About NATA and Good Laboratory Practice (GLP) recognition

August 2022

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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 our 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 therefore, helps to reduce barriers to trade for organisations that have NATA accreditation.

NATA also represents Australia in the OECD Working Group (WG) on Good Laboratory Practice (GLP) and is periodically evaluated by the WG as 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;
- recognises NATA as the national GLP compliance monitoring authority.

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.

Good Laboratory Practice

What is GLP?

GLP is a quality system concerned with organisational processes and conditions for the planning, performance, monitoring, recording, archiving and reporting of non-clinical health and environmental safety studies.

GLP studies fall into one of the following categories:

- physical-chemical;
- toxicity;
- mutagenicity;
- environmental toxicity;
- bioaccumulation;
- residue;
- effects of mesocosms and natural ecosystem;
- safety studies of medical devices;
- analytical and clinical chemistry associated with non-clinical studies;
- validation of virus inactivation;
- statistical analysis of data.

For further information on the types of activities currently recognised by NATA, refer to the *Specific Accreditation Guidance: OECD GLP Program - Types of Studies* available from the NATA website.

The OECD Principles of GLP

The Principles of GLP were developed by the Organisation for the Economic Co-operation and Development (OECD) in the late 1970s to promote the development of comparable quality test data and to form the basis for the Mutual Acceptance of Data (MAD) arrangement between OECD member countries and non-member countries who adhere to the arrangement. By relying on test data, under the arrangement, duplicated testing and barriers to trade can be avoided, and time and resources saved, while improving the protection of human health and the environment.

The Principles are applicable to test items including those contained in pharmaceuticals, pesticides, cosmetics, veterinary drugs, food additives, feed additives and industrial chemicals.

The Principles do not apply to clinical studies.

Copies of the OECD Principles, together with supporting documents, can be obtained from the OECD Environment Directorate (www.oecd.org/env/glp).

The Australian GLP program

Recognition by NATA for compliance with the OECD Principles is available to any Australian facility performing 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, and similar products or for the regulation of industrial chemicals.

Most overseas regulators also require non-clinical health and environmental safety studies to be performed in compliance with the OECD Principles of GLP.

The assessment, regulation, and management of chemicals in Australia are the responsibility of various Australian regulatory agencies: These include:

Agency	Product
Therapeutics Goods Administration (TGA)	Pharmaceutical
Australian Pesticide and Veterinary Medicine Authority (APVMA) (*Formerly* the National Registration Authority (NRA))	Veterinary and agricultural chemicals
Australian Industrial Chemicals Introduction Scheme (AICIS)	Industrial chemicals

GLP recognition for overseas test facilities

NATA is only obliged, under the Mutual Acceptance of Data (MAD) directives, to assess Australian facilities. These directives are an integral part of the OECD Principles. They state that data must be accepted internationally for the purpose of assessment by OECD member countries and non-member countries (who adhere to the MAD directives) if it is generated in a facility that is recognised as GLP compliant by the national GLP compliance monitoring authority.

Requests for GLP recognition of facilities located in countries that are adherents to the MAD directives are directed to the relevant national GLP compliance monitoring authority. A list of these can be found on the GLP section of the OECD website.

NATA may only inspect facilities located overseas if:

- a request was received from the relevant Australian regulator;
- the facility was in a country that does not have a GLP compliance monitoring authority adhering to the MAD directives.

In such cases, there is no obligation on the part of regulators in other countries to accept the outcome of NATA assessment of these overseas facilities. The facility would be listed in NATA's annual report to the OECD GLP Working Group, however, it would not be included in the Australian GLP compliance monitoring program and it would not be able to claim recognition under the Australian program.

Roles and responsibilities of GLP sponsors

The Sponsor is the entity that commissions, supports and /or submits a non-clinical health and environmental safety study.

The Sponsor should understand the requirements of the OECD Principles, in particular those related to the responsibilities of the test facility management and the Study Director/Principal Investigator.

Further information on the role of the Sponsor is detailed in *OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11, Advisory Document of the Panel on Good Laboratory Practice: The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP* available from the OECD website.

Reporting to other GLP compliance monitoring authorities

NATA provides an annual report to all GLP compliance monitoring authorities via the OECD. This report lists the facilities that are in the Australian program and their current GLP status.

NATA notifies all members of the OECD GLP Working Group and Australian regulators of any studies, or any facilities found to be GLP non-compliant.

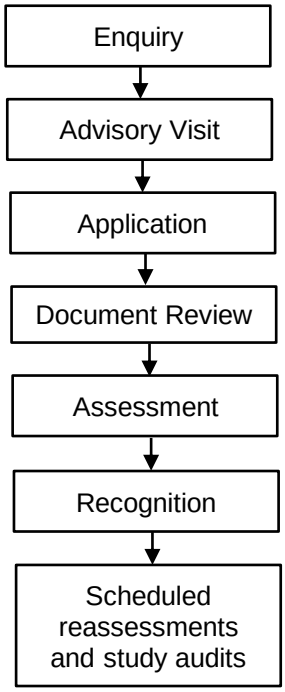
NATA's criteria for GLP recognition

The OECD Principles used to recognise facilities are also supported by additional NATA documents. The "package" of documents applicable to GLP is described in the *NATA Procedures for Accreditation.* Both the "package" and the *NATA Procedures for Accreditation* are available from the NATA website.

Facilities seeking recognition for compliance with the OECD Principles are also encouraged to seek ISO/IEC 17025 accreditation for the testing component associated with their GLP activities. Accreditation against the latter standard affords recognition of technical competence.

Steps to NATA GLP recognition

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



Should you require further information on NATA's GLP recognition program please contact Ms Louise Calder, GLP Program Advisor, located in NATA's Sydney office on (02) 9736 8222 or at Louise.Calder@nata.com.au

Other NATA services

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 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.

The accreditation programs offered by NATA cover:

- Calibration and testing;

  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

- Human pathology testing;
- Inspection;
- Medical imaging;
- Proficiency testing scheme providers;
- Reference material producers;
- Sleep disorders services;
- Biobanking.

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 based on their technical knowledge, expertise, and familiarity with relevant professional issues. This ensures that the NATA assessment is always current regarding 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.

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.

Diagnostic Imaging Accreditation Scheme (DIAS)

NATA is one of several accrediting bodies offering DIAS recognition.

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

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, accreditation criteria, guidance documents, etc.

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

Addresses of NATA

Website

www.nata.com.au

Registered office

Sydney Office

7 Leeds Street
RHODES NSW 2138
(PO Box 7507
SILVERWATER NSW 2128)
Telephone: (02) 9736 8222
Fax: (02) 9743 5311

Branch offices

Melbourne office

Level 1, 2-6 Railway Parade
CAMBERWELL VIC 3124
Telephone: (03) 9274 8200
Fax: (03) 9882 8249

Adelaide office

Level 1, 203 Fullarton Road
EASTWOOD SA 5063
Telephone: (08) 8179 3400
Fax: (08) 8179 3498

Brisbane office

628 Ipswich Road
ANNERLEY QLD 4103
(PO Box 1122
ARCHERFIELD QLD 4108)
Telephone: (07) 3721 7300
Fax: (07) 3848 3660

Perth office

Business Centre
2a Brodie Hall Drive
BENTLEY WA 6102
Telephone: (08) 9486 2800
Fax: (08) 9486 2828

Amendment table

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

Section	Amendment
Whole document	Editorially updated.