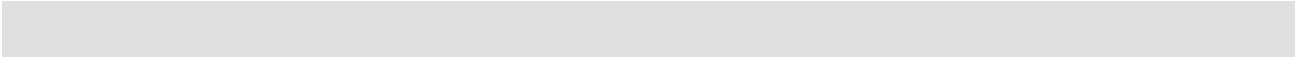




## **Policy Circular 42 — August 2016**

**Issued:** February 2013 **Amended and reissued:** July 2013, October 2013, November 2014, April 2016, August 2016

### **Accreditation of new branch sites**



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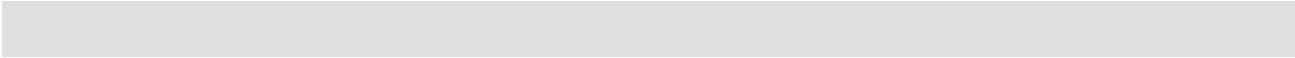
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# Accreditation of new branch sites

## 1. Introduction

It is recognised that a NATA accredited facility (referred to hereafter as the ‘base’ site) may establish a permanent branch (or satellite) site located away from the accredited base site and require accreditation for this site at short notice to service the needs of its customers.

This policy details the requirements to allow the base site to claim accreditation for the activities (in whole or in part) conducted by the branch site, prior to the latter site gaining accreditation in its own right.

This policy is applicable to both single site and corporate facilities (refer also to NATA Policy Circular 1).

To be considered for this policy, the base site must have a sound accreditation history with NATA. Facilities, at which significant non-conformances have been found at reassessments and/or surveillance visits or with a history of not providing timely close-out of non-conformances, will not be considered.

This policy does not apply to the following:

- where there is a field / program specific provision for the establishment of sites which are short-term or project-specific sites (further information is available in the relevant field / program Application Documents).
- Organisations that are recognised as compliant with the OECD Principles of GLP undertaking activities at sites located away from the main facilities;
- field work or activities performed at a client’s premises where there is not an ongoing or permanent testing facility to which the Branch Site application pertains;

**Note:** Field work, or testing at client’s premises, may be delivered from an established Branch Site wherever permitted in the applicable accreditation criteria

- medical imaging facilities (including DIAS);
- calibration facilities;
- testing performed for Department of Agriculture and Water Resources purposes;
- where other regulatory requirements are applicable, for example, pathology facilities seeking Medicare Benefit payments.

**Note:** The facility should ensure regulatory requirements do not prevent claiming of accreditation of its applicant branch site under the accreditation of the base site.

In addition to this policy, the following will continue to apply:

- for Sleep Disorders Services, Annex A of the *NATA ASA Accreditation Application Document* regarding branch and satellite services;
- for Construction Materials Testing, Appendix D for the *Construction Materials Testing ISO/IEC 17025 Application Document* regarding annex facilities.

As a signatory to the ILAC and APLAC Mutual Recognition Agreements (MRA), NATA is obligated to encourage facilities seeking accreditation in other economies (than Australia) to do so with the local Accreditation Body (AB) of those economies in the first instance. Accordingly, this policy will not generally be applicable to the establishment of branch sites in other economies.

Further advice can be provided by contacting your Client Coordinator on the application of this policy in relation to the facility’s particular circumstances.

## 2. Specific requirements relating to a new branch site and how to apply for accreditation

### 2.1 Applying for accreditation of a branch site

The Authorised Representative of the base site is encouraged to hold discussion with his/her NATA Client Coordinator prior to lodging a formal written request for the accreditation of a new branch site. This discussion will help determine the applicability of this policy.

Should this policy be applicable, the Authorised Representative must submit a written request to the Client Coordinator together with supporting documentation demonstrating compliance with the criteria. The documentation provided will be reviewed and the Authorised Representative advised if further information is required. This review is a chargeable activity in accordance with NATA's current Fee Schedule available from our website.

Once NATA has determined the criteria have been satisfied, the Authorised Representative will be advised and requested to complete the relevant application form. Upon receipt of the completed form and payment of the application fee (in accordance with the current Fee Schedule), formal notification that the activities offered by the branch site are covered by the accreditation of the base site will be provided along with the updated Scope of Accreditation of the base site.

Accreditation for the activities performed by the branch site can only be claimed under the Scope of Accreditation of the base site once written notification from NATA is received.

### 2.2 Criteria

All of the following must be satisfied. Where relevant records demonstrating compliance with the following will be reviewed during the initial assessment:

1. The base site must have a sound accreditation history with NATA. If the base site forms part of a corporate accreditation, then the entire facility must have a sound accreditation history;
2. The base site must have held accreditation with NATA for at least one full assessment cycle (i.e. three or four years depending on the field or program of accreditation);
3. The base site must ensure that there are no regulatory or client requirements which would preclude it from applying for branch site accreditation;
4. The scope of activities performed by the branch site must be the same as, or a subset of, the activities conducted at the base site as described in the base site's Scope of Accreditation. Activities performed at the branch site that are not covered by the Scope of Accreditation of the base site cannot be considered under this policy;
5. The branch site must comply with all relevant NATA Accreditation Criteria;
6. The base site's management system must be implemented at the branch site and at least one internal audit of the branch site must have been conducted;
7. Supervision of the branch site must be provided by the base site. Records of supervision must be maintained;

**Note:** Electronic access between the base and branch sites' LIMS (Laboratory Information Management System), for example, may facilitate this.

8. The competence of staff employed at the branch site must be established by the base site. Such staff must also be authorised to undertake all relevant specific activities;
9. Test methods (or related activities), techniques, key analytical equipment and quality control processes (or other measures to monitor the quality of results) at the branch site must be the same type as those employed at the base site and must be suitably verified before use;
10. At least one proficiency testing (PT) activity for each major area of test, measurement or related activity to be covered by the Scope of Accreditation at the branch site must have been performed and results available, together with a PT participation plan in accordance with *Policy Circular 2* and any associated field or program specific proficiency testing policy. Where formal PT programs are not available, other means of assuring the quality and performance of the activities must be investigated;
11. The facility must be able to identify the site at which activities were performed (i.e. the base site or branch site);
12. Reports may only be issued by the base site on activities performed by the branch site. These reports must include the name of the base site in which the accreditation is held and also the location of the branch site.

### 2.3 Initial assessment of branch sites and maintaining the base sites accreditation to establish branch sites

The branch site must undergo an initial assessment within six months of the abovementioned notification and it is expected that accreditation will be achieved within six months of the assessment. Failure on behalf of the facility to meet these timeframes will result in NATA no longer recognising that the branch site is covered by the accreditation of the base site.

**Note:** Where removal of recognition has occurred, the branch site’s application will remain current for accreditation in its own right for the 24 months specified on the application form. In such a case, the application will be treated as per NATA’s normal procedures for the accreditation of a single stand-alone site or a site forming part of a corporate accreditation. Refer to the *NATA procedures for accreditation* available from the NATA website for further information.

Records relating to activities conducted at the branch site whilst it was operational must be available for review at either the initial assessment of the branch site or the next scheduled visit of the base site (where an initial assessment of the branch site did not proceed for whatever reason). Failure to have these records available for review or where significant non-conformities are found may result in some or all of the reports issued containing work performed at the branch site to be withdrawn and affected clients required to be advised. Further, the eligibility of the base site to establish branch sites may be suspended.

#### AMENDMENTS

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

Section	Amendment
1	Third dot point – further clarification of circumstances under which field testing or testing from client premises may be carried out from a Branch Site