# Specific Accreditation Criteria

# Human Pathology

## NATA/RCPA accreditation surveillance model for Human Pathology

**January 2018**

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## 1. Background

NATA introduced a new assessment model for Human Pathology from 1 July 2013. This document provides details on the model and practical issues around how it is applied.

### Rationale for change

NATA sought the input and feedback of Pathology stakeholders with respect to the three year reassessment model which was in place for Human Pathology for many years. The outcome of this review was that the model was outdated and a more contemporary model should be implemented which could identify trends and potential risks earlier.

For the majority of other fields and programs of accreditation NATA offers, a revised assessment model was adopted in 2008. The model sought to review the effectiveness of our use of our very valuable Technical Assessor resource and to also reconsider the approach and role played by our Lead Assessors during assessment.

Approaches to assessment adopted by other accreditation bodies around the world, and the requirements of the standard to which NATA must comply, ISO/IEC 17011 *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies* were also considered.

The outcome of these considerations was a revised model which provides an improved assessment process for pathology facilities and allows better and more regular communication between NATA and accredited facilities.

## 2. The accreditation surveillance model

### An explanation of the types of visits

The assessment model involves three types of activity over a four year period.

Online assessment activity: An in-office activity at NATA by a NATA Lead Assessor at 12 and 36 months.

Selected technical and management system requirements are reviewed, including a consideration of the findings from the previous visit. The activity may result in selected material being sent to a Technical Assessor for review and comment.

Surveillance visit: An on-site visit by a NATA Lead Assessor at 24 months. Selected technical areas and the management system are reviewed.

No Scope of Accreditation extensions i.e. additions, are able to be considered without arrangement and agreement prior to the visit.

Reassessment visit: An on-site visit by a NATA Lead Assessor and the relevant number of Technical Assessors (to review the Scope of Accreditation) every four years. The visit covers selected management and all technical areas.

The combination of assessment activities is aimed at assuring NATA of the continued compliance of the accredited facility with the accreditation criteria. Thus, findings at the online activity or surveillance visit may lead to an early reassessment being conducted or a follow-up on-site visit.

NATA reserves the right to perform extraordinary visits outside of the routine surveillance cycle. These may take the form of a NATA staff visit, follow-up assessment or shortened reassessment visit. In these cases, the visit is chargeable in accordance with the NATA Fee Schedule current at the time.

## What to expect for an online activity

The online assessment activity involves the following:

1. A follow up of action taken on significant major conditions (C) raised at the previous assessment with evidence submitted to confirm ongoing compliance with the original issue. Previously sighted evidence should not be requested;
2. A limited review of the facility's management system. It may include elements such as management review, selected internal audits, complaints handling, etc.;
3. A review of specific technical issues. These may include, but not limited to, verification or validation data in relation to the implementation of new equipment and methods; enrolment, participation and performance in quality assurance programs; and changes to test lists;
4. A review of any changes which may impact on a facility's accreditation e.g. changes to staff, changes to ownership or governance. (Facilities are, however, expected to continue to inform NATA of such changes at the time that these occur in accordance with the *NATA Rules*).

As of March 2016, significant amendments were made to the way Online Surveillance activities are conducted. These changes are summarised below:

- The activity is now conducted in two stages: Stage One is standardised information gathering and Stage Two seeks specific information to support the Stage One information. For example, where changes are advised to methods or equipment a test list will be forwarded for updating or where QAP summation is not satisfactory.

- A Stage Two submission may not always be required.

- Corporate accreditations (compliant with NATA's *Corporate accreditations –NATA accreditation of multiple site and/or multiple activity type facilities*) and large single site laboratories comprising of multiple departments are treated as a single accreditation and a single online activity is performed for all sites/departments as part of the one activity. For corporate accreditations this activity is aligned with the client's nominated main site.

  Individual online assessment activities for each site/department are no longer performed.

- Evidence is now required of senior management review of quality indicators and quality objectives (however named) since the last onsite visit (refer to ISO 15189:2012 Clause 4.1.2.4, 4.14.7, 4.15.2 f). It is expected that this review will encompass all services and sites/departments.

- Rather than requesting specific Quality Assurance Program (QAP) reports a performance review summary of QAPs is now required. This review should be performed by senior management and provide a summation of enrolment, participation and performance of all QAP for all sites/departments. It should be detailed enough to provide NATA with confidence that QAP is being appropriately monitored and discrepancies and areas of concern are actioned in a timely manner. It is expected that this summary will encompass all technical competencies and locations. The summary content will then be confirmed at the next onsite visit. Where a performance review summary is not available, is insufficient, or is unsatisfactory, then additional submissions will be required (Stage 2).

### 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. The consideration of any delay will take into account NATA's APLAC and ILAC MRA obligations for the conduct of scheduled visits and the current requirements to conduct an on-site visit (re/assessment and surveillance visits) at a maximum interval of 24 months. Where a delay is requested and approved any lapse in the ability to claim MBS reimbursement (where appropriate) will be the responsibility of the facility.

### Requests for Scope of Accreditation extensions and additional testing recognition within an existing scope class and sub-class of test at the time of an online activity

Additions to the Scope of Accreditation will not be considered during an online assessment activity.

A facility may, however, request an extension to the Scope of Accreditation at any time by way of a chargeable variation as is currently the case. Upon receipt of a written request for an extension to scope, NATA will determine how best to proceed. A fee will be levied for such requests in accordance with the NATA Fee Schedule current at the time.

Additional test recognition within an existing scope class or sub-class of test will not normally be considered during an online surveillance activity (Stage 1) as this activity does not include a Technical Assessor. Of consideration will be whether the facility is already accredited for similar tests within that class or sub-class using similar competencies. NATA may request additional information (Stage 2) e.g. verification data, for review in-house or by a Technical Assessor. Similar considerations will be made where a change in test method or test platform has been identified.

### Administrative arrangements for an online activity

Approximately two months prior to the scheduled activity, NATA will forward a pre-assessment document which will identify the information to be returned. The completed document must be uploaded to the Members Portal or emailed as applicable by the due date of the activity. Any changes to the Quality Manual and associated procedures will also be requested at this time.

Where the online activity reveals that new methods have been introduced which are covered by the Scope of Accreditation, or that deviations to methods covered by the scope have been made, a sample of records of verification or validation will be requested (Stage 2). This information will be reviewed in accordance with NATA procedures and may be referred for technical review.

### Reports on online activity

A formal assessment report will not be forwarded to the facility. Instead a letter will be forwarded within four weeks of the provision of the completed pre-assessment document and requested records. The letter will either:

- outline any additional information required (Stage 2). The facility will be required to respond in the usual manner within the agreed timeframe (usually four weeks); or
- confirm that a recommendation will be made to the Human Pathology Accreditation Advisory Committee to continue accreditation.

### What to expect at a surveillance visit

The surveillance visit involves the following:

1. A review of action taken on any conditions that were raised at the previous assessment/reassessment and online activity;
2. A full review of the facility's management system, including a document review of the quality manual and associated procedures;
3. A review of specific technical issues including pre-analytical activities; the methods/procedures in use; status of equipment calibrations/checks; quality control procedures and records; enrolment, participation and performance in proficiency testing; records and reports; and continuing suitability of the facility's accommodation; and
4. A review of any changes which may impact on a facility's accreditation e.g. changes to staff. Facilities are, however, expected to continue to inform NATA of such changes at the time that these occur.

### Requests for Scope of Accreditation extensions and additional testing recognition within an existing scope class and sub-class of test at the time of a surveillance visit

Additional test recognition within an existing scope class or sub-class of test will not normally be considered during a surveillance visit as these visits do not include a Technical Assessor. Of consideration will be whether the facility is already accredited for similar tests within that class or sub-class using similar competencies. NATA may request additional information e.g. verification data, for review in-house or by a Technical Assessor. Similar considerations will be made where a change in test method or test platform has been identified.

Any such requests should therefore be made before the surveillance visit so that a decision can be made as to how to best meet the request without compromising the aim and focus of the surveillance visit. To accommodate the request, an additional variation visit, which could be concurrent, may be arranged. Such a visit is a chargeable activity in accordance with NATA's Fee Schedule current at the time.

### Administrative arrangements for a surveillance visit

Approximately three months prior to a scheduled visit, NATA will forward a pre-assessment document for completion. This document will request information relating to the Scope of Accreditation, staff, equipment and proficiency testing. The completed document must be returned to NATA together with a copy of the facility's quality manual (and associated procedures).

Information relating to additions to the Scope of Accreditation will also be requested so that the best approach to incorporating these can be determined (refer above).

Where the surveillance visit reveals that new methods have been introduced, or that deviations to methods covered by the Scope of Accreditation have been made, records of verification or validation will be requested. This information will be reviewed in accordance with NATA procedures and a separate chargeable activity will be arranged. Such an activity may include a desk-top review or an on-site variation visit and be charged in accordance with NATA's Fee Schedule current at the time.

### Reports on surveillance visits

An interim written report will be left at the end of the visit. A confirmed report will be forwarded in line with NATA's Charter of Service. The report will use the current approach to coding of findings and the facility will be required to respond to any conditions in the usual manner within the agreed timeframe (usually four weeks).

Continued accreditation will be confirmed in writing following receipt of a satisfactory response from the facility to any conditions identified in the report.

### What to expect at the reassessment visit

Reassessment visits will include on-site peer review with assessment teams led by a NATA Lead Assessor. These visits will focus on the technical aspects of the laboratory.

Aspects of the management system will also be reviewed during reassessments, including changes to policies/procedures since the previous surveillance visit and specific records such as internal audits, management review, complaints, etc.

Where a laboratory seeks to extend its Scope of Accreditation it may be incorporated as part of the reassessment visit. However, where additional assessment effort is required to review the additional testing, a separate or concurrent variation activity will be arranged and charge for in accordance with NATA's Fee Schedule current at the time.

Facilities that hold Corporate Accreditation in line with NATA's *Corporate accreditations – NATA accreditation of multiple site and/or multiple activity type facilities* will normally undergo the assessment activities as described above. This is the default assessment model.

There is a provision for such facilities to apply for inclusion in the corporate surveillance 'sampling' assessment model as described below.

### Corporate surveillance 'sampling' assessment model

For organisations that hold corporate accreditation there is provision for a corporate surveillance 'sampling' program. This program includes alternative visit types, with a focus on confirming the application of the corporate quality management system and sampling

the technical competencies covered by the Scope of Accreditation for the whole organisation. Specific criteria are outlined below.

The program outlined in this document recognises the corporate structure of the organisation and aims to provide a flexible assessment approach which better reflects its governance structure.

The corporate surveillance program is not mandatory. Should an organisation meet the criteria as detailed below it may apply in writing to be included in the program. NATA reserves the right, as part of the corporate surveillance program, to perform a full or partial technical assessment of any site should issues of serious concern be raised at any visit. Such visits will be charged as per the current NATA Fee Schedule.

If accreditation activities consistently reveal deviations in procedures across sites within the corporate accreditation the corporate surveillance program will be rendered unavailable and the organisation returned to the routine assessment model as outlined above. The status of the organisation's corporate accreditation may also be reviewed.

**Eligibility criteria**

The following criteria must be satisfied for an organisation to be considered for the corporate surveillance program:

1. The organisation must hold NATA corporate accreditation (refer to NATA's *Corporate accreditations –NATA accreditation of multiple site and/or multiple activity type facilities* );
2. The main and branch sites must have a sound assessment history. The history must include the main site being subject to two routine reassessments (as a minimum). A branch site must have undergone at least one routine reassessment before it can be included in the corporate surveillance program;
3. Arrangements for technical supervision, roles and accountabilities i.e. pathologist and non-pathologist supervision must be outlined in the application for corporate surveillance. The following must be detailed (including any site specific or hub arrangements):
    a) supervision of each discipline;
    b) quality assurance programs;
    c) internal quality control (QC) programs (including setting acceptance ranges and the review of the RCPA Internal Quality Assurance (IQA) Framework);
    d) continuing education and competency assessment;
    e) implementation of new and changed tests, methods and equipment;
    f) new and changed biological reference ranges;
    g) new and changed laboratory information systems;
    h) new and changed information communication technology e.g. electronic reports, electronic test requests;
    i) advisory services.
4. Stability in senior management must be demonstrated.

Following a written request and receipt of the appropriate application form for corporate accreditation (if corporate accreditation is not already held), NATA will perform an onsite technical assessment at the main laboratory to review governance arrangements to determine if the above criteria have been satisfied.

**Assessment model**

The model includes:

1. a four year visit plan tailored and designed in consultation with the organisation;

   **Note:** Sites performing only point of care testing are excluded from the corporate surveillance 'sampling' assessment model.

2. a technical assessment to the main site to review the organisation's governance structure, supervision arrangements, and geographic spread of the sites nominated for inclusion in the corporate surveillance program. Timing of visits and visit types will also be discussed. This technical governance visit is performed at the commencement of every four year plan;
3. reassessment or partial technical assessment of each site once per cycle;
4. surveillance visits to each site once per cycle;
5. partial technical assessments and surveillance visits will be conducted with only 10 days advance notice;
6. a NATA Lead Assessor desk top activity at the 24 month mark to confirm continued compliance with the criteria in this document. The main focus of this activity is:
   a) ensure senior management's ongoing monitoring and delivery of the supervision arrangements that were deemed compliant at the commencement of the four year cycle;
   b) review of any changes to criteria a) to h) listed under 'Eligibility criteria' of this document;
   c) changes to governance;
   d) confirmation of the remainder of the four year plan.

The four year visit plan will include:

1. reassessment of all competencies at the main site and larger sites within the organisation (hubs);
2. technical reassessment of any branch site competencies that are not performed at the main laboratory e.g. immunohaematology;
3. partial technical reassessment of each branch site:
   a) each partial technical reassessment includes Technical Assessors but not all disciplines may be covered at every branch site;
   b) at least one discipline per branch site will be covered by a Technical Assessor;
   c) all disciplines will be covered by a Technical Assessor for each site at least every two cycles (eight years);
   d) IQA and QAP results to be submitted with every Accreditation Information Document (AID) for Anatomical Pathology performed outside of the main or hub sites.

e) the discipline(s) not assessed by a Technical Assessor(s) will be subject to a technical record review by the NATA Lead Assessor.

**Note:** The organisation's NATA Authorised Representative is to formally request in writing when any site's Scope of Accreditation wishes to be extended. NATA will determine if such requests can be considered concurrently during a partial reassessment. This will be dependent on sufficient notice from the organisation and whether additional time and effort, including a Technical Assessor(s), will be required, separate to the already agreed corporate surveillance 'sampling' assessment model. Where additional time and effort will be necessary, these will be charged for in accordance with the NATA Fee Schedule current at the time.

4. surveillance visit for each site

a) the main site will undergo a full management system review;

b) each branch site will include confirmation of implementation of the organisation's management system.

### Withdrawal from the corporate surveillance program

An organisation may withdraw from a corporate surveillance 'sampling' assessment model at any time and revert to routine assessment cycle. A plan outlining how all sites will be returned to routine assessment will be provided by NATA once withdrawal from corporate 'sampling' assessment model is confirmed.

NATA reserves the right to withdraw an organisation from a corporate surveillance 'sampling' assessment model should the requirements outlined in this document not be met. This would usually be evidenced in an increased number of, or increased significance of, conditions raised during the assessment cycle. Additionally, failure to meet the requirements of accreditation at any site will also prompt review of the organisation's ongoing eligibility.

### Annual fees

The annual fees charged to an organisation remain unchanged. Any additional activities required e.g. requests for extensions to the Scope of Accreditation, beyond those already included in the agreed corporate surveillance 'sampling' assessment model will be charged according to the NATA Fee Schedule current at the time.

## 3. Implementation dates, impacts on fees and visit scheduling

### Applicant facilities

Applicant facilities will be subject to the following schedule of visits prior to being placed on the routine surveillance model outlined above or included in the corporate surveillance 'sampling' assessment model.

Applicant facilities will undergo an initial assessment. Should accreditation be granted following the initial assessment, the facility will be subject to a surveillance visit 12 months from the date of the initial assessment. The first reassessment will then occur 12 months from the surveillance visit (which is 24 months from the initial assessment as is currently

the case).

Once the first reassessment at 24 months has been performed and accreditation has been continued and should there be no requirement for a follow-up or shortened reassessment visit, the facility will be placed on the four year routine assessment model, or included in the corporate surveillance 'sampling' model.

Initial assessments for applicant facilities are charged in accordance with NATA's Fee Schedule current at the time.

### Annual fees

Once a facility becomes accredited fees are charged on an annual basis in accordance with NATA's Fee Schedule current at the time.

## 4. Further information

If you have any further queries relating to the surveillance model, please do not hesitate to contact your Client Coordinator or Andrew Griffin in the Melbourne office on (03) 9274 8200 or by email at Andrew.Griffin@nata.com.au

## 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 Policy Circular 46. The technical content is unchanged.<br>The document has been reviewed and updated to reflect the new accreditation criteria documentation structure. |