About NATA and accreditation

January 2019

Table of Contents

About NATA

The National Association of Testing Authorities (NATA) is the national accreditation body for Australia.

NATA's role is to serve the national and public interest, by ensuring that organisations (accredited facilities) comply with relevant international and Australian standards and so are competent to provide consistently reliable outputs and data to government, industry and the wider community.

NATA accreditation provides an assurance of the competence, impartiality and integrity of facilities.

Corporate aims

NATA aims:

- to support Australia's technical infrastructure, underpinning all activities that rely on testing, measurement, inspection and related services;
- to deliver best practice and cost effective accreditation and complementary services that serve members and the national interest.

Structure and governance

NATA was established in 1947. It is a government-endorsed, independent, not-for-profit company, operating as an association owned by its members (where all accredited organisations are members).

NATA is governed by a Board of Directors, drawn from its members and Stakeholders, that is responsible for overseeing all of NATA's activities. The Board is supported in the day-to-day running of the company's activities by an Executive drawn from senior NATA staff.

The Board receives technical advice from specialist technical committees that it appoints, referred to as Accreditation Advisory Committees (AACs).

NATA has a number of AACs supporting the various accreditation programs it offers. AAC members are drawn from industry, government, professional bodies, academia and accredited facilities.

NATA's professional status and expertise is underpinned by the specialist knowledge of its staff based around Australia in most Australian capital cities. NATA's staff are committed to providing a quality service to our clients and for the public good.

In accordance with the NATA's objectives, as described in the Constitution, NATA has established a permanent forum of elected members' representatives to act as a conduit between NATA's Executive Management and members.

International arrangements

NATA's competence as an accreditation provider is regularly evaluated by the International Laboratory Accreditation Cooperation (ILAC) and the Asia Pacific Accreditation Cooperation (APAC) for continued inclusion in Mutual Recognition Arrangements. Evaluation teams comprise of individuals from accreditation bodies in Europe, North America and the Asia-Pacific region. This ensures NATA's operations remain consistent with international practices. NATA similarly participates in evaluations of its mutual recognition partners.

NATA's involvement in international groups such as ILAC and APAC provides for mutual recognition of accreditation bodies at an international level and hence the global acceptance of reports, certificates and conformity statements issued by NATA accredited facilities. This reduces the need for multiple assessments of suppliers of these services and as a consequence, helps to reduce barriers to trade for organisations that have NATA accreditation.

NATA also represents Australia in the OECD Working Group on Good Laboratory Practice (GLP) and is Australia's GLP Compliance Monitoring Authority.

Domestic arrangements

NATA has signed agreements (Memoranda of Understanding and/or Deeds of Agreement) with some government agencies having specific requirements for NATA accreditation. These agreements provide the basis for a strengthened and ongoing relationship with the relevant agencies and provide a formalised mechanism to facilitate the exchange of information which may otherwise be privileged and confidential. Many of the current agreements also provide for the exchange of high level strategic information to ensure the availability of accredited infrastructure to meet current and emerging needs.

Australian Government recognition

The above roles are recognised by the Australian Government in a Memorandum of Understanding (MoU) with NATA. Under this MoU, the Government:

- uses NATA accredited facilities to meet its testing needs, wherever possible;
- encourages State Governments and other instrumentalities to do likewise;
- commits all Commonwealth Government laboratories to obtain and maintain NATA accreditation, where appropriate.

Financial support

NATA receives approximately 85% of its total revenue from fees paid by accredited facilities. Other sources of income include training services revenue, investment income and funding from the Australian Government specifically for approved purposes deemed to be in the national interest.

For further details of NATA's source of revenue, refer to the NATA Annual Report available from the NATA website.

The value of peer assessment

NATA assessments are first and foremost a peer review process. As such, NATA relies heavily on the specialised knowledge and experience of its volunteer technical assessors.

Technical assessors are selected on the basis of their technical knowledge, expertise, and familiarity with relevant professional issues. This ensures that the NATA assessment is always current with regard to new technical developments and trends.

The volunteer work offered to NATA is well recognised within the scientific and technical fraternity and the support offered by organisations in making their staff

available to NATA as volunteers is acknowledged. NATA is fortunate to have access to over 3000 technical assessors.

Technical assessors work under the direction of the NATA lead assessor (NATA staff member) during assessments. They provide support by reviewing activities performed by the facility and offering their feedback to the lead assessor. As well as participating in on-site assessments, technical assessors may be asked to provide follow up advice and guidance to NATA on post assessment activities, such as reviewing a facility's response to assessment findings.

The vast majority of technical assessors work in NATA accredited facilities, or are individuals who are well recognised by the profession in their field of expertise including those from academia.

Technical assessors are drawn from individuals who display the following qualities:

- professional expertise and experience;
- knowledge of testing, calibration, inspection or related activities which NATA accredits;
- understanding of management systems;
- analytical approach and an ability to critically evaluate;
- ability to work as a team member;
- communication skills and commitment to the accreditation process.

Accreditation activities

Accreditation provides a means of determining, formally recognising and promoting that a facility is competent to perform specific types of conformity assessment activities, including but not limited to, testing, inspection, calibration, and other related activities in a reliable, credible and valid manner. The activities for which accreditation is granted, which may not be all activities a facility performs, are described in a scope of accreditation.

The provision of accreditation must be:

- objective, transparent and effective;
- use highly professional competent assessors (experts) who are reliable, ethical and competent in both accreditation processes and the relevant technical disciplines.

Accreditation delivers confidence in reports, certificates and conformity statements. It underpins the quality of results by ensuring their traceability, comparability, validity and commutability.

Accreditation is distinct from certification. The latter focuses on an organisation's overall compliance with systems and product standards rather than technical competence.

The criteria for determining a facility's competence are based on the relevant international standard (e.g. ISO/IEC 17025, ISO 15189, ISO/IEC 17020) and include: the qualifications, training and experience of staff; correct equipment that is properly calibrated and maintained; adequate quality assurance procedures; appropriate sampling practices, and so on. The standards used to accredited facilities are also supported by interpretative documents and other NATA criteria. The "package" of criteria documents applicable to each of the accreditation programs NATA offers are

detailed in the *NATA Procedures for Accreditation* and are available from the NATA website.

The vast majority of facilities NATA accredits are based in Australia with a small number overseas.

The following diagram illustrates the key steps in the NATA accreditation process. There may however be some variation between accreditation programs and these differences are outlined in the *NATA Procedures for Accreditation*.

Steps to accreditation

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│  Advisory Visit │
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│   Application   │
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│    Document     │
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│   Scheduled     │
│  reassessments  │
│ and surveillance│
│     visits      │
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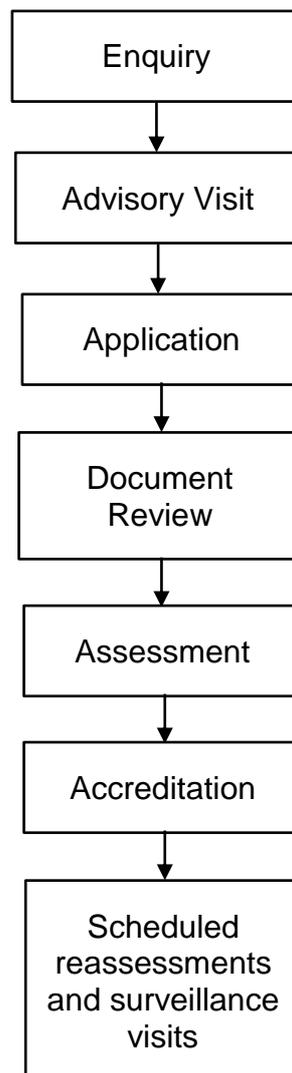
Calibration and testing

NATA accredits calibration and testing facilities against the requirements of ISO/IEC 17025 *General requirements for the competence of calibration and testing laboratories.*

The activities covered are categorised into the following areas reflective of industry:

- Agribusiness;
- Animal Health;
- Calibration;
- Environment;
- Food and Beverage;
- Healthcare, Pharmaceutical and Media Products;
- Human Testing for Workplace and/or Community Screening;
- Infrastructure and Asset Integrity;
- Legal;
- Materials;
- Manufactured Goods.

Human pathology testing

NATA accredits pathology testing facilities against the requirements of ISO 15189 *Medical laboratories - Requirements for quality and competence* and the relevant NPAAC (National Pathology Accreditation Advisory Council) standards.

The accreditation program is administered jointly with the RCPA (Royal College of Pathologist of Australasia).

Accreditation is available for all pathology disciplines and federal health funding, through Medicare, is able to be claimed for accredited services.

Inspection

Inspection involves the formal evaluation of a product or process (however named) against defined specifications using experience and professional judgement.

NATA's inspection accreditation program is conducted against the requirements of *ISO/IEC 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection.*

Medical imaging

The accreditation program for medical imaging practices is administered jointly with the RANZCR (Royal Australian and New Zealand College of Radiologists) and has adopted the RANZCR *Standards of Practice for Diagnostic and Interventional Radiology* as the requirements for accreditation.

The RANZCR standards include the principles from ISO/IEC 17025. The adoption of the ISO/IEC principles to the RANZCR standards raises practice accreditation to an internationally recognised level.

Accredited medical imaging services are able to seek federal health funding through Medicare.

Proficiency testing scheme providers

Proficiency testing scheme providers are accredited against the requirements of ISO/IEC 17043 *Conformity assessment - General requirements for proficiency testing*.

Accreditation recognises the competence of providers to design proficiency testing schemes, test samples for homogeneity and stability, assign property values to samples and to evaluate participants' results.

As participation in proficiency testing is a requirement of ISO/IEC 17025, testing and calibration facilities can have confidence when taking part in schemes offered by accredited providers.

Reference material producers

Reference material producers are accredited against the requirements of ISO 17034 *General requirements for the competence of reference material producers*.

Accreditation recognises the competence of producers to produce, characterise and assign property values to reference materials. The program covers the production of both reference materials and certified reference materials.

Facilities using reference materials from accredited producers can have confidence in the traceability of the assigned values.

Research and development (R&D)

NATA has developed a set of 7 principles for the accreditation of R&D facilities. Compliance with these principles is demonstrated through the implementation of an applicable code or standard relevant to the R&D activity for which accreditation is sought.

To-date, NATA accredited R&D facilities have adopted either ISO/IEC 17025 or ISO 15189. According to the specific R&D activity being conducted (e.g. testing on human samples), the relevant accreditation criteria applicable to that activity are also applied.

The benefits of accreditation for R&D facilities include a potential reduction in client audits, evidence of appropriate procedures and systems in place to satisfy funding body requirements and greater confidence in the R&D outcomes.

Sleep disorders services

The accreditation program for sleep disorders services is administered jointly with the ASA (Australasian Sleep Association) and has adopted the ASA *Standard for Sleep Disorders Services* as the requirements for accreditation.

The ASA standard includes the principles from the international standard ISO 15189. The adoption of the ISO principles to the ASA Standard raises accreditation to an internationally recognised level.

Refer to *About NATA and the ASA/NATA Sleep Disorders Services accreditation program* for further details on this program.

Recognition activities

Diagnostic Imaging Accreditation Scheme (DIAS)

NATA is one of a number of accrediting bodies offering DIAS recognition.

The Australian Department of Health established the Scheme. Diagnostic imaging services which are deemed to comply with the Scheme are able to access federal health funding through Medicare.

OECD Principles of Good Laboratory Practice (GLP)

NATA recognition is offered for compliance with the OECD *Principles of GLP* to any Australian facility undertaking non-clinical health and environmental safety studies. These studies may be required by regulations for the purpose of registering or licensing pharmaceuticals, pesticides, veterinary drug products and similar products, and for the regulation of industrial chemicals.

Refer to the *About NATA and GLP Recognition* document for further details on this program.

Other services

Training and seminar services

NATA offers public and tailored in-house training courses both in Australia and overseas. On-line courses are additionally available.

From time to time, NATA also runs sessions on specific topics to its members.

Details of NATA's training services can be found on the NATA website.

Public database of NATA accredited and recognised facilities

NATA maintains an on-line directory of its accredited and recognised facilities, which can be accessed via the NATA website.

NATA publications

NATA publishes a range of technical and information documents. These include *NATA News*, *NATA Technical Assessor News*, information about accreditation, user guides, accreditation criteria etc.

Refer to the NATA website to access the full range of documents available.

Addresses of NATA

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Amendment table

The table below provides a summary of changes made to the document with this issue.

Section	Amendment
Whole document	Editorially updated and information reorganised into new headings.
	Detailed information on NATA's accreditation criteria removed and reference to the *NATA Procedures for accreditation* included where this information can be found.
	Inclusion of information on the Diagnostic Imaging Accreditation Scheme.