



General Accreditation Criteria

Accreditation of multi-site facilities

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Purpose

This document describes NATA's policy on the assessment of facilities operating from multiple sites.

An accredited facility operating from multiple sites may maintain one accreditation or have each site accredited separately.

This policy only applies to facilities that maintain a single accreditation (i.e. one accreditation number).

Benefits

Maintaining one accreditation for a multi-site facility allows for greater flexibility in tailoring an assessment program (and assessment plans) reflective of the operational structures and the processes adopted across all sites.

The benefits include:

- an assessment program developed, based on how the organisation is structured and its processes managed and confirmed prior to the commencement of each accreditation cycle;
- activities performed at more than one site may not necessarily be assessed at each site during an accreditation cycle if these are centrally managed or the same processes adopted (i.e. reducing duplication in assessment effort);

Notes: Centrally managed activities could include the management system, supervision / technical control, validation of new or modified methods, etc.

For facilities accredited in NATA's Human Pathology program (ISO 15189) and the RANZCR/NATA program, refer to the *NATA Procedures for accreditation*.

- provision of a summary report of assessment findings covering all sites falling under the accreditation.

Note: This summary provides a consolidated overview which would facilitate the identification of trends, areas of risk and improvement opportunities both at the organisational and site levels.

Definitions

Accreditation number	An accredited facility is issued a unique accreditation number and each site falling under the accreditation is also issued a unique site number.
Accreditation cycle	An accreditation cycle is either 3 or 4 years dependent on the accreditation program (refer to the <i>NATA Procedures for accreditation</i>).
Accreditation program	NATA offers its accreditation programs based on ISO or industry Standards. The list of available programs is detailed in the relevant schedule of the <i>NATA Rules</i> .
Assessment effort	The effort required to perform an assessment which includes the time and resources necessary.
Assessment plan	A description of the arrangements for a given assessment which includes the activities to be assessed (sampled) and the assessment techniques to be used.
Assessment program	The set of assessments scheduled during an accreditation cycle for a specific facility.
Assessment technique	The assessment may be on-site or remote and include: <ul style="list-style-type: none"> • witnessing of activities performed • document review • vertical audit (e.g. file review) • review of performance in proficiency testing and other interlaboratory comparisons • interviewing relevant staff
Facility	A facility is an accredited organisation and a legal entity which may operate from a single site or from multiple sites and may be accredited in one or more accreditation programs. A facility may also be referred to as a Conformity Assessment Body (CAB). Each accredited facility may only nominate one NATA Authorised Representative.
Site	A fixed physical location from where accredited activities are performed. A site may only be accredited in one accreditation program.
Site number	Refer to Accreditation number.

Eligibility

One NATA Authorised Representative must be appointed by the facility to be the point of contact with NATA. Refer to *General Accreditation Criteria: Responsibilities of Authorised Representatives* for further details.

The following criteria apply:

- a single management system must be consistently applied across all sites covered by the accreditation, however, site specific processes may vary reflective of the activities performed at each site;
- the facility must identify a primary site which will be the first site to be assessed in the accreditation cycle;

Notes: The assessment of the primary site will include review of the management system.

For facilities accredited in NATA's Human Pathology program (ISO 15189) and the RANZCR/NATA program refer to the *NATA Procedures for accreditation*.

- the relevant accreditation criteria must be implemented at all sites;
- each site must participate in suitable proficiency testing activities, when available, covering the activities for which accreditation is held. Refer to *General Accreditation Criteria: Proficiency Testing Policy* for further details.

Note: The facility should also consider a process for intra-laboratory comparisons where the same techniques / procedures / methods are adopted between sites in order to determine comparability of results.

- the response to any non-conformity(ies) identified during an assessment of any site must include evidence that the cause analysis and corrective action taken have considered all other applicable sites.

Assessment program

Prior to the commencement of the next accreditation cycle, a questionnaire will be sent to the facility seeking information to inform the preparation of the assessment program for the new cycle.

The assessment program will adopt a sampling approach taking into account:

- the scope of accreditation for the facility and the accredited activities performed at each site;
- the number of sites;
- the assessment history of the facility (e.g. significance and associated risks of non-conformities raised, the stability of the organisation, the internal control and monitoring processes, etc);
- any applicable regulatory / government agency arrangement(s) or customer requirements the facility may have (e.g. contractual) which specify the activities (e.g. test methods) needing to be assessed and the frequency of assessments.

The program will include the scheduled assessments to be performed, the accredited activities to be assessed and the type of assessment techniques to be used.

A risk-based approach to how the facility manages the following will be considered for each assessment program:

- technical and managerial supervision including control of remote activities (e.g. branch sites, mobile sites, multi-site crime scene services, annexes as defined in the respective accreditation criteria);
- maintenance of equipment, method validation and/or verification and proficiency testing performance;
- management system elements (e.g. management review, internal audits, document control, corrective action and complaints investigation).

The extent of assessment will be dependent on the facility's established processes. Efficiencies can be gained, potentially reducing the assessment effort, if uniform processes are adopted (e.g. centrally managed management system, method validation etc which are adopted by all sites).

The program may be adjusted during the accreditation cycle based on the findings of any given assessment (e.g. the significance of the findings). Further NATA reserves that right to also perform additional assessments. Such visits, including requests from the facility for the addition of new sites or requests for changes to the scope of accreditation will be chargeable in accordance with NATA's current *Fee Schedule*.

Notes: For facilities accredited in NATA's Human Pathology program (ISO 15189) and the RANZCR/NATA program, the assessment program is described in the *NATA Procedures for accreditation*.

For facilities accredited in NATA's Sleep Disorders Services program, refer to the *Specific Accreditation Criteria: Sleep Disorders Services - Accreditation of 'Branch' Services*.

Addition of new and/or branch sites

Additional and/or branch sites may be added anytime during an accreditation cycle by completing the application form following discussion with your NATA client coordinator.

An initial assessment of an applicant site will be performed prior to the scope of accreditation of the facility being extended to include the activities covered by the new site. The extent of this assessment will be dependent on the activities performed by the site (e.g. whether these are already performed at other sites covered by the scope of accreditation) and the assessment history of the facility.

Changes to the scope of accreditation

A sampling approach may be applied for addition(s) to the scope of accreditation across the facility, where one site:

- has supervisory / technical control over the roll out of the addition(s) across other relevant sites;
- performs the validation or verification prior to verification at all other relevant sites.

Changes to the scope of accreditation can be made at any time by completing the *Application for changes to the scope of accreditation* form available from the NATA website.

Non-compliance with the accreditation criteria

Where significant non-conformities result in the accreditation status of any site being reviewed (e.g. suspended in part or full), this may affect the accreditation status of other sites or the facility's accreditation status in its entirety. Depending on the significance of the non-conformities, NATA may perform additional assessments at other sites to determine the extent of the issue/s. Such additional assessments will be chargeable.

Refer to the *NATA Procedures for accreditation* for further information regarding non-compliance with the accreditation criteria.

Where suspension does occur, NATA may adjust the assessment program for the accreditation cycle including the need to perform additional assessments.

Applying for multi-site accreditation

A facility wishing to apply for one accreditation covering multiple sites should contact NATA to discuss their request.

A facility currently holding separate accreditation for each of its sites may also convert these into one accreditation by contacting NATA.

The relevant application form will be provided to the facility and will need to be completed following discussion with NATA.

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

NATA Publications

Application for changes to the scope of accreditation

General Accreditation Criteria: Responsibilities of Authorised Representatives

General Accreditation Criteria: Proficiency Testing Policy

NATA Fee Schedules

NATA Procedures for accreditation

NATA Rules

Amendment table

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

Section or Clause	Amendment
Whole document	This is a new policy replacing the previous <i>General Accreditation Criteria: Corporate accreditation - accreditation of multiple site facilities and/or facilities accredited in multiple programs</i> .