NATIONAL ASSOCIATION OF TESTING AUTHORITIES, AUSTRALIA

A Guide to using NATA Accreditation in Legislation, Regulation and Specification

2nd edition

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Preface

NATA serves the national and public interest by facilitating the provision of a reliable calibration, measurement, testing and inspection infrastructure to government, industry and the wider community through its peer-assessment based accreditation services.

NATA accreditation is used in many regulatory and quasi-regulatory arrangements as a means of mitigating risk. This might be financial risk associated with a product or system failure, loss of reputation/credibility of Australian industry or through directly protecting public health and safety.

To policy makers and specifiers in government agencies, the knowledge of NATA's existence, purpose, role, mode of operation and scope of coverage is highly variable; ranging from very good to non-existent. Not surprisingly then, the range of applications of NATA accreditation in regulation and specification ranges from very appropriate to non-existent.

Until 2009, there had been total reliance on Government policy and specification writers being "in the know" about NATA or, failing this, having heard enough about NATA to prompt a call to ask just what NATA did and why NATA accreditation might be useful in helping their agency:

• reach a regulatory objective; or

• have confidence that a procurement specification would be met.

The first edition of this guide served to consolidate into one document the explanation of NATA itself, where it fits into Australia's standards and conformance infrastructure and how it can be usefully employed by government agencies to meet a particular need.

This second edition contains a number of refinements of this information to make it more user friendly and some additional material added to address deficiencies in the first edition identified by users.

Executive Summary

NATA's primary role is to serve the national and public interest by facilitating the provision of a reliable calibration, measurement, testing and inspection infrastructure to government, industry and the wider community.

To this end, NATA accredits facilities offering these services. Accreditation is a high-level process of recognising, through demonstration, the collective and specific competencies of these service providers. NATA accreditation is a third-party and objective assurance that the service provider possesses all the competencies necessary to deliver sound technical/scientific data – reliable outputs on which decisions can be made with confidence.

NATA accreditation is

- technically focussed;
- uses international standards; and
- carries international recognition.

NATA is a private, not-for-profit company with government-recognition as a peak provider of assurance services for testing laboratories, inspection bodies and related service providers.

This guide provides essential background information about

- NATA, its role, and accreditation processes;
- How NATA accreditation facilitates a reliable calibration, measurement, testing and inspection infrastructure that underpins government policy, business and the broader public interest;
- Using NATA accreditation as part of the regulatory tool kit.

A number of case studies are included to demonstrate key considerations in implementing a suitable regulatory structure.

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Acronyms

APLAC	Asia Pacific Laboratory Accreditation Cooperation
AS	Australian Standard
CAB	Conformity Assessment Body
GLP	Good Laboratory Practice – as defined by the OECD
HACCP	Hazard Analysis and Critical Control Points
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
JAS–ANZ	Joint Accreditation Scheme for Australia and New Zealand
MoU	Memorandum of Understanding
MRA	Mutual Recognition Agreement (sometimes Arrangement)
NMI	National Measurement Institute
OECD	Organisation for Economic Co-operation and Development
SI	International System of Units
TBT	Technical Barriers to Trade
WTO	World Trade Organization

Glossary

Term	Working definition
(NATA) accreditation	Procedure by which an authoritative body (NATA) gives formal recognition that a body or person (facility) is competent to carry out specific tasks as described in a published scope of accreditation. (Based on the ISO/IEC Guide 2 definition)
Assessment/ reassessment	An on-site evaluation of a facility's competence and capability to deliver reliable results conducted against one or more recognised standards and undertaken by a NATA Lead Assessor and one or more peer assessors
Conformity assessment	As used internationally, the process(es) involved in determining the conformity of a product or service with a specification or other defined requirement. Note: Accreditation is not conformity assessment.
Conformity assessment body (CAB)	A body that undertakes conformity assessment activities. In the case of NATA accreditation, the term is applicable to all types of laboratory, inspection body, proficiency testing scheme provider and reference material producer. Note: The application of the term to some laboratory and associated activities is sometimes the point of argument but, in the context of this document, facilities that NATA accredits are CABs
Deed of Agreement	An arrangement between a government agency and NATA that provides recognition of NATA's role in a regulatory activity and defines each party's obligations.
Facility	Any entity undertaking an activity that NATA can accredit such as (but not limited to) measurement, testing, inspection, imaging. This is typically a laboratory, inspection body, medical imaging practice, proficiency testing scheme provider or reference material producer.
Memorandum of Understanding (MoU)	An arrangement between a government agency and NATA that provides recognition of NATA's role in national interest/public benefit activity(ies) and defines each party's undertaking to support the arrangement.
NATA endorsement	Use of the NATA logo and approved wording (as described by the NATA Rules) on reports issued by accredited facilities under their scope of accreditation providing the recipient with assurance that that facility is appropriately accredited for the services provided.
National authority	Government recognition of a body as the sole authority for one or more activities.
Peak body	Government recognition as being an authority for one or more activities.
Scope of accreditation	A description of the specific activities for which an accredited facility has been peer assessed and demonstrated its competence and capability.
Standards and Conformance Infrastructure	The four bodies – National Association of Testing Authorities, National Measurement Institute, Standards Australia and the Joint Accreditation Scheme for Australia and New Zealand – that together provide Australia's measurement, standards and accreditation framework.
Surveillance visit	An on-site visit to a NATA-accredited facility conducted by a NATA lead assessor to review the management system in full (including a document review) and selected technical elements against the accreditation requirements.

1. Introduction

1.1 The role of NATA

NATA's primary role is to serve the national and public interest by facilitating the provision of a reliable calibration, measurement, testing and inspection infrastructure to government, industry and the wider community.

NATA is a private, not–for–profit company, owned by its members and governed by a Board of Directors elected from NATA's advisory Council. The Council has representation from government, industry and professional bodies. The Commonwealth recognises NATA as:

- The national authority for accreditation of laboratories and similar testing facilities
- The national authority for accreditation of producers of certified reference materials
- A peak body for the accreditation of inspection bodies
- A peak body for the accreditation of proficiency testing scheme providers
- Australia's compliance monitoring authority for the OECD Principles of Good Laboratory Practice (NATA represents Australia on the OECD GLP Working Group)

1.2 Government agencies as NATA stakeholders

Commonwealth, State and local government departments and authorities are all key stakeholders in NATA's accreditation activities. This stakeholder role takes three forms.

1. Government as regulators mandating/encouraging the use of NATA accredited facilities as a means of providing confidence that activities such as testing, measurement and inspection will contribute to achieving regulatory objectives.
2. Government as a customer of testing, measurement or inspection activities and specifying the use of NATA-accredited facilities as a means of meeting objectives for quality, risk management and accountability.
3. Government laboratories and inspection authorities themselves being accredited by NATA as a means of providing public confidence in their competence and capability.

1.3 Government recognition of NATA

A Memorandum of Understanding (MoU) between NATA and the Commonwealth[1] recognises NATA's role as the national authority for accreditation of laboratories and reference material producers and as a peak body for the accreditation of inspection bodies and proficiency testing scheme providers.

The underpinning rationale for this MoU is expressed by the statement of common goals contained in the preamble of the document.

"The Commonwealth and NATA , in collaboration, desire to assist the wider Australian community by facilitating the availability of competent services

1 The current MoU was signed in May 2013.

to provide reliable results of measurement, test, inspection and similar technical activities. The parties recognise that confidence in the reliability of such results is a prerequisite for sound decision making by government, business and individuals. It contributes to efficiency in the public and private sectors, the competitiveness of Australian industry in domestic and international markets and the general welfare of all Australians."

The MoU contains a number of mutual undertakings. Those of the Commonwealth include the provision of officers' time on NATA's governing and technical advisory committees. They also state that the Commonwealth will:

- include the specification of NATA accreditation in legislation and regulation when justified through a regulatory impact evaluation – Government as regulator;
- use accredited facilities to satisfy its own testing, measurement or inspection needs where merited – Government as customer (specifier); and
- for its own laboratories having the principal function of providing calibration, measurement, testing or related services, as appropriate, be NATA accredited – Government as an accredited facility.

The MoU provides NATA with recognition not only nationally but also internationally with regard to representation in accreditation fora, mutual recognition arrangements and trade arrangements in sectors for which testing, measurement and inspection are required for acceptance of products.

1.4 Purpose of this guide

Despite the MoU's existence and NATA's long and extensive involvement in various national and international activities, information is not always readily available to those developing or implementing policy. Government departments and agencies often lack accurate information about what NATA accreditation is, how it might be used as a tool in various types of legislation, regulation or codes of practice and how it can be used in specifications to achieve the government's objectives.

This guide provides some essential information about NATA, its role, the scope of accreditation activities, the accreditation process and how NATA accreditation can be an important part of the regulatory tool kit in instances where reliable calibration, measurement, testing and inspection are needed to meet regulatory objectives. It also provides information to specification/ contract writers who need to address issues relating to measurement, testing or inspection in government purchasing.

As with all guides, there are bound to be issues that the information or guidance provided does not seem to adequately address. If this is the case, please contact NATA. Staff are more than willing to assist if at all possible.

2. What is NATA accreditation?

2.1 Defining "accreditation"

Accreditation has become a much-used word. It appears in a number of contexts and is applied to things, people, and organisations, or parts thereof. Accreditation is also a word that is used with increasing frequency in legislation and regulation.

Consulting the Best Practice Regulation Handbook and similar publications, "accreditation" and "accreditation schemes" are identified as appropriate tools that can be used in quasi–regulation. These guides do not, however, offer any definition or explanation beyond this.

When used in legislation and legislative instruments, accreditation is defined infrequently. Even when defined there can be variation between the definition and its application.

In NATA's vocabulary, which is also that used in the international arena of testing, calibration, inspection and certification (collectively known as conformity assessment activities), accreditation has a very specific meaning that is particularly important in trade. A definition developed internationally, and which best defines NATA's own activities, is that of ISO/IEC Guide 2 :

"Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks."

ISO/IEC Guide 2

2.2 Defining "NATA accreditation"

NATA accreditation is primarily focussed on activities that produce technical/scientific data and information used in making informed decisions. Generally speaking, this refers to the production of test, measurement and calibration data/reports and/or the reports arising from inspection activities.

With this in mind, looking at the elements of the ISO/IEC Guide 2 definition in more detail develops a better appreciation of NATA accreditation:

- *"… authoritative body …"* This is a public or private sector organisation operating an accreditation program in compliance with ISO/IEC 17011 and having the confidence and recognition of the relevant stakeholders – governments, regulators, industry and the wider community.

  NATA is recognised by the Commonwealth through a Memorandum of Understanding (MoU) as the national authority for accreditation of laboratories and reference material producers and as a peak body for the accreditation of inspection bodies and proficiency testing scheme providers.

- *"… competent …"* The KEY to having confidence in the technical/scientific data and information produced by any accredited facility is the competence of the staff performing the specific activities for which it is accredited. The best management systems will never compensate for an inadequate level of practical competence in an organisation.

  Staff involved in a laboratory or inspection-type activity need to demonstrate this competence collectively through peer assessment as part of an accreditation process.

Clearly, the notion of peer assessment also necessitates that the peer assessors themselves are competent to undertake such activities.

- *"… specific [technical] tasks."* The recognition provided by NATA accreditation is for specific rather than general capabilities. The accreditation process yields a scope of accreditation which defines the capabilities that have been peer assessed and found to be satisfactory. This scope, listed on NATA's public access website, together with an accreditation certificate provides the "formal recognition".

To summarise, NATA accreditation is a high level process of recognising collective, specific and demonstrated competencies that are necessary to deliver sound technical/scientific data and information on which decisions can be made with confidence.

Box 1. Why is the focus on competency rather than qualifications?

Many of NATA's accreditation activities are undertaken in disciplines that are usually undertaken by people having tertiary qualifications in a scientific or engineering discipline. This raises two questions.

- If a laboratory or inspection body has staff with these qualifications, aren't such staff competent by definition?
- Is NATA getting into professional credentialling?

The answer to both questions is "no".

If NATA's long history in laboratory accreditation has shown anything, it is that even formal qualifications in a relevant discipline do not always translate into practical competency and proficiency. It is sometimes observed that academically qualified individuals do not always exhibit the practical abilities demanded by a laboratory or inspection environment. In other cases, the qualifications have lost currency due to movements in technology and/or a lack of continuing education. Forty years in a laboratory does not necessarily equate to forty years of experience and continuing education in a laboratory.

A NATA assessment is not a re–examination of academically acquired knowledge but a process of collecting evidence that the staff are applying their knowledge, howsoever gained, in a scientifically/technically appropriate manner.

It also needs to be recognised that many activities undertaken by some types of laboratory – such as instrument calibration or product testing – are not taught in formal courses. They are skills acquired on the job. The person undertaking the task may well have an appropriate science or engineering degree, and therefore have knowledge of the relevant theory, but the skill set necessary will probably have been gained some time after finishing formal studies.

In some cases, however, staff that have no formal qualifications at all are able to demonstrate a high level of competency and proficiency because of their extensive experience in the activity under assessment.

Returning to the main question, NATA must be assured that the people in any accredited facility don't just have the potential to be effective in producing reliable measurement, test or inspection data but that they actually are effective.

The core of NATA accreditation is the third party, objective, peer assessment process at a scientific/ technical level that provides assurance of the laboratory or inspection body's capability to produce reliable outputs.

2.3 What NATA accreditation is not

With the now common and broad use of the term "accreditation" and some longer standing misconceptions of what NATA accreditation involves, it is important that there is clarity about what NATA accreditation is not.

- It is not merely a means of registering or listing someone or something.
- It is not a management system review dressed up with some scientific/technical elements.
- It is not the recognition of reputation/affiliation – these things change over time.
- It is not the recognition of future capabilities.
- It is not the recognition of an individual's qualifications.
- It is not broad approval of everything a facility might do.

2.4 Accreditation and certification

The terms "accreditation" and "certification" are increasingly used either interchangeably or with "accreditation" being used to describe a "certification" activity. This has reached a point where some legislation and/ or regulations do not make the distinction. It is particularly prevalent in the health care sector.

NATA accreditation has been defined in 2.2 but what is certification and how does it differ from accreditation? Does it matter?

In the international vocabulary of conformity assessment, certification is the process of attesting to the conformity of a product or service with a specification. Examples of certification in practice, and what they are designed to deliver, are:

- ISO 9000 management system certification – a level of confidence in a manufacturing or service delivery process;
- HACCP certification in the food industry – the safety of food;
- product certification systems – that a particular product will meet a standard that sets safety or performance criteria.

These certification activities are undertaken by what are generically called conformity assessment bodies (CABs). Laboratories and inspection bodies are also defined as CABs in this vocabulary.

CABs become accredited – recognised for their competence to perform specific tasks – for the certification activities they perform.

In general then:

- Accreditation is the peak activity
- Certification (conformity assessment) is an activity itself subject to accreditation.

Box 2. Accreditation and certification – but aren't they doing the same thing?

So what does all this mean in practice? Accreditation and certification both seem to be aimed at delivering confidence/assurance. They both involve some form of third party assessment. In NATA's patch, isn't it possible to either certify a laboratory's management system or accredit the laboratory?

The fact is there are many similarities between what accreditation bodies and conformity assessment bodies do and the techniques employed to achieve their aims. Leaving aside the formal definitions, the difference between the two might best be observed by comparing the actual assessments in terms of depth and the scope of what is examined.

As an example, take a laboratory of some type that is part of a larger organisation and that two assessments are conducted – one by NATA and one by an ISO 9001 management system certifier. In our comparison, we will take just one aspect – documentation.ISO 9001 (the standard for quality management systems) and ISO/IEC 17025 (the standard for competency in a laboratory) both expect that key procedures are documented and that such documents are subjected to some form of control system to make sure they are always current and available to the staff needing them. There is not much use having procedures if they are out of date or not at hand when needed.

The following table shows where typical NATA and ISO 9001 assessments are likely to be similar and where they will differ.

Activity/Requirement	NATA Assessment	ISO 9001 Assessment
Scope	Laboratory only	Entire organisation
Assessment team	NATA Lead Assessor and one or more peer specialists in the laboratory's activities	ISO 9001 Lead assessor (maybe more than one for a large organisation) and may include a specialist for some activities
Document control	Sample of laboratory documentation	Sample of organisational documentation which may or may not include a laboratory
Document validity	Sample of laboratory test procedures covered by the scope of accreditation examined including validation data – staff understanding of validation will be probed	For critical documents but may or may not include a laboratory

Document usage	Sample of laboratory documentation – including test procedures Peer assessors will seek a practical demonstration by staff and probe understanding of the procedure	Sample of organisational documentation which may or may not include a laboratory Practical demonstration and staff understanding not within assessment scope
Staff	Sample of records for qualifications, training and experience of laboratory staff Peer assessors will probe the level of practical competence and understanding of the specific tests, measurements and/or inspections under accreditation	Sample of records for qualifications, training and experience of a range of organisational staff

So even for an element primarily related to the way a management system would operate, the NATA accreditation approach is:

- focussed on competency aspects;
- applied to the activity that produces data – the tests, measurements or inspections performed; and
- concentrated on how it contributes to producing correct test, measurement or inspection data.

Overall, NATA's peer assessment of the actual scientific and technical activities that take place in a laboratory or inspection environment is outcome focussed – reliable data on which to base decisions.

Even though ISO 9001 can be applied to the laboratory only, it is not designed to achieve the same level of confidence in the outputs – test and/or measurement and/or inspection data.

Ultimately, it is the NATA accreditation process and the confidence it can provide that is the key consideration for policy makers, not what it is called. There are, however, instances where terminology should be used carefully. Chapter 6 gives one important example – international trade.

3. NATA accreditation – process and approach

3.1 NATA's process

To gain accreditation, applicants undergo on–site assessment by a team consisting of:

- one or more peer (technical) assessor(s) having the relevant expertise to assess staff competency for the specific activities for which accreditation is sought; and
- a NATA lead assessor.

The time taken depends on a number of factors. Obviously the wider the range of tests, measurements and/or inspections a facility performs, the greater will be the assessment effort required. Other factors include the number of operational staff available to the assessment team, the number of peer assessors required and logistics (particularly where there is a need to observe field work away from the facility's premises).

When deficiencies in knowledge, laboratory/inspection practice, records or documentation are identified, the facility's management is notified in a written report which is usually provided at the conclusion of the assessment visit.

Improvement opportunities may also be mentioned in the assessment report but in a way that recognises the necessity for NATA to be impartial.

Facilities need to take action to remedy any deficiencies that have been identified and provide NATA with appropriate evidence of these actions. Once these are determined to be satisfactory, accreditation can be granted. Responses are frequently dealt with via correspondence but occasionally a supplementary assessment visit is required. Not surprisingly, deficiencies in knowledge and/or experience cannot always be addressed in a short period of time. In such cases, it may not be possible to grant accreditation for some time, if at all.

Accreditation findings and the facility's responses are reviewed by the peer assessor(s) and also by representatives of NATA's Accreditation Advisory Committee(s) that cover the relevant technical/scientific disciplines. These committees are made up of persons having specialist technical knowledge.

Once accredited, facilities must undergo routine reassessment and surveillance visits to ensure their ongoing competency and compliance with the accreditation criteria.

The accredited capabilities of a facility are listed in a scope of accreditation. It is important to note that this scope may not cover all of the activities that the facility undertakes. Only those activities that have been assessed, and for which competency has been demonstrated, will be included.

3.2 NATA's approach

An assessment is an exercise in gathering and evaluating information and objective evidence with the aim of being able to judge the collective competency and capability of the staff and facilities. It is essential that assessments be conducted in a non–threatening and cooperative manner so as not only to determine this competency and capability but also to promote

improved performance. Conducting assessments with this outlook is also likely to produce open and effective communications.

Hence, the assessment technique used involves:

- asking questions and analysing the answers given;
- discussing issues;
- checking documents;
- observing practical demonstrations of activities;
- examining facilities and equipment;
- reviewing records; and
- ensuring the quality of reports.

The objective is to acquire enough evidence that the facility is capable and likely to produce consistently reliable data and information on which sound decisions can be made. There are, however, side benefits. Laboratories and inspection bodies that approach the accreditation process openly and cooperatively frequently report benefits in terms of efficiency gains, business process improvements, and better outcomes that are largely delivered by interactions with peers.

The selection of peer (technical) assessors is clearly critical to the success of any assessment. Assessors are primarily selected on the basis of their expertise, but factors such as interpersonal skills and their affiliation are also taken into account.

With regard to issues of affiliation, it must be noted that an assessor operating in a competitive environment does not necessarily disqualify him or her from assessing a similar facility. Competition does not necessarily compromise objectivity. When NATA is considering experts from commercial facilities for invitation to become assessors, a key factor considered is that they have shown the attribute of objectivity. After being invited and trained, such assessors are monitored to ensure they demonstrate an ability to be objective even in a competitor's facility.

Such an ability is a product of their own integrity combined with their belief in the ideals of NATA – that it is in the national and public interest for all NATA accredited facilities to be of an appropriate minimum standard. The benefit to the facility under assessment is that the assessor is not only a peer in terms of expertise but also in understanding the facility's commercial and business imperatives. The result is a balanced and thorough assessment.

4. Standards used in NATA accreditation

4.1 Standard for Accreditation Bodies

Accreditation bodies such as NATA that undertake the accreditation of certification activities, are obliged internationally to operate in accordance with the requirements of ISO/IEC 17011:2004 – *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.*

This standard serves two purposes. Firstly it provides the ground rules for any organisation that is involved in the accreditation of conformity assessment bodies. While not exhaustive in its coverage of accreditation activities, it covers many elements that are considered essential to providing a system with efficacy, independence and credibility.

The second purpose of the standard is to facilitate recognition internationally. An accreditation body's compliance with ISO/IEC 17011 has become a prerequisite for them entering into international mutual recognition arrangements, something that has become important in areas relating to trade. This is discussed in more detail in section 6.

4.2 Standards used by NATA as accreditation criteria

NATA's accreditation criteria are generally based on the relevant ISO/IEC international standards or guides. There are currently five standards that form the main criteria for NATA assessment and accreditation activity.

- *ISO/IEC 17025:2005* – General requirements for the competence of testing and calibration laboratories
- *ISO/IEC 17020:2012* – Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- *ISO 15189:2012* – Medical laboratories – Requirements for quality and competence
- *ISO/IEC 17043:2010* – Conformity assessment — General requirements for proficiency testing
- *ISO Guide 34:2009* – General requirements for the competence of reference material producers

These documents are sometimes termed "accreditation standards". This is not strictly correct. Each exists independently of the accreditation community. ISO/IEC 17025, for example, is a standard that defines the requirements for operating a laboratory in a competent and reliable manner. It describes what laboratory practitioners regard as the fundamentals of sound laboratory practice. Any laboratory can apply these fundamentals whether accredited or not.

These documents, however, written in a manner that allows their adoption into accreditation systems for use as accreditation criteria. Despite this, they cannot be used as the sole criteria. Accreditation is an activity that requires rules for accredited facilities to follow in order to become, and continue to be, accredited. These rules include: obligations to act in a manner that does not bring NATA and its accredited facilities into disrepute, notification of changes to a facility, payment of fees and so on. Thus there is the *NATA Rules* publication that forms part of NATA's accreditation criteria.

There can also be accreditation arrangements that include other parties. Two of NATA's accreditation programs are run in conjunction with professional bodies.

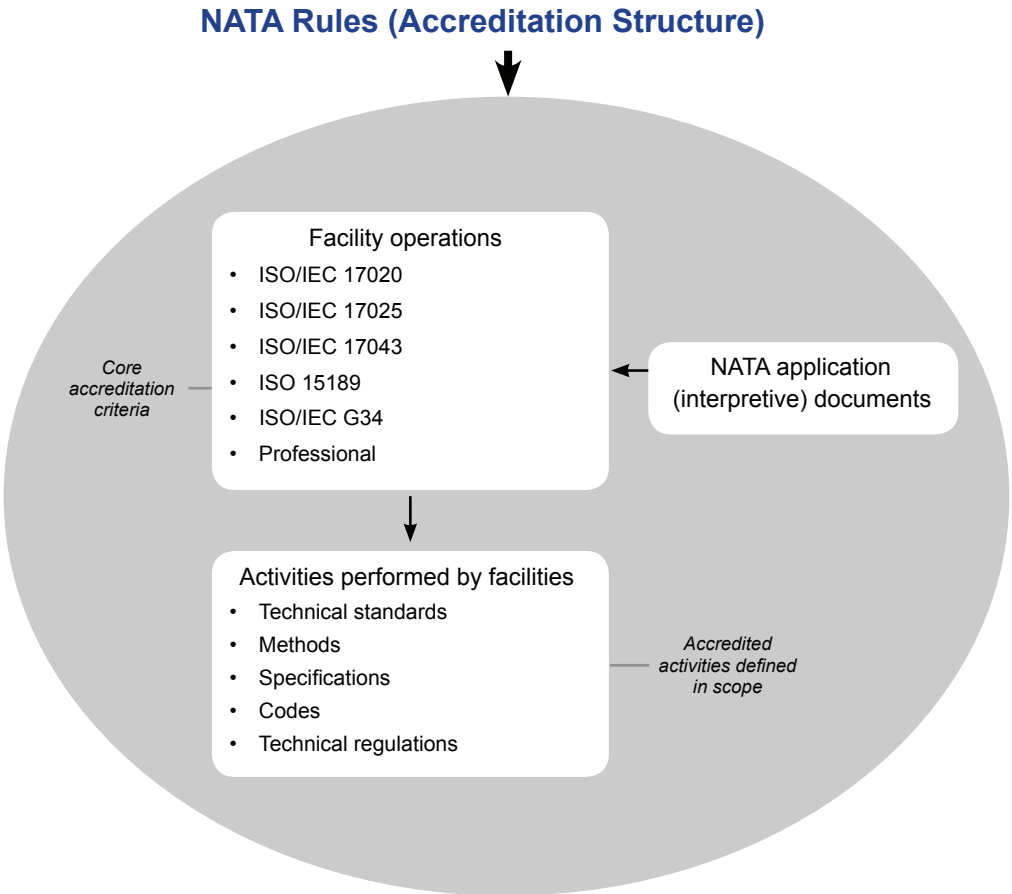
- For pathology laboratories, NATA operates a joint accreditation program with the Royal College of Pathologists of Australasia (RCPA). Laboratories must gain joint NATA/RCPA accreditation to be eligible to claim payments from Medicare Australia.
- In medical imaging, there is a joint program with the Royal Australian and New Zealand College of Radiologists (RANZCR). This is a voluntary program established with the College to encourage imaging facilities to meet or exceed a minimum standard of practice.

Both of these programs have criteria that are developed by professional stakeholders.

There is also a third layer of documents – most often specifications, methods and standards – that form part of the assessment criteria. These are the technical standards that often describe methods, specifications and limits for particular activities for which the facility is accredited. These documents will often be referenced in an accredited facility's scope of accreditation, the publicly available listing that defines the activities that have been peer assessed as being competently performed.

There is a broad range of these technical standards available from many sources. Many are described as product standards – they contain information on manufacturing and minimum performance-related characteristics of a particular product – and may also include some information on testing. Others are purely test methodologies for specific types of test, independent of the product or material to which they will be applied.

It is standards of this level that are usually core to the assessment of facilities performing product or material tests or inspections. The peer assessment will focus on how well the laboratory staff understand and apply the requirements that are described.



Box 3. A word about standards

To those not immersed in the accreditation community, the word "standard" can be very confusing. There are three distinct usages that are context specific and, unfortunately, they can all come into usage when dealing with accreditation.

1. Standard – the subjective term relating to quality, thoroughness, reliability and so on.
2. Standard – relating to a physical measurement standard such as a 1 kg mass or a reference measuring instrument in a laboratory.
3. Standard – the document produced by a national or international standards writing body that contains specifications, methods and criteria for a product, activity or service. The language of such a standard is usually a combination of normative (the essential or minimum requirements expressed as "shall" or "must") and informative (the recommended but non–essential expressed as "should").

In the world of standards and conformance infrastructure, the following sentence is not complete nonsense:

"The standard will depend on the **standard** specified by the **standard."**

This can be translated as:

"The accuracy or reliability of the measurement will depend on the **physical reference standard** specified by the **measurement method."**

Hence, it should be no surprise that the message about NATA's accreditation activities can become skewed when even publications aiming to assist policy and specification writers through the maze sometimes use the word "standard" in a way that can be ambiguous.

4.3 Minimum standards or ideal standards

The international standards that form the basis of NATA's accreditation criteria are, like most standards that describe technical requirements and methodologies, minimum standards. ISO 15189 and ISO/IEC 17025, for example, define the competencies and processes of routine laboratory activity that need to be present for effective and reliable operation.

There is a perception by some in government and industry that NATA accreditation is aimed at ideal standards or exemplary performance. This is not so. The standards used as the basis of accreditation criteria do not describe ideals at all. This is often observed through the assessment process when accredited facilities exceed the minimum requirements by a significant margin. Hence, the standards used in NATA accreditation are clearly describing requirements that are readily achievable.

As with the discussion of NATA's accreditation approach, best practice is certainly not discouraged and it is not uncommon for assessment discussions to touch upon areas where the existing practices are adequate but could be improved. NATA's and other accreditation systems must, however, remain aware of the need to ensure minimum standards are achieved but not demand a level of laboratory or inspection practice that is not commercially sustainable.

4.4 Standards development

ISO/IEC 17000 series and related standards – Development of the ISO/IEC 17000 series of standards that form the basis for operations of accreditation bodies and those used as the basis for accreditation criteria is undertaken by the ISO Committee on Conformity Assessment (ISO CASCO). Representation on this committee comes from stakeholders in ISO member countries. This includes practitioners – accreditation bodies for ISO/IEC 17011, laboratories for ISO/IEC 17025 and inspection bodies for ISO/IEC 17020. This involvement ensures that standards are both relevant and focussed on the essential requirements of the activities to which they apply.

The international development of standards used in accreditation also facilitates mutual recognition of accreditation systems and of the accredited facilities themselves. This aspect has become increasingly important to international trade.

Technical standards – Development of technical standards is frequently undertaken by either international or national standards writing bodies. Others are developed by industry bodies or associations, professional bodies and occasionally by government agencies themselves. Generally, technical standards are also developed along the same lines as the ISO/IEC 17000 series – by committees made up of stakeholders and via a consensus process.

In the Australian context, most standards are developed for adoption on a voluntary basis (excepting those produced by government, which would almost exclusively be used for the purpose of regulation). Voluntary sector standards may, however, be called up in regulation and, hence, compliance with them may be mandated.

NATA's contribution – It has become conventional wisdom that the development of standards that might be used as accreditation criteria should be independent of any accreditation activity that uses them. It is recognised by all – including NATA – that there is a potential conflict of interest in one organisation performing both functions.

NATA accreditation does, however, sometimes reveal deficiencies in standards which, for example, make it difficult for testing to be undertaken consistently. This could be due to an error, an omission or perhaps some ambiguity in the stated requirements. In such cases, NATA accreditation does have a role to play in feeding such information gained from assessments back into the standards writing process. For this reason, NATA staff do sometimes sit on standards writing committees to ensure that such deficiencies are understood and remedied through the committee process.

5. Australia's standards and conformance infrastructure

5.1 NATA's broader context

NATA plays a key role as one of the four constituents of Australia's standards and conformance infrastructure, which provides an important mechanism for improving the business efficiency and competitiveness of Australian industry in international and national markets.

In considering the role NATA accreditation might play in any issue of policy or regulation, it is often necessary to consider associated factors such as measurement standards, documentary standards and complementary types of competency-based accreditation. For this reason it will sometimes be appropriate to look at the standards and conformance infrastructure as a whole.

NATA and the other three standards and conformance bodies are happy to provide individual assistance but the four have also formed the Technical Infrastructure Alliance which provides for a single point of entry to regulatory and industry bodies seeking advice on standards and conformance issues.

Box 4. Conformity assessment

The term "conformity assessment" is certainly not a part of everyday speech. Indeed, its use domestically is primarily the domain of the four organisations that are the subject of this section and a number of regulators and trade officials.

ISO/IEC 17000 *Conformity assessment – Vocabulary and general principles* is a source of information on what is meant by conformity assessment and a range of other related terms. It is not the purpose of this guide to provide another discourse on the topic so readers should avail themselves of a copy if interested.

For the purposes of this discussion:

- "conformity assessment" is what is done by "conformity assessment bodies";
- "conformity assessment bodies" (frequently just called CABs) provide attestations that products, processes and systems are doing what they are supposed to do;
- NATA and JAS-ANZ accredit these CABs so that the users of their services can have confidence in their outputs – laboratories, inspection bodies, product certifiers, management system certifiers and so on;
- standards – both measurement and documentary are absolutely necessary to underpin the processes used in accreditation systems and the confidence they deliver in CABs.

So from the perspective of a regulatory or policy objective, conformity assessment, supported by standards and conformance infrastructure bodies, provides confidence that services and products are reliable and consistent.

5.2 The National Measurement Institute (NMI)

NMI is responsible for Australia's national infrastructure in terms of physical, chemical, biological and legal measurements. Under the National Measurement Act 1960, NMI is responsible for coordinating Australia's national measurement system, and for establishing, maintaining and realising Australia's units and standards of measurement. This allows Australian industry to operate competitively in a global environment. NMI also has national responsibility for trade measurement which provides industry and consumers with assurance that commercial transactions that are based on measurement – mass (weight), volume, time interval, etc. – are performed with instruments that are fit-for-purpose and calibrated in a way that links the measurements to the national standards. This provides measurement traceability.

Where a potential regulatory issue or element of an issue relates to any form of measurement, NMI has an important role in advising on appropriate methodologies and reference standards. Discussion of possible solutions should also include consideration of the availability of facilities with appropriate NATA accreditation.

5.3 Joint Accreditation Scheme of Australia and New Zealand (JAS–ANZ)

JAS–ANZ is the government–appointed accreditation body for Australia and New Zealand responsible for providing accreditation of conformity assessment bodies (CABs) undertaking management system and product certification, and for inspection. Note that JAS–ANZ accreditation, like NATA's, is built upon a competency based peer assessment process.

JAS-ANZ accreditation of conformity assessment bodies provides confidence in their capability to deliver reliable certification activities. In areas such as product safety, where a combination of testing and product certification could be an appropriate regulatory response to an issue, it may be appropriate to consult NATA and JAS-ANZ jointly.

5.4 Standards Australia (SA)

Standards Australia is recognised by the Commonwealth Government as Australia's peak Standards body. It coordinates standards development (known in the business as standardisation) activities, develops internationally aligned Australian Standards of public benefit and national interest and facilitates the accreditation of other Standards Development Organisations.

While NATA does not develop standards, there is frequent dialogue between the organisations with regard to interpretative issues of standards that arise as part of NATA's assessment processes. Joint discussion with NATA and Standards Australia may be appropriate where a potential regulatory approach could best be addressed through a standards and NATA accreditation solution. (www.standards.org.au)

More information on these organisations is available on their websites:

National Measurement Institute (NMI) - www.measurement.gov.au

Joint Accreditation - www.jas–anz.org

Standards - www.standards.org.au

6. The international context of NATA accreditation

6.1 Development of Mutual Recognition Arrangements – international trade

One of the drivers for the development of international cooperation between laboratory accreditation bodies was the identification of non–acceptance of test data being used by some countries as a technical barrier to trade (TBT). This became a matter of significant importance following the Uruguay round of discussions on the General Agreement on Tariffs and Trade (GATT). It was recognised that there was a need to develop mechanisms for mutual recognition of test data to reduce these TBTs.

An outcome was the rapid development of laboratory accreditation systems around the globe as well as international and regional cooperations between laboratory accreditation bodies.

The International Laboratory Accreditation Cooperation (ILAC) and the Asia–Pacific Laboratory Accreditation Cooperation (APLAC) began as bodies with the primary focus of developing and harmonising accreditation practices. This focus evolved into formulation and then implementation of peer evaluation processes used to determine the equivalence of the accreditation practices of accreditation bodies.

Peer evaluation by accreditation practitioners using the international standard ISO/IEC 17011 as the criteria has enabled the development of mutual recognition arrangements (MRAs) to facilitate trade by allowing testing or measurement to be performed in the country of manufacture in accordance with the importing country's requirements.

NATA was one of the inaugural signatories to both the APLAC and ILAC Mutual Recognition Arrangements. These arrangements are between national accreditation bodies on a voluntary basis but they provide governments with a mechanism for confidence in the measurements, tests and inspections that might be performed in another jurisdiction.

6.2 Government use of NATA's MRAs

Commonwealth departments and agencies have been quick to take advantage of NATA's participation in MRAs with many having written into regulations and specifications that measurements, tests and inspections must be conducted by a facility "accredited by NATA or a NATA MRA partner," or similar wording. There are many instances where this recognition of NATA's MRA partners has facilitated a faster time to market for products at a reduced cost to both business and consumers through removing the need for repeated tests or measurements.

Apart from these time and cost benefits, the use of NATA's MRA partners contributes to Australia's meeting the obligations under the World Trade Organisation to reduce and remove technical barriers to trade.

As discussed earlier, accreditation has become a much-used term in a variety of applications. In the international trade context, however the ISO/IEC 17000 series of standards and associated vocabulary of conformity assessment – including the definition of "accreditation" – need to be used with much more precision. The inappropriate use of terms such as accreditation and certification in regulation may cause market confusion and disputation. It may also compromise the delivery of the outcomes sought by regulatory intervention.

6.3 Government-to-Government arrangements utilising NATA's MRAs

The ILAC and APLAC MRAs can be utilised in government-to-government arrangements on trade. A number of mutual recognition agreements/ arrangements between governments make specific use of the mutual recognition between accreditation bodies. Free trade agreements may also utilise mutual recognition between accreditation bodies to provide confidence in conformity assessment activities.

APEC Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment – The APEC Telecommunications and Information Working Group (APEC TEL) developed a multi-lateral MRA covering the testing and certification of telecommunications equipment. An issue in its development was how one economy could have confidence in the quality and validity of testing and/or certification performed in another economy. The matter was addressed by utilising the existing accreditation systems for laboratories as recognised under the APLAC MRA and product certifiers as recognised under the Pacific Accreditation Cooperation Multi–Lateral Arrangement .

The arrangement came into effect in 1999 and was the first of its type in the APEC region. The TEL MRA provides for two phases of implementation by participating economies who may choose the extent to which they participate. Phase 1 was substantially reliant on the APLAC MRA to provide confidence in the reliability of product tests conducted against the importing economy's technical requirements. Laboratories that were accredited for testing according to the requirements of another economy's technical requirements could be "designated" to the importing economy's regulatory authority. Phase 2 covers the mutual recognition of product certifications from appropriately accredited certification bodies. In this case, the accreditation bodies such as JAS-ANZ should be signatories to the Pacific Accreditation Forum Multi-Lateral Arrangement (MLA).

Agreement on Mutual Recognition in relation to conformity assessment, certificates and markings between Australia and the European Community – This MRA covers products subject to one or more of seven regulatory regimes and allows conformity assessment procedures to be undertaken in the exporting economy. This allows Australian manufacturers to have their products assessed by appropriately designated laboratories and inspection bodies for compliance with European technical requirements.

For five of the regulatory regimes, NATA is both the recognised accreditation body for laboratories and inspection bodies and the designating authority appointed by the Commonwealth.

6.4 "Internationalisation" of non-trade related testing

There is a growing trend for some testing services to be undertaken across international borders, particularly in the health sciences. An example where NATA has seen a demand is in the area of teleradiology. In such cases, radiology practices may use the services of a remotely based radiologist to examine electronically transmitted images and provide diagnoses. The radiologist may be based in the same country but not necessarily so. Clearly this is a critically important diagnostic activity and the reliability of such services is vital to patient safety. Mutual recognition arrangements between accreditation bodies is one mechanism that may be used to provide confidence in the competence and capability of the "teleradiologist", wherever located.

NATA also sees instances of testing performed in laboratories in other economies, the results of which are utilised in Australia. For example, specialised forensic analysis may be required in some criminal investigations where particular expertise is not available in Australia. Evidentiary samples are generally sent to laboratories with a sound reputation but there could be a benefit to the Courts if it could be ensured that laboratories had been accredited by one of NATA's MRA partners and that reliance is not being placed on reputation alone.

7. NATA and competition policy

NATA is Australia's only ISO/IEC 17011 compliant, laboratory accreditation body recognised both domestically and internationally. This position is recognised by the Commonwealth through a Memorandum of Understanding. As such, NATA has been given sole responsibility for laboratory accreditation and also for the accreditation of reference material producers.

NATA's status has been the subject of a number of reviews over the past two decades. The most recent was a 2006 Productivity Commission review. The Commission evaluated the rationale for NATA's status as the national authority for a range of accreditation activities and examined a number of arguments for the opening of laboratory and associated accreditation activities to competition. Eventually, it concluded:

"Given the potential for competition to harm Australian exports, and the uncertainty about whether it would improve accreditation services, there is little reason for the government to remove its recognition of NATA, especially since NATA appears to be doing an effective job."

The Inter–Departmental Committee that reviewed the Productivity Commission's recommendations agreed. As a result, a re-negotiated MoU between NATA and the Commonwealth was signed in April 2008.

As has been described in sections 3 and 4, accreditation in the international vocabulary of conformity assessment is a peak activity. Accreditation is a process designed to ensure that conformity assessment activities are undertaken competently and on a "level playing field" to the benefit of all users of the accredited facilities who need to make decisions based on sound data.

While accreditation delivers benefits to the facilities themselves – peer-to-peer discussion, efficiencies, continuous improvement, technical networks, etc. – the objective of accreditation is to provide confidence to the customers of accredited facilities and other stakeholders who are dependent on measurement, test or inspection data to underpin their decision-making processes. On this basis, it is essential that the process be undertaken fairly, transparently and without pressures that could compromise the integrity of the accreditation system and/or the decision making processes involved in particular accreditations.

The Commonwealth recognised this when establishing NATA in 1947 as reflected in the organisation's name. It formalised NATA's national authority status with the first version of the MoU in 1988 and has now agreed to maintain this into the future.

8. When to use NATA accreditation

NATA's accreditation programs exist to provide the users of laboratory or inspection body services with confidence that the test, measurement or calibration data, or the output from the inspection process, is competently produced. The reported results can then provide the users of this information with the confidence to make sound decisions.

Where a laboratory or inspection activity might be required in the context of government legislation or regulation, accreditation is a means of providing a higher level of confidence in the outputs than might otherwise be possible without such a third-party system of verifying performance at a scientific/technical level.

In addition, to confidence, NATA accreditation provides those who administer regulations and specifications with:

- a resource to resolve disputes relating to laboratory or inspection body services;
- an ability to outsource to an independent, objective authority the monitoring of laboratory or inspection body performance and the conduct of surveillance activities;
- NATA's extensive voluntary technical committee network that can provide information and recommendations on measurement, testing and inspection requirements.

A general approach to developing Regulatory Impact Statements is described in the *Best Practice Regulation Handbook*. Similar State/Territory Government publications offer equivalent approaches. The following guidelines outline the types of questions Australian Goverment's to be asked and the issues to be considered in deciding if NATA accreditation is an appropriate regulatory tool. They follow the recommended section headings from the *Best Practice Regulation Handbook* but are also compatible with most similar publications.

8.1 NATA and the Regulatory Impact Statement

Should regulation mandate or encourage NATA accreditation in all circumstances where measurement, test or inspection results and information are important to a decision making process?

Principles of good regulatory practice consider risk, cost and benefit in the context of balancing the regulatory burden on business with the public interest. Armed with the information about NATA's role in the Australian community, the answer to the question of when to utilise NATA accreditation will hopefully become clearer through the process of preparing the regulatory impact statement.

8.1.1 Assessing the problem

It is clear that NATA accreditation is only relevant in circumstances where measurement, test or inspection data is relevant to a regulatory issue. If the issue does involve such data, the preliminary investigations should consider the questions:

i) Could unreliability of measurement, test or inspection data contribute to the problem, be the real source of the problem or become an additional problem in the implementation of any of the possible solutions?

ii) If yes, are there existing monitoring processes to address the reliability of this data?

iii) If yes, are these processes working?

In response to these questions, it should become obvious if unreliable data could contribute to or create a problem. Indeed, if it is established that measurement, testing or inspection is a necessary step in a process that might be subject to regulation, reliability of the data would be a prerequisite.

The answer to the second question should also be clear.

The third question – are existing monitoring processes assuring the reliability of the measurement, test or inspection data – may not be so obvious. If delivery of a product or service is subject to a complex system having many interrelated and co–dependent steps, root cause analysis of a failure may be exceedingly difficult.

This difficulty arises from the complexity itself; but within the system it is likely there will be different parties having commercial needs, egos and legal advisers wanting to ensure that the failure is someone else's problem. Those who perform laboratory or inspection activities are sometimes targeted as being the source of a problem. Laboratory and inspection people are not immune from participating in the "blame game" themselves.

If it can be determined that existing processes are not working or need to be improved, NATA accreditation should be considered.

8.1.2 Objectives of government action

If an assessment of the problem reveals that the reliability of measurement, test or inspection data could be a factor in addressing the regulatory problem, the next consideration is whether improving the reliability is core to meeting the regulatory objective.

Box 5. Reaching the regulatory objective

In just about all regulatory practice guides, from OECD Principles down, there is a focus on ensuring that regulation is only used when necessary and, when it is used, that it is the minimum needed to achieve the regulatory objective. The aim is to manage an identified risk appropriately, not to kill a sector of the economy with huge overheads. Regulation should be "fit for purpose".

If measurement, testing or inspection is an activity identified as a necessary step in a process, and if a form of regulation is determined to be necessary to manage the risk identified in the process, what is the appropriate standard (using the subjective version relating to quality and reliability) that should be required of the measuring, testing or inspection phase?

A measurement, test or inspection is not an end in itself but a means of collecting information on which to make a decision. It is also self evident that if the information is not correct, any decision based on the information is likely to be incorrect.

So the answer to the above question is – it needs to be consistently right, correct, accurate, … whatever word you choose to apply. It is actually hard to assign a level of quality to something black and white. A low "quality" test of a product that yields an answer of "pass" when the real answer is "fail", is not only of low quality, it is of zero value as it may result in a course of action that may actually cause harm. In a medical situation, failure of a pathology test to detect evidence of a malignant tumour does not even rate a zero on the value scale. Low quality testing can be worse than no testing at all.

Returning to the matter of regulation, if measurement, testing or inspection is determined to be a necessary step in a process, failing to adopt the means of achieving confidence in the quality of the information may well undermine the entire regulatory objective.

8.1.3 Options that may achieve the objectives

The use of NATA accreditation obviously needs to be considered in the list of options to deal with regulatory problems that may relate to the reliability of measurement, test or inspection data. Three options that are available are:

i) Encouraging industry adoption of accreditation to achieve the desired outcome;

ii) Encouraging the use of accredited facilities through regulation; or

iii) Mandating the use of accreditation.

Where the reliability of measurement, test or inspection data is adjudged to be important but not critical, and/or there is a regulatory action that could lessen the level of importance of data to the objective, NATA accreditation might be specified as a preferred but not mandatory path.

At the industry encouragement end of the scale, regulatory guides in whatever form may be an effective means of encouraging the desired behaviour. Those subject to the regulation can then choose whether to reduce the risk of non–compliance with regulation by using a NATA accredited facility. If this approach is taken, there can be "carrot and stick" incentives. For example, action for regulatory non–compliance might be less severe when accredited facilities are used.

Case Study 1. Encouraging the use of NATA accreditation in product safety testing

The Australian Competition and Consumer Commission has published a Product Testing Guide to assist suppliers of a broad range of products understand their obligations under the Competition and Consumer Act 2010 (previously the Trade Practices Act) to supply safe products to the market.

There is no obligation under the Act to undertake testing, and certainly no obligation to use a NATA accredited – or MRA partner accredited – laboratory if one does choose to test. Indeed, the ACCC guide states:

While goods supplied must comply with mandatory consumer product standards, this does not mean suppliers are legally required to test for compliance with such standards.

The ACCC does, however, provide strong encouragement to undertake testing for a raft of reasons but particularly for risk management.

However when the ACCC pursues an allegation that a supplier's product does not comply with a mandatory standard, one of the first questions typically asked is whether the supplier has a test report showing the product complies with the standard. If the supplier is able to produce a valid test report that demonstrates the product's compliance with the standard then the allegation of non-compliance may be quickly resolved.

To further manage risk, the ACCC also suggests that it is wise to use appropriately accredited facilities as a means of providing confidence in the test results.

Although it is not always compulsory for test laboratories to carry accreditation, it is preferable to commission and/or otherwise obtain reports and testing from accredited laboratories because:

- *they are subject to regular and vigorous assessment by an independent agency*
- *their reports have more credibility in the event of a court case.*

Accreditation bodies such as The National Association of Testing Authorities, Australia (NATA) and its international counterparts provide strict independent assessments of, and accreditation for, competence in testing against specific safety standards.

Even within a single regulatory regime, risk – whether this risk relates to user safety, the potential for economic loss or a combination of the two - often needs to be considered as a spectrum. In such cases, it is appropriate to have different approaches within a single regulatory regime. Requiring use of an accredited facility in situations at the higher end of the risk spectrum may be the best approach, whereas a supplier declaration alone may be appropriate in benign situations.

Case Study 2. Risk based regulation - Electromagnetic compatibility (EMC)

The Australian Communications and Media Authority (ACMA) administers the Radiocommunications Act. One of the requirements is to ensure that the electromagnetic spectrum – think radio and microwave transmission – is managed and protected from unwanted interference. Part of this management is to ensure that electrical and electronic products do not inadvertently emit interference. Hence, there is an EMC framework requiring products having the potential to cause interference to be tested.

ACMA has taken a risk based approach. Products deemed to present high risk – those that might present a safety or health risk from excessive emissions – require pre–market type testing in a laboratory accredited for EMC testing by NATA or a NATA MRA partner. Products deemed to be of lower risk – if they did emit unwanted signals, it might be a nuisance to others but not to an extent that would pose a risk to safety or health – may be tested in unaccredited laboratories.

Even for low risk products, the legislation requires compliance with the specified limits, but ACMA leaves it solely to the supplier to determine whether they will use a low risk approach by going to an accredited laboratory or do their own risk assessment and use an unaccredited facility. Such an approach to regulatory compliance allows industry some choice of paths to market. ACMA itself describes it as a “shared risk” approach.

The efficacy of the ACMA approach is aided by the fact that most developed economies have EMC requirements and of these, the majority have mandated the test methods and limits defined in the relevant international standards. This has benefited the industry which is now used to considering EMC compliance in the product design phase.

If, however, test data are critical to a situation that would appear to need regulation, there are no equivalent processes to NATA laboratory accreditation. There are other non–equivalent processes – such as management system certification of a laboratory – that deal with aspects of a laboratory’s operations, but none of these alternatives address the fundamentals of competency and the reliable production and reporting of valid data. In such cases, mandating the use of accredited facilities may be necessary.

8.1.4 Impact analysis – risks, costs and benefits

The evaluation of a range of risk factors, costs and benefits will clarify any decision on mandating or encouraging the use of NATA accreditation for measurement, testing or inspection activities.

Risk factors to consider – In considering the merits of mandating or encouraging NATA accreditation, the implications of getting a wrong answer should be considered. Some questions on the following list of examples are applicable to products or materials. That is, what are the risks associated with supplying something to a market based on incorrect test, measurement or inspection data? Other factors relate more to services, such as a calibration, a pathology result or an inspection, where the risk is associated with subsequent decision making.

- Are there health and safety risks associated with a non–conformity?
  - to people using the product or service
  - to staff of the facility in which the product is installed/ connected
  - to the general public
  - liabilities of use
- Are there consumer protection issues (apart from safety)?
  - purchase cost to the consumer
  - existence of other consumer protection legislation
- Is there potential for significant economic loss?
  - to people using the product or service
  - to the organisation in whose facility the product is installed/ connected
  - to the general public
- Do product-specific factors make regulation difficult?
  - operational life
  - product market life
- What are the costs?
  - to the consumer
  - to the manufacturer and/or supplier
  - to the regulator/ specifier operationally
- Are there issues of international trade?
  - testing or inspection being a requirement of the purchaser
  - potential for non–acceptance of test data to be used as a trade barrier
- Does the issue relate to significant expenditure of public money?
  - direct public funding of measurement, test or inspection services
  - payment for products or services of a required quality
  - subsidies or rebates for activities that need to be of a measured quality
- Are there potential downstream costs that could arise from inadequate regulatory intervention?

Product regulation – In a product environment, there may also be instances where there is a need to consider in regulation or specification the balance between mechanisms for establishing pre–market compliance of a product (e.g. pre–market type testing of a product) with downstream monitoring such as post–market surveillance (testing).

The complexity of modern supply chains means that pre-market compliance arrangements may not be the most effective means of reaching the regulatory objective. Production variation or drift has always been a challenge in some manufacturing sectors. The trend to contract manufacturing arrangements sometimes involving multiple suppliers can introduce quality control and consistency issues that limit the value of pre-market arrangements.

Post-market surveillance may be a more effective and appropriate tool for detecting non-compliant product. It can be applied in either regulatory or co-regulatory arrangements.

Case Study 3. Post-market surveillance - Energy efficiency labelling

Under the Greenhouse and Energy Minimum Standards (GEMS) regulatory framework covering the energy efficiency labelling of appliances, suppliers are obliged to label appliances with an energy rating label. The “star rating” and associated annual energy consumption figure are determined through testing against Australian Standards. To register a product, the supplier is allowed to use a laboratory of choice, whether accredited by NATA or a NATA MRA partner or not.

Encouraging accurate labelling is a system of “check testing”. This involves purchase of an appliance and having it tested at a laboratory accredited by NATA for the relevant tests. If the energy rating is confirmed, there is no further action. If the product fails, further tests may be conducted to confirm the result. If it becomes clear that the energy label overstates the efficiency (understates consumption), action will be taken which may involve recall of products from retailers and possibly a requirement for the supplier to pay compensation to consumers who have already purchased the product.

This illustrates that while there is often a focus on pre–market type testing in a product environment, appropriately designed post market surveillance testing may in some cases provide better incentives for compliance and improved consumer protection.

The ACCC product safety guide referenced in Case Study 1 addresses the need to ensure ongoing compliance of products over their production/market cycle. It recommends voluntary post-market monitoring and encourages the use of accredited facilities to perform any testing necessary as part of this surveillance.

Post market surveillance may be used as an alternative to, or in conjunction with, pre-market arrangements. In some sectors, time-to-market is the most critical consideration for manufacturers and suppliers. Pre-market compliance arrangements can be costly in terms of lost market opportunities so a post-market approach will be more acceptable to industry and potentially benefit consumers.

Mandatory post-market arrangements clearly have costs associated with them. Hence, their use needs to be proportional with the level of health, safety or financial risk associated with a product’s non-compliance with a specification.

If there is a case to be made for mandatory post-market arrangements then consideration should include:

- whether there need for routine or random sampling of product;
- the use of “targeted” surveillance based on product history, supplier track record, “dob-ins” by competitors or consumers, etc;
- funding of the arrangements; and
- whether any testing required should cover all aspects of the product’s compliance or only those aspects of specific interest.

The design of any post market arrangements can strongly influence the pre-market behaviour of those on the supply side.

Costs – NATA charges for its accreditation programs. There are charges for application, initial assessments and changes to the accreditation. Accredited facilities also pay fees to remain accredited as there are the costs of ongoing administration, reassessments and surveillance visits.

As discussed, NATA:

- is a not–for–profit body
- is the national authority for two accreditation activities and a peak body for another two
- has a responsibility to the wider community to facilitate a reliable technical infrastructure.

Having a role that is important to the national and public interest and a position of significant responsibility, it is essential that NATA maintains its fees and charges with an appropriate balance between a robust accreditation system and a cost that is not a significant burden on the accredited facilities and their customers.

Accreditation costs are generally proportional to the amount of assessment effort required. This in turn is generally dictated by the scope of the facility's activities rather than the size of the facility. Hence, a broad accreditation scope costs more than a very narrow accreditation scope.

The cost of accreditation for some facilities, particularly those having only two or three staff, may not be trivial and NATA recognises that this must be taken into account in the regulatory impact statement. Ultimately, the decision of any organisation to achieve and maintain NATA accreditation requires a business case. Even where there may be a mandatory requirement for accreditation to do certain tasks, there is usually the option of not taking on the business, particularly where the anticipated throughput of work may make the business case very marginal.

It is very important, however, that true costs of NATA accreditation are utilised in any business cost calculator and not those sometimes inappropriately attributed.

Box 6. Stacking the deck – cost shifting

The total cost of NATA accreditation – aside from direct charges and fees – has always been a challenge for anyone attempting to get a clear picture of costs associated with NATA accreditation.

As discussed in section 4.3, the primary criteria for accreditation are the minimum standards agreed by the standards developers as the set of prerequisites and activities necessary to achieve reliable measurement, test or inspection data. Laboratories and inspection bodies that consistently generate reliable data and information will in all likelihood do so because they already meet these standards – and NATA's accreditation requirements. For those that do, the direct accreditation fees, the time needed to provide information and any down–time associated with the assessment account for virtually all of the costs of accreditation.

But what is heard from some facilities – particularly those for which accreditation is mandatory rather than voluntary – are comments such as:

"Accreditation means we have to spend all this money on having these equipment calibrations done".

"Accreditation has cost us lots of money because we had to have written procedures".

"We have had to do additional training because NATA found there was not enough expertise in the laboratory".

The obvious responses are:

"Surely reliable laboratories calibrate instruments to ensure their accuracy, not because of NATA?"

"Surely reliable facilities need formal procedures to operate and train new staff?"

"Surely expertise is essential to being a reliable facility?"

At the consultation is phase of the regulatory impact process, the shifting of normal business costs and those of addressing inadequate aspects of operations will almost certainty be raised as accreditation costs by those not in favour of NATA accreditation. Policy makers need to be aware that NATA accreditation does have costs but that some of the costs attributed by facilities not wanting to be accredited may actually constitute an admission of a need to improve.

The other side of the equation is the potential costs of getting incorrect information and making incorrect decisions based on this information. Parties affected may include the measurement, testing or inspection facility's customers, the customers of customers, government, industry, the users of products and services tested or inspected, and the wider community.

Case Study 4. ATO rebates under the Product Stewardship for Oil Programme

In some instances, companies engaged in activities deemed to be in the national or public interest may claim a rebate from the Australian Taxation Office. Some of these relate to environmental issues where a particular behaviour is being encouraged – such as recycling. Where rebates relate to the conformity of an activity or product with a specification, the regulation may mandate the use of accredited laboratories to give a high level of confidence that the rebates are based on sound technical evidence.

An example of this is the Product Stewardship (Oil) Regulations 2000. These regulations specify a range of parameters for recycled oil products which must be tested in a NATA accredited laboratory. Most tests are routine but some require a highly specialised capability that is costly to maintain due to the low volume of work available to laboratories.

In some instances, the benefit may suggest that proceeding with regulation, or at least with mandatory accreditation, does not justify the cost. In a case such as the Product Stewardship (Oil) Regulations 2000, however, it is important to note that many millions of dollars in rebates are available. As such, the cost of testing in an accredited facility may appear substantial but it is dwarfed by the dollar value of the rebates involved.

The benefits of utilising NATA accreditation vary depending on the application but all revolve around confidence and risk management. The objectives and processes of NATA accreditation have been dealt with in detail in previous sections and hopefully, a number of the benefits are by now evident – either explicitly or implicitly.

In particular, NATA accreditation:

- provides formal recognition of a facility's ongoing and specific competence and capability by an authoritative third party;
- facilitates confidence in the test, measurement and inspection data on which sound decisions need be made;
- gives regulators and other government agencies a mechanism to out-source the oversight of facilities undertaking activities important to reaching a regulatory or policy objective;
- provides a means of facilitating the resolution of disputes relating to test, measurement and inspection results through NATA's complaint investigation procedures.

8.1.5 Consultation

NATA is always prepared to be part of the consultation process for any consideration of accreditation in a regulatory context. NATA recommends that this occurs early in development of legislation or regulation. Particularly where a department or authority may have had little past experience with NATA, early contact is encouraged to ensure that both parties have an adequate understanding of the regulatory problem and where NATA's accredited facilities might contribute to a solution.

The consultation phase should also involve the other standards and conformity infrastructure bodies as necessary and appropriate (see section 4). The availability of applicable standards – specifications and requirements – measurement capability and accreditation infrastructure could well be an issue in some instances.

In conjunction with standards and conformity infrastructure body discussions, it is also important to consider some of the bodies that undertake the testing, measurement or inspection activities. They can provide a "reality check" in terms of the viability of a proposed regulatory approach. They may be sources of valuable information such as:

- the size of a testing or inspection market – e.g. will laboratories or inspection bodies bother developing or maintaining the capability?
- the reliability of methods and/or instrumentation available to meet the regulatory requirements – e.g. is a validated test method with enough sensitivity available to detect a concentration of a particular substance subject to regulation?
- the availability of the required technical expertise in the testing or inspection community – e.g. are there enough technical "experts" in a particular field to cope with an increase in demand driven by a new regulation?

In any proposed regulatory regime where measurement, testing and inspection is a consideration, there will always be those who do not regard NATA accreditation as desirable, almost certainly on the basis of cost. It is not uncommon for inflated estimates of the cost to be proposed – inflated not by tens of percent but sometimes by hundreds of percent. This inflation of accreditation costs is usually achieved by shifting costs associated with everyday business to accreditation.

This is not to say that the cost of NATA accreditation is trivial. The technical rigour of the processes is delivered at cost but it is certainly not free. If a facility seeking NATA accreditation is operating well below consensus minimum standards, there will also be costs associated with bringing the service up to the required level.

As highlighted in Box 6, it is suggested that dollar amounts that might be quoted by some participants in the consultation process be carefully evaluated against real data before being presented as hard fact in a regulatory impact statement.

Such factors need to be addressed when using the "business cost calculator" described in the *Best Practice Regulation Handbook* and similar state and territory publications.

In summary, NATA and the broader standards and conformance infrastructure are always willing to assist in the identification of potential policy and implementation issues and in their solution if at all possible.

9. Policy and implementation issues

9.1 Availability of infrastructure

There are times when a needed measurement or testing capability does not exist within NATA's accreditation system, or does not exist in the country at all. There have been instances where a regulation has called up a measurement or testing requirement for which there is no accredited, or even unaccredited, capability anywhere in Australia, public or private sector.

Not surprisingly, this can be embarrassing to government and policy makers.

There can arise a "chicken and egg" situation. Investment in infrastructure won't take place until there is some certainty that regulation will necessitate that infrastructure. Yet regulators will not mandate requirements that are not supported by the necessary technical infrastructure!

Early consultation with NATA and the wider standards and conformity infrastructure may not always solve a regulatory dilemma but it will inform the decision making process and maximise the likelihood of developing a means of meeting the regulatory objective. Given enough forewarning of a regulatory need for some form of measurement, testing or inspection, NATA and the other infrastructure bodies can utilise their scientific and technical networks to increase the chances that the necessary facilities will be available by the time any new requirement comes into effect.

9.2 Writing the requirements

Once a decision has been made to specify or encourage the use of NATA accredited facilities in regulation, there are important considerations for the policy writer.

9.2.1 Amendments to published standards and issue dates

Australian and international standards have issue dates. It is usual practice in regulation to specify this date because the production and review of standards is not a government function (although Standards Australia would always invite one or more relevant representatives from affected government departments to participate). The standards body producing the document may from time to time issue amendments or new editions.

In many regulatory regimes that require compliance with one or more Australian or international standards, a new edition or a change in standard is accommodated by an overlap period. For example, for a period up to say two years, the market can choose to comply with an existing standard or the new one. This is effective in allowing any additional supporting infrastructure to be developed and, if necessary, become accredited.

One reason a standard may be amended is that it has not addressed a particular circumstance – possible something that could not be foreseen by the standards writers – or some innovation has occurred that is not addressed appropriately by the existing requirements or specifications. This amendment may be fairly minor with regard to any measurement, testing or inspection requirements but sometimes, one will require a new test, or a new instrument, or some significant change of procedure and staff training. When this happens, it is possible to go

from a situation of having the necessary laboratory or inspection infrastructure to having gaps in capability.

Policy makers need to give due attention to how the regulation they are writing deals with new editions, new standards and amendments to standards. As with many issues, early consultation – including those in the standards and conformance infrastructure – will often avoid downstream problems.

9.2.2 Compliance limits and rules

Technical regulation often means dealing with some type of limit. Some examples follow.

- The upper level of a particular chemical or biological contaminant allowed in a food product
- The maximum level of electromagnetic radiation emitted from a hand-held communications device
- The maximum level of tint allowed in a vehicle windscreen
- The tolerance – allowable error – on the volume of fuel dispensed at a service station.

The bad news is that whatever is being regulated, the unit of measurement and the type of measurement or test that is to be employed, no result from any facility, whether accredited or not, will be perfect. There is always an uncertainty in the result. Measurement uncertainty is an inconvenient fact of life and it can be especially inconvenient for a regulator who has a limit to enforce.

In some types of measurement or test, the uncertainty of the result can be very small. Indeed, the National Measurement Institute can measure some parameters such as length, time interval and D.C. voltage with uncertainties small enough to boggle the imagination – time interval can be measured with an uncertainty better than +/– 0.000 000 001%!

Unfortunately, not everything can be measured this accurately. Some tests yield uncertainties approaching +/– 100%. This is not because the testing is bad but because the thing that a laboratory is trying to measure is small or hard to find or difficult to sample or is hard to differentiate from similar agents, or a raft of other reasons. In real life, it is quite possible that a regulator may be faced with data from three laboratories for the same test on the same material yielding one pass, one failure and one borderline. The policy writer can ignore this variability and specify an absolute compliance limit but the outcome may be a range of new problems for the policy implementer.

It is important that these realities are accommodated in regulation if possible. There are means by which a policy writer can deal with the variability of results, or at least reduce the potential angst for those attempting enforcement.

Early consultation with NATA staff, the other standards and conformity infrastructure bodies and industry organisations can assist in addressing this issue and make for regulation that is practical and robust.

9.2.3 Individuals versus facilities

It is important to remember that it is a facility – a laboratory, a mobile testing service, an inspection body – that NATA accredits, not an individual. There can be a problem if the legislation calls for NATA accreditation but does not take account of this fact.

There are also examples of legislation that require a person to take responsibility for the integrity of measurements, tests or inspections performed, not the accredited facility by which the person is employed. In some sectors requiring microbiological or chemical analyses of products, it is not uncommon

for such individuals to be appointed as “approved analysts”. This sometimes provides advantages in the courts where certificates from such government appointed analysts are deemed to be prima facie evidence for the purposes of prosecutions.

If it is necessary to specify a person rather than a facility in a particular circumstance, NATA should be contacted to assist in development of suitable wordings as there are working examples in existing regulation that can be used as a guide. Otherwise, it is strongly recommended that requirements be written around laboratory or inspection entities. This has a benefit in that laboratories and inspection bodies close down rather less frequently than individuals change employers. Hence, the administrative burden of having to track “approved” individuals will be less.

One further consideration is that competent individuals can have their performance compromised by poor management practices or other pressures. NATA accreditation provides confidence that competent individuals will be able to conduct their analyses under conditions conducive to the production of reliable test, measurement and inspection data.

9.2.4 Sampling

To this point, the focus has been on how to assess the merits of using NATA accreditation. There is another issue that can bring the very best testing and measurement activities completely unravelled and result in a regulatory “solution” being a complete waste of effort sampling and sample integrity.

No test or measurement can ever compensate for an unrepresentative sample or one that has been compromised in the course of collecting it and delivering it to the laboratory’s front door. Failure to address this as part of a regulatory solution can invalidate the outcome.

An obvious example would be a food testing regime. Whether the regime is targeting a food processing factory or the local pizza shop, there is significant scope for either taking an unrepresentative sample or, in the process of transportation, cross contaminating the sample or compromising it through such poor practices as incorrect packaging lack of temperature control.

There is a range of measures that can be used to address sampling issues. These include:

- requiring the sampling to be managed by the laboratory performing the testing or measurement;
- requiring the sampling to be managed by an appropriately NATA accredited inspection body; and/or
- requiring the individual performing the sampling to have completed an appropriate sampling and sample management course.

Additionally, if there is a need for samples to be treated in a manner that will ensure that test and measurement results are admissible in court, NATA offers an addition to laboratory or inspection body accreditation covering sample management and chain of custody under its forensic science program.

9.2.5 Specifying published standards and standard test methods

A number of questions relating to standards and/or standard test methods need to be considered in preparing regulation that relates to testing, measurement or inspection. These include the following:

- Are there standards and/or standard test methods available?;
- If there is a specification limit involved, is the limit dependent on the test or measurement method? (e.g. for electromagnetic interference testing, the limits specified in the applicable standards are specific to a particular test methodology);
- Does the scope of the specification align with the scope and limitations set out in the standard?;
- Do the language and definitions of the specification align with the definitions used in the standard?
- Is the specification of a particular standard and/or standard test method going to restrict innovation?

Good regulatory practice principles dictate that where available, international standards should be used in preference to national standards or industry specifications unless there are sound reasons for not doing so. Standards should not be used as a non–tariff technical barrier to trade.

9.3 Facilitating international trade

As discussed in section 6, NATA is a signatory to Mutual Recognition Arrangements (MRAs) covering over sixty accreditation bodies in fifty–two countries. The aim of these MRAs is trade facilitation, specifically, the avoidance of a need to measure, test or inspect a product in the destination economy. Non–acceptance of measurement and test data has a long history as a technical barrier to trade (TBT) and accreditation by NATA or a NATA MRA partners has gone a long way to reducing its incidence.

Australia is obliged under WTO rules to avoid imposing TBTs and indeed has a strong record on acceptance of testing based on accreditation. Not only measurement and test data from NATA accredited facilities but that from facilities accredited by MRA partners is now routinely accepted by regulatory authorities at both Commonwealth and State/Territory Government level.

Generally speaking, policy makers who have decided that mandating or encouraging NATA accreditation within regulation should ensure that the legislation and associated instruments also recognise measurement, test or inspection data from MRA partner accredited facilities.

10. Formal government/NATA arrangements

Section 1.3 describes the recognition of NATA by the Commonwealth through a Memorandum of Understanding (MoU). As mentioned, the MoU details each party's undertakings as well as a number that are joint. Hence the MoU establishes NATA's overall position in Australia's technical infrastructure. What the MoU neither does nor can do is describe specific roles for NATA in particular regulatory environments.

Similarly, NATA also has general MoUs with the States of Tasmania and Victoria as well as the Australian Capital Territory. These build on the MoU with the Commonwealth through a number of complementary undertakings for each Party.

There may be instances, however, when a regulatory authority wants a more specific undertaking than those described in the Commonwealth or State/Territory MoUs. For example, a regulator may:

- have particular technical needs that go beyond NATA's assessment process, such as their own interpretation of a technical standard/test method or the way a test/inspection is reported;
- want to have additional or customised services delivered by NATA such as the assessment of sampling practices not normally within the scope of a laboratory's activities;
- require a greater level of information about accredited facilities than NATA can normally provide, such as is the case with some State health authorities.

NATA may not be able to accommodate everything requested by a government department or regulator. Some requests NATA has received would require powers well beyond those of any non-government organisation. Nonetheless, NATA is always prepared to discuss any request.

If NATA can provide the appropriate service, it may be accommodated through an addition to NATA's accreditation criteria for that particular accreditation activity. Where a department or regulator wishes to have arrangements established at a formal level, it may be best to address this via a MoU or a Deed of Agreement.

10.1 Memoranda of Understanding

An activity-specific MoU may be useful where there is a need to identify undertakings between two or more parties. Such arrangements are not binding on the parties but usually describe processes and/or provide rationale and justification for non-routine practices. They also impose some discipline on the parties to ensure effective communications, especially when staff changes may cause a loss of "corporate memory".

An example of these MoUs are those between NATA and a number of State Departments of Health. This describes the way NATA will provide the Departments with "early warning" of facilities whose performance has been revealed by an on-site assessment to constitute a potential public health issue.

10.2 Deeds of Agreement

Deeds of Agreement are more task-oriented than MoU and carry obligations, not just undertakings. They apply a much higher level of discipline to the parties and usually cover issues such as indemnity and dispute resolution in addition to the primary matter driving the need for a deed.

NATA has a Deed of Agreement with the Australian Quarantine Inspection Service that addresses aspects of NATA's accreditation of microbiology laboratories testing meat for export. It covers things such as the test methodologies that NATA must assess and laboratory surveillance arrangements, and obliges AQIS itself to provide certain information and resources.

11. Use of NATA accreditation in specification

To date, the focus has been on "government as a regulator". A number of the issues discussed also apply to "government as a customer" of NATA's accreditation system, that is, when a department or authority has a need to use the services of laboratories or inspection bodies. But there are also factors that need to be taken into account by those responsible for purchasing and writing contract specifications.

11.1 Consultation

It is strongly recommended that government officers writing specifications involving measurement, testing and inspection contact NATA to determine the availability of existing accredited infrastructure. When dealing with requirements that relate to new technologies (e.g. nanotechnology or leading edge defence related technology) or developing issues (e.g. measurement of greenhouse gases being emitted from a particular type of industry), it needs to be recognised that the supporting standards and conformity infrastructure may not have reached the necessary level of maturity.

A lack of current infrastructure – either because there is no–one doing the work or that it is not yet accredited – does not, however, mean that it cannot be developed within a reasonable time frame. If there is a need, the market will generally respond. Time is usually the issue and, as with writing regulation, specification/contract writers incorporating new or innovative requirements should provide as much advanced notice to industry (and to NATA) as possible.

It is also wise to consult NATA in situations where measurements or tests are "old" but where the demand for such is very limited. Because accreditation does incur fees, and rarely performed measurements and tests may be hard to justify under an accreditation, available capability may be very limited. (See Case Study 4)

11.2 Writing specifications

Care needs to be exercised at the drafting stage for specifications. As has been explained in Section 2, accreditation is for specific and demonstrated competencies, not for every activity a laboratory or inspection body might perform.

Specifications that incorporate a requirement for accreditation need to be constructed to ensure the required confidence is achieved. The question that must be asked of a laboratory or inspection body that might tender for government contacts is:

- "Do you hold NATA accreditation for the specified test/ measurement/ calibration/ inspection?"

A common pitfall is to ask this question in two distinct parts.

- "Do you hold NATA accreditation?"
- "Can you perform the specified test/ measurement/ calibration/ inspection?"

This approach may not achieve the desired outcome. A laboratory or inspection body could honestly answer "yes" to both but still not meet the specifier's objective of requiring NATA accreditation. In most disciplines, NATA does not require a facility to have all measurements, tests or inspections services it may offer accredited. As such, the NATA accreditation may be different measurements, tests or inspections than those required by the specifier.

As NATA accredited laboratories and inspection bodies are able to add the NATA endorsement to reports covering accredited activities, a more concise specification is to simply require that the results of all tests, measurements, calibrations or inspections are provided on NATA endorsed reports.

11.3 Other issues

In writing specifications that deal with measurement, testing or inspection, the issues addressed in section 9.2 often apply and need to be considered.

The selection of appropriate standards to reference and the inclusion of dates/ editions of standards should be given careful attention, particularly in cases where a contract may relate to the supply of material, products or services over a long period. A standard referenced in a contract may be subject to amendment or reissue.

The laboratory and inspection infrastructure tends to adopt new standards and amendments as a means of remaining competitive. The outcome of this may be that a contractor who is required by a government specification to have measurements, tests or inspections performed to a particular edition or amendment of a standard will, over time, have difficulty sourcing the necessary capability.

Appendix 1 – NATA's accreditation and associated programs

The following identifies NATA's current programs. It needs to be noted that this listing is not fixed. NATA adds programs from time to time as needs arise.

Hence, if there is an activity that would seem to fit the NATA accreditation process and it is not found here, it should not be assumed that NATA cannot or will not develop a program. If in doubt, contact NATA and discuss the need.

A1.1 Laboratory accreditation – ISO/IEC 17025 based

The term "laboratory" is taken to mean any legally identifiable entity undertaking calibration, measurement and testing whether or not it is carried out in a laboratory environment or not. For example, laboratory accreditation is still applicable to entities undertaking mobile or in situ activities such as:

- calibration of process control instrumentation in a factory;
- X–ray (non–destructive testing) on a structure;
- pressure testing of a pipeline.

The entity may be a stand-alone organisation of one or more staff undertaking only calibration, measurement and testing activities or it may be the part of a larger organisation undertaking the activities subject to accreditation.

Disciplines currently covered by NATA's ISO/IEC 17025 based laboratory accreditation programs are as follows:

Biological Testing – Biological Testing covers a variety of microbiological, biochemical and physical tests on foods, waters, pharmaceuticals, toiletries, biocides and other materials and products. It also covers tests related to monitoring defined environments and hygiene of manufacturing areas as well as tests relevant to the study of environmental biology, zoology, botany, protozoology, phycology, mycology and plant pathology. Plant Health is another discipline within biological testing. Identification of plant pests is fundamental in keeping Australia safe from outbreaks of disease. The work performed by government quarantine facilities as well as private industry is critical in maintaining this barrier which, if broken, could impact greatly on crops, food supply and unique flora.

Calibration – This includes all calibration type activities in the following areas: acoustic, chemical, dimensional, electrical, optical, physical, radiometric (both ionising and non-ionising radiation), thermal and vibration.

Chemical Testing – Chemical Testing comprises those laboratories performing tests on: metals and ores, cement and concrete, asbestos, fuels and lubricants, surface coatings, plastics, foods, agricultural products, environmental, and residues in the environment. Chemical Testing accredits laboratories for sampling in the environment (e.g. waters and air) and also covers calibration laboratories in the areas of gas analysers for the mining and OH&S industries, as well as breathalysers.

Construction Materials Testing – Accreditation for Construction Materials Testing is applicable to any facility undertaking physical tests on the following: cement, concrete, cement and clay based products, refractories, rocks,

aggregates, bituminous materials (including asphalt), soils, masonry units and segmental pavers, gypsum and gypsum products, road pavement and surfaces, masonry, road-marking materials, pedestrian surfaces, and construction materials testing equipment.

Forensic Science – Accreditation is provided to facilities that provide services to the criminal justice system, State Coroners Courts and the Family Law Court. The program currently covers the following disciplines: controlled substances, forensic chemistry/criminalistics, fingerprinting, parentage testing, toxicology, forensic biology (including DNA), firearms, crime scene investigation, signal processing and questioned documents.

Additionally, the requirements of the Forensic Operations Module (FOM) covering sampling and sample custody requirements can be assessed and added to other relevant disciplines where there is a need for legally robust management of samples that are analysed for court-related purposes.

Information and Communications Technology – Information Communication Technology covers all types of testing activities associated with software and hardware systems. This also includes the accreditation of facilities registered with Defence Signals Directorate for the evaluation of software and hardware systems for security purposes under the Australasian Information Security Evaluation Program. The endorsement achieved by completion of evaluation provides all consumers, both within government and non–government sectors, with a level of assurance that a product will adequately meet their individual security needs.

Mechanical Testing – Mechanical testing comprises facilities that undertake the physical testing of materials. It is broadly classified into metallurgy, lifting gear, timber products, textiles, paper, rubber, plastic, wool, motor vehicle safety tests, assemblies, packing, plumbing fittings, pressure testing, controlled environments and corrosion.

Non-Destructive Testing – Non-Destructive Testing involves assessing the integrity of equipment or other items (typically metallic) by testing for defects and/or deterioration of the material from which the items are constituted. Major Non Destructive Testing users include energy producers (oil, gas and electricity), transportation (air, rail, sea and road), civil construction, equipment manufacturing, chemical plants and the mining industry.

Product and material safety and performance testing – This area covers a broad range of tests and examinations of manufactured materials and industrial and consumer products addressing both performance and safety aspects. It includes materials that are subject to acoustic, thermal and optical performance standards, as well as safety and efficiency tests most domestic and industrial appliances.

Veterinary Testing – Veterinary testing covers tests on specimens of animal origin for the purposes of diagnostic and health assessment testing in the disciplines of microbiology, parasitology, serology, clinical immunology, haematology, biochemistry, toxicology, anatomical pathology, genetic testing and veterinary practice pathology.

A1.2 Laboratory accreditation – ISO 15189 based

Medical Testing – Medical Testing covers testing of samples of human origin and includes diagnostic testing in the disciplines of anatomical pathology, assisted reproduction procedures, chemical pathology, cytogenetics, genetic testing, haematology, immunohaematology, immunology, medical practice pathology and microbiology. It also covers testing of samples of human origin for other purposes such as those associated with blood transfusion services and clinical trials. Testing is most commonly laboratory based but accreditation sometimes covers "point-of-care" testing. The program also includes clinical non-human testing.

A1.3 Research and Development laboratory accreditation

The Research and Development Program is currently an ISO/IEC 17025 based program (the same standard as for routine testing facilities) but with the standard being interpreted specifically for the research environment. The program has a focus on technical competency and robust research management – both essential elements in the conduct of solid accountable research − and is suited to all research environments that have a testing basis. It is also suited to environments where a "blend" of routine testing and research activities are performed.

NATA accreditation for research and development laboratories may not be appropriate in all circumstances but it should be viewed by policy makers and specifiers as a means of delivering greater levels of confidence in the competency of laboratories, the traceability of the measurements made and the integrity of the records supporting research conclusions.

A1.4 Inspection body accreditation

Inspection involves "examination of a product design, product, service, process or plant and determination of their conformity with specific criteria or, on the basis of professional judgement, general requirements"(ISO/IEC 17020:2012). The process is "conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging" (ISO Guide 2:1996). The aim of this accreditation program is to ensure that these activities are conducted by competent and objective personnel, and hence the inspection data and reports can be used for sound decision-making processes.

Types of inspection that can be covered by NATA's Inspection accreditation program are diverse. Accreditations can be gained in areas including agriculture and agricultural products, industrial equipment and machinery, manufactured goods, natural resources and refined products, industrial and commercial construction and maintenance, building construction and maintenance, transport, tourism accommodation and environment. Inspection accreditation can be utilised in industry, by regulatory authorities and by the wider community.

A1.5 Medical Imaging practice accreditation

The Medical Imaging program includes procedures covering the modalities of general radiography, ultrasound, mammography, computerised tomography, interventional radiology, magnetic resonance imaging, nuclear

medicine and bone mineral densitometry. The standards used are those produced by the Royal Australian and New Zealand College of Radiologists (RANZCR).

A1.6 Sleep disorders services accreditation

The Sleep Disorders Services program covers the diagnostic procedures and treaments by facilities offering various sleep studies, including sleep apnoea, sleep phase disorders, narcolepsy and insomnia. It is run in conjuction with the Australian Sleep Association (ASA). The requirements for the competence of services offering Sleep Disorders Services are described in the ASA Standard for Sleep Disorders Services.

A1.7 Reference material producers accreditation

Certified reference materials (CRMs) and reference materials (RMs) are widely used in the calibration of equipment, validation of measurement procedures, quality control and for ensuring that the end-user of measurement data can have confidence in an unbroken chain of traceability to national and/or international primary measurement units (for example, SI units). NATA conducts assessments of Reference Material Producers (RMPs) for compliance with the requirements of ISO Guides 34, 31 and 35 together with the applicable requirements of ISO/IEC 17025 (for the tests and measurements involved in the characterisation and assignment of property values to the CRM/RM).

A1.8 Proficiency Testing scheme provider accreditation

Proficiency testing is a tool for laboratories to compare their performance to that of similar laboratories. It also has a profound role in the education and training of a laboratory's staff and therefore provides an ongoing contribution to the improvement of a laboratory's services. This accreditation program gives confidence that providers are competent to design, conduct and report on Proficiency Testing programs in the specific disciplines defined in their scope of accreditation.

A1.9 OECD Principles of Good Laboratory Practice

The OECD Principles of Good Laboratory Practice apply to the conduct of non-clinical health and environmental safety studies. These studies are required by national regulations for the purpose of registering or licensing pharmaceuticals, pesticides, veterinary drug products, industrial chemicals and similar products. The OECD Principles cover the managerial concept by which the studies are planned, performed, monitored, recorded, reported and archived.

The OECD Principles are an integral part of the OECD Council Directives on Mutual Acceptance of Data in the assessment of chemicals. This states that data generated in a facility that adheres to the OECD Principles of GLP and is recognised as GLP compliant by a national GLP compliance monitoring authority must be accepted internationally.

In Australia, NATA fills the role as the compliance monitoring authority. GLP is not an accreditation program but being laboratory oriented, it is consistent with NATA's broader laboratory related activities.

Appendix 2 – Further assistance

NATA is pleased to be of service in providing additional information about any subject relating to NATA accreditation.

If you are considering a requirement for NATA accreditation in a regulation or specification, staff are available to assist in any way possible to meet your needs and those of your stakeholders. This service is generally provided at no charge.

Complaints – NATA also recognises that despite best intentions and a robust accreditation system, things can go wrong. If you are experiencing difficulties with any NATA accredited facility or in the reliability of the services they provide, NATA is available to assist in resolving such problems. In such cases, it is recommended that you contact NATA by telephone to discuss the general nature of any concerns and assist us in identifying the most appropriate person to help. You should then follow this up with a written account of the issues.

NATA has a comprehensive complaints handling process and treats any issues raised very seriously.

Area of interest	**Contact**
NATA Website	www.nata.com.au
General information about NATA	New South Wales (Head Office) and Australian Capital Territory Ph: 02 9736 8222 or Email: Susan.Jones@nata.com.au
	Queensland Ph: 07 3870 3844 or Email: Darina.Ross@nata.com.au
	South Australia and Northern Territory Ph: 08 8179 3400 or Email: Susan.Harry@nata.com.au
	Victoria and Tasmania Ph: 03 9274 8200 or Email: Peter.Williams@nata.com.au
	Western Australia Ph: 08 9486 2800 or Email: Barbara.Wraith@nata.com.au
Technical issues with testing, measurement or inspection	General Manager, Operations and Technical Ph: 03 9274 8200 or Email: John.Styzinski@nata.com.au
Problems with NATA accredited facilities	General Manager, Compliance and Governance Ph: 03 9274 8200 or Email: Tony.Vandenberg@nata.com.au
Existing or proposed use of NATA accreditation in regulation or specification	Manager, Government Relations Ph: 03 9274 8200 or Email: John.Mitchell@nata.com.au

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