




Specific Accreditation Guidance
Human Pathology

**Laboratories seeking approval as an
Accredited Pathology Laboratory under
Section 23DN of the Health Insurance Act
1973**

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Laboratories seeking approval as an Accredited Pathology Laboratory under Section 23DN of the Health Insurance Act 1973

1. Introduction

This document is to provide laboratories seeking approval as an Accredited Pathology Laboratory (APL) under Section 23DN of the *Health Insurance Act 1973* (the Act) with current information on the operational processes in place for NATA to comply with the *Health Insurance (Accredited Pathology Laboratories — Approval) Principles 2002* (the Principles).

This paper replaces the Communiqué released in February 2012.

Note: *The NATA Procedures for Accreditation will be updated in due course to reflect these procedural changes.*

1.1 Advisory Visits and Reports

A review of NATA's processes has been conducted in conjunction with negotiation of a new Deed of Agreement between NATA and the Department of Human Services (DHS) (Medicare). The purpose of this has been to ensure that:

- NATA meets its obligations under the Principles;
- laboratories that have achieved appointment as an APL under the Act do meet NATA/RCPA accreditation requirements, and hence, the applicable accreditation materials listed in Schedule 1 of the Principles; and
- public health and safety is protected.

NATA advisory visits are conducted to determine a laboratory's level of preparedness for an initial assessment and to collect sufficient evidence to support the issuing of an advisory report, previously entitled "report on laboratory premises".

The Principles require NATA to include in an advisory report the following assurances:

- (c) *that the independent body is satisfied with a high level of confidence, taking into account the arrangements in relation to the operation of the premises, that:*
 - (i) *the premises can be expected to meet relevant standards for a 6 month period; and*
 - (ii) *the premises are, or will be, appropriately staffed with persons to carry out, and persons to direct, control and supervise, the pathology services to be performed at the premises; and*
 - (iii) *the laboratory is, or will be at the relevant time, participating in a quality assurance program of an independent quality assurance body designed to ensure that the laboratory operates in accordance with the accreditation materials applicable to the kinds of pathology services to which approval of the premises would relate;*

A review of the outcomes of initial assessments over the term of the previous Deed of Agreement has shown that NATA needs to modify both the timing of advisory visits and the level of evidence collected in order to meet an acceptable threshold for "high level of confidence".

This will provide greater confidence to applicant laboratories that the initial assessment will result in the desired outcome and the continuity of APL status.

In order to achieve a more appropriate level of confidence, the processes around advisory visits is as described in Annex A. The key change is the need for laboratories to have undertaken activities and to provide evidence of data / information as covered in the Annex.

1.2 Assessment, Reassessment, Surveillance Visits and Assessment Reports

An Assessment report (previously titled “report on laboratory premises) is issued following an Initial Assessment and thereafter following a Reassessment or Surveillance visit. In addition these reports may be linked to the intermediate On-line activity depending on timeframes.

The Principles require NATA to include in an assessment report the following:

- (2) *An assessment report:*
 - (a) *must state whether or not it has been established with a high level of confidence that the pathology services provided at the premises subject to the report meet, and can be expected to continue to meet relevant standards; and*
 - (b) *if so established, must also state:*
 - (iii) *the period of time for which the premises can be expected to meet relevant standards.*

The criteria for “*a high level of confidence*” that a laboratory does “*meet, and can be expected to continue to meet relevant standards*” is not met if there are outstanding non-compliances.

Hence, the Assessment Report can only be issued once the Laboratory has addressed all corrective actions and NATA has granted or continued the laboratory’s NATA/RCPA accreditation and not following receipt of the first satisfactory laboratory response.

1.3 Relocation of Laboratory premises

Where a Laboratory relocates premises a new APL application must be made to DHS. As such NATA will reissue the Advisory or Assessment Report prior to relocation with the new Address but referencing the existing APL Number. The new Assessment Report will replace the report issued for the previous laboratory premises but include the same expiry date and scope of accreditation.

The provision of the new Assessment report is contingent on the Authorised Representative attesting that the existing personnel resources and scope of testing will continue.

NATA will perform a site visit at the new location to confirm that the laboratory continues to meet the Relevant Standards, the timing of which shall be in accordance with the *NATA procedures for accreditation*. If the site visit reveals that the relocation has resulted in the personnel and/or the scope of testing being altered significantly, or that there are concerns around the laboratory’s ability to meet the Relevant Standards, NATA reserves the right to perform an Assessment visit and issue a new Assessment Report.

1.4 Changes of Ownership

Where a Laboratory undergoes a change of ownership, the Facility Details Update form is to be completed and returned to NATA and a new APL application must be made to DHS. Once the NATA accreditation application has been received NATA will issue a new accreditation number and issue a new Assessment Report which acknowledges the change in laboratory name (if appropriate) and the new accreditation number. The new Assessment Report will replace the report issued under the previous ownership but include the same expiry date and scope of accreditation.

The provision of the new Assessment report is contingent on the Authorised Representative attesting that the existing personnel resources and scope of testing will continue.

NATA may perform a site visit to confirm that the laboratory continues to meet the Relevant Standards under the new ownership, the timing of which shall be in accordance with NATA procedures. If the site visit reveals that the change of ownership has resulted in the personnel and/or the scope of testing being altered significantly, or that there are concerns around the laboratory’s ability to meet the Relevant Standards, NATA reserves the right to perform an Assessment visit and issue a new Assessment Report.

1.5 Fees

Routine reassessment visits, surveillance visits and on-line surveillance activities are covered by the annual fees.

Any other activity, including Advisory Visits, Follow-up Initial Assessments, Follow-up Reassessments, Variation Visits (on-site or desk-top reviews for extensions to the scope of accreditation), Shortened Reassessments, Shortened Surveillance Visits and staff visits will be charged in accordance with the current fee schedule.

NATA invoices on a monthly basis for any additional accreditation services performed outside of regular reassessments or surveillance visits.

1.6 Further Information

Should you require any further information please contact your Client Coordinator or Mr Andrew Griffin, Sector Manager - Legal & Clinical Services on (03) 9274 8200 or at Andrew.Griffin@nata.com.au

ANNEX A - Advisory Visit Process

NATA will normally request information prior to the Advisory visit being conducted. This information may include but not be limited to:

- CVs of all staff involved in testing
- the Laboratory Quality Manual
- Methods manuals;
- Validation and/or verification data;
- Quality Control and Quality Assurance data; and
- Where a suitable QAP is not available, what alternative process has been considered/implemented.

If not requested prior it would be expected that this information be available at the Advisory visit.

If the Laboratory's Representative fails to facilitate the visit including failure to provide the documentary materials required, NATA is not obliged to conduct the Advisory visit.

At the Advisory Visit, the laboratory must demonstrate:

- A suitable premises for conducting the scope of services provided;
- Quality Assurance Program (QAP) enrolment covering all areas of testing, where available;
- Testing equipment that is appropriate to the range of testing offered;
- Evidence that staff have the experience and qualifications that meet the relevant NPAAC Category.

Where the Pre- Advisory activity and Advisory visit has concluded that the Laboratory is in a state of readiness to operate and provide pathology services in accordance with the Standards, the Laboratory must provide NATA with a completed Application for Accreditation and payment of accreditation application fee.

After receipt of these an Advisory Report will be issued. The approval period will be for a maximum 6 month period and begin from the date that the Advisory visit occurred.

Where the laboratory is not appropriately equipped and/or is not at an appropriate state of readiness to operate and provide pathology services in accordance with the Standards, NATA is not obliged to issue an Advisory report but will instead identify those areas to be addressed in writing. These will need to be addressed prior to consideration of further activity on NATAs behalf.

The laboratory should not submit an application and the associated fee until it has achieved an appropriate stage of preparedness for an initial assessment.

ANNEX B - Assessment Process

To ensure the timely provision of an Assessment Report the routine assessment activity will be conducted not less than six months prior to the expiry date of the Assessment Report.

Requests for Delay of Assessment Activity

Requests to delay assessment activity will be reviewed on a case by case basis, and will only be approved where extraordinary circumstances apply. Where a facility requests a delay and it is approved, any lapse in APL status pending the provision of a new Assessment Report will be the responsibility of the Laboratory.

The consideration of any delay will also take into account NATA's ISO 17011 obligations for Surveillance activity and the current requirements to conduct an On-site visit at a maximum interval of 24 months.

Follow up activity

On occasion NATA is unable to determine that a Laboratory has met or will continue to meet relevant Standards with a high level of confidence. This is especially the case where due to the nature and number of assessment findings a subsequent follow up visit is required.

A follow up visit is determined at the discretion of the Operations Manager, and/or the relevant Sector Manager and AAC Chair and/or the General Manager, Operations and Technical and/or the General Manager, Compliance and Governance.

The following factors are considered:

- (a) number and nature of the non-compliances identified;
- (b) accreditation history of the facility;
- (c) length of operation of the facility;
- (d) changes to facility management, test techniques and testing staff; and
- (e) the significance of test results.

Where a follow up visit is required NATA/RCPA accreditation cannot be granted or extended and therefore the provision of a new Assessment report cannot be made. Where this is the case the Laboratory risks revocation of MBS Funding for those services.

A new Assessment Report can only be issued once a high level of confidence has been established and NATA/RCPA accreditation granted or continued.

AMENDMENTS

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

Section	Amendment
New document	This document represents a direct adoption of the former Information Paper 14.