




## **About NATA and GLP recognition**

**Information on the Australian scheme for monitoring compliance with the OECD Principles of GLP**

**February 2007**




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# NATA's GLP recognition requirements

The NATA GLP Recognition Requirements (NRR) are presented in this binder as a series of booklets, designed to present the information in a logical and helpful manner. The contents of the NAR are:

1. *About NATA and GLP Recognition* (this document)
2. This section is reserved for you to add your copy of the OECD series on the Principles of GLP
3. OECD Principles of GLP Interpretation Document
4. NATA Rules
5. Current Policy/Technical Circulars (where relevant)

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## 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 competent laboratory practice, and as the Australian GLP compliance monitoring authority. NATA also represents Australia in the International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and on the OECD<sup>1</sup> Working Group on Good Laboratory Practice (GLP). Through this working group, it is also the organisation responsible for international liaison on OECD GLP compliance monitoring issues.

## 2. Corporate aims

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.

## 3. The Australian GLP program

Recognition is offered by NATA for compliance with the OECD Principles of GLP. This is available to any 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 ecosystems
- target animal safety studies
- worker exposure studies
- analytical and clinical chemistry and histology associated with GLP studies

Facilities should note that receiving regulatory authorities, including the USFDA<sup>2</sup>, do not require GLP for clinical studies as GLP applies only to non-clinical trials. GCP<sup>3</sup> (ICH<sup>4</sup>, VICH<sup>5</sup>) is the applicable code for clinical studies.

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

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).

As of January 2003 the APVMA, formerly the NRA (National Registration Authority), has 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 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.

Since 1947 the National Association of Testing Authorities, Australia (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 and Good Laboratory Practice, together with supporting consensus and guidance documents, can be obtained from:

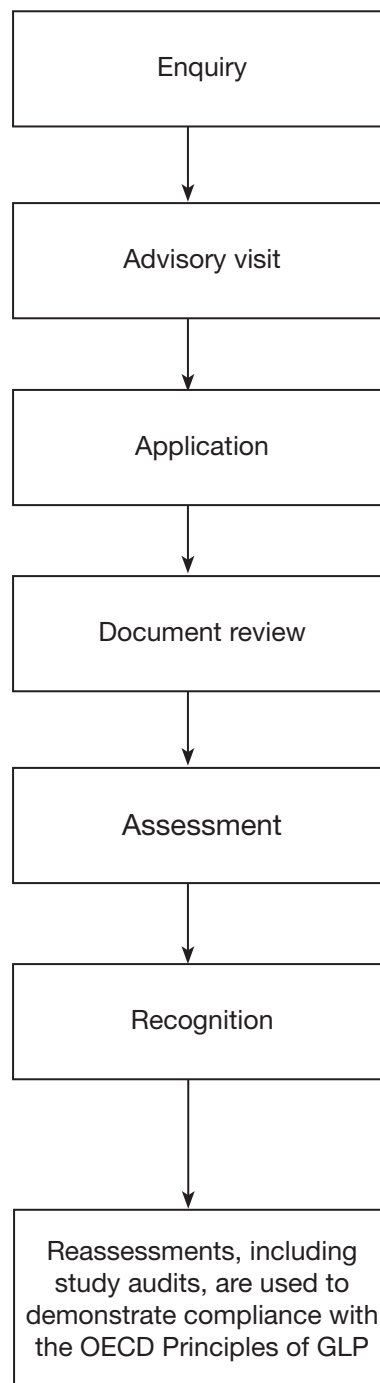
OECD Environment Directorate  
Environmental Health and Safety Division  
2 André-Pascal  
75775 Paris Cedex 16  
FRANCE  
fax: +33 1 4524 1675  
email: ehscont@oecd.org

The documents can also be obtained from the OECD's website at [www.oecd.org/env/glp](http://www.oecd.org/env/glp). Interpretative criteria are defined in NATA's publication OECD Principles of GLP - Interpretation Document. This is to be read in conjunction with the OECD Principles of GLP. This document can be ordered from 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 manager of the relevant field of testing should be contacted for further information.

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. Such differences are described in the individual field Application Documents.

## Steps to Recognition



## 4. Accreditation activities

### Laboratory accreditation

NATA is recognised as the largest and most diverse laboratory accreditation body in the world. Laboratory accreditation also represents NATA's largest accreditation activity with over 2500 sites holding accreditation, including 40 located overseas.

Laboratory accreditation provides a means by which recognition is given to the competence of testing and calibration laboratories. NATA accredits laboratories against the criteria in ISO<sup>6</sup>/IEC<sup>7</sup> 17025:2005 *General requirements for the competence of calibration and testing laboratories*. Laboratories are accredited in the fields of Biological Testing, Chemical Testing, Construction Materials Testing, Forensic Science, Information Technology Testing, Measurement Science and Technology, Mechanical Testing, Medical Testing, Non-destructive Testing and Veterinary Testing.

In 2004, a new program for the accreditation of practices offering medical imaging services was implemented. This program is a joint program with the Royal Australian and New Zealand College of Radiologists (RANZCR). Please refer to the *About RANZCR, NATA and Accreditation* document for further details on this program.

### 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 carried out against AS/NZS/ISO 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 providers of proficiency testing schemes

NATA also operates an accreditation program for proficiency testing scheme providers. Proficiency testing scheme providers are assessed against ILAC G13:2000 *Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes* and the specific criteria set out in NATA's Requirements for the Accreditation of Providers of Proficiency Testing Schemes.

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, the world's first accreditation program for producers of reference materials.

The reference material producer, and any subcontracted organisations it uses, are evaluated against the ISO Guide 34:2000 *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 G12:2000 *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 laboratories with confidence in and traceability of the values that have been assigned to the reference materials they use. It gives formal recognition of competence to reference material producers through one single assessment process.

### Research and development accreditation (R&D)

NATA offers accreditation to facilities involved with research and development.

At this stage ISO/IEC 17025, the Eurachem<sup>8</sup>/CITAC<sup>9</sup> document *Quality Assurance for Research and Development and Non-routine Analysis* and the relevant FAD, if applicable, are used to carry out 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.

## Construction materials testers accreditation scheme

Many materials in the construction industry undergo sampling and field testing outside the confines of an accredited laboratory. Such activities may also be performed by personnel who are not employed by an accredited laboratory. NATA offers a scheme that recognises the competence of those involved in field testing and sampling of construction materials. The scheme therefore complements the services of accredited laboratories.

The accreditation process involves a written examination and a practical demonstration of the relevant tests. Successful applicants receive an identity card and are listed in a register of accredited testers.

## 5. 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.

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.asn.au](http://www.nata.asn.au).

### NATA publications

NATA publishes a range of technical and information documents covering laboratory practice and evaluation. These include the quarterly, *NATA News*, and many Technical Notes designed to assist laboratories to understand more complex technical issues.

## 6. 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 the Association.

NATA is guided and monitored by a Board elected from its Council. The Council comprises elected Association members and representatives from industry, government and professional bodies.

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 organisation and provide training services.

### International responsibilities

NATA actively promotes its accredited laboratories 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<sup>10</sup>/OIML<sup>11</sup>, ISO/IEC, IAF<sup>12</sup>, and the WTO<sup>13</sup>. NATA is a signatory to the ILAC Arrangement and has established mutual recognition arrangements (MRA) 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<sup>14</sup>, IUPAC<sup>15</sup> and the OECD Working Group on Good Laboratory Practice.

NATA currently holds the Secretariat of 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 and calibration and, more recently, was also an inaugural signatory to the extended APLAC MRA for inspection. NATA also provides a consultancy service for many developing laboratory accreditation bodies in this and other developing regions, and provides training for their staff, both offshore and in Australia.

## 7. Addresses of NATA

### Registered office

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## Definitions

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