Specific Accreditation Criteria

Transition Policy for the implementation of ISO 15189:2022

Issued: March 2023

Effective: August 2023

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Purpose

This policy is effective from 1 August 2023 and describes changes to the NATA Accreditation Criteria (NAC) applicable to all applicant and accredited human pathology facilities.

Background information

In December 2022, ISO 15189 *Medical laboratories - Requirements for quality and competence* was published. This document replaces ISO 15189:2012 *Medical laboratories - Requirements for quality and competence*.

The standard is to be adopted in full as an Australian Standard in due course and published as AS ISO 15189:2023.

Accredited facilities or those seeking accreditation must obtain a copy of the revised standard directly from a supplier of ISO or Australian Standards.

The International Laboratory Accreditation Cooperation (ILAC) has mandated a three-year transition period from the date of publication of the standard. The transition date prescribed by ILAC ends in December 2025. As a signatory to the ILAC MRA, NATA is obligated to ensure transition of facilities to the new version occurs by this date. At the end of the period, accreditation of a facility to ISO 15189:2012 will no longer be recognised under the ILAC arrangement.

Assessment of facilities to ISO 15189:2022

From 1 August 2023, all assessments will be conducted against ISO 15189:2022.

Those facilities that have not transitioned to ISO 15189:2022 by 22 December 2025 will have their accreditation suspended.

Applicant facilities

Applicant facilities will be assessed against ISO 15189:2022 if they have not yet had an assessment conducted by NATA prior to 1 August 2023.

Accredited facilities

The changes between ISO 15189:2012 and ISO 15189:2022 are such that an assessment will be necessary to convert accreditation to the new standard.

Assessment to the new standard can occur either:

- at the time of the next scheduled NATA assessment after 1 August 2023; or
- on request of the facility as a chargeable variation to accreditation.

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 15189:2022 which can be downloaded from the NATA website at www.nata.com.au.

An additional *ISO 15189:2022 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 will be published in due course prior to the start of the transition date. To accompany this checklist a corresponding comparison table between ISO 15189:2022, ISO 15189:2012 and the NPAAC Tier 2

and 3A documents has also been prepared and will be available with the *Implementation checklist*.

Assessment against ISO 15189:2022 at the next scheduled NATA visit

From 1 August 2023, accredited facilities will be assessed to the new standard at the time of their next routine assessment visit.

Facilities will be required to complete the *ISO 15189:2022 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 assessment.

Any areas of non-compliance identified at the scheduled assessment will be detailed in the assessment report as non-conformities 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 non-conformities have been raised, following a satisfactory response to these.

Assessment against the new standard on request of the facility

A facility may seek accreditation against the new standard prior to a scheduled NATA assessment by requesting a chargeable variation to its scope of accreditation. In order for this request to be considered, the facility must formally advise NATA in writing and submit supporting evidence, as described above, to demonstrate compliance to the new standard.

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

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

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

Transition of networks (multi-site facilities) to ISO 15189:2022

Where a facility is recognised as a pathology network (has a single governance structure and centrally managed management system) it is expected that the transition will occur for the entire network. This will be assessed at the next scheduled NATA assessment of the primary site (e.g. GX/S laboratory) and transition will occur for the entire facility, including all associated sites (e.g. B laboratories). For network transition to occur, the facility must be able to demonstrate all sites within its network have been included in the implementation of ISO 15189:2022.

Where this cannot be demonstrated the facility will no longer be recognised as a network with wider implications, including each site being individually assessed for compliance against ISO 15189:2022 and transitioned accordingly.

Further information

Further information can be obtained by contacting your NATA client coordinator.

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.

Standards

ISO 15189 *Medical laboratories - Requirements for quality and competence*

Amendment table

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

Section or Clause	Amendment
All	New