prepare, publish and, where appropriate, review and revise its procedures and standards to ensure that these will:

4.2.1 conform with international standards;

4.2.2 meet national interest requirements;

4.2.3 facilitate international trade;

4.2.4 satisfy the requirements for public health, safety and environmental protection; 4.2.5 enhance quality and performance of products, materials and related services;

4.2.6 be suitable for uniform reference in Australian governments' laws, regulations and public purchasing contracts; and

4.2.7 provide the laboratory testing, measurement and calibration basis for certification systems.

4.3 NATA will ensure that the Association and its committees develop practices which are in harmony with international standards for good laboratory practice and for the operation of laboratory and related accreditation systems.

4.4 NATA will recognise, and cooperate with, other key infrastructure bodies including Standards Australia, the National Standards Commission, the National Measurement Laboratory, the Joint Accreditation System of Australia and New Zealand, and the Australian Government Analytical Laboratories and will participate in annual meetings with these bodies.

4.5 In seeking to develop international compatibility and uniformity of testing, measurement and calibration throughout Australia, NATA will seek consensus and a fair and acceptable balance of all relevant interests in its work, and encourage full participation which reflects not only sound and modern technical practice but also takes full account of the needs of manufacturers, service providers and users.

4.6 NATA will assist the Commonwealth in attaining the objectives of the National Measurement Act 1960. In particular NATA will:

4.6.1 promote the use by its accredited laboratories of the legal units of measurement prescribed under the Act;

4.6.2 collaborate with the National Measurement Laboratory in promoting the use of Australia's primary and secondary standards of physical measurement;

4.6.3 collaborate with the National Standards Commission in matters pertaining to legal metrology; and

4.6.4 collaborate with the Australian Government Analytical Laboratory, the National Measurement Laboratory and the National Standards Commission in matters pertaining to chemical and biological metrology.

4.7 NATA, in developing and implementing its corporate objectives, will seek to assist industry to improve its competitive advantage by providing a world class testing and

measurement system and through this, promote community benefits. It will evaluate ways in which its services can be provided more efficiently and, consistent with international standards, apply innovative techniques to its accreditation process.

4.8 NATA will represent Australia in the International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC), the OECD Panel on Good Laboratory Practice and other such fora as may be agreed between the Parties from time to time.

4.9 In its role as Australia's representative NATA will act in the national interest identified by the Commonwealth and take into account the priorities of Australian industry.

4.10 In representing the Australian view at international meetings NATA will:

4.10.1 ensure that it consults with other interested bodies including industry, government, other infrastructure bodies and consumer organisations;

4.10.2 advise the Commonwealth in advance of the formation of Australian delegations to attend any international meetings;

4.10.3 when requested, provide the Commonwealth with the brief for the Australian delegation prior to such meetings; and

4.10.4 when requested, provide the Commonwealth with a report on the meeting within 90 days of the conclusion of the meeting.

4.11 NATA will develop and maintain links with foreign national accreditation bodies responsible for accredited service providers and maintain its operations in harmony with those foreign accreditation systems considered appropriate for development of reciprocal recognition agreements, bilateral or multilateral, which are considered in the national interest. In developing such reciprocal agreements, NATA will consult with the Commonwealth on the relevance of each agreement to the national interest or to the support of business efficiency and competitiveness and trade opportunities for Australian industry and services.

4.12 NATA will be the national authority responsible for monitoring compliance with the OECD Principles of Good Laboratory Practice and will ensure that relevant Australian codes of practice are in harmony with those principles.

4.13 NATA will provide a national database of accredited service providers in Australia, and will encourage increased community and industry access to its work and data base.

4.14 NATA will promote an awareness of the importance of its work to quality and the national interest, in educational institutions, industry and the general community.

4.15 NATA will develop plans to increase the involvement of industry in its laboratory accreditation scheme, to encourage all laboratories (including Commonwealth and State) to be accredited and to promote recognition of the scheme by all users of test and measurement data.

4.16 NATA will encourage accredited service providers to identify the specific needs of industry. Fulfillment of such needs would assist in improving export performance, and will ensure that NATA's planned activities are brought to the attention of the widest possible audience of relevant interest.

4.17 NATA will ensure that proficiency testing at an appropriate level is an integral part of its laboratory accreditation program.

4.18 NATA will ensure that there is adequate separation from its commercial subsidiary, NCS International Pty Limited.

4.19 NATA will ensure that any such complementary business activities referred to in Article 3.4 do not conflict with or divert attention from its core activities.

4.20 NATA will work with APLAC and other regional fora to ensure that the national interest priorities of the Commonwealth and Australian industry are taken into account in APEC, the WTO, AFTA/CER and other trade agreements and arrangements.

4.21 Where NATA intends to enter into an agreement with a Commonwealth agency for the purpose of accrediting laboratories or inspection bodies, it will, in advance of concluding the agreement, advise the Department of Industry, Tourism and Resources of the terms and conditions of the agreement to ensure consistency with this Memorandum.

4.22 NATA will respond to concerns raised by Commonwealth agencies with respect to the performance or competence of NATA accredited laboratories and laboratories accredited by NATA's MRA partners and will provide timely feedback to the relevant agency on actions taken to address those concerns.

Article 5 Commonwealth Undertakings

5.1 The Commonwealth may, through a grant-in-aid, provide financial assistance in relation to activities assessed as being in the national interest which will be addressed in detail in the annual Deed of Agreement between the Parties.

5.2 Consistent with its obligations, the Commonwealth will continue to:

5.2.1 advise other governments and relevant international conformance organisations that NATA is the nationally recognised laboratory accreditation body; and

5.2.2 inform the laboratory community and users of laboratory accreditation services that NATA is the only Commonwealth Government recognised accreditor; and

5.3 The Commonwealth and its agencies will, to the maximum extent possible, participate on NATA Technical Committees and Council. Where Commonwealth officers assist NATA in furtherance of its work as members of Council, its committees or as assessors, no recovery will be sought for the salary and salary-related costs involved. The use of Commonwealth officers in assisting any other NATA activity shall require further agreement with the Commonwealth.

5.4 To the maximum extent possible the Commonwealth shall, to satisfy its own testing needs, use NATA accredited laboratories or laboratories accredited by organisations with which NATA has a mutual recognition agreement.

5.5 The Commonwealth will encourage other Australian governments and instrumentalities to adopt a similar approach to that indicated in Article 5.4.

5.6 All Commonwealth laboratories whose principal function is to provide calibration, measurement, testing or related services to either Government or outside agencies will, as appropriate, obtain and maintain accreditation by NATA.

5.7 The Commonwealth shall support NATA's efforts to achieve international harmonisation of standards and codes of practice on laboratory accreditation, inspection body accreditation and accreditation of suppliers of certified reference materials.

5.8 The Commonwealth will, where appropriate, invite NATA to participate in

national, regional and international intergovernmental discussions involving the standards and conformance infrastructure, unless there are reasons of confidentiality for not doing so. Where such discussions may give rise to intergovernmental agreements, the Commonwealth will, as appropriate, take into account NATA's views on how best to implement such agreements.

5.9 Commonwealth regulatory agencies will work with NATA as appropriate to ensure that laboratories accredited by NATA or its MRA partners maintain the required level of competence to satisfy relevant regulatory requirements.

Article 6 Joint Undertakings

6.1 The Commonwealth and NATA will, where appropriate, encourage service providers in all sectors of the Australian community to adhere to the principles of good laboratory practice embodied in NATA's criteria for accreditation, to have such adherence recognised through NATA accreditation and as necessary to incorporate use of accredited laboratories in appropriate purchasing decisions, regulations, quality assurance requirements and operational procedures.

6.2 The Commonwealth and NATA will promote understanding and awareness of principles of good laboratory practice and the objectives and mechanisms of laboratory accreditation through educational, training and international activities. Furthermore, NATA and the Commonwealth shall seek to strengthen national information services on technical regulations, national and international laboratory accreditation and associated certification and approvals schemes.

6.3 The Parties will work together to arrive at mutually acceptable solutions to any problems or disputes that may arise in relation to this Memorandum.

Article 7 Variation

This Memorandum may be varied by agreement of the Parties and any such variation shall be set out in writing and signed by both Parties.

Article 8 Termination

The Commonwealth or NATA may, upon giving twelve calendar months notice in writing of its intention so to do, terminate the Memorandum

Article 9 Notices

9.1 Notices or communication by NATA to the Commonwealth about this Memorandum shall, unless otherwise notified in writing by the Commonwealth to NATA, be addressed to the Commonwealth as follows:

General Manager

Trade and International Branch
Department of Industry, Tourism and Resources
GPO Box 9839
CANBERRA ACT 2601

9.2 Notices or communication by the Commonwealth to NATA shall unless otherwise notified in writing by NATA to the Commonwealth, be addressed to NATA as follows:

Chief Executive
National Association of Testing Authorities, Australia
7 Leeds Street
RHODES NSW 2138

IN WITNESS WHEREOF the Parties have executed this Memorandum on the date first above written.

SIGNED for and on behalf of the)
COMMONWEALTH OF AUSTRALIA)
By WARREN ENTSCH) _____
Parliamentary Secretary to) Parliamentary Secretary
The Minister for Industry, Tourism and Resources,)
in the presence of:)

_____

SIGNED for and on behalf of the)
NATIONAL ASSOCIATION OF TESTING)
AUTHORITIES, AUSTRALIA)
by BARRY DAVID INGLIS) _____
~~Board Director,~~) NATA Board Director
in the presence of:)

Annex K - Relationship between NATA and PTA

31 December 2005

Dear Member

NATA Proficiency Testing Subsidiary – Proficiency Testing Australia

As a result of NATA's needs to comply with the new International Standard, ISO/IEC 17011 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*, it has become necessary for NATA to separate its proficiency testing activities into a "Related Body" as provided for in Clause 4.3.7 ("impartiality") of ISO/IEC 17011.

To remain as a signatory of the ILAC and APLAC Mutual Recognition Agreements, NATA is required to comply with this new standard.

As many Members will be aware, historically NATA has conducted about 30 separate proficiency testing programs a year plus numerous measurement audits for applicant and accredited laboratories.

NATA's own proficiency testing activities are accredited by the American Association for Laboratory Accreditation (A2LA). However, NATA also accredits other proficiency testing (PT) providers in Australia and abroad and this has led to the need for NATA to separate its PT activities into a "related body".

Accordingly, NATA has established a wholly-owned subsidiary organisation, "Proficiency Testing Australia" which, like NATA itself, is a company limited by guarantee. (NATA is the sole member). Its corporate logo is reproduced below:

Impact on Accredited and Applicant Laboratories

Effectively, there should be no major impacts resulting from this change. Members will be served by the same proficiency testing personnel and will be required to continue to participate in programs which have been historically required by NATA or which may be identified as new programs by NATA's Accreditation Advisory Committees. The main difference will be the need to report to *Proficiency Testing Australia, (PTA)* rather than NATA directly. As a condition of continuing accreditation Members will continue to be required to allow access by NATA to details of their performance in specific programs.

PTA will also be responsible for invoicing participants in its PT program.

Subsequently any follow-up and confirmation of corrective actions, where required, will be conducted by NATA itself.

NATA Proficiency Testing Policy
NATA's requirements for continuing participation in proficiency testing programs are currently detailed in *NATA Policy Circular 2 – December 2002*.

This circular will be reviewed shortly to take account of the establishment of Proficiency Testing Australia. The policy does, however, already provide for participation in PT programs operated by other bodies, including PT providers accredited for compliance with ILAC G13:2000. As part of its transfer of PT activities into *Proficiency Testings Australia*, NATA will be seeking to also transfer its A2LA accreditation to the new subsidiary.

During 2006, NATA will be reviewing further the processes used to identify suitable programs for proficiency testing used in its accreditation processes. This will include precise specification of PT needs by the Association's Accreditation Advisory Committees for the scope of activities considered appropriate for each field of testing.

In Australia, we are fortunate to have a growing number of accredited PT providers as well as the PT resources historically provided by NATA itself, and in future to be provided by the new NATA subsidiary, (PTA). This should enhance the future use of PT, not only for accreditation purposes, but for their use as a quality assurance tool and in providing educational opportunities for laboratory staff.

The decision to establish a new subsidiary by NATA's Board was taken after long and detailed investigation of the options available to maintain an appropriate level of proficiency testing across the broad spectrum of NATA's accreditation fields. This decision was also endorsed by the Association's Council at its annual meeting in October 2005.

Members seeking any additional details are invited to contact:

NATA:
Regina Robertson
Manager Technical and Corporate Development
Ph: 02 9736 8222
Email: Regina.Robertson@nata.asn.au

OR

Sharon Kelly
Assistant Technical Manager
Ph: 02 9736 8222
Email: Sharon.Kelly@nata.asn.au

Proficiency Testing Australia:
Philip Briggs
General Manager
Proficiency Testing Australia
Ph: 02 9736 8397
Fax: 02 9743 6664
Email: Philip.Briggs@pta.asn.au
Web: www.pta.asn.au

We trust Members will appreciate the critical significance of proficiency testing as a component of NATA's accreditation activities and the need for continuation of NATA's access to appropriate PT programs.

Yours sincerely

Anthony J Russell
Chief Executive

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Annex M - Glossary

A2LA	American Association for Laboratory Accreditation
AAC	Accreditation Advisory Committee
ACHS	Australian Council on Healthcare Standards
ACMA	Australian Communications and Media Authority
AFTA	Asean Free Trade Area
APEC	Asia Pacific Economic Cooperation
APEC MIP	APEC Market Integration Program
APLAC	Asia-Pacific Laboratory Accreditation Cooperation
AQIS	Australian Quarantine and Inspection Service
ASAQ	Agreement on Standards, Accreditation and Quality
ASEAN	Association of Southeast Asian Nations
BAM	Bundesanstalt für Materialforschung und – prüfung (Federal Institute for Materials Research and Testing)
BIPM	Bureau International des Poids et Mesures
CAC	Codex Alimentarius Commission
CCMAS	Codex Committee on Methods of Analysis and Samples
CE mark/marking	European Conformity marking
CER	Closer Economic Relations
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAR	Deutscher Akkreditierungsrat (German Accreditation Council)
DEH	Department of Environment and Heritage
DFAT	Department of Foreign Affairs and Trade
DITR	Department of Industry Tourism and Resources
EA	European Cooperation on Accreditation
EC	European Commission
EU	European Union
EMC	Electromagnetic compatibility
FSIS	Food Safety Inspection Service
GLP	Good Laboratory Practice
HKAS	Hong Kong Accreditation Scheme
HOKLAS	predecessor to HKAS
IAF	International Accreditation Forum
IAJapan	International Accreditation Japan
IANZ	International Accreditation New Zealand
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Co-operation

IOOC	International Olive Oil Council
ISO	International Organisation for Standardization
ISO/CASCO	ISO Committee on Conformity Assessment
IT	information technology
JAB	The Japan Accreditation Board for Conformity Assessment
JAS-ANZ	Joint Accreditation System of Australia and New Zealand
MoU	Memorandum of Understanding
MRA	Mutual Recognition Arrangement / Agreement
NACCB	predecessor to UKAS (merged with NAMAS to form UKAS)
NAMAS	predecessor to UKAS (merged with NACCB to form UKAS)
NATA	National Association of Testing Authorities, Australia
NCSI	NCS International Pty Ltd
NMI	National Measurement Institute
NVLAP	National Voluntary Laboratory Accreditation Program
OECD	Organisation for Economic Cooperation and Development
OIML	International Organisation for Legal Metrology
PAC MLA	Pacific Accreditation Cooperation Multilateral Recognition Agreement
PNGLAS	Papua New Guinea Laboratory Accreditation Scheme
PTA	Proficiency Testing Australia
QMS	quality management systems
RANZCR	The Royal Australian and New Zealand College of Radiologists
RCPA	The Royal College of Pathologists of Australasia
RVA	Raad voor Accreditatie *(Dutch Council for Accreditation)*
SANAS	South African National Accreditation System
SPS	Sanitary and Phytosanitary Measures
SQAM	Standards, Quality, Accreditation and Metrology
Sterlab	predecessor to RVA
SWEDAC	The Swedish Board for Accreditation and Conformity Assessment
TBT	Technical Barriers to Trade
Telarc	predecessor to IANZ
TGA	Therapeutic Goods Administration
WTO	World Trade Organization
UKAS	United Kingdom Accreditation Service