General Accreditation Criteria

Transition Policy for the implementation of ISO/IEC 17025:2017

April 2018

Transition Policy for the implementation of ISO/IEC 17025:2017

1. Introduction

This policy is effective from 1 August 2018 and describes changes to the NATA Accreditation Criteria (NAR) applicable to all applicant and accredited calibration and testing facilities.

2. Background

In November 2017, ISO/IEC 17025 was republished following a three year revision process. The standard was adopted in full as an Australian Standard in April 2018 and published as AS ISO/IEC 17025:2018.

As part of NATA's obligations as a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, NATA is required to implement ISO/IEC 17025:2017 as per the resolution below:

> **ILAC Resolution GA 20.15**
>
> *As the revised version of ISO/IEC 17025 is scheduled for publication in 2017, the General Assembly endorses the recommendation of the AIC that a transition period of 3 years from the date of publication be adopted. At the end of the transition period, accreditation of a laboratory to ISO/IEC 17025:2005 will not be recognised under the ILAC Arrangement.*

3. Assessment of facilities to ISO/IEC 17025:2017

As described in the *NATA Procedures for Accreditation*, facilities must obtain a copy of the standard for which accreditation is held or being sought. Accordingly, calibration and testing facilities must purchase a copy of the revised standard (either from a supplier of ISO or Australian standards).

3.1 Applicant facilities

Applicant facilities will be assessed against the new standard if they have not yet had an assessment conducted by NATA prior to 1 August 2018.

3.2 Accredited facilities

Assessment to the new standard can occur either:

- at the time of the next scheduled NATA visit after 1 August 2018 (refer to 3.2.1); or
- on request of the facility as a chargeable variation to accreditation (refer to 3.2.2).

The changes between the ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are such that some assessment will be necessary to convert accreditation to the new standard.

To assist facilities, a *Gap Analysis* between the two editions of the standard has been prepared, identifying the new and amended requirements detailed in ISO/IEC 17025:2017. This document can be downloaded from the NATA website at www.nata.com.au.

An additional *ISO/IEC 17025:2017 Implementation Checklist* has been prepared which identifies the specific changes accredited facilities need to adopt to satisfy the requirements of the new standard. This checklist is appended to this policy.

3.2.1 Assessment against the new standard at the next scheduled NATA visit

From 1 August 2018, accredited facilities will be assessed to the new standard at the time of their next routine surveillance or reassessment visit.

Facilities will be required to complete the *ISO/IEC 17025 Implementation Checklist* and to supply evidence (policies, procedures and/or records as necessary) demonstrating compliance with the new standard, as part of the routine preliminary arrangements prior to the on-site visit.

Any areas of non-compliance identified at the scheduled on-site visit will be detailed in the assessment report as conditions as per the current NATA process. Facilities will need to respond to these in the usual manner prior to accreditation being continued and granted to the new standard.

The scope of accreditation will be updated to reference the new standard following confirmation of compliance, or where conditions have been raised, following a satisfactory response to these.

3.2.2 Assessment against the new standard on request of the facility

Facilities may seek accreditation against the new standard prior to a scheduled NATA visit by requesting a chargeable variation to the scope of accreditation. In order for this request to be considered, the facility must formally advise NATA in writing and submit supporting evidence to demonstrate compliance to the new standard. As per 3.2.1 above, NATA will request information to be provided.

Following review of the supporting information provided, NATA may request further evidence be provided, or may determine that an on-site review is necessary, should compliance against the new standard not be confirmed through desk-top review.

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Variation visits are chargeable activities in accordance with NATA's Fee Schedule current at the time.

4. Further information

Further information can be obtained by contacting your NATA Client Coordinator.

ISO/IEC 17025:2017 Implementation Checklist

Where highlighted (bold) text has been included for clauses identified as a “Major Change”, it emphasizes the key change(s) of the requirement (compared to the previous version of the standard).

ISO/IEC 17025:2017 Clause No.	**Emphasis of Change**	**Summary of text/extract from ISO/IEC 17025:2017**	**Action taken with reference to supporting evidence (as necessary)** **(Attach supporting evidence separately and include reference to the clause number)**
4.1.4	New	On an ongoing basis, the laboratory must identify risks to impartiality, including those arising from its activities or relationships or the relationships of its personnel.	
4.1.5	New	The laboratory must be able to demonstrate how it minimises or eliminates the risks it identifies.	

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4.2.1	Major	The laboratory is responsible**, through legally enforceable commitments**, for the management of information obtained or created during its activities. **If the laboratory intends to place information in the public domain, it must inform the customer in advance. Unless agreed between the laboratory and customer or the customer makes the information publicly available, all other information is to be regarded proprietary and confidential.**	
4.2.2	New	When the laboratory is required by law or authorised by contractual arrangements to release otherwise confidential information, the customer or individual is to be notified (unless the notification is prohibited by law).	
4.2.3	New	Information about the customer, obtained from other sources, is to be regarded as confidential. The source is to remain confidential to the customer unless otherwise agreed to by the source.	

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4.2.4	New	Personnel must keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.	
5.3	New	The laboratory needs to define and document the range of activities which it claims conformity to the Standard. The range of activities cannot include externally provided laboratory activities on an ongoing basis.	
6.2.5	Major	Procedures and records need to be maintained for personnel covering: a) **determination of competence requirements**; b) to e) **selection**, training, supervision and authorisation; and a) monitoring of competence.	

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6.2.6	Major	Personnel must be authorised to perform specific activities including: a) **develop, modify, verify and validate methods**; b) **analysis of results, statements of conformity** and opinions / interpretations; c) report, review and authorise results.	
6.4.7	Major	A calibration program shall be established, reviewed and adjusted as necessary, to ensure confidence in the status of calibrations.	

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6.6.2	Major	A procedure and records are required for: a) defining, reviewing and approving externally provided products and services; b) **the criteria for evaluation, selection, monitoring and re-evaluation of external providers**; c) ensuring, prior to use or supply to customer, externally provided products and services conform to the laboratory's established requirements or the Standard; d) **actions arising from evaluations, monitoring or re-evaluations of external providers**.	
6.6.3	New	Communication to external providers is required for: a) the products and services to be provided; b) acceptance criteria; c) competence of personnel; d) activities to be performed by the laboratory or laboratory customers at the external provider's premises.	

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7.1.3	New	The standard or specification and the decision rule must be clearly defined when the customer requests a statement of conformity to a specification or standard for a test or calibration. The decision rule must be communicated to and agreed with the customer, unless inherent in the requested specification of standard.	
7.4.3	Major	Upon receipt of the item, abnormalities or deviations from specified conditions must be recorded. If there is doubt as to the suitability of the item or when the item does not conform to the description provided, the customer must be consulted before proceeding and record the results of the consultation. Following, if the item is to proceed to testing or calibration, **the laboratory must include a disclaimer in the report indicating that results may be compromised**.	

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7.8.2.2	New	The laboratory is responsible for all the information in the report, except that provided by the customer. Data provided by the customer is to be clearly identified. Additionally, a disclaimer must be included when information is supplied by the customer which can affect the validity of the results. When the laboratory is not responsible for sampling, e.g. the sample has been supplied by the customer, it must state in the report that the results apply to the sample as received.	
7.8.4.1	New (c)	In addition to 7.8.2, calibration certificates must include: a) a statement to indicate how the measurements are metrologically traceable;	
7.8.4.2	New	When the laboratory is responsible for sampling, calibration certificates must meet the requirements in 7.8.5, where necessary for the measurement results.	

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7.8.5	New f)	When the laboratory is responsible for sampling, in addition to 7.8.2 reports must also include the following where necessary for the interpretation of results: f) information required to evaluate MU for subsequent testing or calibration.	
7.8.6.1	New	When a statement of conformity to a specification or standard is provided, the laboratory must document the decision rule it employs, taking into account the level of risk associated with the decision rule, and apply the decision rule.	
7.8.6.2	Major	The laboratory must report on the statement of conformity: a) the results to which the statement of conformity applies; b) which specifications, standards or parts thereof that are met or not met; c) the decision rule applied (unless inherent in the requested specification or standard).	

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7.8.8.1	New	When an issued report requires changing, amendment, or reissuing, any change of information must be clearly identified. Where appropriate, the reason for the change is to be included in the report.	
7.9.2	New	A description of the complaint handling process must be available to any interested party on request. Upon receiving a complaint, the laboratory must determine if it relates to the laboratory activities it is responsible for and if so, needs to deal with the complaint. The laboratory is responsible for all decisions in handling the complaint.	
7.9.3	New	The complaints handling process must include: a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; b) tracking and recording complaints, including actions taken to resolve them; c) ensuring that any appropriate action is taken.	

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7.9.4	New	The laboratory receiving the complaint is responsible for gathering and verifying all information to validate the complaint.	
7.9.5	New	Whenever possible, the laboratory must acknowledge receipt of the complaint and provide the complainant progress reports and the outcome.	
7.9.6	New	The outcomes are to be communicated to the complainant by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.	

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7.9.7	New	Whenever possible, the laboratory is to give formal notice of the end of the complaint handling to the complainant.	
7.10.2	New	Records must be retained of nonconforming work and actions as specified in 7.10.1 b) to f).	
7.11.1	New	The laboratory must have access to the data and information needed to perform its activities.	

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7.11.4	New	If the LIMS is maintained off-site or by an external provider, the laboratory must ensure that the provider complies with all applicable requirements of the Standard.	
8.1.3	New	Only applicable if **Option B** is adopted. A laboratory that maintains a management system, in accordance with the requirements of ISO 9001 which supports and demonstrates the consistent fulfilment of clauses 4 to 7, fulfils the intent of the management system requirements of 8.2 to 8.9.	
8.5.1	New	Only applicable if **Option A** is adopted. Risks and opportunities associated with the laboratory activities must be considered in order to: • give assurance the management system achieve its intended results; • enhance opportunities to achieve the purpose and objectives of the laboratory; • prevent or reduce impacts and potential failures in the laboratory activities; • achieve improvement.	

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8.5.2	New	Only applicable if **Option A** is adopted. The laboratory must plan; a) actions to address risks and opportunities; b) how to integrate and implement the actions into its management system in addition to evaluating the effectiveness of the actions.	
8.5.3	New	Only applicable if **Option A** is adopted. Actions taken to address risks and opportunities need to be proportional to the potential impact on the validity of the laboratory results.	
8.9.2	New	Only applicable if **Option A** is adopted. Inputs to the management review are to be recorded and also include information related to: a) changes in relevant internal and external issues; b) fulfilment of objectives; d) status of actions from previous k) management reviews; l) results of risk identification.	