Specific Accreditation Guidance

Human Pathology

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

March 2021

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Purpose

This document provides laboratories, who seek 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 2017* (the Principles).

A revised *Deed of Agreement* between NATA, Services Australia and the Commonwealth Department of Health was signed in March 2021. As a result of this Deed, a review of NATA's processes was conducted to ensure that:

- NATA meets its obligations in accordance with the latest Principles;
- only laboratories that meet NATA/RCPA accreditation requirements and hence, the applicable accreditation materials listed in Schedule 1 of the Principles, can gain and maintain approval as an APL under the Act; and
- public health and safety is protected.

Terminology and Definitions

Advisory Report means a report provided by NATA in accordance with subsection 12(3) of the Principles.

Assessment Report means a report provided by NATA in accordance with Section 9 of the Principles. This is not the same document as that provide to the laboratory at the conclusion of a NATA/RCPA assessment activity.

The Report on Laboratory Premises (Advisory Reports and Assessment Reports) remain the property of the Commonwealth upon creation. These reports are used as the basis for the Minister to approve a laboratory as an APL in accordance with the Act.

Advisory Visits and Advisory Reports

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 the Report on Laboratory Premises (Advisory Report).

The Principles [Part 3, 12, (3), (c)] require NATA to include in the Advisory Report the following:

> *(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;

The processes necessary for NATA to achieve "*a high level of confidence*" from advisory visits are described in Annex A.

Assessments and Assessment Reports

A Report on Laboratory Premises (Assessment Report) is issued following an initial assessment and thereafter following reassessments.

The Principles [Part 2, 9, (2)], require NATA to include in the 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:

(i) relevant standards; and

(ii) if the independent body preparing an assessment report considers that it is reasonably necessary to also apply additional standards - those standards.

(b) if so established, must also state:

(i) by reference to items in the pathology services table, or by reference to groups of items in the pathology services table, the kind of pathology services in respect of which the premises should be approved or should remain approved; and

(ii) the category to which the premises should be allocated or remain allocated; and

(iii) the period of time for which the premises can be expected to meet relevant standards.

The processes necessary for NATA to achieve "*a high level of confidence*" that a laboratory does "*meet, and can be expected to continue to meet relevant standards*" are described in Annex B.

Relocation of Laboratory Premises

Where a laboratory relocates premises, a new APL application must be made to Services Australia. As such, NATA will reissue the Advisory or Assessment Report prior to relocation with the new laboratory address but referencing the existing APL number.

The new report will replace the one issued for the laboratory's previous premises and include the same expiry date, "Laboratory Category" and "Groups of Pathology"

disciplines, unless changes to the latter two have been notified to NATA and an assessment has occurred.

The provision of the new report is also dependent on the NATA Authorised Representative attesting that the existing personnel resources and scope of testing remain unchanged.

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* and within a "*reasonable timeframe to allow the Commonwealth to make a determination of the accreditation status of the APL*".

If the site visit reveals that the relocation has resulted in the personnel and/or the scope of testing (including methods and/or equipment used) having altered, or that there are concerns around the laboratory's ability to meet the relevant standards, NATA shall perform an on-site assessment. A new Assessment Report will be issued, but only following the close-out of any non-conformities and the accreditation status of the laboratory having been confirmed.

Change of Laboratory Ownership

Where a laboratory undergoes a change of ownership, the *Facility Details Update* form (provided by NATA once notification of the change is received), must be completed and returned. Following the receipt of the completed form by NATA, a new Assessment Report will be issued which acknowledges the change in laboratory name (if appropriate) and the new NATA/RCPA accreditation number (where necessary). The laboratory is responsible for submitting the new APL application to Services Australia.

The new Assessment Report will replace the one issued under the previous ownership but include the same APL number, expiry date, "Laboratory Category" and "Groups of Pathology" disciplines, unless changes to the latter two have been notified to NATA and an assessment has occurred.

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

NATA shall 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 agreed with the Commonwealth" and within a "reasonable timeframe that allows the Commonwealth to make a determination of the APL status of the laboratory".

If the site visit reveals that the change of ownership has resulted in the personnel and/or the scope of testing (including methods and/or equipment used) having altered, or that there are concerns around the laboratory's ability to meet the relevant standards, NATA shall perform an on-site assessment visit. A new Assessment Report will be issued, but only following the close-out of any non-conformities and the accreditation status of the laboratory has been confirmed.

Fees

Routine reassessment visits are covered by the annual fees.

Other than scheduled reassessments, any other assessment activity will be charged in accordance with the current *Fee Schedule* available from the NATA website.

Further Information

Should you require any further information please contact your NATA Client Coordinator.

ANNEX A

Advisory Visit Process

NATA will request information prior to the Advisory visit being conducted or expect that the information be available during the visit. This information may include but not be limited to:

- CVs of all staff involved in testing;
- the laboratory's Quality Manual;
- methods manuals;
- validation and/or verification data;
- Quality Control (QC) and Quality Assurance Program (QAP) data and where suitable QAP is not available, what alternative process(es) has / have been considered and implemented.

If the laboratory's NATA Authorised Representative fails to facilitate the visit, including failure to provide the documentary materials required, NATA is not obliged to conduct the advisory visit or to issue the Advisory Report.

During the advisory visit, the laboratory must demonstrate:

- suitable premises to perform the scope of services provided;
- QAP enrolment covering all areas of testing or, alternative process(es), where QAP is not available, has / have been considered and implemented;
- testing equipment that is appropriate for the range of testing offered;
- evidence that staff have the experience and qualifications that meet the relevant NPAAC Category.

Where the advisory visit has concluded that the laboratory is in a state of readiness to operate and provide pathology services in accordance with the relevant standards, the laboratory must provide NATA with a completed application form and payment of the accreditation application fee. Following receipt of these, the Advisory Report will be issued. The approval period will be for a maximum of 6 months and begin from the date that the advisory visit occurred.

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

Where the laboratory is not appropriately equipped and/or is not at an appropriate state of readiness to provide pathology services in accordance with the relevant standards, NATA is not obliged to issue the Advisory Report but will instead confirm in writing the areas needing to be addressed. Once the laboratory formally advises of the action taken, NATA will consider the next steps and whether the Advisory Report can be issued.

ANNEX B

Assessment Process

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

Non-conformities identified at an assessment

The Assessment Report can only be issued once the laboratory has addressed any non-conformities which have been identified at an assessment and once accreditation has been granted following an initial assessment or continued following a reassessment. This is necessary, as NATA is not able to confirm with "*a high level of confidence*" that a laboratory does "*meet, and can be expected to continue to meet relevant standards*" where non-conformities have been identified and not yet closed-out.

Requests to delay an assessment

Requests to delay an 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 which is approved, any lapse in APL status pending the provision of a new Assessment Report is the responsibility of the laboratory.

The consideration of any delay will also take into account NATA's ILAC (International Laboratory Accreditation Cooperation) obligations, which includes the need to perform an assessment at least every two years.

Follow-up assessments

On occasion, NATA is unable to determine that a laboratory has met or will continue to meet the relevant standards with "*a high level of confidence*" (e.g. due to the nature and number of assessment findings). In such cases, a subsequent follow up assessment may be required at NATA/RCPA's discretion.

The following key factors are some which are considered when determining the need for a follow-up assessment:

- the number and nature of the non-conformities identified at an assessment;
- the accreditation history of the laboratory;
- any changes to key personnel (including supervisory staff), test methods and equipment;
- the significance of services provided; and
- any other relevant matter(s).

Where a follow-up assessment is required, NATA/RCPA accreditation cannot be granted or extended and thus, a new Assessment Report cannot be issued. This may result in the current APL approval lapsing which is the laboratory's responsibility to maintain.

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 or clause	Amendment
Whole document	This document has been updated to reflect the changes to the *Deed of Agreement* between NATA and the Commonwealth signed in March 2021. The document has also been editorial amended, including the addition of a table of contents.