About NATA and GLP recognition

Information on the OECD Principles of Good Laboratory Practice compliance monitoring program

January 2018

NATA's OECD GLP Recognition Criteria

The NATA OECD GLP Recognition Criteria (NRC) are made up of a number of documents, available for download from the 'Accreditation Information' section of the NATA website, www.nata.com.au. These documents are:

1. The OECD series on the Principles of GLP – not provided by NATA, is to be obtained by the facility, from

   OECD Environment Directorate
   Environmental Health and Safety Division
   2 André-Pascal
   75775 Paris Cedex 16
   FRANCE
   fax: +33 1 4524 1675
   email: ehscont@oecd.org
   website: www.oecd.org/env/**glp**

2. OECD Principles of GLP Recognition Application Document
3. General NATA Documents, including NATA Rules
4. General Accreditation Criteria

Other informative documents are also available from the NATA website, Including General Accreditation Guidance that can be applicable to all activity types, such as *About NATA and GLP recognition* (this document) and Specific Accreditation Guidance applicable to a single activity type.

Contents

1. About NATA

The National Association of Testing Authorities, Australia (NATA) is the national organisation for conformity assessment of technical operations such as laboratories, inspection bodies, proficiency testing scheme providers and reference material producers. By way of a Memorandum of Understanding, the Commonwealth Government recognises NATA as the sole national accreditation body for establishing and maintaining competent laboratory practice. NATA also represents Australia in the International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and on the OECD[1] Working Group on Good Laboratory Practice.

2. Corporate aims and the value of peer assessment

NATA aims:

- to provide, in the national interest, an accreditation service which meets the needs of stakeholders, and also facilitates the recognition and acceptance of their products and services; and
- to promote the science and practice of accreditation to enhance the acceptance of Australian products and services both in Australia and overseas.

The cornerstone of NATA accreditation is peer assessment. The role of the peer (Technical Assessor) is to evaluate the facility's technical competence. 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. We are fortunate to have access to over 3000 such peers or technical experts who volunteer their time to assist in the assessment of technical competence. Further support is provided by a Technical Committee system, also composed of technical experts.

3. The Australian GLP program

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

These studies will fall into one of the following services:

- 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

They do not apply to clinical studies or routine QC testing required as part of manufacturing chemicals. The appropriate good laboratory practice standard for this testing is ISO/IEC 17025. Accreditation to ISO/IEC 17025 demonstrates technical competence, therefore laboratories that are accredited to this standard are demonstrating that they follow 'good laboratory practice' and that the data produced is technically valid. GCP, ICH or VICH are the applicable codes for clinical studies.

The Principles cover the managerial concept by which the studies are planned, performed, monitored, recorded, reported and archived.

The assessment, regulation and management of chemicals in Australia is the responsibility of various Australian regulatory agencies, specifically the Therapeutics Goods Administration (TGA), the Australian
Pesticide and Veterinary Medicine Authority (APVMA) and National Industrial Chemicals Notification

and Assessment Scheme (NICNAS).

In January 2003 the APVMA, formerly the NRA (National Registration Authority), mandated that all residue studies must be done in compliance with the OECD Principles of Good Laboratory Practice. Further details, including exemptions to this requirement, can be found in the NRA Gazette No 3, 5 March 2002. A number of organisations in Australia have also initiated studies in compliance with GLP to meet client demands and overseas requirements.

The Australian Regulatory Guidelines for Prescription Medicines states that non-clinical health and environmental safety studies should be conducted in accordance with the OECD Principles of Good Laboratory Practice and Australian facilities undertaking such studies should be in the Australian GLP Compliance Monitoring Program.

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

Copies of the OECD Principles of GLP, together with supporting consensus and guidance documents, can be obtained from the OECD Environment Directorate, as described above.
Interpretive criteria are defined in NATA's publication *OECD Principles of GLP – Recognition Application Document* which is to be read in conjunction with the *OECD Principles of GLP*. This document can be downloaded from the 'Accreditation Information' section of NATA's website.

Facilities seeking recognition of their compliance with the OECD Principles of GLP are encouraged to have an ISO/IEC 17025 accreditation for the testing component associated with their GLP activities. This is, however, not mandatory. The Sector Manager of the relevant activity type or the GLP Program Adviser should be contacted for further information.

4. GLP recognition for overseas test facilities

NATA has a number of overseas member facilities accredited to ISO/IEC 17025. This is because either there is no domestic accreditation body or the domestic accreditation body is not in a Mutual Recognition Agreement or does not currently offer accreditation in the required activity type.

Facilities located in countries without a national GLP compliance monitoring program may also wish to be recognised as GLP compliant. However, NATA is only obliged, under the Mutual Acceptance of Data (MAD) directives, to inspect Australian facilities. These directives are an integral part of the OECD Principles of GLP. They state that data must be accepted internationally for purposes of assessment by OECD member countries and non-member countries (which are adherents to the MAD decision) if it is generated in a facility that is recognised as GLP compliant by the national GLP compliance monitoring authority.

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

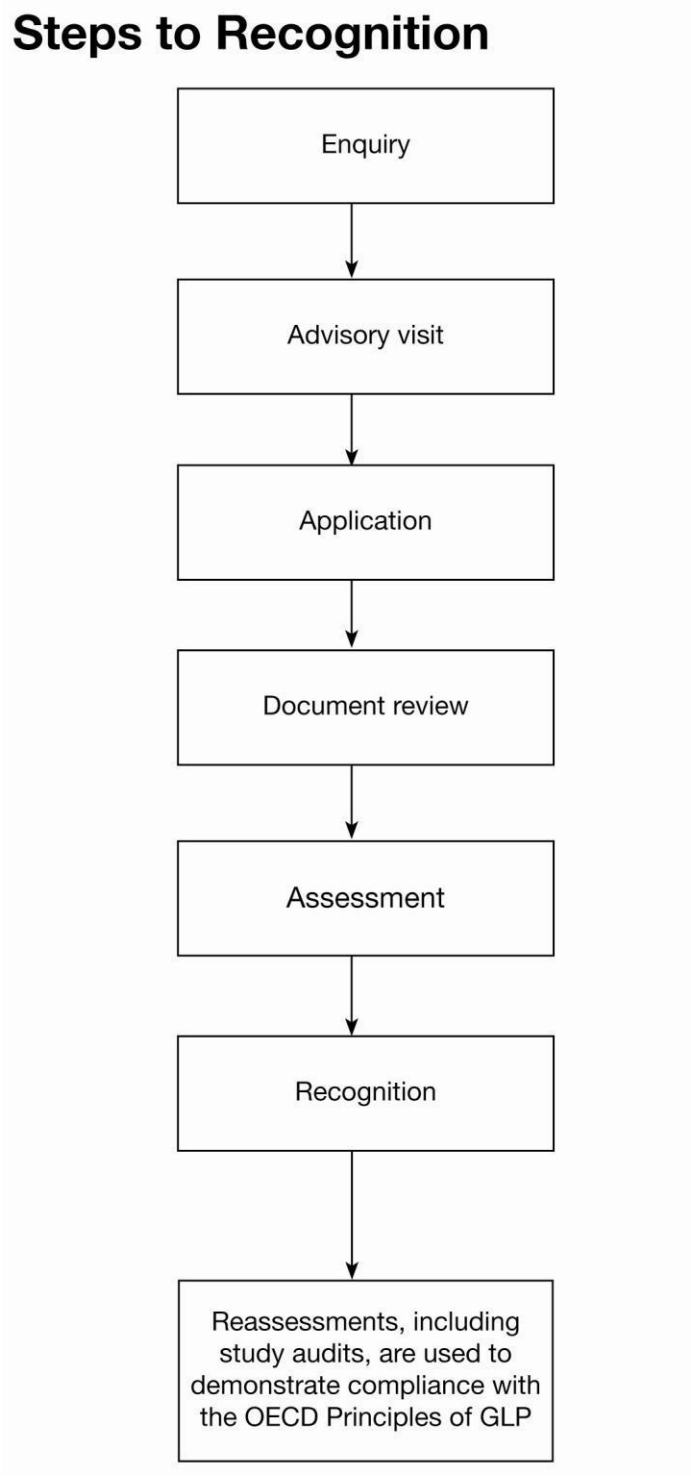
NATA would only inspect facilities or sites located overseas if:

- a request was received from the relevant Australian regulator, and
- the facility or site was located in a country that does not have a GLP compliance monitoring authority adhering to the Mutual Acceptance of Data (MAD) directives.

There would be no obligation on the part of regulators in other countries to accept the outcome of an inspection to these overseas test sites by NATA. The facility or site inspected 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.

5. Accreditation and recognition activities

The following diagram illustrates the key steps in the NATA GLP recognition process. There may however be some variation between the GLP Program and NATA's accreditation activities or from activity type to activity type and these differences are outlined in the NATA Procedures for Accreditation.



6. Accreditation activities

NATA offers an extensive accreditation service. NATA accredits facilities against the criteria in ISO[2]/IEC[3] 17025 *General requirements for the competence of calibration and testing laboratories*. Testing facilities are accredited in the activity types of Agribusiness, Animal Health, Calibration, Environment, Food and Beverage, Healthcare, Pharmaceutical and Media Products, Human Pathology*, Human Testing for Workplace and/or Community Screening, Infrastructure and Asset Integrity, Legal, Materials and Manufactured Goods. Calibration facilities are accredited in a number of activity types including dimensional metrology, force metrology, mass and weighing devices, volume and density, flow metrology, pressure metrology, torque, speed and velocity, DC and Low Frequency Electrical Metrology, magnetism, time and frequency metrology, Communications, EMR and EMC Equipment, optical metrology, ionising radiation, temperature metrology, acoustical metrology, vibration metrology, ultrasonics and chemical metrology.

* **Note**: The Standard AS ISO 15189 *Medical laboratories - Particular requirements for quality and competence* is used for Human Pathology.

Accreditation programs are also offered in the following areas:

- Sleep Disorders Services (using the ASA Standard for Sleep Disorders Services)
- Medical Imaging (using the RANZCR *Standards of Practice for Diagnostic and Interventional Radiology*)
- Proficiency Testing Scheme Providers (using the standard ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing)*
- Reference Material Producers (using the standard ISO17034 *General requirements for the competence of reference material producers)*
- Inspection (using AS/NZS ISO/IEC 17020 *General criteria for the operation of various types of bodies performing inspection)*
- Research and Development (using ISO/IEC 17025 and the Eurachem[4]/CITAC[5] document *Quality Assurance for Research and Development and Non-routine Analysis)*

7. Other services

Training and seminar services

NATA offers public and tailored in-house training programs, in Australia and internationally. These programs support laboratory activities and management and cover areas such as Quality Management in the Laboratory, Documenting and Implementing Your Laboratory Management System, Internal Audits and Aspects of Quality Control in Microbiological Laboratories. Details of NATA Training Group activities can be found in the 'Training' section of the NATA website (www.nata.com.au).

NATA also offers training to facilities in the OECD Principles of GLP.

From time to time, NATA also runs seminars and workshops on special topics of interest to its members.

Public database of NATA accredited facilities

NATA maintains an on-line directory of its accredited and GLP-recognised facilities, which can be accessed via the NATA website at www.nata.com.au.

NATA publications

NATA publishes a range of technical and information documents covering laboratory practice and evaluation. These include the *NATA News* (issued bi-monthly), and many guidance documents designed to provide guidance on matters related to accreditation.

8. More about NATA

Structure and governance

NATA was established in 1947. It is an independent, private company, operating as an Association and owned by its members. All NATA accredited organisations and GLP-recognised facilities are members of NATA.

NATA is guided and monitored by a Board elected from its members and stakeholders.

NATA's competence as an accreditation provider is regularly evaluated by its mutual recognition partners from Europe, Africa, the Americas and the Asia-Pacific region, to ensure its operations remain consistent with international practices. (NATA similarly undertakes evaluations of its mutual recognition partners).

NATA has a secretariat of over 100 people, spread across most Australian capital cities. This includes scientific staff who administer and undertake the assessments of applicant and accredited or recognised organisations and provide training services.

International responsibilities

NATA actively promotes its accredited facilities both within Australia and internationally. It is an active participant in the International Laboratory Accreditation Cooperation (ILAC) and liaises with other international bodies such as BIPM[9]/OIML[10], ISO/IEC, IAF[11], and the WTO[12]. NATA is a signatory to the ILAC Arrangement and has established Mutual Recognition Arrangements (MRAs) with laboratory accreditation bodies in many economies as detailed on the ILAC website. These arrangements are crucial in the recognition of Australian test and calibration data overseas, and in the acceptance of Australian goods in foreign markets.

Regional involvement

NATA is one of the founding members of the Asia-Pacific Laboratory Accreditation Cooperation (APLAC), which is a cooperation between the various laboratory accreditation bodies in Asia and the Pacific Rim. NATA was an inaugural signatory of the APLAC MRA for testing, calibration and inspection

9. Addresses of NATA

Registered office

Sydney Office

7 Leeds Street
RHODES NSW 2138
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Telephone: (02) 9736 8222
Fax: (02) 9743 5311

Branch offices

Melbourne office

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

Brisbane office

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

Adelaide office

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

Perth office

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

10. Definitions

1. OECD - Organization for Economic Cooperation and Development
2. ISO - International Organization for Standardization
3. IEC - International Electrotechnical Commission
4. GCP - Good Clinical Practice
5. ICH - International Conference on Harmonizations of Technical Requirements for Registration of Pharmaceuticals for Human Use
6. VICH - International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
7. Eurachem - A network of organisations in Europe involved with establishing a system for international traceability of chemical measurements
8. CITAC - Co-operation on International Traceability in Chemistry
9. BIPM - International Bureau of Weights and Measures
10. OIML - International Organisation of Legal Metrology
11. IAF - International Accreditation Forum
12. WTO - World Trade Organization
13. REMCO - ISO Committee on Reference Materials
14. IUPAC - International Union of Pure and Applied Chemistry

AMENDMENTS

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

Section	Amendment
Entire document	This document replaces the former About NATA and GLP Recognition. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure and replace field with activity type.
Section 9	Change of address, Adelaide office