Application for changes to the scope of accreditation

Purpose

This form is to be used by accredited facilities wishing to make changes to their existing scope of accreditation.

Changes include:

- additions (including updates e.g. changes to existing methods; calibration and measurement capability (CMC);
- deletions;
- editorial.

This form is to be completed and submitted, together with the supporting documentation, using the NATA Portal or alternatively to your NATA Client Coordinator.

This form does not apply to the following and any such requests should be discussed with your NATA Client Coordinator:

- conversion to corporate accreditation;
- application for a new site or in a new Program;
- application for a branch site;
- application to establish Annexes for Geotechnical and Civil Construction Materials Testing;
- changes to your facility's details (including the name in which accreditation is held, contact details, ABN/ACN and/or Authorised Representative);
- request to withdraw accreditation for a given site.

Facility and site details

Facility accreditation number:	
Facility name:	
Site number:	
Site name:	

Authorised Representative's declaration

I declare to the best of my knowledge that the information provided in support of this application for changes to my facility's scope of accreditation is correct.

Signature:	
Name:	
Date:	

General information

Once a facility has gained accreditation, NATA will accept at any time an application for a change to its scope of accreditation.

A request for an addition (and in some cases a deletion) to the scope of accreditation may require an assessment activity (e.g. on-site, desk-top review of documentation or by remote means). NATA will confirm the type of assessment activity once this application form is completed and the supporting documentation provided. On occasion, additional documentation may be requested.

Once the request has been processed and the accreditation status confirmed, NATA will formally advise the facility and its updated scope of accreditation will be published on the NATA website.

NATA Portal

The Portal is used to exchange accreditation documentation and provides users with notifications of news and publications in their areas of interest. A profile is automatically created for the Authorised Representative.

As an interface between the facility and NATA the Portal allows:

- safe and secure submission of documents;
- the exchange of large sized files outside email;
- notifications to the receiving party when Site or Job related documents are uploaded to the Portal;
- access to relevant information relating to your accreditation such as Facility, Site and Job details;
- access to targeted communications, information and publications including email and dashboard notifications of any new or modified NATA publication available via the Portal.

By accessing or using the Portal, you agree to the *Portal Terms and Conditions* which can be accessed via the NATA Portal home page at the NATA website www.nata.com.au.

In addition to the Authorised Representative, other staff may be granted Portal access. To request this access visit the NATA website > NATA Portal and submit the completed *NATA Portal Request* form to portalsupport@nata.com.au.

Fees

Charges will not be raised for deletions or editorial changes to the scope of accreditation where the effort required to make such changes is less than 3 hours.

Assessments conducted for additions to the scope of accreditation are charged in accordance with NATA's *Fee Schedule* current at the time. Prior to the assessment, NATA will provide a cost estimate to the facility.

Requests for additions may be accommodated at the same time as a scheduled routine reassessment or surveillance visit, however, only where review of the additional activities does not compromise the purpose of the reassessment or surveillance visit. Where additional effort is required to accommodate the request, fees will be charged in accordance with NATA's *Fee Schedule* current at the time.

Confidentiality

All information provided to NATA will be considered as a privileged communication, in accordance with NATA Rule R.39.

Privacy

NATA respects and upholds the rights of individuals to privacy protection under the Australian Privacy Principles contained in the Privacy Amendment (Enhancing Privacy Protection) Act 2012. A copy of NATA's Privacy Policy can be obtained from the NATA website (www.nata.com.au) or by contacting one of the NATA offices. This policy describes how NATA manages the personal information we hold.

Type of request for changes to the scope of accreditation

More than one request type may apply.

Request Type	Instruction
Additions (including changes to existing methods; calibration and measurement capability (CMC))	Complete the tables on pages 6 and 8 as necessary and also provide the supporting documentation as indicated on pages 9 to 16.
Deletions	Attach an annotated copy of your current scope of accreditation (available from the NATA website) indicating the items to be deleted (withdrawn). Also indicate the reason(s) for the requested deletion(s) either below or on the annotated scope of accreditation. **Notes:** You should consider the impact of any deletions on the remaining activities covered by your scope of accreditation. For example, remaining activities may be dependent on the requested deletion(s). Based on the reason(s) for the deletion(s), an assessment activity may be necessary before the items can be removed. <u>Reasons for deletion(s)</u>
Editorials	Attach an annotated copy of your current scope of accreditation detailing the editorial amendments required. **Note:** Editorial amendments pertain to correcting errors (e.g. typographical).

Additions to the scope of accreditation

Complete the table below to indicate the **additions** requested (if insufficient room, please photocopy the page).

Activity	**Service** Refer to Note 1 & 2	**Material / Item / Product**	**Determination**	**Technique**	**Procedure** Refer to Note 3, 4, 5 & 6	**Regulatory requirements** Refer to Note 7 & 8
Example Environment	Analysis for elements	Ground waters; Bore waters;	Lead	Flame/furnace/AAS ICP/AES	APHA (Method 304); In-house (Method 6A)	

Note 1: Refer to the *Specific Accreditation Guidance: Scope of accreditation - Service descriptors* documents in the relevant NATA Accreditation Criteria (NAC) packages available from the NATA website. These documents describe the activities currently able to be accredited. Where an activity to be accredited is not described in one of these documents, provide as much information as possible in the table above.

Note 2: For Animal Health facilities only:

- list the generic animal grouping(s) for any new "Services" for which the method has been validated: companion animals; production animals; production avian species; laboratory animals; zoo animals; wildlife; aquatic animals; equine species; avian species; bees/apiculture.
- if the laboratory has only validated the method for specific species within an animal group please also indicate these, for example, canine, feline for companion animals, caprine for production animals, etc.

Note 3: For Calibration facilities only*:*

In the table below or on a separate sheet, provide the ranges and measurement uncertainties (MU) estimates for each measurand, including for calibrations performed on-site at the customer's premises;

Note: Where activities are performed at both the laboratory and customer premises, the scope of accreditation will identify the calibration and measurement capability at each location.

Note 4: For Proficiency Testing Scheme Provider (PTSP) facilities only*:*

In the table below or on a separate sheet, provide the ranges and uncertainties for calibration based schemes.

Note 5: For Reference Materials Producer (RMP) facilities only*:*

In the table below or on a separate sheet, provide the ranges and uncertainties for all certified reference materials.

Note 6: For OECD Principles of Good Laboratory Practice (GLP) facilities only*:*

List relevant OECD Test Guideline(s), CITAC method(s) etc.

Note 7: If any of the additions are subject to, or used by your customers to meet, regulatory requirements (e.g. test products covered by Consumer Safety Law, WHS regulations, trade measurement, food regulation, etc) indicate the relevant regulation (including regulatory body and/or regulatory ruling), standard or other applicable document as appropriate. For example:

- testing of children's nightwear for flammability in accordance with AS/NZS 1249;
- testing of trolley jacks in accordance with Consumer Protection Notice No. 10:2008 (ACCC).

Note 8: For testing on human samples:

Any testing on human samples may be subject to the Therapeutic Goods Administration (TGA) In-Vitro Diagnostic (IVD) Medical Device Framework and assessment against the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the Development and Use of In-house In-Vitro Diagnostic Medical Devices*. It is the facility's responsibility to confirm this with the TGA. If the testing is subject to the TGA Framework, indicate the Class of IVD and whether the test is commercial or in-house.

Complete the following table where indicated in the notes on the previous page for **Calibration** facilities, **Proficiency Testing Scheme Providers** or **Reference Material Producers**

Capability Ranges and measurement uncertainties (MU) (**Note:** Ensure that the ranges and MU included below are linked to the relevant addition included in the table on page 6)
Example 0.03% of reading from 10 µA to 15 A 0.25% of reading from 15 A to 20 A 0.50% of reading from 20 A to 200 A 1% of reading up to 1000 A using multi-turn coil

Documentation to provide in support of the request for addition(s) to the scope of accreditation

The information and checklists on the following pages provide instructions and detail the documentation necessary to be submitted in support of your request for the addition(s) to your scope of accreditation.

Complete only the relevant checklists as they apply to your request. Ensure that you tick the relevant check boxes and provide the documentation in an organised manner to facilitate its review and to minimise the effort required.

Notes: Incomplete documentation provided will delay your request for addition(s) to your scope of accreditation.

Documentation provided in an unorganised manner may also be returned and you requested to resubmit it in a manner to facilitate its review.

Good Laboratory Practice (GLP) only

Only complete the table on page 6 (the remainder of the checklists below do not need to be completed) and submit this form to progress your request.

1) All Accreditation Programs

Item	Documentation required	Check
Staff	List of all relevant staff, including: • qualifications (as necessary); • training, competency and authorisation sign-off records.	☐

2) Testing (including Human Pathology), Calibration and Inspection

(Also for any Proficiency Testing Scheme Providers and/or Reference Material Producers conducting tests, measurements or related activities)

Item	Documentation required	Check
Measurement, calibration or inspection procedures	For standard methods or other recognised specifications, copies of these and verification data (including summaries and MU estimations) must be provided.	☐
	For non-standard and in-house developed methods, copies of the test method(s) and validation data (including summaries and MU estimations) must be provided.	☐
Equipment (includes but is not limited to: measuring instruments, auxiliary apparatus, software, measurement standards, reference materials, reference data, reagents and consumables)	List of all equipment required including: • name / make; • measurement / working range; • other relevant information; • maintenance records; • calibration / check records.	☐
Proficiency testing (PT)	Evidence of enrolment and participation in PT, interlaboratory comparison or measurement audit as per the NATA *General Accreditation Criteria, Proficiency Testing Policy*.	☐
Reports and/or certificates	Sample copy of a completed report or certificate together with the supporting records (e.g. completed worksheet).	☐

2.1) Calibration - additional information required

Item	Documentation required	Check
Measurement uncertainty (MU) estimates	For each calibration service, the supporting data and calculations for the least uncertainty estimates for the ranges and MU requested (as indicated in the table on page 8).	☐

2.2) Human Pathology - additional information required

Certain requests for additions to the scope of accreditation do not require a "real time" assessment activity before the scope of accreditation is granted. Such requests do not include the introduction of new methods / procedures / analysers / technologies but instead may include, but not limited to the following:

- the addition of new "Determinations" to an existing "Service";
- the addition of new "Products" to an existing "Service" where no specific considerations are applicable;
- the addition of a new "Service" using a "Technique" already covered by another "Service" and where no specific considerations are applicable.

Note: Where an addition changes a commercial IVD to an in-house IVD (e.g. the IVD is only intended for use for a given product), then the facility will be required to perform a validation (i.e. establish the parameters for the new product for which the commercial IVD was not intended).

The above only applies where the IVD Class is low risk (i.e. Class 1 or 2), regardless whether commercially supplied or in-house. Class 3 In-house IVDs for infectious diseases and Class 4 IVDs always require a "real time" assessment activity. Other Class 3 IVDs will be considered on a case by case basis.

If unsure whether the additions requested will require a "real time" assessment, contact your NATA Client Coordinator. The table on page 6 is still required to be completed and this application form submitted in order to process your request.

The records indicated in the table on this page must be maintained but do not need to be submitted with this application form for additions not requiring a "real time" assessment.

Item	Check
Table on page 6 has been completed	☐
Records of the following are available:	
• training and competency sign-off	☐
• verification and/or validation data (including summaries)	☐
• equipment calibration, check and/or maintenance	☐
• enrolment and participation in proficiency testing	☐

The records indicated in the table above may be reviewed at the next assessment. Failure to have these records available, or where significant non-conformities are found in relation to the additions made to the scope of accreditation, may result in some or all of the reports issued to be withdrawn and affected customers required to be advised. Further, the eligibility of the facility to request additions without "real time" assessment will be reconsidered.

3) Medical Imaging

Item	Documentation required	Check
Procedures	Documented procedures for the imaging services to be performed	☐
Equipment	List of all equipment required including: • modality; • manufacturer / model; • installation certificates; • Certificate of Compliance (where required) • maintenance records; • calibration / check records.	☐
Quality Assurance	Evidence of enrolment and participation in the relevant Quality Assurance Programs as per the NATA *General Accreditation Criteria, Proficiency Testing Policy*.	☐
Reports	Sample copy of completed reports together with the supporting records (e.g. patient referral, completed worksheet).	☐

4) Sleep Disorders Services

Item	Documentation required	Check
Methods	For standard methods or other recognised specifications, copies of these and verification data (including summaries) must be provided.	☐
	For non-standard and in-house developed methods, copies of the test method(s) and validation data (including) must be provided.	☐
Equipment (includes but is not limited to: measuring instruments, auxiliary equipment, software, measurement standards, reference materials, reference data)	List of all equipment required including: • manufacturer / model; • maintenance records; • calibration / check records.	☐
Proficiency testing (PT)	Evidence of enrolment and participation in a PT programme appropriate to the sleep studies performed as per the NATA *General Accreditation Criteria, Proficiency Testing Policy*.	☐
Reports	Sample copy of a completed report together with the supporting records (e.g. patient referral, completed worksheet).	☐

5) Reference Materials Producers

Item	Documentation required	Check
Production planning	Provide relevant documentation for each reference material.	☐
Homogeneity and stability	Provide relevant documentation for each reference material.	☐
Assignment of property values and characterisation	Provide relevant documentation for each reference material.	☐
Metrological traceability	For each certified reference material, the metrological traceability data.	☐
Measurement uncertainty (MU) estimates	For each certified reference material, the supporting data and calculations for the least uncertainty estimates for the ranges (as indicated in the table on page 8).	☐
Reference material documents and labels	Sample copies of documents and labels.	☐

Based on the additions requested, NATA will advise if any additional documentation is required prior to processing your request.

On the following page, indicate in the table, or on a separate sheet, any activities which are subcontracted:

Note that ISO/IEC 17034:2016 does not allow the subcontracting of the following:

- the production planning;
- the selection of subcontractors;
- the assignment of property values and their uncertainties;
- the authorisation of property values and their uncertainties;
- the authorisation of reference material documents.

Activity (e.g. measurement procedures)	Subcontractor	Subcontractor accreditation status and/or competency determination

6) Proficiency Testing Scheme Providers

Item	Documentation required	Check
Proficiency testing (PT) scheme plan	Provide a copy of the documented plan, including any records from advisory group(s).	☐
Homogeneity and stability	Provide relevant documentation for each scheme.	☐
Assignment of property values or characteristics for the measurand(s)	Provide relevant documentation for each scheme.	☐
Measurement uncertainty (MU) estimates	For any calibration schemes, the supporting data and calculations for the least uncertainty estimates (as indicated in the table on page 8).	☐
Evaluation of participants' performance and reporting	Provide the documented procedure used to evaluate performance and a sample report (e.g. from a pilot program).	☐

Based on the additions requested, NATA will advise of any additional documentation required prior to processing your request.

On the following page, indicate in the table, or on a separate sheet, any activities which are subcontracted:

Note that ISO/IEC 17043:2010 does not allow the subcontracting of the following:

- the planning of the proficiency test scheme;
- the evaluation of performance;
- the authorisation of the final report.

Activity (e.g. assessment of homogeneity)	Subcontractor	Subcontractor accreditation status and/or competency determination