NATA procedures for accreditation

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This document is for information purposes only. It is not intended to create any legal obligation on NATA or other party. If there is any inconsistency between this document and the NATA Constitution and Regulations (together the Rules) the Rules apply

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Section 1: General information

Terminology and presentation

It is recognised that not all conformity assessment activities (e.g. testing, calibration inspection, reference material production or proficiency testing services) 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. 'Notes' may also be included, which cover information of an advisory nature.

In the OECD Good Laboratory Practice (GLP) documents, the word 'should' is used to describe 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 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 to the *OECD Principles of Good Laboratory Practice.*

Abbreviations

AAC	Accreditation Advisory Committee
ACC	Approved Collection Centre
APL	Approved Pathology Laboratory
APAC	Asia Pacific Accreditation Cooperation
ASA	Australasian Sleep Association
DHS	Department of Human Services
GLP	Good Laboratory Practice
HCP	Hospital Collection Points
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
MoU	Memorandum of Understanding
NAC	NATA Accreditation Criteria
NPAAC	National Pathology Accreditation Advisory Council
OECD	Organisation for Economic Cooperation and Development
RANZCR	Royal Australian and New Zealand College of Radiologists
RCPA	Royal Australasian College of Pathologists
SAD	Standard Application Document
WADA	World Anti-Doping Association

Scope

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

The *NATA Rules* define the current accreditation programs offered.

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
Producers of Certified Reference Materials	ISO 17034
Proficiency Testing Scheme Providers	ISO/IEC 17043
Testing and Calibration	ISO/IEC 17025
Good Laboratory Practice	OECD Principles of Good Laboratory Practice
Medical Imaging	RANZCR Standards of Practice for Diagnostic and Interventional Radiology
Sleep Disorders Services	ASA Standard for Sleep Disorders Services

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 for the SADs have also been developed to provide interpretation for specific industries as necessary.

Facilities are required to comply with the NATA Rules, the relevant ISO or industry standard, relevant SAD, relevant Appendices and Annexes, other relevant NATA Accreditation Criteria publications (see below) and any relevant statutory requirements.

Facilities seeking NATA/RCPA accreditation for Human Pathology testing are also required 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). In the scopes of accreditation NATA publishes, the industries are identified as ‘activity types’ (e.g. Agribusiness, Manufactured Goods etc).

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 15189	Human Pathology	Supplier of ISO standards	
ISO/IEC 17020	Inspection	Supplier of ISO standards	
ISO/IEC 17025	Testing and Calibration	Supplier of ISO standards	
ISO 17034	Reference Material Producers	Supplier of ISO standards	
ISO/IEC 17043	Proficiency Testing Scheme Providers	Supplier of ISO standards	
ASA Standard for Sleep Disorders Services	Sleep Disorders Services	Australasian Sleep Association	www.sleep.org.au
NPAAC Standards	Human Pathology	National Pathology Accreditation Advisory Council (NPAAC)	www.health.gov/au/npaac
OECD Principles of Good Laboratory Practice	GLP Recognition	OECD Environment Directorate Environmental Health and Safety Division	www.oecd.org/env/glp
RANZCR Standards	Medical Imaging	RANZCR	www.ranzcr.edu.au

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

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

    (Summarises NATA's accreditation procedures and includes an overview of assessment activities and NATA's responsibilities.)

  - Charter of Service
- General Accreditation Criteria
  - relevant Standard Application Document (SAD)

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

    The SADs may also be supplemented with Appendices and associated Annexes for specific activities.)

  - relevant policies

- General Accreditation Guidance
  - General Equipment Table

    (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

    (Some accreditation programs also have additional documents that form part of the accreditation criteria which are referenced in the SAD.

    Human Pathology laboratories are also assessed against relevant NPAAC standards. 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).)

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

The General 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 particular industries.

A copy of the complete NAC package(s) applicable to a facility's scope of accreditation (or proposed scope for applicants) must be available to the facility staff.

Other informative documents are available from:

- ILAC (International Laboratory Accreditation Cooperation) www.ilac.org
- APAC (Asia Pacific Laboratory Accreditation Cooperation) www.apac-accreditation.org

In addition to the relevant NAC(s), NATA technical assessors are provided with a guidance document entitled *Assessor Information and Guidance*.

Applicability

The accreditation criteria are applicable to all facilities, irrespective of size, range of service or number of personnel.

It should be noted that it is not possible to set rigid criteria for all aspects of a facility's operation. 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.

Administration

NATA's accreditation programs are administered, under the Board's direction, by the Accreditation Advisory Committees (AACs). Each AAC provides support for defined conformity assessment activities covered by the various accreditation programs and/or for specific industries.

The current NATA Rules outline the functions of the Board and the AACs.

Human Pathology

NATA/RCPA

The ISO/IEC 15189 accreditation program is run jointly with the Royal College of Pathologists of Australasia (RCPA). The College has representation on the AAC and 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, professional bodies, 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.

Further information on NPAAC can be obtained by visiting its 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*.

Medical Imaging

The Medical Imaging Accreditation Program is run jointly with the Royal Australian and New Zealand College of Radiologists (RANZCR).

Research & Development

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

Sleep Disorders Services

The Sleep Disorders Services Accreditation Program is run jointly with the Australasian Sleep Association (ASA).

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 the NAC.

It is strongly recommended that facilities hold copies of relevant legislation.

Safety, environment and heritage

NATA does not define mandatory safety measures nor 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, inspection codes etc 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.

It should be noted that there may be some differences between the accreditation programs with regard to the order in which these steps are followed, as a result of limitations that have been placed on NATA's processes by outside influences, such as regulatory or industry-specific requirements.

Where an organisation may require accreditation in a number of different programs and/or industries, every attempt is made to harmonise and coordinate accreditation activities. Corporate accreditation is available in defined circumstances to assist this process and is covered in the NATA *General Accreditation Criteria: Corporate Accreditations - NATA Accreditation of Multiple Site and Multiple Activity Types*.

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.

NATA Client Coordinator

Every applicant and accredited facility is appointed a NATA Client Coordinator. This person serves as the facility's point of contact with NATA for all matters relating to its accreditation and other general NATA enquiries.

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, using the *Facility Details Update* form.

The rights and legal obligations of the Authorised Representative are detailed in the *NATA Rules* and in the NATA *General Accreditation Criteria: Responsibilities of Authorised Representatives*.

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 of those matters detailed under Regulation 27.1 in the *NATA Rules*.

Site contact person

The site is the physical location(s) of activities and services.

Recognising that the Authorised Representative is not necessarily the most appropriate person to answer day to day and technical queries regarding an accredited site'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, business telephone, mobile phone and email address of the Site contact may be made available to enquirers requiring the services of NATA accredited facilities. The Site contact details may also be included in the NATA website directory however this information can be withheld from publication if you wish.

Communication

A facility is required to direct all communication to NATA arising from assessment activities, or in relation to any other accreditation matter. The facility is not to contact a technical assessor directly (or vice versa) 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 NATA's 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 staff prior to lodging a formal application for accreditation.

When seeking accreditation, facility staff should also familiarise themselves with the relevant NAC.

Advisory visit

An advisory visit to the facility is undertaken by a NATA staff member (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 is the process whereby fulfilment of the accreditation criteria, by the facility, is determined.

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

An advisory visit is generally considered mandatory and is usually conducted prior to an application for accreditation.

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. This, however, does not apply to overseas facilities where an advisory visit is always considered mandatory.

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'.

Charges are levied for an advisory visit in accordance with NATA's current *Fee Schedule*.

Human Pathology

Facilities wishing to claim Medicare benefits must undertake the mandatory advisory visit (linked to Medicare Australia's registration). The additional objective of this visit is to confirm the facility'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.

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.

The document review provides a comparison of the facility's documentation and procedures with the accreditation criteria as detailed in the relevant NAC(s) (applicable to the proposed scope of accreditation) and is most often conducted by the NATA Lead Assessor who will be involved in the assessment of the facility.

The NATA Lead Assessor will make 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.

Where the document review cannot be conducted off-site (e.g. it may not be possible for the facility documents to be released), NATA will conduct the review on site.

Charges are levied for the document review in accordance with NATA's current *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 reflective of the state of readiness of the facility for accreditation. The application must be accompanied by the application fee in accordance with the current NATA *Fee Schedule*.

If an initial assessment has not been conducted within twelve months of the application date and the delay has been caused primarily by the applicant, an additional application fee will be charged. If the application is still pending after two years of the application date, the application will lapse.

Human Pathology

Following the advisory visit and receipt of the application and fee for NATA accreditation, the *Report on Laboratory Premises* will be forwarded to the facility. This is then lodged with DHS by the facility in conjunction with its application for recognition as an APL. The facility 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 pre-application / 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 with NATA.

Assessment

The fulfilment of the accreditation criteria by an applicant 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 relevant NAC(s). The assessment team reports its findings to both the facility seeking accreditation and the relevant 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 while the technical assessors concentrate on the technical activities performed by the facility. The size of the assessment team is generally dependent upon the breadth of the activities to be covered by the facility's accreditation.

Technical assessors are chosen according to their specialist knowledge and are matched as closely to the activities offered by the facility as is possible.

Consideration is given to possible concerns with conflicts of interest when selecting assessors.

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

Prior to the assessment, the NATA Lead Assessor will develop a plan covering the activities to be assessed, the locations at which the activities will be assessed, specific personnel who should be present, and the assessment techniques to be utilised, including witnessing (demonstration) where appropriate or applicable. The date(s) and plan for the assessment will be confirmed with the facility.

During the assessment, facility staff will be called upon to discuss issues and demonstrate activities (arrangements for this may be requested by NATA prior to the assessment as part of the assessment plan, 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, or other external personnel, are associated with a facility, NATA reserves the right to contact these persons to establish their involvement in activities (to be covered by the scope of accreditation) if they are not present at the assessment.

An exit 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. 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 together with an analysis of the extent and cause (e.g. root cause analysis) for all non-conformities by the due date indicated on the front page of the report. In the case that any non-conformity has not been able to be addressed by the due date, the reason why and a progress summary is still required to be provided.

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

Human Pathology

The NATA/RCPA Memorandum of Understanding (MoU) details the need for a technical assessor, who is a pathologist, to also be present on the assessment team.

The NATA/RCPA accreditation program includes the on-site assessment of Approved Collection Centres (ACCs), Hospital Collection Points (HCPs) and any other collection activity connected to an accredited facility.

It is recognised that the collection of specimens can be performed in a variety of locations and not all of these locations are within the control of the accredited facility, but may be, for example, controlled by a separate department within the organisation.

However, where the collection activity is under the control of an accredited facility, the assessment of ACCs and/or HCPs will form part of the NATA assessment. Any comments and findings will be included in the assessment report.

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

In-house calibration

In-house calibration refers to the process where a facility calibrates its own equipment instead of having it performed externally. Where a facility performs its own calibrations, the assessment of such will be covered during initial assessments and reassessments. Charges may be levied, in accordance with the current NATA *Fee Schedule* where significant additional assessment time or technical assessors are required.

Where a recognised standard method is followed in full for the in-house calibration, additional expertise from a calibration technical assessor is generally not required (e.g. calibration of POVAs against AS 2162.2). Specialist calibration technical assessors will only be used when the calibration is outside the area of expertise of

the technical assessors who would normally conduct the initial assessment / reassessment.

The pre-assessment documentation sent to the Authorised Representative will seek specific information on in-house calibrations.

The assessment of in-house calibration will be limited to focus on the testing activities which the calibration supports. A facility's measurement capabilities and expertise, may therefore, be quite different between in-house calibrations and for calibration services provided to external clients.

The assessment of in-house calibrations includes the relevant clauses of ISO/IEC 17025 as described in the *General Accreditation Criteria: Equipment assurance, in-house calibrations and equipment verification*. Measurement audits or inter-laboratory comparisons are not required where a standard method is followed in full.

As in-house calibrations are limited to the testing activities it supports, a facility's ability to perform in-house calibrations is not included under its scope of accreditation and hence, the activity is not able to be offered externally by the facility as an accredited activity.

Refer to the NATA *General Accreditation Criteria: Equipment assurance, in-house calibration and equipment verification* for further information.

Proficiency testing (PT)

Each applicant or accredited facility is required to participate in appropriate proficiency testing or equivalent activities. Note that measurement audits are considered a form of PT activity.

PT is not applicable to the GLP Program.

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 facility's performance and response to proficiency testing results will be reviewed during on-site assessments. 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 as detailed in the NACs) for each major area of test, measurement or related activity covered by the scope of accreditation, where such programs are available.

Refer to the NATA *General Accreditation Criteria: Proficiency Testing Policy* for further information.

Management system options

CASCO is the ISO (International Organization for Standardization) committee responsible for issues relating to conformity assessment. CASCO develops and maintains standards, including ISO/IEC 17020, ISO/IEC 17025, ISO 17034 and ISO/IEC 17043, which are used by NATA for specific accreditation programs.

The latest standards published by CASCO include two options for the management system requirements. These two options are progressively being included into all of the CASCO standards at the time they are next revised.

The two options are A and B: Option A lists the minimum requirements for implementation of a management system and Option B allows the adoption of the requirements of ISO 9001. Conformity of the management system with the requirements of ISO 9001 does not, in itself, demonstrate the technical competence of the facility.

Adoption of only one of the options is required.

Facilities that adopt Option A will generally operate in accordance with the principles of ISO 9001.

Regardless of the option adopted, the management system must be able to support the consistent fulfilment of the General, Structural, Resource and Process requirements in the relevant standard.

Further information on NATA's process in assessing the management system requirements can be found in the relevant SAD for the specific accreditation programs which currently allow the two management system options.

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, but not limited to, concerns about the competence of the facility, the inability to assess certain aspects of the facility during the scheduled visit due to lack of availability of key facility staff, or to review the effective implementation of the corrective action taken as a result of the previous scheduled 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.

Granting accreditation

NATA's Chief Executive grants accreditation following a recommendation by the relevant AAC. This recommendation is made once the facility has demonstrated meeting all the criteria for accreditation (as determined at an assessment) and has addressed any findings (i.e. nonconformities) raised.

The Authorised Representative is formally advised of the granting of the accreditation and is issued with a certificate and the scope of accreditation.

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.

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 reports and calibration certificates is a contravention of ISO/IEC 17021 *Conformity assessment – Requirement for bodies providing audit and certification of management systems*.

Refer to the *NATA Rules* and the NATA *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation* for further details of the circumstances under which the endorsement may 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.

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 NATA *General Accreditation Criteria: OECD Principles of Good Laboratory Practice (GLP) Recognition, Application Document*.

Scope of Accreditation

The collective expression of a facility's accreditation is known as its 'Scope of Accreditation' which references, as a minimum, the accreditation standard, the activities (industry classifications), the services offered, the materials, items or products (tested, calibrated, inspected etc), and the determinations or analytes. Techniques and procedures may also be references as necessary, and for calibration facilities, the measurement capability is additionally included.

Where activities are conducted away from the accredited facility (e.g. at a customer's premises) the scope of accreditation will identify this.

Where procedures are referenced in the scope of accreditation, NATA does not list the version numbers of the standards / methods as facilities are expected to comply with the latest version. In such cases where a facility wishes to be accredited for a superseded or withdrawn standard, either due to contractual reasons or at the customer's request, the version of the standard / method will be included in the scope of accreditation.

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

GLP program

Recognised GLP facilities are issues with a 'Notification of GLP Recognition' document as described in the NATA *General Accreditation Criteria: OECD Principles of Good Laboratory Practice (GLP) Recognition, Application Document*.

After accreditation – surveillance visit and reassessment

NATA accredited facilities are expected to continue to comply with all accreditation criteria detailed in the NAC(s). In order to ensure continued compliance with these criteria, scheduled assessments 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 AAC or follow up on-site visits may be necessary. Such intervals and any requirement for follow up will be determined on the significance of issues identified during a prior scheduled assessment to a facility and/or any doubt over a facility'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 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 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. The NATA Lead Assessor 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 response due 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.

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

GLP program

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

Human Pathology

The assessment cycle for 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. The NATA/RCPA program also offers a corporate surveillance scheme 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 assessment model are provided in the NATA *Specific Accreditation Criteria: NATA/RCPA accreditation surveillance model for Human Pathology*.

Inspection

The purpose and scope of surveillance visits for the inspection program are the same as described above. However, unlike surveillance visits in NATA's other programs, at least one technical assessor is included in the assessment team, in addition to the NATA Lead Assessor. This reflects the broad coverage of the Inspection Program and the fact that the NATA Lead Assessor may not be sufficiently familiar with the technical activities covered by the facility's scope of accreditation.

A surveillance visit with only a NATA Lead Assessor may take place if the Lead Assessor is familiar with the industry covered by the scope of accreditation of the facility being assessed.

Medical Imaging

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

All assessment activities are charged at the hourly rate as per the current NATA *Fee Schedule*.

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.

Variations to Scope of Accreditation

Accredited facilities may request variations to their scope of accreditation at any time once accredited. NATA 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 etc).

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 scheduled assessment, which are applicable to the activities requested by the scope extension, have been addressed.

Requests for withdrawal of accreditation

Where an 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 the *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 in accordance with the current NATA *Fee Schedule*.

Facility rights and obligations

Regulations R.25 to R.30 in the NATA Rules detail the rights and obligations of accredited facilities.

Of note, facilities are obligated to cooperate with NATA to allow the conduct of necessary accreditation activities (i.e. assessments of any type) to verify that the accreditation criteria are satisfied.

Fraudulent activity

Fraudulent behaviour, including the provision of false or misleading information, or concealment, is considered to be in breach of the *NATA Rules*, specifically Regulations R.8 and R.9.

NATA will cease processing applications, or review the accreditation status of accredited facilities (e.g. initiate the suspension process) where breaches have been proven.

Changes to facility details or Authorised Representative

Changes to Authorised Representative and facility or site details such as change of name, trade names and change of legal entity can be requested by completing the *Facility Details Update* form available from the NATA website. On receipt 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.

Additional documentation may be requested and/or additional accreditation activities may be necessary following review of the information.

Any accreditation activities deemed necessary by NATA may attract fees in accordance with the current NATA *Fee Schedule*. Further advice will be provided at the time of receipt of the request advising of changes.

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 issues are confirmed and the failure is such that cancellation of an accreditation is not warranted a recommendation may be made to suspend an accreditation.

In making a recommendation for suspension, consideration will be given to the nature of the any non-conformity(ies) with the accreditation criteria identified, the impact on the reliability and validity of the activities the facility performs and the risk to NATA's reputation.

Should suspension proceed, the Authorised Representative will be issued with a *Correction Notice* advising of the suspension in part or full.

In these circumstances the facility is not able to issue endorsed reports or claim to be accredited for those activities covered by the scope of accreditation affected by the suspension. The facility will also be required to inform affected clients of the suspension.

Should the accredited facility 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 scopes of accreditation and approved reporters for parentage testing

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 reporters for parentage testing will also be made available upon request.

<u>Family Law Regulations</u>

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).

Provision of information on suspended and withdrawn accreditation

NATA includes two listings on its website for suspended and withdrawn accreditations.

The suspensions listing identifies whether the scope of accreditation is suspended in part or in full. The listing for withdrawn accreditation identifies those which have been withdrawn in full.

Both listings include the date of suspension or withdrawal and whether the suspension/withdrawal is voluntary.

Information on withdrawn accreditation is removed after a defined period and for suspended accreditation, once a change to the status of the accreditation occurs.

Complaints and feedback

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

When investigating a complaint against an applicant or accredited facility, assistance may be sought from the facility's NATA Authorised Representative.

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

Complaints and feedback can be provided via the *Contact NATA* 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.*

Calibration

Facilities who have applied for, or who have been appointed Legal Authorities should be aware that NATA will exchange information with the National Measurement Institute (NMI). The assessment of Legal Authorities may include relevant NMI staff, either as technical assessors, where appropriate, or as observers.

GLP

NATA has additional responsibilities relating to non-compliant facilities. Refer to the NATA *General Accreditation Criteria: OECD Principles of Good Laboratory Practice (GLP) Recognition, Application Document.*

Privacy

NATA respects and upholds the rights of individuals to privacy protection under the Privacy Act 1988 (Cth). A copy of the *NATA Privacy Policy* can be obtained from the NATA website. This policy describes how NATA manages the personal information it holds.

References

Standards

AS 2243	Safety in Laboratories
ISO 15189	Medical laboratories - 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 17034	General requirements for the competence of reference material producers
ISO/IEC 17043	Conformity assessment - General requirements for proficiency testing
ISO 9001	Quality management system - Requirements

ASA Standard for Sleep Disorders Services

OECD Principles of Good Laboratory Practice

RANZCR Standards of Practice for Diagnostic and Interventional Radiology

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

NATA Publications

Fee Schedules

NATA Privacy Policy

NATA Rules

General Accreditation Criteria	Corporate accreditations – NATA accreditation of multiple site and/or multiple field facilities
General Accreditation Criteria	Proficiency testing 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

Privacy Act 1988 (Cth)

Amendment Table

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

Section or Clause	Amendments
Section 2	The role of the Authorised Representative Withdrawal of reference to the *Nomination of New Authorised Representative* form and replaced with *Facility Details Update* form. Site contact person Reduction in requested contact details and clarification of publication of contact details on NATA website. Advisory Visit Human Pathology: Clarification of the requirement for the mandatory advisory visit and additional visit objective i.e. linked to Medicare Australia's registration. Changes to facility details or Authorised Representative Withdrawal of reference to the *Nomination of New Authorised Representative* form and replaced with *Facility Details Update* form.