NATA procedures for accreditation

January 2018

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Section 1: General information

Terminology and presentation

It is recognised that not all testing, calibration or inspection activities are performed in a 'laboratory'. Accordingly, the expression 'facility' is used throughout this document.

The words 'shall' and 'must' are used interchangeably throughout NATA's documents and describe mandatory criteria for accreditation. The word 'should' is used where guidance is provided but does not preclude other acceptable practices. Where a smaller size font has been used i.e. a 'Note', this indicates a matter of an advisory or informative nature.

Note that the word 'should' is used in the OECD GLP documents and describes mandatory criteria for recognition. As with all NATA publications, the term "OECD GLP Recognition" may be interchanged for "accreditation" and vice versa.

Any references to NATA publications, including the NATA Rules, Fee Schedule, General Accreditation Criteria, Specific Accreditation Criteria etc., imply the current version of such documents.

Where the words 'policy' and 'procedure' are used, it is possible that one document may satisfy the accreditation criteria. This will be determined at assessment.

Any reference to 'standard' is equally applicable Principles (e.g. *OECD Principles of Good Laboratory Practice).*

Scope

The *NATA Procedures for Accreditation* are applicable to any type of facility seeking or holding accreditation.

The following ISO or industry standards describe the general requirements facilities seeking accreditation (or recognition in the case of GLP) must comply with:

Human pathology	ISO 15189
Inspection	ISO/IEC 17020
Testing and calibration	ISO/IEC 17025
Producers of certified reference materials	ISO 17034
Proficiency testing scheme providers	ISO/IEC 17043
Sleep Disorders Services	*ASA Standard for Sleep Disorders Services*
Medical Imaging	*RANZCR Standards of Practice for Diagnostic and Interventional Radiology*
Good Laboratory Practice	*OECD Principles of Good Laboratory Practice*

Each ISO standard (including the OECD Principles) is accompanied by a Standard Application Document (SAD) prepared by NATA which provides an explanation of the application of the standard. Appendices and annexes (with respect to ISO/IEC 17025 accreditation) have also been developed to provide interpretation for specific industries.

Facilities are required to comply with the *NATA Rules* the relevant ISO or industry standard, relevant SAD, in the case of ISO/IEC 17025 the relevant appendices and annexes, other relevant NATA Accreditation Criteria publicastions (see below) and any relevant statutory requirements.

Facilities seeking NATA/RCPA accreditation for human pathology are also expected to comply with all the relevant *National Pathology Accreditation Advisory Council (NPAAC)* standards.

All of the NATA criteria documents are available as a package applicable to each standard or, in the case of ISO/IEC 17025, to an industry. These packages are referred to as the NATA Accreditation Criteria (NAC).

NATA's Accreditation Criteria

The NAC packages are made up of a number of documents, which are available for download from the NATA website, www.nata.com.au, however they do not include the relevant ISO or industry standard.

The relevant standard (or principles in the case of GLP) for which accreditation is held or sought must be obtained separately by the facility. The following table provides information about where to obtain the applicable standards.

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)	www.health.gov/au/npaac
RANZCR Standards	Medical Imaging	RANZCR	www.ranzcr.edu.au

Standard/ document	Program	Organisation	Website
OECD Principles of Good Laboratory Practice	GLP Recognition	OECD Environment Directorate Environmental Health and Safety Division	www.oecd.org/env/glp
ASA Standard for Sleep Disorders Services	Sleep Disorders Services	Australasian Sleep Association	www.sleep.org.au

The NACs are packaged to align with the relevant standard (accreditation program) and industry classification where relevant. In the scopes of accreditation NATA publishes, the industry classifications are identified as "activity types".

Each NAC includes the following document categories (with key publications identified):

- General NATA Documents
  - NATA Rules
  - NATA Procedures for Accreditation

    (summarises NATA's procedures for accreditation and includes an overview of assessment activities and NATA's responsibilities)
  - Charter of Service
- General Accreditation Criteria
  - relevant Standard Application Document (SAD)

    Notes: A separate SAD is available for each international (ISO or OECD) standard.

    For ISO/IEC 17025, the relevant SAD is supplemented with an Activity Type Appendix and which may also have associated Annexes.
  - relevant policies
- General Accreditation Guidance
  - General Equipment Table

    Notes: This document provides guidance on calibration and check intervals for equipment. The intervals specified are not mandatory for accreditation, however, should facilities not wish to establish their own intervals then those specified in this document may be used.
- Specific Accreditation Criteria
  - relevant SAD appendices and annexes

    Notes: Some accreditation programs also have additional documents that form part of the accreditation criteria which are referenced in the SAD and/or appendices and annexes.

    As Human Pathology laboratories are also assessed against relevant NPAAC standards, copies of these requirements must also be maintained. Refer to National Pathology Accreditation Advisory Council below.

Facilities accredited or seeking accreditation to undertake testing for the World Anti-Doping Agency (WADA) must also comply with the requirements of the latest version of the WADA International Standard for Laboratories (ISL).

The Sleep Disorders Services program has additional documents that also form part of the accreditation criteria that are referenced in the *ASA Standard for Sleep Disorders Services*.

- Specific Accreditation Guidance
  - relevant scope of accreditation descriptors
- General Accreditation Forms
- Specific Accreditation Forms

The General documents, Criteria, Guidance and Forms are applicable to all accredited and applicant facilities as relevant for a given accreditation program, while the Specific Criteria, Guidance and Forms are applicable to only one activity type.

A copy of the documents applicable for each accreditation program and activity type in which accreditation is held, or being sought, must be readily available to staff working in a NATA accredited or applicant facility.

Other informative documents are available from:

- ILAC (International Laboratory Accreditation Cooperation) www.ilac.org
- APLAC (Asia Pacific Laboratory Accreditation Cooperation) www.aplac.org

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).

Applicability

The accreditation criteria are applicable to all facilities, irrespective of size, range of service or number of personnel. It should, however, be noted that it is not possible to set rigid criteria for all aspects of a facility's operation. Some flexibility is necessary so that each facility's unique situation can be considered. The acceptability (or otherwise) of certain practices can therefore only be determined by assessment. Information on the assessment process is contained in Section 2 of this document.

Administration

NATA's accreditation programs are administered, under the Board's direction, by the Accreditation Advisory Committee relevant to the activity type(s). The current NATA Rules outline the functions of the Board and the Accreditation Advisory Committees.

Notes: Human Pathology

NATA/RCPA

The Human Pathology accreditation scheme is run jointly with the Royal College of Pathologists of Australasia (RCPA). The College has representation on the Human Pathology Accreditation Advisory Committee (MTAAC). There is a Memorandum of Understanding (MOU) between the RCPA and NATA.

National Pathology Accreditation Advisory Council (NPAAC)

NPAAC, established in 1979, is a body chaired by an appointee of the Commonwealth Department of Health. It has nominees from all states and territories, private and public pathology peak bodies (PA, NCOPP), professional bodies (RCPA, AMA, AIMS, AACB, HGSA,

and ASM), consumer representation and representation from the Department of Health. Its primary task is the development of standards and guidelines for the accreditation of pathology laboratories.

Laboratories are expected to hold current editions of the relevant NPAAC documents available from the NPAAC website (www.health.gov.au/npaac).

Department of Human Services

NATA has a formal agreement to assess laboratories for the Department of Human Services (DHS) Australia. This agreement is detailed in the Deed for inspection of premises for the purpose of sub-section 23DN (1) of the Health Insurance Act 1973 and is applicable only for Australian laboratories seeking recognition as an Approved Pathology Laboratory (APL).

DHS requires that a report from NATA be submitted by every laboratory with its application or renewal form for recognition as an APL. Usually, the Report on Laboratory Premises is issued by NATA after advisory visits and assessments.

Each physical laboratory site requires separate accreditation in order for NATA to issue a Report on Laboratory Premises.

Research & Development

A specific R&D Accreditation Advisory Committee has not been established due to the broad scope of activities which may fall under the program. NATA's other program/activity types Accreditation Advisory Committees support the R&D program as necessary.

Sleep Disorders Services

The Sleep Disorders Services Accreditation Program is run jointly between the Australasian Sleep Association and NATA.

Legislation

It is the responsibility of each facility 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 also strongly recommended that facilities hold copies of relevant legislation.

Safety, environment and heritage

NATA does not define mandatory safety measures nor does it define measures to protect the environment or heritage values, but does draw attention to any unsuitable work practices that are observed in the course of an assessment. When clauses covering safety, environmental or heritage protection are written into test methods, specifications or standard inspection codes covered by the Scope of Accreditation these must be observed by the facility and are subject to assessment. Facilities are also encouraged to apply the relevant sections of AS 2243 *Safety in Laboratories*.

Section 2: Accreditation procedures

The following information is provided to assist facilities who seek or hold accreditation or wish to extend the scope of their accreditation. General information is also provided with regard to NATA's policies and procedures.

It should be noted that there are some differences between the programs/activity types with regard to the order in which these steps are followed and may be due to limitations that have been placed on the NATA process by outside influences, such as regulatory or industry-specific requirements.

Where an organisation may require accreditation in a number of different programs and/or activity types, every attempt is made to harmonise and coordinate accreditation activities. Corporate accreditation is available in defined circumstances to assist this process. A document *Corporate Accreditations - NATA Accreditation of Multiple Site and Multiple Activity Types* is available and can be obtained from the NATA website.

There may also be a need to vary the steps detailed below in the case of applications from overseas facilities. Once again, every attempt is made to ensure the accreditation process is carried out in the most efficient and effective way for all parties concerned.

ISO/IEC 17025 and ISO 9001

ISO/IEC 17025 (clause 1.6) states that facilities that comply with ISO/IEC 17025 meet the 'principles of ISO 9001'. Facilities interested in making a statement regarding this issue for their customers should refer to the *Joint ISO-ILAC-IAF Communiqué on the Management Systems Requirements of ISO/IEC 17025: 2005* available from the ILAC website http://ilac.org/about-ilac/partnerships/international-partners/iso/

In conducting assessments, however, NATA cannot accept a facility's ISO 9001 certification as the sole statement of compliance with the management requirements of ISO/IEC 17025. ISO 9001 is an outcome based standard and has fewer requirements for documented procedures and records. It is also necessary to consider how the system is applied at a technical level. Therefore, the management system requirements of ISO/IEC 17025 will still be assessed in these situations.

Facilities accredited or recognised to other Standards or Principles

Assessments conducted in NATA's other accreditation and recognition programs also comprise a full review of the management system documentation and records to ensure compliance with the management system elements of the Standard/ Principles and supplementary requirements applicable to that program. This is because different standards and principles whilst having the same or similar outcomes from a management system require different levels of documentation.

The role of the Authorised Representative

The Authorised Representative is the person nominated by the facility to be its representative in all matters relating to the application or accreditation and is the recognised official contact with NATA. Nomination is made on the application form or

when changes are required thereafter, on the 'Nomination of New Authorised Representative' form available for this purpose.

The rights and legal obligations of the Authorised Representative are detailed in the NATA Rules and in the document *Responsibilities of Authorised Representatives* available from the NATA website. At a practical level, the Authorised Representative is normally a senior staff member who is in a position to make decisions regarding the facility's accreditation and to effectively communicate with facility staff. The Authorised Representative may also choose to direct NATA to other facility personnel with whom relevant issues may be discussed.

The Authorised Representative is required to notify NATA within 14 days if:

- the name or ownership of the facility changes;
- there are changes in duties or departures of key staff; or
- significant changes occur to the functions or accommodation of the facility.

Facility contact person

Recognising that the Authorised Representative is not necessarily the most appropriate person to answer day to day and technical queries regarding an accredited facility's activities, NATA provides facilities the opportunity to nominate a person to deal with technical and other enquiries. This person can, however, also be the Authorised Representative. Personal information collected such as name, position, business address, business telephone, mobile phone, fax numbers and email address of the Authorised Representative or the Facility Contact may be made available to enquirers requiring the services of NATA accredited facilities. The facility contact details are also included in the NATA website directory.

Communication

All communication arising from assessment activities or in relation to any other NATA accreditation activity shall be directed to NATA. The facility should not normally contact a Technical Assessor directly (or vice versa) in relation to assessment or other accreditation activity matters unless an alternative arrangement has been agreed to by NATA.

Fees for services

The various parts of the accreditation process where charges are levied are indicated in this document. Specific information on charges can be obtained from our current Fee Schedule (available from the NATA website) or by contacting a NATA office.

Preliminary steps

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

When seeking accreditation, facility staff should also familiarise themselves with the NATA Accreditation Criteria (NAC). The NAC packages can be obtained from the NATA website.

Advisory visit

An advisory visit to the facility is undertaken by a NATA technical staff officer (Lead Assessor) to further discuss the assessment process and to explain the significant criteria that relate to accreditation. Such a visit includes an informal review of the facility 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 (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 generally considered to be mandatory for Australian based facilities and is conducted either prior to, or after, an application for accreditation has been made, however, it is strongly advised that such a visit be conducted prior to the application.

There are, of course, situations when a facility has good knowledge of NATA through existing contacts or accreditations. In such cases, the merit in conducting an advisory visit should be discussed with NATA.

Prior to an advisory visit, the facility 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 'document review' and is described below.

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

NOTE:

Human Pathology

A pre-application (advisory) visit is to be undertaken to laboratories (linked to Medicare Australia's registration) for the payment of Medicare benefits.

The object of the visit is to confirm the laboratory's readiness to conduct testing. The following are reviewed:

- Staffing, as per proposed NPAAC category;
- Range of testing;
- Quality Assurance Program (QAP) enrolment;
- Physical address of laboratory; and
- Availability and appropriateness of equipment to conduct testing.

The NATA Lead Assessor conducting the visit will also outline the accreditation process and timing of the assessment for accreditation.

It is also strongly recommended that applicant laboratories also avail themselves of an extended advisory visit as detailed above.

Document review

Depending on the state of readiness of the facility 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, calibration and/or test 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 facility.

The document review provides a comparison of the facility's documentation and procedures with the accreditation criteria as detailed in the NAC. The NATA Lead Assessor also makes note of particular references within the facility'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 facility 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.

Note: The document review will be conducted on site, where (for whatever reason) it may not be possible for the facility documents to be released to NATA to review off-site.

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 in accordance with NATA's Fee Schedule.

NOTE:

Human Pathology

On receipt of the application, the Report on Laboratory Premises will be forwarded to the laboratory. This is then lodged with DHS by the laboratory in conjunction with the application for recognition as an APL. The laboratory is not eligible to receive benefits from DHS until this application is processed. The Report on Laboratory Premises usually recommends an initial approval period of six months from the date of the advisory visit.

Medical Imaging

An application fee is also payable to the RANZCR (Royal Australian and New Zealand College of Radiologists) and the amount should be confirmed with the College (www.ranzcr.edu.au) prior to submitting an application for accreditation.

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 facility can competently perform the activities for which accreditation is being sought. The NATA assessment team is required to investigate the operation of the facility against the criteria detailed in the NATA Accreditation Criteria. The assessment team reports its findings to both the facility seeking accreditation and the relevant Accreditation Advisory Committee (AAC).

The assessment team is comprised of at least one NATA Lead Assessor and one or more specialist volunteer Technical Assessors. Review of the management system is essentially conducted by the NATA Lead Assessor whilst the volunteer assessors concentrate on the technical activities performed by the facility. The size of the

assessment team is dependent upon the areas that must be covered in the course of the assessment.

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

NOTES;

Human Pathology

1. The need for an Assessor who is a pathologist to also be present on the assessment team is detailed in the NATA/RCPA Memorandum of Understanding (MoU).
2. As part of the NATA/RCPA accreditation program an assessment of pre-analytical processes will be undertaken. This includes the on-site assessment of Approved Collection Centres (ACCs), Hospital Collection Points (HCPs) and any other collection activity connected to an accredited organisation.

   It is recognised that the collection of specimens for Medical Pathology can be collected in a variety of locations and not all of these locations are within the control of the accredited organisation. It is also acknowledged that the control of collection operations may not be under the direct control of a laboratory itself but controlled by a separate department within the organisation.

   However where the collection activity is under the control of an accredited organisation the assessment of ACCs and/or HCPs will form part of the assessment of laboratories, regardless of where direct control of these activities lie. Any comments and findings will be included in the assessment report of the laboratory undergoing assessment.

   The assessments of ACCs and HCPs will be performed on a sampling basis. More than one off-site location may be assessed each cycle as determined by the Client Coordinator. The laboratory will be advised at short notice (or on the day of assessment) which specific ACCs and/or HCPs will undergo an on-site visit.

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.

Facility staff will be called upon to discuss issues and demonstrate activities (arrangements for this may be requested by NATA prior to the assessment or during the course of the assessment) relating to activities to be covered by the Scope of Accreditation. Occasionally, discussions may be hypothetical. Facilities should ensure that relevant staff (notably key personnel) 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 facility, 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 facility 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 meeting is to allow frank and open discussion about the findings of the assessment. Facilities 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 facility 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 and where relevant, the AAC, prior to the issue of the final report to the facility. 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 AAC) where further advice is sought. In such cases, the identity of the facility concerned is kept confidential. Where necessary, the final report will detail any non-conformities needing to be addressed by the facility to allow accreditation to be recommended. In these cases, the facility will be asked to provide NATA with the necessary evidence that action has been taken, as claimed, generally within 20 working days of the issue of the confirmed report.

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

Follow up on-site activities

Occasionally, the AAC may recommend that 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 facility, the inability to assess certain aspects of the facility 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 the area(s) found to be deficient or specific areas of concern.

NOTES:

1. An application for accreditation is valid for 24 months. Where an initial assessment of the facility has not been conducted within twelve months of receipt of the application and the delay has not been caused by NATA, a further application fee will be charged.
2. **Human Pathology**

   Should a follow up on-site activity be required in relation to collection activities it will be scheduled as part of an activity of the laboratory at which the collection was assessed, regardless of where direct control of these activities lies.

Granting accreditation

NATA's Chief Executive grants accreditation following a recommendation by the relevant AAC. This recommendation is made when the facility has met all the criteria 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 standard, activity type, service, material/item/product, and determination (as a minimum). The collective expression of a facility's accreditation is known as its 'Scope of Accreditation'.

Activities conducted away from the accredited facility (e.g. testing at a customer's premises) will be uniquely identified in the Scope of Accreditation.

NATA does not list the version numbers of standards on its Scopes of Accreditation as facilities accredited for national or internal standards are expected to comply with the latest version of that standard. In such cases where a facility wishes to be accredited for a superseded or withdrawn standard, either due to contractual reasons or at the client's request, the version of the standard will be listed on the Scope of Accreditation.

The Scopes of Accreditation of all NATA accredited facilities are available on the NATA website.

Note: GLP program

This section is not relevant for the GLP program. Please refer to the OECD Principles of Good Laboratory Practice Recognition Application Document for details.

After accreditation – surveillance and reassessment

NATA accredited facilities are expected to continue to comply with all accreditation criteria detailed in the NATA Accreditation Criteria. In order to ensure continued compliance with these criteria, scheduled visits to facilities are arranged.

Generally the assessment cycle is three years which includes a surveillance visit at 18 months followed by a reassessment at 36 months.

Shorter intervals may also be specified by the relevant Accreditation Advisory Committee or follow up on-site visits may be necessary. Such intervals and any requirement for follow up visits will be determined on the significance of issues identified during a prior scheduled visit to a facility and/or any doubt over a facility's continuing compliance with the accreditation criteria.

NOTE:

GLP program

The reassessment cycle for GLP facilities is two years. In addition, a study audit is conducted at 12 months after the initial assessment. Please refer to the OECD Principles of Good Laboratory Practice Annex A: Program Specific Information.

Human Pathology

The assessment cycle for Human Pathology facilities is four years which includes a surveillance visit at 24 months and a reassessment at 48 months. There is also an on-line surveillance visit at 12 and 36 months. Human Pathology also offers a corporate surveillance program for multi-site laboratory networks who have demonstrated a sound, mature quality management system across all sites and a satisfactory assessment history. Further details of the current Human Pathology surveillance model are provided in the criteria document *NATA/RCPA Accreditation Surveillance Model for Human Pathology* which can be found on the NATA website.

Medical Imaging

Generally the assessment cycle is four years which includes an on-site surveillance (short notice) visit between 18 – 30 months followed by an on-site reassessment at 48 months.

All assessment activities are charged at the current hourly rate. Please refer to the current fee schedule available from the NATA website.

Sleep Disorders Services

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.

Reassessments follow the same general process as the initial assessment. The scope of review covers all of the facility's technical activities and selected elements of the management system. A document review is generally not conducted prior to a scheduled reassessment.

Extensions to the Scope of Accreditation (and/or signatories) 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). Fees will be charged where additional resources and time are required to accommodate the request as part of a scheduled reassessment. NATA technical staff will provide further information.

Surveillance visits are conducted by a NATA Lead Assessor and involves review of the management system in full (including a document review) and selected technical elements against the accreditation criteria detailed in the NAC. Extensions to the Scope of Accreditation will normally not be considered as such visits do not include Technical Assessors.

Facilities are to respond to reassessment and surveillance visit findings by the nominated response date, otherwise the status of their accreditation will be reviewed.

The annual membership fees payable by accredited facilities generally cover the costs of reassessments and surveillance visits.

Requests for variations to the Scope of Accreditation outside routine reassessments may also be considered (see Variations to Scope of Accreditation).

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

Variations to Scope of Accreditation

Accredited facilities may request variations to their Scope of Accreditation at any time once accredited. NATA technical staff will provide direction on the information required, the process that will be followed and the charges that will be levied.

Extensions to the scope of a facility's accreditation may be accommodated at the same time as a scheduled routine reassessment but only where review of the additional activity(ies) will not compromise the purpose of the reassessment (which is to review the existing Scope of Accreditation to determine ongoing compliance with the accreditation criteria). Adequate notice by the facility is also to be provided in

order for the variation to be considered. Variations to the Scope of Accreditation must be supported by relevant documentation in advance of the assessment (e.g. proposed scope, calibration or test procedures, sample worksheet, report and uncertainty calculations). Fees will be charged for extensions to the Scope of Accreditation conducted during a routine reassessment where additional effort is necessary (e.g. additional time and/or Technical Assessors are required).

In general, an extension to the Scope of Accreditation will only be granted once any relevant issues raised at the previous assessment (e.g. reassessment, surveillance visit), which apply to the activities requested by the scope extension, have been addressed.

Changes to facility details

A change to the name in which accreditation is held can be processed when the request is received on the prescribed form, together with appropriate supporting documentation.

A transfer of Accreditation may also be granted to a new legal entity where a new legal entity has been created following one or a number of changes to an existing accredited entity and such changes are not considered to impact on the new entity's ability to comply with accreditation criteria, e.g. a change to ABN/ACN. The request to transfer Accreditation must also be received on the prescribed form, together with appropriate supporting documentation. Where there has been a change to any of the following: staff, equipment, scope, physical location, management system or procedures, it may not be possible to proceed further with the transfer request and the facility will be advised accordingly.

When NATA receives advice that a facility's physical location will change or has changed, then the Authorised Representative will be sent a *Facility Details Update Form*. On return of the completed form, along with any applicable supporting evidence, NATA will review the information provided and determine whether or not an on-site visit is required.

The form to change a facility's details will be provided on request. Changes in name may be accompanied by changes to Australian Business Number/Australian Company Number, ownership, facility management etc. Additional documentation may be requested and/or additional accreditation activities may be necessary as a result of a review of the information provided. Additional accreditation activities may attract fees in accordance with the NATA Fee Schedule. A separate *Application for Accreditation* form and *Assessment Information Document* may need to be completed.

Requests for withdrawal of accreditation

Where a NATA accredited facility intends to withdraw its accreditation, NATA will request written confirmation from the Authorised Representative. Until such time as the withdrawal request has been processed, the accredited facility continues to be bound by NATA Rules. Dependent on a NATA accredited facility's accreditation history, NATA may consider that an additional accreditation activity is necessary prior to confirming the withdrawal. Charges may be levied for such an activity.

Reports and use of the NATA endorsement

Accredited facilities are encouraged to apply the NATA endorsement to reports on those activities covered by their accreditation. In addition, the NATA endorsement may need to be applied due to customer request, legislation, regulation or contract criteria or in the case of calibration certificates being supplied to an accredited facility.

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

The endorsement may not be applied to reports on activities outside the facility's Scope of Accreditation. Such documents must not include the NATA emblem, reference to the accreditation or any other reference to NATA. Also refer to NATA's Rules and the document *Use of the NATA Emblem, NATA Endorsement and References to Accreditation* for further details of the circumstances under which the endorsement must not be applied.

Where unendorsed reports are issued on work covered by the Scope of Accreditation, all aspects of the activities, including the reports, must meet the accreditation criteria.

Note:

Inspection

The terms 'report' and 'certificate' are often used interchangeably. It is generally accepted that an inspection report is a detailed description of the inspection conducted and its results. Inspection certificates are shorter statements that may be issued, sometimes with statutory or legal authority. An inspection body may issue either, provided that the minimum reporting criteria are met and that relevant laws and regulations are observed.

In some industries the term 'certificate' is associated with compliance under a product certification scheme. In these industries the terms 'inspection report' or 'inspection statement' are preferred to avoid misunderstanding.

GLP program

For additional information on the use of the NATA endorsement in the GLP Program please refer to the OECD Principles of Good Laboratory Practice Application Document for details.

Equipment assurance

Where possible, the assessment of in-house calibrations and equipment verifications will be covered as part of the equipment and metrological traceability aspects within the normal reassessment. Where significant additional assessment time or additional Technical Assessors are required, there will be an additional cost associated with this activity. Specialist calibration assessors will only be used when either the calibration is outside the area of expertise of the Technical Assessors who would normally conduct the reassessment or it will be more time or cost effective. In some cases, additional post-assessment follow-up may be necessary.

The Assessment Information Document (AID) will seek specific information on equipment assurance activities carried out in-house as defined by the document *Equipment assurance, in-house calibration and equipment verification.* Facilities will be advised of any likely additional costs prior to their reassessment, based on the information provided in the AID. It is therefore important that facilities complete this document as accurately as possible.

Note: Formal recognition of these activities will often be required where the tests, measurement and calibrations are normally carried out by external authorities. It may therefore cover such activities as balance calibrations, equipment servicing or performance testing temperature controlled enclosures, but not, for example, calibration of a gas chromatograph and other such analytical instrumentation which are 'calibrated' through use of reference standards as part of normal use.

In instances where in-house calibrations and equipment verifications are routine and do not change over time, consideration will be given to the frequency of assessment of these supporting activities.

It should be noted that the ability to perform in-house calibrations is not listed in a facility's Scope of Accreditation as found on the NATA website, but will be captured in NATA records to ensure suitable technical expertise is available during assessment.

Further information on NATA policy on equipment assurance may be found in the criteria document *Equipment assurance, in-house calibration and equipment verification.*

Proficiency testing (PT)

Note: This section is not applicable to the GLP Program

Each applicant or accredited facility is required to participate in appropriate proficiency testing or equivalent activities.

Facilities are encouraged to participate in as broad a range of PT activities as practicable and available, but at least once every two years (different frequencies may be stated for the various program/activity type) for each major area of test, measurement or related activity covered by the Scope of Accreditation, where such programs are available. Program/activity type specific PT criteria can be found in the relevant SAD or SAD Appendix relevant to the activity type.

Note: Measurement audits are considered a form of PT activity.

Participation in proficiency testing may be required, as follows:

- prior to gaining accreditation with NATA;
- when requesting significant extensions or variations to the Scope of Accreditation.

A facilities' performance and response to proficiency testing results will be reviewed during on-site visits.

Non-compliance with accreditation criteria

In accordance with the NATA Rules, non-compliance with the accreditation criteria may lead to the accreditation status of a facility being suspended or cancelled.

Where significant non-compliance is confirmed and the failure is such that cancellation of an accreditation is not warranted a recommendation can be made to suspend an accreditation.

In making a recommendation for suspension, consideration will be given to the nature of the failure(s) to comply and the risk to NATA's reputation and/or the impact on the facility's clients. Under these circumstances, a submission received to the non-conformities identified may not necessarily alter the necessity to proceed with the recommendation.

The Authorised Representative will subsequently be issued with a Correction Notice that from the date of that notice the accreditation is suspended in part or in full.

In these circumstances the facility is not able to issue endorsed reports or claim to be accredited for those services affected by the change in status.

Should the accredited facility then fail to comply with the Correction Notice within the prescribed time period a Notice to Show Cause why the accreditation should not be cancelled may be issued.

Provision of information on Scope of Accreditation, approved signatories (where relevant) and approved reporters for parentage testing (Legal - Forensic Science).

Details of a facility's Scope of Accreditation are posted on the NATA website once accreditation has been granted and are also made available to enquirers. Where relevant, the names of approved forensic science reporters (Parentage Testing) will also be made available upon request.

Note: Legal - Forensic Science

Family Law Regulations

In accordance with the Family Law Regulations, NATA will advise the Attorney-General, the Family Court of Australia, Federal Magistrates Court and the Family Court of Western Australia when a facility is granted accreditation for parentage testing or if the accreditation status of a facility changes and, for each accredited facility, the name(s) of its nominated reporter(s).

Complaints and feedback

NATA encourages and welcomes feedback from facilities. Such feedback, for example, may relate to the apparent inconsistent application of the criteria for accreditation, compliments regarding NATA staff etc.

NATA maintains a complaints procedure for the investigation of concerns which may be raised against applicant or accredited facilities, or any aspects regarding the services or activities which NATA offers or the conduct of its staff.

All such feedback should be referred to the Quality Manager or via the *Contact Us/Feedback* link on the NATA website.

Appeals Process

The NATA Rules outline the appeals process relating to any decision made about the accreditation status of a facility.

Confidentiality

All information provided by a facility in connection with an enquiry or an application for accreditation, and all information obtained in connection with an assessment, is treated as confidential by NATA staff, Technical Assessors, Committee and Board members. All such personnel are made aware of this requirement and have signed confidentiality agreements.

Under circumstances defined in the NATA Rules, including where NATA has an agreement with another party, NATA may pass information out of its custody and that of its staff, Technical Assessors, appropriate committees and Board.

Agreements, as referred to in the NATA Rules are maintained in a listing available from the NATA website under *About Us/Structure/Formal Agreements/Listing of agreements with other parties*.

Note: Calibration

Facilities who have applied for, or who have been appointed Legal Authorities should be aware that NATA will exchange information with the Legal Metrology National Measurement Institute (NMI). Relevant NMI staff may also attend these assessments, either as Technical Assessors, where appropriate, or as observers.

Note: GLP

NATA has additional responsibilities relating to non-compliance. Please refer to the OECD Principles of Good Laboratory Practice Application Document.

Privacy

NATA respects and upholds the rights of individuals to privacy protection under the Australian Privacy Principles contained in the Privacy Amendment (Enhancing Privacy Protection) Act 2012. A copy of *NATA's Privacy Policy* can be obtained from the NATA website (www.nata.com.au) or by contacting one of the NATA offices. This policy describes how NATA manages the personal information we hold.

References

Standards

AS 2243	Safety in Laboratories
ISO 17034	General requirements for the competence of reference material producers
ISO 9000	Quality Management
ISO 15189	Medical laboratories — Particular requirements for quality and competence
ISO/IEC 17020	Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
ISO/IEC 17021	Conformity assessment -- Requirements for bodies providing audit and certification of management systems
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17043	Conformity assessment -- General requirements for proficiency testing

Joint ISO-ILAC-IAF Communiqué on the Management Systems Requirements of ISO/IEC 17025: 2005

OECD Principles of Good Laboratory Practice

RANZCR Standards of Practice for Diagnostic and Interventional Radiology

WADA (World Anti-Doping Agency) International Standards for Laboratories

NATA Publications

About NATA and Accreditation

Fee Schedules

NATA Rules

General Accreditation Criteria	Corporate accreditations – NATA accreditation of multiple site and/or multiple field facilities
General Accreditation Criteria	NATA Privacy Policy
General Accreditation Criteria	Responsibilities of Authorised Representatives
General Accreditation Criteria	Use of NATA emblem, NATA endorsement and references to accreditation

Other Publications

Family Law Regulations

Health Insurance Act 1973

Australian Privacy Principles, Privacy Amendment (Enhancing Privacy Protection) Act 2012

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Entire Document	This document replaces the former NATA Procedures for Accreditation. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure and replace field with activity type