About NATA and the ASA/NATA Sleep Disorders Services Accreditation program

January 2016

NATA's accreditation criteria

The NATA Accreditation Criteria are available from the 'Accreditation Publications' section of the NATA website, www.nata.com.au. The information in the 'field and program accreditation criteria' includes:

1. The relevant standard for which accreditation is held or sought (ASA *Standard for Sleep Disorders Services*). This must be obtained by the service and is available on the following website: www.sleep.org.au
2. The relevant annexes for the sleep disorders services accreditation program
3. NATA Rules (available from the NATA website)
4. Current Policy/Technical Circulars (where relevant) (available from the NATA website)

Technical Notes are also available to assist facilities in relation to particular technical matters. They are intended to provide guidance and therefore do not contain requirements for accreditation. Copies may be obtained from the NATA website.

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

   a. *About NATA and the ASA/NATA Sleep Disorders Accreditation Program* (this document)
   b. *NATA Procedures for Accreditation*
   c. *NATA General Policies, Technical Notes and General Information,*
      which are applicable to all fields and programs of accreditation
   d. Equipment Calibration and Checks
   e. Proficiency Testing Guidance

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

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.   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*. Facilities are accredited in the fields of Biological Testing, Calibration, Chemical Testing, Construction Materials Testing, Forensic Science, Information and Communications Technology Testing, Performance and Approvals Testing, 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.

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 ISO Guide 34 *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)*
- Recognition is offered by NATA for compliance with the OECD *Principles of GLP*.

4.   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 Academy of Sleep Medicine AASM.

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 *Standard for Sleep Disorders Services* (ASA Standard) as the technical and managerial standard against which sleep disorders services would be assessed.

The Sleep Disorders Services Accreditation Program is run jointly between NATA and the ASA. The Program provides quality assurance through credentialing of sleep laboratories.

The ASA is responsible for maintaining the standards used in the accreditation process.

NATA is responsible for the administration of the accreditation program. The program is overseen by NATA's Sleep Disorders Services Accreditation Advisory Committee (SDSAAC). The current NATA *Rules* outline the functions of the Accreditation Advisory Committee.

Broadly speaking, the role of the SDSAAC includes professional/technical guidance together with strategic planning and administrative support for the management of the program. The SDSAAC is chaired by a member of the ASA, who also sits on the ASA Clinical Committee. The SDSAAC must include members who represent:
- Physicians (minimum two members)
- Scientists/technicians (minimum two members)
- Paediatric physician (1 member)

Terminology and presentation

It is recognised that not all testing activities are performed in a 'laboratory'. Accordingly, the expression 'service' is used throughout this document. The term 'service' refers to both sleep disorders services centres and/or laboratories.

Any references to the Fee Schedule relate to the Fee Schedule for the ASA/NATA Sleep Disorders Services Accreditation Program.

Any references to the NATA Rules, Fee Schedule, and Technical Policies etc. imply the current version of such documents.

Where the words 'policy' and 'procedure' are used in the ASA Standard, it is possible that one document may meet the requirements of the Standard. This will be determined at assessment.

Applicability

The /NATA ASA program covers the diagnostic procedures and treatments for services offering various sleep disorders services in the categories summarised below:

- Clinical Management Service
- Adult Testing Service
- Paediatric Testing Service

Further details on these categories are contained in the document Categories of Sleep Disorders Services, available from the NATA website.

The accreditation criteria are applicable to all services irrespective of size, range of studies or number of personnel. It should, however, be noted that it is not possible to set rigid requirements for all aspects of a service's operation. Some flexibility is necessary so that each service's unique situation can be considered. The acceptability (or otherwise) of a service's activities can therefore only be determined by assessment. Information on the assessment process is outlined below.

Legislation

It is the responsibility of each service to ensure that it complies with all relevant legislation. Legislative requirements may take precedence over, or provide additional criteria to, those detailed in this document. It is strongly recommended that services hold copies of relevant legislation.

Safety

Whilst an ASA/NATA assessment does not constitute a safety assessment there are some safety requirements that have been mandated in this program as detailed throughout the ASA Standard.

5. The accreditation process

The following diagram illustrates the key steps in the accreditation process.

Steps to accreditation

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│           Enquiry           │
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               ▼
┌─────────────────────────────┐
│        Advisory visit       │
└─────────────────────────────┘
               │
               ▼
┌─────────────────────────────┐
│         Application         │
└─────────────────────────────┘
               │
               ▼
┌─────────────────────────────┐
│       Document review       │
└─────────────────────────────┘
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               ▼
┌─────────────────────────────┐
│         Assessment          │
└─────────────────────────────┘
               │
               ▼
┌─────────────────────────────┐
│        Accreditation        │
└─────────────────────────────┘
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               ▼
┌─────────────────────────────┐
│   Reassessments are used to │
│      demonstrate ongoing    │
│       compliance with the   │
│      accreditation criteria │
└─────────────────────────────┘
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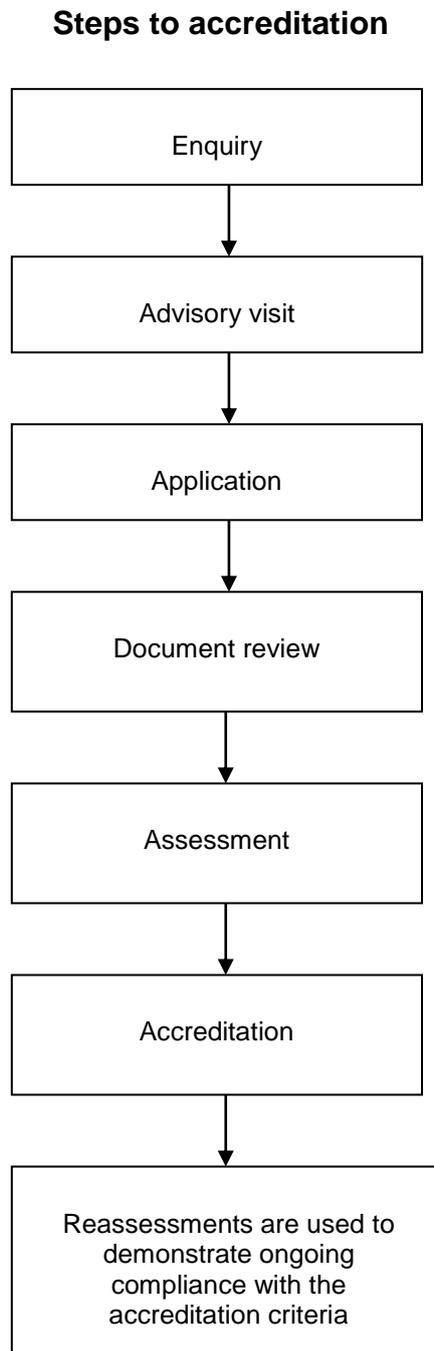
Enquiry

The service is encouraged to hold discussions with relevant NATA technical staff before lodging a formal application for accreditation.

When seeking accreditation, service staff should also familiarise themselves with the Sleep Disorders Services NATA Accreditation Criteria. The NATA Accreditation Criteria can be obtained from the NATA website.

Advisory visit

An advisory visit to the Sleep Disorders Service can be undertaken by one of NATA's staff (lead assessor) to further discuss the assessment process and to explain the significant requirements that relate to accreditation. Such a visit constitutes an informal review of the service which can help determine its state of readiness for accreditation. It should, however, be remembered that the NATA lead assessor, whilst an experienced scientist, is not a technical assessor. Accordingly, the formal assessment process (refer below) is the process whereby compliance with the accreditation criteria is determined.

Following the visit, a written report is provided which summarises the key points of discussion.

An advisory visit is usually conducted prior to an application for accreditation being submitted, however, the most appropriate timing for such a visit will be a matter for negotiation between the service and the NATA lead assessor.

While an advisory visit is not mandatory it is strongly recommended that services avail themselves of this visit prior to applying for accreditation. There are of course cases in which services have a good knowledge of NATA through existing contacts or accreditations. In such cases, the merits of an advisory visit should still be discussed with relevant NATA technical staff.

Prior to an advisory visit, the service will be asked to provide relevant documentation for review. The NATA lead assessor will advise exactly what information is required. This activity is known as a 'document review' and is described below.

A fee is levied for an advisory visit in accordance with NATA's Fee Schedule.

Document review

Depending on the state of readiness of the service for accreditation, it will be asked (either prior to an advisory visit or after an advisory visit, but before the formal on-site assessment), to submit a copy of its proposed scope of accreditation, current management system documentation, test and/or sleep study procedures and information on staff so that a document review can be undertaken.

A document review is most often conducted by the NATA lead assessor who will be involved in the assessment of the service.

The document review provides a comparison of the service's documentation and procedures with the accreditation criteria. The NATA lead assessor also makes note of particular references within the service's documented system that require review at the assessment or areas that appear to require further explanation or investigation. Written feedback will be provided on the findings of the document review. Depending on the extent of the action required, the service may be asked to provide further information prior to the assessment or this information will be sought at the assessment.

A fee is levied for the document review in accordance with NATA's Fee Schedule.

Application for accreditation

Applications for accreditation may be made by any legally identifiable organisation and must be made on the prescribed application form. This form will be provided at an appropriate time with regard to the intended time of application. The application must be accompanied by the current application fee, or a request for invoice, in accordance with NATA's Fee Schedule.

Assessment

Compliance of an applicant with the accreditation criteria is determined primarily by an on-site assessment.

The objective of an assessment is to establish whether the service can competently perform the activities for which accreditation is being sought. The NATA assessment team is required to investigate the operation of the service against the requirements detailed in the NATA Accreditation Criteria (NAC). The assessment team reports its findings to both the service seeking accreditation and the SDSAAC.

The assessment will involve peer review; and the assessment team will include at least one accredited sleep physician, one sleep technologist/scientist and one NATA lead assessor. The accredited sleep physician will be a Paediatric physician where a Paediatric Service is being assessed. The size of the assessment team is dependent upon the areas that must be covered in the course of the assessment.

Review of the management system is essentially conducted by the NATA lead assessor whilst the volunteer peer (technical) assessors concentrate on the technical activities performed by the service.

Technical assessors are chosen according to their specialist knowledge and are matched as closely to the activities of the service as is possible. Consideration is given to possible concerns about conflicts of interest in selecting assessors.

Assessments will generally take at least one working day and may extend over a number of days depending on the range of activities to be covered.

Service staff will be called upon to discuss, with the technical assessors, technical issues relating to the sleep studies or testing that are in progress or carried out by the service. Occasionally, such discussion may be hypothetical. NATA may also request prior to the assessment, or in the course of the assessment, that particular procedures or tests be demonstrated. Services should ensure that relevant staff are available during an assessment and should expect all activities for which accreditation is sought to be covered in some way.

Where consultants are associated with a service, NATA reserves the right to contact these persons to establish their level of involvement if they are not present at the assessment.

An exit interview or meeting is held at the conclusion of the assessment at which the assessment findings are presented by the NATA lead assessor. It is the prerogative of the service to decide which of their staff should attend this meeting. Generally, the authorised representative would be expected to attend as well as relevant senior staff. The purpose of the exit discussion is to allow frank and open discussion about the findings of the assessment. Services are strongly encouraged to clarify issues they consider may have been misunderstood by the assessment team and to seek clarification about assessment findings where this may be necessary. Where the assessment team and service do not agree on a finding or the emphasis placed on an issue, this will be noted by the NATA lead assessor and considered during the report review process (refer below). Further information may also be requested by NATA and included in the final report where this information was not available during the assessment.

An interim written report is usually left on the day. This report is subsequently reviewed by NATA senior staff and where relevant, the SDSAAC, prior to the issue of the final report to the service. This review ensures that the assessment team findings are appropriate and in accordance with the accreditation criteria, that evidence gathered at the assessment support the findings and that there is consistent interpretation and appropriate application of the accreditation criteria. Occasionally, a specific issue raised in the report may also be referred for review to other technical experts (not members of the SDSAAC) where further advice is sought. In such cases, the identity of the service concerned is kept confidential. Where necessary, the final report will detail the non-conformities needing to be addressed by the service to allow accreditation to be recommended. In these cases the service will be asked to provide NATA with the necessary evidence that action has been taken, as claimed.

Occasionally, the SDSAAC may recommend a further visit by a NATA lead assessor or that another assessment be conducted. There are a number of reasons for this, including concerns about the competence of the service, the inability to assess certain aspects of the service during the scheduled visit because of lack of availability of key staff, or to review the effective implementation of the corrective action taken as a result of the assessment. The same procedures for assessment will be followed but may concentrate on only area(s) found to be deficient.

Fees are levied for the conduct of assessments in accordance with NATA's Fee Schedule.

Granting accreditation

NATA's Chief Executive grants accreditation following a recommendation by the SDSAAC. This recommendation is made when the service has met all the requirements for accreditation. The authorised representative is formally advised of the granting of the accreditation and issued with a certificate and the scope of accreditation.

Scope of accreditation

Accreditation is described by categories of sleep services. The collective expression or scope of a service's accreditation is known as its 'scope of accreditation'. The categories af sleep services are fixed descriptors, free text being used to restrict or amplify the scope as necessary. Where the scope of accreditation of a service cannot be adequately described by existing descriptors, the SDSAAC may from time to time include new categories of sleep service. A copy of the types of services available in the field of Sleep Disorders is provided in the document *Categories of Sleep Disorder Services*. Types of sleep service, however, will be

reviewed and may be revised from time to time so for the most current version please contact a NATA office or visit our website.

Applications for accreditation may be made for one or more types of sleep service.

The scopes of accreditation of all NATA accredited sites are available on the NATA website.

After accreditation

ASA/NATA accredited services must continue to comply with all accreditation criteria as detailed on the NATA website. In order to ensure continued compliance with these criteria, routine visits and surveillance activities are scheduled during each assessment cycle.

Generally, the assessment cycle is four years which includes on-line reporting of key requirements of the ASA Standard and uploading of documentation at 24 months followed by an on-site reassessment at 48 months.

Shorter intervals for a service may also be specified by the SDSAAC. Such intervals will be determined based on the significance of issues identified during a visit to a service and/or any doubt over a service's continuing compliance with the accreditation criteria.

Reassessments follow the same general process as the initial assessment. The scope of review covers all of the service's technical activities, however only selected elements of the management system are reviewed against the accreditation criteria as detailed on the NATA website. A document review is generally not conducted prior to a scheduled reassessment.

Extensions to the scope of a service's accreditation requested as part of a scheduled reassessment will only be accommodated where such requests do not compromise the purpose of the reassessment (see Variations to scope of accreditation). NATA technical staff will provide further information.

All services are required to participate in proficiency programs (as available) for the services provided. A service's performance and response to proficiency program findings will be reviewed at reassessment and during the 24 month on-line performance review.

Unscheduled assessments may be conducted to investigate a complaint or following the receipt of information that casts doubt over the service's continuing compliance with the accreditation criteria. At such visits, specific activities may be targeted for review rather than the entire operation of the service.

Services must respond to reassessment and on-line reporting and submission findings by the nominated response date, otherwise the status of their accreditation will be reviewed.

Requests for variations to the scope of accreditation outside reassessments may also be considered (see Variations to scope of accreditation).

Fees are levied for the conduct of reassessments and the review of documentation submitted on-line in accordance with NATA's Fee Schedule.

Reports and use of the ASA/NATA endorsement

Quality documentation must include or reference the scope of accreditation and a policy on the use of the ASA/NATA endorsement.

Accredited services are encouraged to apply the ASA/NATA endorsement to reports on those activities covered by their accreditation. Any other endorsement must be approved by NATA's Chief Executive. ASA/NATA accreditation may also be referred to on request forms and other appropriate stationery under the following conditions:
a)   both the NATA and the ASA logos must be used;
b)   accreditation of non-accredited services must not be implied.

In addition, the ASA/NATA endorsement may need to be applied due to client request, legislation, regulation or contractual requirements. Additional details relating to the appropriate forms of endorsement and the reproduction of endorsed reports are provided in the relevant schedule of the NATA Rules.

The endorsement may not be applied to reports on work outside its scope of accreditation. Such documents must not include the ASA or NATA emblem, reference to the accreditation or any other reference to ASA or

NATA. Also refer to NATA's Rules and Policy Circular 18 for further details of the circumstances under which the endorsement must not be applied.

Where unendorsed reports (i.e. those that do not display the logos and accompanying wording) are issued on work covered by the scope of accreditation, all aspects of the testing and/or sleep studies, including the reports, must meet the accreditation criteria.

Work on tests and/or sleep studies outside the scope of accreditation, and the associated unendorsed reports, must avoid any conflict with the proper interests of the client or the public and avoid bringing NATA into disrepute.

For results of tests and/or sleep studies not covered by the scope of accreditation, the notation 'ASA/NATA accreditation does not cover the performance of this service' must be applied.

The inclusion of certification body 'marks' (i.e. logos or emblems) on test and/or sleep study reports and calibration certificates is a contravention of clause 8.4.2 of AS ISO/IEC 17021 *Conformity assessment – Requirement for bodies providing audit and certification of management systems.*

Proficiency testing

Participation in proficiency testing is mandatory. To the extent that is possible, each applicant or accredited service is required to participate in appropriate proficiency testing or equivalent activities.

NATA's Proficiency Testing Policy (NATA Policy Circular 2) available from the NATA website, provides further detail.

Branch and Satellite services

It is recognised that a Sleep Disorders Service may offer services at another site located away from the accredited site. Where these additional services are to be included under the accreditation of the parent site, the accredited service will notify NATA of the other site/s, known as 'branch' or 'satellite' sites.

A 'branch' service is defined as any additional facility operating under the control of the parent site and meets the eligibility criteria as defined in the document Sleep Disorders Services *Annex A*. A 'branch' service Accreditation of services at a branch site will require a site visit.

A 'satellite' service is defined as a service providing diagnostic PSG studies only and operating under the control of a parent site and which meets the eligibility criteria as defined in the document Sleep Disorders Services *Annex A*. Accreditation of satellite services will involve a site visit to a selection of these services.

Fees are levied for the conduct of assessments and reassessments of satellite services in accordance with NATA's Fee Schedule.

6.   Other NATA 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.

7.   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[6]/OIML[7], ISO/IEC, IAF[8], and the WTO[9]. 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/REMCO[10], IUPAC[11] 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 co-operation 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.

8. 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

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

Melbourne office

2-6 Railway Parade
CAMBERWELL VIC 3124
Telephone: (03) 9882 8249
Fax: (03) 9421 0887

Perth office

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

9. 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
Address of NATA	Updated Melbourne office address