Specific Accreditation Criteria
Reference Material Producers

Implementation of ISO 17034:2016

January 2018

Implementation of ISO 17034:2016

1. Introduction

This policy is effective from 1 September 2017 and details changes to the NATA Accreditation Criteria (NAR) applicable to all applicant and accredited Reference Material Producers (RMPs).

2. Background

The standard currently forming part of the accreditation criteria in NATA's RMP program is *ISO Guide 34:2009 General requirements for the competence of reference material producers*. On 1 November 2016, this guide was republished as a standard as *ISO 17034:2016 General requirements for the competence of reference material producers*. It is anticipated that Standards Australia will adopt the document as an identical national standard.

As part of NATA's obligations as a signatory to the Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangements for RMP, NATA is required to implement ISO 17034:2016 as per the ILAC resolution below.

> **ILAC Resolution GA 20.14**
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> *As a result of the publication of ISO 17034 in November 2016, replacing ISO Guide 34:2009, the General Assembly endorses the recommendation from the AIC (Accreditation Committee), that accreditation of reference material producers be conducted in accordance with ISO 17034 and that an implementation period of 3 years be adopted.*

3. Assessment of facilities to ISO 17034:2016

3.1 Applicant facilities

Applicant facilities that have not yet had an assessment conducted by NATA from the date of publication of this policy shall be assessed against the new standard.

3.2 Accredited facilities

Facilities are expected to obtain a copy of the revised standard (either from a supplier of ISO standards or the national adoption when available) and to comply with the new version of the standard from 1 September 2017.

Assessment to the new standard can occur either:

- at the time of the next scheduled NATA visit after 1 September 2017 (refer to 3.2.1); or
- upon request of the facility as a variation to accreditation (refer to 3.2.2).

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

The changes between ISO Guide 34:2009 and ISO 17034:2016 are such that some assessment will be necessary to convert accreditation to the new standard.

To assist facilities in identifying the changes between ISO Guide 34 and ISO 17034:2016, a *Gap Analysis* checklist has been developed and included in the RMP NATA

Accreditation Requirements (NAR) package available from the NATA website. The RMP Standard Application Document has also been updated and included in the NAR.

An additional *ISO 17034:2016 Implementation Checklist* is attached to the end of this policy which identifies the specific changes RMPs already accredited to ISO Guide 34 need to adopt to satisfy the requirements of the new standard.

3.2.1 Assessment of RMPs who are already accredited against ISO Guide 34 against the new standard at the next scheduled NATA visit

Facilities will be required to supply information demonstrating compliance with the new standard as part of the routine preliminary arrangements prior to the on-site visit. This information will include as a minimum:

- the completed *ISO 17034:2016 Implementation Checklist* (appended to the end of this policy) with any evidence necessary to demonstrate that the new and amended requirements have been satisfied;
- the facility's *Quality Manual* (however named) and associated documentation.

Any areas of non-compliance identified during the on-site visit will be detailed in the assessment report as conditions for accreditation 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.

A new certificate of accreditation will also be issued at this time with reference to ISO/IEC 17034:2016.

3.2.2 Assessment of RMPs who are already accredited against ISO Guide 34 against the new standard upon request

Already accredited facilities may seek accreditation against the new standard prior to a scheduled NATA visit by requesting a chargeable unscheduled variation assessment. In order for this request to be considered, the facility must formally advise NATA in writing. As per 3.2.1 above, NATA will request information to be provided.

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

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.

A new certificate of accreditation will also be issued at this time with reference to ISO/IEC 17034:2016.

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

Further information

Further information can be obtained by contacting Paul McMullen, Sector Manager, Calibration, in our Melbourne office by telephone on (03) 92748200 or email to paul.mcmullen@nata.com.au

ISO 17034:2016 Implementation Checklist

ISO 17034:2016 Clause No.	Amended / New	Summary of text / extract from ISO 17034:2016	Action taken with supporting evidence (as necessary)
4.2.1	New	The RMP shall be structured and managed so as to safeguard impartiality.	
4.2.2	New	The RMP shall b) identify risks to its impartiality; c) be able to demonstrate, if a risk to impartiality is identified, how the risk is managed; d) top management commitment to impartiality.	
4.3.1	Minor change	The RMP shall be responsible for and shall treat in an appropriate manner all information obtained, including confidential information.	
4.3.2	New	When the RMP is required by law or authorized by contractual arrangements to release confidential information, the individual or the body concerned shall be notified.	
5.3	New	The RMP shall: b) define the parts of the organization covered by the management system; g) shall have adequate provision to cover liabilities.	

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5.4	New	The RMP shall: a) ensure internal and external communication mechanisms are established; b) communications takes place regarding the effectiveness of the management system; c) ensure staff are advised of the importance of meeting customer and other requirements.	
6.2.1	Major change	Where an RMP uses subcontractors, it shall have procedures to ensure the subcontractor's experience and technical competence are sufficient and comply with the relevant clauses of ISO 17034 and other appropriate standards.	
6.2.8	New	When working with subcontractors, the RMP shall have personnel with sufficient knowledge of the subcontractor's task in order to evaluate the subcontractor's activity.	
6.3.1	Minor change	The RMP shall have procedures in place for the selection of equipment, services and supplies.	
6.4.4	New	Access to areas shall be controlled.	

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7.2.3	New + major changes	The RMP shall address during the planning stage: b) verification of the identity of the material; h) specification of acceptance criteria for homogeneity; i) specification of acceptance criteria for stability and monitoring of this, including sampling.	
7.3	Major change	The RMP shall verify the implementation of the production plan and that deviations from the plan are documented and approved.	
7.4.5	Major change	The RMP shall define procedures for the transport of RMs to the customer.	
7.5.2	New	Equipment used in material processing shall be operated in accordance with documented procedures.	
7.8.3	New	Statistical procedures used in monitoring, testing, calibration or value assignment of RMs shall be appropriate.	
7.9.6	New	Secondary parameters that have a significant influence on the certified value or its uncertainty shall have evidence of metrological traceability.	

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7.11.1	New	The RMP shall: c) establish any necessary advice on storage and use of the material to maintain stability; d) select a scheme for monitoring the stability of materials held in long term; f) assess the possible effects on the stability of the material and take appropriate action, where repeated sampling from an RM unit or repeated use of an entire RM unit is permitted by the instructions for use.	
7.12.1	New	Where the RMP assigns property values, characterization of the RM is required.	
7.12.2	New	The RMP shall clearly define whether a quantitative or a qualitative property will be characterized and, if quantitative, whether the measurand is operationally defined or is defined independently of any specific procedure.	

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7.12.4	Major change	The RMP shall specify the characterization study so that the properties of interest are each characterized with appropriate traceability and sufficient reliability whether or not traceability and measurement uncertainty are reported on the RM documentation. To this end, the RMP shall: a) document a measurement plan that describes the tasks to be performed and communicate this to staff responsible for measurements used in characterization; b) for certified values, demonstrate the competence of each laboratory involved by using data from each laboratory that was not obtained on the material to be characterized.	
7.12.5	New	When evaluating the characterization data, the RMP shall perform a technical evaluation of the data and documents involved in characterization to confirm adherence to the measurement plan as defined in 7.12.4, bullet a), and, in the case of deviations from the plan, assess whether the deviation necessitates exclusion of the data from characterization.	
7.13.3	New	The RMP shall take due account of technical information on test methods and equipment, including reported uncertainty information, and of any evidence of laboratory performance when assigning the property values of interest.	

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7.17.2	Major change	Procedures shall ensure: b) the actions to be taken when any non-conforming work and/or RMs are identified including root cause analysis and a system that ensures that they are effectively implemented: c) an evaluation of the significance of the non-conforming work is made and identification and implementation of correction and corrective action: h) ensure where necessary, an internal audit is conducted to verify the closure and effectiveness of the corrective actions taken.	
7.18.2	New	A description of the handling process for complaints shall be available to any interested party.	
7.18.3	New	Upon receipt of a complaint, the RMP shall confirm whether the complaint relates to activities that it is responsible for and, if so, shall deal with it.	
7.18.4	New	The RMP shall be responsible for all decisions at all levels of the handling process for complaints.	
7.18.5	New	Investigation and decision on complaints shall not result in any discriminatory actions.	

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7.18.6	New	The process for handling complaints shall include: a) a description of the process for receiving, validating, investigating and deciding what actions are to be taken; b) tracking and recording, including action taken; c) ensuring appropriate action is taken.	
7.18.7	New	The RMP receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.	
7.18.8	New	Whenever possible, the RMP shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.	
7.18.9	New	The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original RM activities in question.	
7.18.10	New	Whenever possible, the RMP shall give formal notice of the end of the complaint handling process to the complainant.	
8.1.1	New	The RMP shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B.	

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8.1.3	New This is only applicable if an RMP chooses Option B. The NATA's *ISO 17034 Standard Application* Document provides further information.	An RMP that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of this International Standard (ISO 17034), fulfils the management system clause requirements in 8.2 to 8.11.	
8.8.1	New This is only applicable if an RMP chooses Option A.	The RMP shall consider the risks and opportunities to: a) give assurance that the management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.	
8.8.2	New This is only applicable if an RMP chooses Option A.	The RMP shall take actions to: a) address these risks and opportunities; b) integrate and implement the actions into its management system processes; c) evaluate the effectiveness of these actions.	

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8.8.3	New	Actions taken to address risks and opportunities shall be proportionate to the potential impact on the quality of the RM production and service.	

Where there is insufficient space to provide your responses, please attach additional information ensuring the relevant ISO 17034 clause number(s) are referenced.