About NATA and GLP recognition

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

January 2016

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 Publications' 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, 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. NATA Rules
4. Current Policy/Technical Circulars (where relevant)

Other informative documents are also available from the NATA website, such as:

1. *About NATA and GLP recognition* (this document)
2. NATA Procedures for Accreditation
3. Equipment calibration and checks
4. Technical Notes and Information Papers
5. Proficiency Testing information
6. Measurement uncertainty and traceability information

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 categories:

- physical-chemical
- testing toxicity studies
- mutagenicity studies
- environmental toxicity studies bioaccumulation
- residue studies
- studies on the effects of mesocosm and natural ecosystem
- target animal safety studies
- worker exposure studies
- analytical and clinical pathology and histology associated with GLP studies

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 facilties 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.

Since 1947 NATA has operated the world's first comprehensive national laboratory accreditation system. Australia has, therefore, used codes of good laboratory practice for many years prior to the issue of the OECD Principles of Good Laboratory Practice.

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*. This is to be read in conjunction with the OECD Principles of GLP. This document can be downloaded from the 'Accreditation Publications' section of the 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 field of testing 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 field of testing.

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.

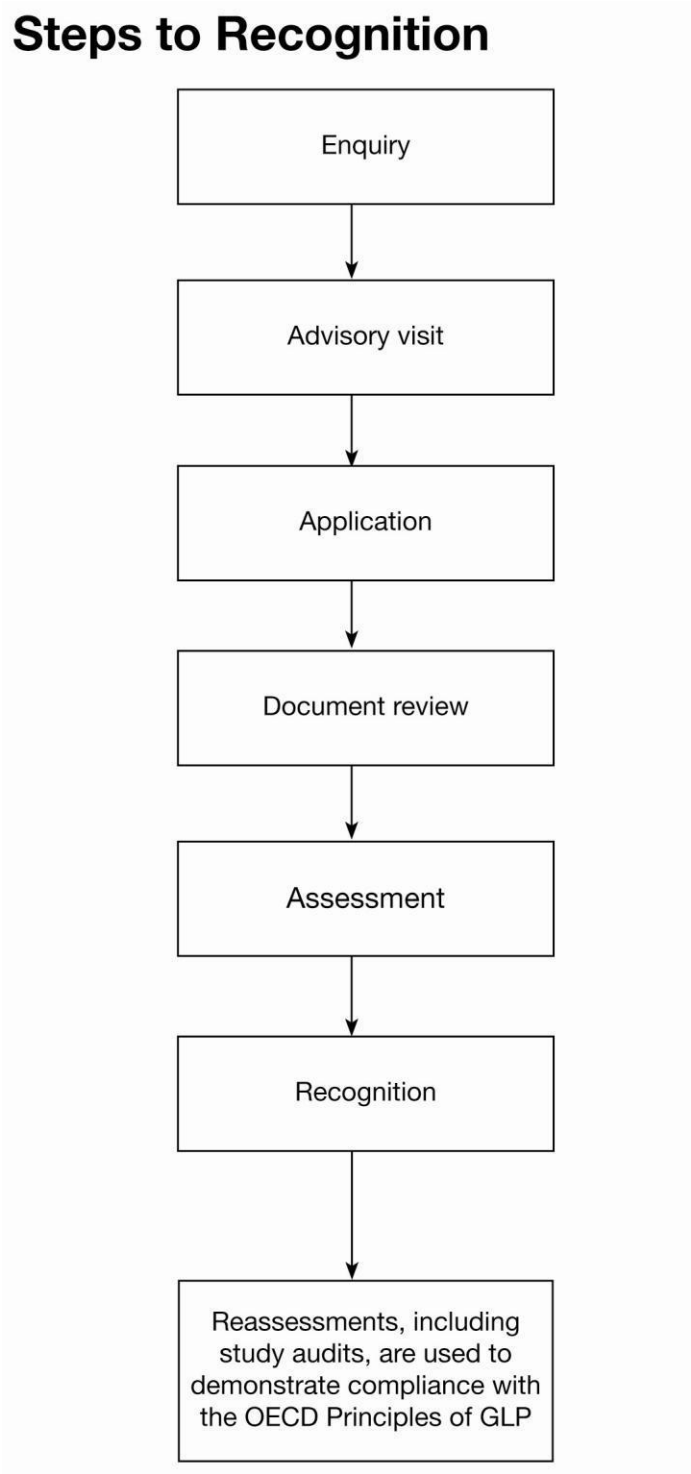
NATA would only inspect facilities or sites located overseas if:

- 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 field to field and these differences are outlined in the NATA Procedures for Accreditation.



6. Laboratory accreditation

Laboratory accreditation represents NATA's largest accreditation activity with over 2500 sites holding accreditation, including a number of facilities located overseas.

Laboratory accreditation provides a means of recognition of the competence of testing and calibration facilities. NATA accredits facilities against the criteria in ISO[2]/IEC[3] 17025 *General requirements for the competence of calibration and testing laboratories*. Facilities are accredited in the fields of Biological Testing, Calibration, Chemical Testing, Construction Materials Testing, Forensic Science, Information and Communications Technology Testing, Mechanical Testing, Medical Testing*, Non-destructive Testing, Performance and Approvals Testing and Veterinary Testing.

* **Note**: The Standard AS ISO 15189 (previously AS 4633) *Medical laboratories - Particular requirements for quality and competence* is used for Medical Testing.

Inspection accreditation

Inspection accreditation provides formal recognition of the competence of an inspection body and its inspectors. Inspection encompasses sensory evaluation coupled with experienced, professional judgement. Inspection accreditation is relevant to a broad spectrum of Australian industries.

NATA's Inspection accreditation program is conducted against AS/NZS ISO/IEC 17020 *General criteria for the operation of various types of bodies performing inspection*. This standard is internationally recognised and was designed specifically for inspection accreditation.

Accreditation of proficiency testing scheme providers

NATA also operates an accreditation program for proficiency testing scheme providers. Proficiency testing scheme providers are assessed against ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing* and the specific criteria set out in NATA's Requirements for the Accreditation of Proficiency Testing Scheme Providers.

The assessment process reviews the competence of the provider in relation to such matters as the design of proficiency testing schemes, homogeneity and stability testing of samples, assignment of property values to samples and the evaluation of participants' results. As well as providing confidence in the competence of any proficiency testing scheme providers that NATA itself may use, it also provides the same confidence in any external programs in which laboratories may participate, the results of which are reviewed during the course of laboratory accreditation assessments. The program also provides proficiency testing scheme providers with formal recognition of their competence in this area.

Accreditation of reference material producers

As a result of requests from Australian reference material producers and the National Measurement Institute, NATA developed, and now operates, an accreditation program for producers of reference materials.

The reference material producer is evaluated against the ISO Guide 34 *General requirements for the competence of reference material producers* and the specific criteria set out in NATA's Requirements for the Accreditation of Reference Material Producers. ILAC G12 *Guidelines for the Requirements for the Competence of Reference Material Producers* is used as a guidance document for assessments.

The assessment process reviews the competence of the reference material producer with regard to the production, characterisation, and assignment of property values to the reference materials being produced. The program covers the production of both reference materials and certified reference materials.

Accreditation of reference material producers provides facilities with confidence in the traceability of the values that have been assigned to the reference materials they use. It also gives formal recognition of the competence of reference material producers.

Research and development accreditation (R&D)

NATA offers accreditation to facilities involved with research and development.

At this stage ISO/IEC 17025, the Eurachem[4]/CITAC[5] document *Quality Assurance for Research and Development and Non-routine Analysis* and the relevant FAD if applicable are used to conduct the assessment process.

Flexibility in the criteria documents used and expression of the scope of accreditation are needed to allow for the broad range of activities covered by organisations carrying out research and development activities, and to ensure aspects currently reviewed are not unnecessarily duplicated.

The benefits of accreditation for these 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 results from organisations carrying out sub-contracted research and development activities.

Accreditation of Medical Imaging facilities

The Royal Australian and New Zealand College of Radiologists' Quality and Accreditation Program

In 1997, The Royal Australian and Zealand College of Radiologists (RANZCR) began developing a program to enhance and continually improve the quality of practices offering medical imaging services. This program became known as the Quality and Accreditation Program.

The College appointed an Accreditation Guidelines and Quality Committee (AGQC), consisting of College Fellows, to oversee the development of the program. With the support of College members and the secretariat, the Committee developed a set of professional, technical and administrative standards referred to collectively as the *Accreditation Standards for Diagnostic and Interventional Radiology*. It is intended that these standards continually evolve as new technologies and professional developments emerge.

To afford recognition to practices satisfying the standards and to facilitate administration of the program, the RANZCR signed a Memorandum of Understanding (MoU) with the National Association of Testing Authorities, Australia (NATA) in 1999.

In early 2002, the College approved the adoption of the international standard, *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*, as the standard against which practices were assessed, for the purpose of gaining RANZCR/NATA accreditation. In March 2009, NATA adopted the RANZCR Standards of Practice for Diagnostic and Interventional Radiology Version 9.0 as the technical and managerial standard against which medical imaging practices would be assessed. The inclusion of the ISO requirements to the existing RANZCR accreditation standards brings practice accreditation to an internationally recognised level.

The program is overseen by the Medical Imaging Accreditation Advisory Committee (MIAAC). This committee is chaired by a RANZCR Fellow and includes a majority membership from the College. Also represented on the committee are nominees from the:

- Australian Diagnostic Imaging Association (ADIA) Australian Institute of Radiography (AIR)
- Australian and New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM) Australasian Society for Ultrasound in Medicine (ASUM)
- Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)

Accreditation of Sleep Disorders Services

The Thoracic Society of Australia and New Zealand (TSANZ) and the Australasian Sleep Association (ASA) established an accreditation process in 1997 to foster excellence in the approach to management of sleep disorders.

The Australasian Sleep Association took over governance of this process in July 2009. The Clinical Committee of the ASA was appointed to oversee the process through an ASA Accreditation Subcommittee. A standard (ASA Accreditation of Sleep Disorders Services) was developed, influenced by programmes established by the Australian Council of Healthcare Standards (ACHS) and the American Sleep Disorders Association.

In 2012, the ASA Standards were amended to include the principles from the international standard ISO 15189 (2007) *Medical laboratories – Particular requirements for quality and competence* and were renamed

ASA Standard for Sleep Disorders Services. The inclusion of the ISO requirements to the existing ASA standards brings sleep disorders services accreditation to an internationally recognised level.

To afford recognition to services satisfying the standards and to facilitate administration of the program, the ASA signed a Memorandum of Understanding (MoU) with the National Association of Testing Authorities, Australia (NATA) in 2011. NATA adopted the ASA Standards for Sleep Disorders Services as the technical and managerial standard against which sleep disorders services would be assessed. The program is overseen by the Sleep Disorders Services Accreditation Advisory Committee (SDSAAC).

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

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 Technical Notes 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 over 40 other laboratory accreditation bodies in more than 35 economies. These arrangements are crucial in the recognition of Australian test and calibration data overseas, and in the acceptance of Australian goods in foreign markets.

NATA's staff also provide input into a number of international committees such as ISO/REMCO[13], IUPAC[14] and the OECD Working Group on Good Laboratory Practice.

NATA currently holds the Secretariat for the International Laboratory Accreditation Cooperation (ILAC).

Regional involvement

NATA is one of the founding members and currently holds the Secretariat 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. NATA also provides a consultancy and training service for laboratory accreditation bodies in developing regions.

9. Addresses of NATA

Registered 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

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

Brisbane office

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ANNERLEY QLD 4103
(PO Box 1122
ARCHERFIELD QLD 4108)
Telephone: (07) 3870 3844
Fax: (07) 3848 3660

Adelaide office

Unit 1, 13 King William Road
UNLEY SA 5061
Telephone: (08) 8179 3400
Fax: (08) 8271 7601

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
Section 9	Change of address, Melbourne office