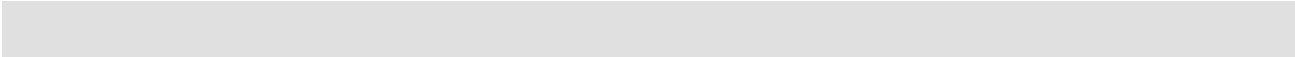




About NATA and accreditation

December 2009

Be Absolutely Assured




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NATA's accreditation requirements

The NATA Accreditation Requirements (NAR) are made up of a number of documents, most of which are included in a zipped file, available for download from the 'Accreditation Publications' section of the NATA website, www.nata.com.au. The documents comprising the NAR are:

1. The relevant standard (eg. 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	Field/Program	Organisation	Website
AS ISO/IEC 17025	Laboratory Accreditation	Supplier of Australian standards	
AS/NZS ISO/IEC 17020	Inspection	Supplier of Australian standards	
AS 4633 (ISO 15189)*	Medical Testing	Supplier of Australian standards	
RANZCR Standards	Medical Imaging	RANZCR	www.ranzcr.edu.au
ILAC Guide 13	Proficiency Testing Scheme Providers	ILAC	www.ilac.org
ISO Guide 34	Reference Material Producers	Supplier of ISO standards	
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	www.oecd.org/env/glp

* **Note:** Standards Australia published AS ISO 15189:2009 (ISO 15189:2007) in August 2009. It has replaced AS 4633 which is now superseded. The implementation date for the use of the 2009 Standard will be January 2010.

2. Relevant field application document (FAD) for the program/field in which accreditation is held or sought (available from the NATA website).
3. NATA Rules (available from the NATA website)
4. Current Policy/Technical Circulars (where relevant) (available from the NATA website)
5. Some fields/programs have additional documents that also form part of the accreditation requirements, and these are referenced in the relevant field application document (FAD).

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

1. *About NATA and Accreditation* (this document)
2. Technical Notes
3. Information Papers
4. Proficiency Testing information

A specific information document is also available from the NATA website on the OECD GLP recognition 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).

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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 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 OECD¹ Working Group on Good Laboratory Practice.

2. Corporate aims and the value of peer assessment

NATA aims:

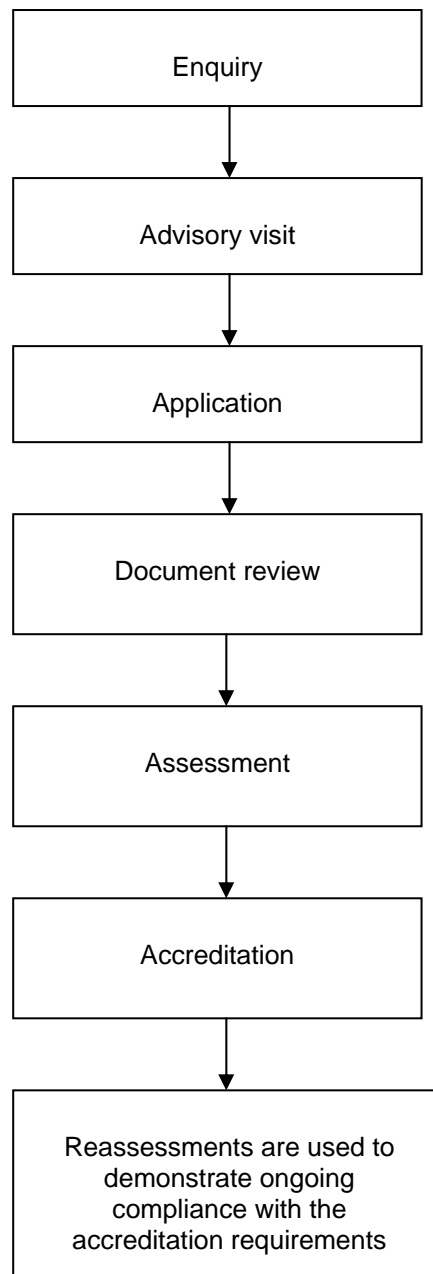
- to provide, in the national interest, an accreditation service which meets the needs of stakeholders, and also facilitates the recognition and acceptance of their products and services; and
- to promote the science and practice of accreditation to enhance the acceptance of Australian products and services 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 field to field. Such differences are described in the individual field or program application documents (FADs).

Steps to accreditation



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 by which recognition is given to the competence of testing and calibration facilities. NATA accredits facilities against the criteria in ISO²/IEC³ 17025 *General requirements for the competence of calibration and testing laboratories*. Facilities are accredited in the fields of Biological Testing, Chemical Testing, Construction Materials Testing, Forensic Science, Information and Communications Technology Testing, Measurement Science and Technology, Mechanical Testing, Medical Testing*, Non-destructive 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.

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 *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 ILAC G13 *Guidelines for the Requirements for the Competence of Proficiency Testing Scheme Providers* 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 Eurachem⁴/CITAC⁵ 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)

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).

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 *NATA News* (issued quarterly), and many Technical Notes 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 Council. The Council comprises elected NATA 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, 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 BIPM⁶/OIML⁷, ISO/IEC, IAF⁸, and the WTO⁹. NATA is a signatory to the ILAC Arrangement that has established mutual recognition arrangements (MRAs) with over 40 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/REMCO¹⁰, IUPAC¹¹ 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 of, and currently holds the secretariat for, 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.

6. Addresses of NATA

Registered office

7 Leeds Street
RHODES NSW 2138
(PO Box 7507
SILVERWATER NSW 2128)
Telephone: (02) 9736 8222
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71-73 Flemington Road
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Fax: (03) 9326 5148

Adelaide office

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

Brisbane office

628 Ipswich Road
ANNERLEY QLD 4103
(PO Box 1122
ARCHERFIELD QLD 4108)
Telephone: (07) 3870 3844
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