



## **About NATA and accreditation**

**September 2018**



**© Copyright National Association of Testing Authorities, Australia 2013**


This publication is protected by copyright under the Commonwealth of Australia Copyright Act 1968.

NATA's accredited facilities or facilities seeking accreditation may use or copy this publication or print or email this publication internally for accreditation purposes.

Individuals may store a copy of this publication for private non-commercial use or copy a reasonable portion of this publication in accordance with the fair dealing provisions in Part III Division 3 of the Copyright Act 1968.

You must include this copyright notice in its complete form if you make a copy of this publication.

Apart from these permitted uses, you must not modify, copy, reproduce, republish, frame, upload to a third party, store in a retrieval system, post, transmit or distribute this content in any way or any form or by any means without express written authority from NATA.



## NATA's accreditation criteria

The NATA Accreditation Criteria (NAC) are made up of a number of documents, available for download from the 'Accreditation Information' section of the NATA website, [www.nata.com.au](http://www.nata.com.au). These documents are:

1. The relevant standard (e.g. AS ISO/IEC 17025 or AS/NZS ISO/IEC 17020) for which accreditation is held or sought. This must be obtained by the facility. The following table provides information about the applicable standards or documents and where to obtain them.

Standard/document	Program	Organisation	Website
ISO/IEC 17025	Testing and Calibration	Supplier of Australian standards	
ISO/IEC 17020	Inspection	Supplier of Australian standards	
ISO/IEC 17043	Proficiency Testing Scheme Providers	Supplier of ISO standards	
ISO 17034	Reference Material Producers	Supplier of ISO standards	
ISO 15189	Human Pathology	Supplier of Australian standards	
NPAAC Standards	Human Pathology	National Pathology Accreditation Advisory Council (NPAAC)	<a href="http://www.health.gov.au/npaac">www.health.gov.au/npaac</a>
RANZCR Standards	Medical Imaging	RANZCR	<a href="http://www.ranzcr.edu.au">www.ranzcr.edu.au</a>
OECD Principles of Good Laboratory Practice	GLP Recognition	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	<a href="http://www.oecd.org/env/glp">www.oecd.org/env/glp</a>
ASA Standard for Sleep Disorders Services	Sleep Disorders Services	Australasian Sleep Association	<a href="http://www.sleep.org.au">www.sleep.org.au</a>

2. Relevant standard and activity type appendix and related annexes for the program/activity type in which accreditation is held or sought.
3. General NATA Documents, including NATA Rules.
4. General Accreditation Criteria
5. Some activity types/programs have additional documents that also form part of the accreditation criteria, Specific Accreditation Criteria and these are referenced in the relevant standard and activity type documents.

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

Guidance documents are also available from the NATA website for the OECD GLP recognition program (*About NATA and GLP recognition*) and the SDS program (*About NATA and the ASA/NATA Sleep Disorders Services Accreditation Program*).

NATA assessors are provided with a package of all relevant documents, as well as an additional guidance document entitled *Assessor Information and Guidance*. The complete package is known as the Assessor Resource Kit (ARK).

## Contents

1.	About NATA	4
2.	Corporate aims and the value of peer assessment	4
3.	Accreditation activities	4
4.	Other services	8
5.	More about NATA	8
6.	Addresses of NATA	9
7.	Definitions	9

### 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<sup>1</sup> Working Group on Good Laboratory Practice.

### 2. Corporate aims and the value of peer assessment

NATA aims:

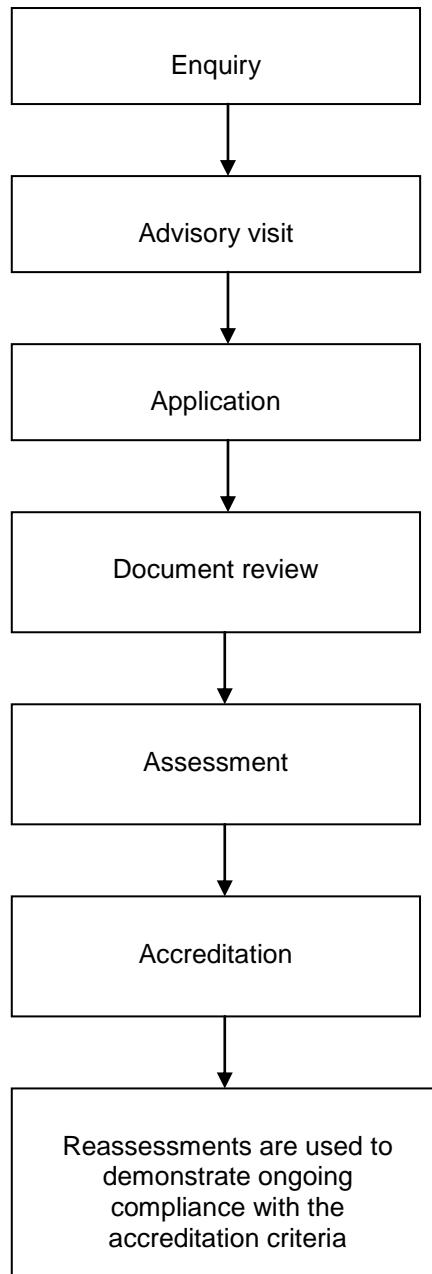
- to provide, in the national interest, an accreditation service which meets the needs of stakeholders, and also facilitates the recognition and acceptance of their products and services; and
- to promote the science and practice of accreditation to enhance the acceptance of Australian products and services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

NATA offers an extensive accreditation service. The following diagram illustrates the key steps in the NATA accreditation process. There may however be some variation from program to program or activity type to activity type and these differences are outlined in the *NATA Procedures for Accreditation*

### Steps to accreditation



### Testing and calibration accreditation

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

Testing and calibration accreditation provides a means by which recognition is given to the competence of testing and calibration facilities. NATA accredits facilities against the criteria in ISO<sup>2</sup>/IEC<sup>3</sup> 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.

## **Recognition for compliance with the OECD Principles of Good Laboratory Practice**

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 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. Non-clinical studies may cover physical-chemical testing; toxicity, mutagenicity, environmental toxicity, bioaccumulation and residues studies; studies of effects on mesocosms and ecosystems; target animal safety studies; worker exposure studies and the analytical chemistry associated with such studies.

The Principles cover the managerial concept by which the studies are planned, performed, monitored, recorded and reported. NATA is Australia's GLP compliance monitoring authority and represents Australia on the OECD GLP Working Group.

Please refer to the *About NATA and GLP Recognition* 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 conducted against *AS/NZS ISO/IEC 17020 Conformity assessment—Requirements 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 17034 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.

#### *About NATA and accreditation*

At this stage ISO/IEC 17025, the Eurachem<sup>4</sup>/CITAC<sup>5</sup> document *Quality Assurance for Research and Development and Non-routine Analysis* and the relevant activity type appendix and annexes (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**

The RANZCR Standards of Practice for Diagnostic and Interventional Radiology include the principles from the international standard, *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*, and have been adopted by NATA as the technical and managerial standard against which medical imaging practices are assessed. The inclusion of the ISO requirements to the RANZCR accreditation standards raised 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 membership from the College, Australian Institute of Radiography (AIR), Australasian Association of Nuclear Medicine Specialists (AANMS), Australasian Society for Ultrasound in Medicine (ASUM), and the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM).

### **Accreditation of Sleep Disorders Services**

The ASA Standard for Sleep Disorders Services includes the principles from the international standard *ISO 15189 Medical laboratories – Particular requirements for quality and competence* and is the technical and managerial standard against which sleep disorders services are assessed. The inclusion of the ISO requirements to the ASA Standards raised accreditation of sleep disorders services to an internationally recognised level.

The program is overseen by the Sleep Disorders Services Accreditation Advisory Committee (SDSAAC). Please refer to *About NATA and the ASA/NATA Sleep Disorders Services accreditation program* for further details on this program.

## **4. 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](http://www.nata.com.au)).

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

### **NATA publications**

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

## 5. 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, the Americas, Africa, 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 lead the assessments of applicant and accredited or recognised organisations.

### 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>6</sup>/OIML<sup>7</sup>, ISO/IEC, IAF<sup>8</sup>, and the WTO<sup>9</sup>. NATA is a signatory to the ILAC Arrangement that 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.

### Financial support

NATA is a not for profit organisation and a registered charity that receives approximately 85% of its total revenue from fees paid by organisations for accreditation services. Other sources of income include training services revenue, investment income, and funding from the Commonwealth Government specifically for approved purposes deemed to be in the national interest.

For further details of NATA's source of revenue, please refer to the Financial Statements in the NATA Annual Report on NATA's website.



## 6. Addresses of NATA

### 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

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

## 7. Definitions

1. OECD Organization for Economic Cooperation and Development
2. ISO International Organization for Standardization
3. IEC International Electrotechnical Commission
4. Eurachem A network of organisations in Europe involved with establishing a system for international traceability of chemical measurements
5. CITAC Co-operation on International Traceability in Chemistry
6. BIPM International Bureau of Weights and Measures
7. OIML International Organisation of Legal Metrology
8. IAF International Accreditation Forum
9. WTO World Trade Organization
10. REMCO ISO Committee on Reference Materials
11. 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 5	General information regarding the means of financial support.