About NATA and the ASA/NATA Sleep Disorders Services accreditation program

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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 clients and for the public good.

In accordance with its 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.

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 size of the assessment team is dependent upon the range of services that must be covered during the course of the assessment. Assessment teams, for the accreditation of sleep disorders services, include at least one sleep physician, one sleep technologist/scientist and one NATA lead assessor.

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. For further information, refer to the NATA *Specific Accreditation Guidance: Scope of accreditation - service descriptors for Sleep Disorders Services*.

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 accredit 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.

Steps to accreditation

The following diagram illustrates the key steps in the accreditation process. For further information, refer to the *NATA Procedures for Accreditation* available from the NATA website.

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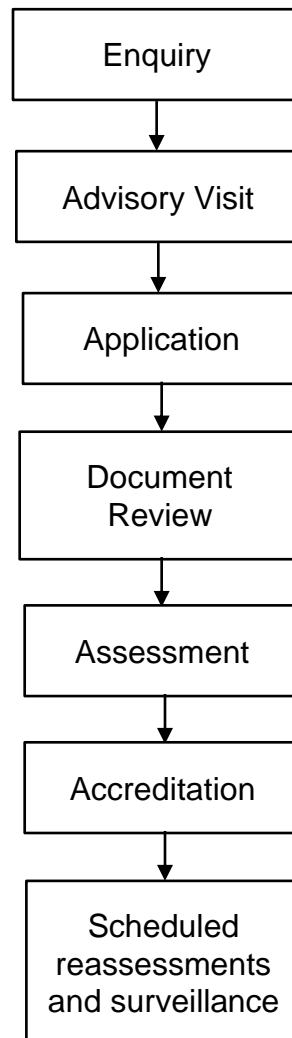
Accreditation Programs

The accreditation programs offered by NATA cover:

- Biobanking

    NATA accredits organisations performing biobanking activities against the requirements of ISO 20387 *Biotechnology – Biobanking – General requirements for biobanking.*

- 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 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.

    The accreditation program is also available to organisations conducting testing and/or related activities in support of research and development work, using established or novel techniques.

- 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).

- Inspection

    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 Clinical Radiology as the requirements for accreditation.

- Proficiency testing scheme providers

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

- Reference material producers

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

- Sleep disorders services

  Sleep Disorders Services are accredited against the ASA *Standard for Sleep Disorders Services.*

Accreditation of Sleep Disorders Services

The accreditation program for sleep disorders services is administered jointly between NATA and the Australasian Sleep Association (ASA) and a Memorandum of Understanding (MoU) has been signed to formalise this arrangement.

The program has adopted the ASA *Standard for Sleep Disorders Services* as the criteria for accreditation. The Standard covers both managerial and technical requirements and includes the principles from the international standard ISO 15189 *Medical laboratories - Requirements for quality and competence*. The adoption of the ISO principles into the ASA Standard raises accreditation to an internationally recognised level.

Whilst an assessment does not constitute a formal safety audit, there are some safety requirements that have been mandated in the ASA Standard which are expected to be satisfied by Sleep Disorders Services.

The ASA is responsible for maintaining the Standard and NATA is responsible for the administration of the accreditation program.

The program is overseen by NATA's Sleep Disorders Services Accreditation Advisory Committee (SDSAAC).

Broadly speaking, the role of the SDSAAC includes professional/technical guidance together with strategic planning and administrative support for the management of the program. The SDSAAC is chaired by a member of the ASA, who also sits on the ASA Clinical Committee. The SDSAAC includes members who represent both adult and paediatric Physicians and Scientists

Accredited services are encouraged to use the ASA/NATA endorsement. The *NATA Rules* and the *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation* outline the circumstances under which the endorsement may be applied.

Branch services

A Sleep Disorders Service may offer services at another site (a "branch" service) located away from the accredited site ("parent" site). Such a site may be recognised under the accreditation of the parent site if the criteria as detailed in the *Specific Accreditation Criteria: Sleep Disorders Services - Accreditation of Branch Services* are satisfied.

Accreditation of services operating with off-site supervision

A Sleep Disorders Service may operate in a non-metropolitan location where the requirements of the *ASA Standard* for on-site presence of the Medical Director and Scientist/Technologist in Charge and the criteria detailed in the NATA *Specific Accreditation Criteria: Sleep Disorders Services, Accreditation of Branch Services* are not satisfied.

Such a service may still gain accreditation if the criteria as detailed in the *Specific Accreditation Criteria: Sleep Disorders Services, Accreditation of a service operating with off-site supervision* are satisfied.

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*, information about accreditation, user guides, accreditation criteria etc.

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

Contact NATA

Telephone: 1800 621 666

Email: corpcomm@nata.com.au

Website: www.nata.com.au

Registered office

Sydney office - Burramattagal Country

7 Leeds Street, Rhodes, NSW 2138
Mail: P.O. Box 7507, Silverwater, NSW 2128

Branch offices

Melbourne office - Wurundjeri Country

2-6 Railway Parade, Camberwell, Vic, 3124

Adelaide office - Kaurna Country

Level 1, 203 Fullarton Road, Eastwood, SA, 5063

Brisbane office - Turrbal Country

628 Ipswich Road, Annerley, Qld, 4103

Perth office - Whadjuk Country

Business Centre, 2A Brodie Hall Drive, Bentley, WA, 6102

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Amendment table

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

Section	Amendment
Accreditation Programs	Updated information regarding Research and Development. Editorial changes to now include Standards for each program.
Accreditation of Sleep Disorders Services	Editorial changes.
Contacts	Contact details updated
Follow our socials	New Section
Whole document	Added Security Classification Label