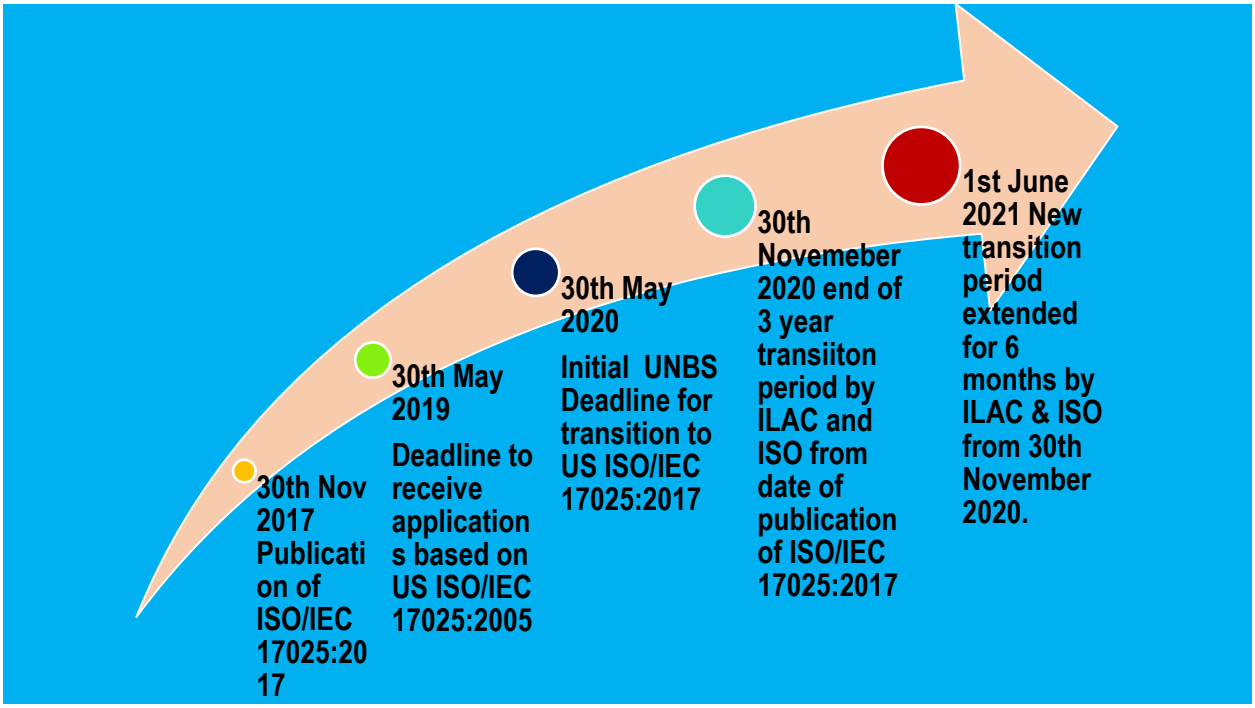
UNBS TRANSITION IMPLEMENTATION GUIDE FOR US ISO/IEC 17025:2017 FOLLOWING THE COVID -19 PANDEMIC



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UNBS Transition Implementation Guide for US ISO/IEC 17025:2017 following the Covid -19 Pandemic

1. Scope and Background

This document provides guidance for the transition from US ISO/IEC 17025:2005 to US ISO/IEC 17025:2017 and was prepared following the UNBS transition guide to new & revised requirements (CERT/OP/14). The transition guide will be communicated to our clients through our website, public stakeholder engagements and by email.

The 2017 version of ISO/IEC 17025:2017 was revised with significant changes and published on the 30th November 2017. The aim of its revision was to reflect the latest changes in market conditions and technology for laboratory environment and work practices. It covers technical changes, vocabulary and developments in IT techniques and takes into consideration the latest version of ISO 9001 on quality management.

The standard is based on Annex SL of the ISO Directives, a high-level structure (HLS) which standardizes sub-clause titles, core text, common terms and core definitions to enhance compatibility and alignment with other ISO management system standards such as ISO 9001 and ISO 14001.

1.1 The main changes in the new version of ISO/IEC 17025:2017 are:

a) The **scope** has been revised to cover testing, calibration and sampling associated with subsequent calibration and testing.
b) The **process approach** now matches that of newer standards such as ISO 9001 (Quality management system), ISO 15189 (Quality management of medical laboratories), and ISO/IEC 17021-1 (requirements for audit and certification bodies).
c) The standard now has **a stronger focus on information technologies** and incorporates the use of computer systems, electronic records and the production of electronic results and reports.
d) A new chapter introduces the **concept of risk-based thinking.**

2.0 The Implementation Plan for the revised standard is as given below:

2.1 Date of Implementation

a) The revised standard ISO/IEC 17025:2017 will be implemented with effect from 30th November 2017.
b) As the transition period permitted by ISO is three years, the existing standard US ISO/IEC 17025:2005 will concurrently remain valid till **1st June 2021** following a **Joint ILAC-ISO Communiqué on the recognition of ISO/IEC 17025 during a Three-Year Transition, dated June 2020 which states that the 3 year transition period has been extended for 6 months from 30th November 2020 to 1st June 2021.**
c) Subsequently, the UNBS transition period has been extended from **30th May 2020** to **1st June 2021.** ILAC and ISO have agreed to this extension to ensure all laboratories are able to transition following the restrictions imposed as a result of the global coronavirus disease 2019 (COVID-19) outbreak.

2.2 Validity of recognition certificates to US ISO/IEC 17025:2005

US ISO/IEC 17025:2005 recognition certificates will not be valid after three years from publication of **ISO/IEC 17025:2017.** The expiry date of recognition certificates to ISO/IEC 17025:2017 issued during the transition period shall correspond to the end of the three-year transition period, which has been extended to 1st June 2021. Certificates that were issued earlier with an expiry period of May 2020 and November 2020 are thus to be re-issued as applicable to correspond to the new transition period of 1st June 2021.

2.3 Processing of Applications

a) UNBS has started registering new applications for recognition as per **ISO/IEC 17025:2017.**

b) Organizations who have already initiated the process of implementation of ISO/IEC 17025:2005 are permitted to apply for the 2005 version up to **30th May 2019** (*At least 1 year before the end of the UNBS transition period)*. After this date, new applications shall be registered only for **ISO/IEC 17025:2017. The deadline to receive applications based on US ISO/IEC 17025:2005 expired and remains the same even under the Covid-19 Pandemic.**

c) Exiting applications for ISO/IEC 17025:2005 may be processed for recognition as per that standard. However, in case organizations opt for recognition against the 2017 version, the same would be permitted in case Initial recognition audit (the Stage 2 Audit) has not been carried out for such applications.

d) After **November 2020**, new licenses shall be granted only against ISO/IEC 17025:2017.

e) All applicants for ISO/IEC 17025:2005 (existing or those to be registered) to note that after November 2020, license would not be granted against US ISO/IEC 17025:2005 even if the application was registered for that version. This means that permits granted in November 2020 will expire not later than **01st June 2021**.

3 Existing Licenses and Transition Assessments

a) Transition of existing licenses to ISO/IEC 17025:2017 shall be permitted only after successful completion of surveillance, renewal of recognition and or special audits against ISO/IEC 17025:2017. Where transition audits are carried out in conjunction with scheduled surveillance or renewal (i.e. progressive or staged approach), additional time is likely to be required to ensure that all activities are covered for the existing and new standards.

b) UNBS shall ensure that the evaluation of a client's conformance to the new requirements during the transition phase does not interfere with the client's on-going conformance to US ISO/IEC 17025:2005.

c) Assessments against ISO/IEC 17025:2017can be conducted after **30th November 2017** to assess the laboratory's management system preparedness for the changes. All assessments done before the end of **November 2020** deadline will assess the management system's preparedness for the changes. At this stage any findings of non-conformance with ISO/IEC 17025:2017 will be reported as an observation where submission of corrective actions to UNBS may not be required.

d) Findings of non-conformance with ISO/IEC 17025:2017 raised during transition audits (*conducted either as single transition audits, combined surveillance & transition audits, combined renewal of recognition & transition audits)* shall be raised as non-conformances and graded accordingly.
e) Existing certificates or new certificates to be issued against ISO/IEC 17025:2005 during the transition period shall be valid only up to **1st June 2021** and the recognition decision shall be taken before the **end of November 2020.**

4 Transition Action Plans

All recognized laboratories are advised to develop and implement transition action plans against which UNBS may track progress of transition for the individual recognized laboratories**.** The action plan must demonstrate how the recognized laboratories has analyzed the new standard and its implications to their management system and operations. The action plan shall also indicate how the laboratories will effectively implement all the changes, system and technical, needed to comply before the transition expiry date. In addition, an ISO/IEC 17025:2017 Transition Self-Assessment Template (CERT/LRS/F02) shall be filled by all laboratories and submitted to UNBS **at least 3 months** before the transition audit and feedback to the laboratory given by the assigned client case officer.

4.1. As a minimum the transition plan should include:

a) All specific actions to be taken to implement the changes.
b) The timelines and milestones for completion of actions;
c) The persons responsible for the actions;
d) Ways to measure progress, implementation, effectiveness and completion of the actions.

The laboratory should keep the UNBS Client Case Officer up to date with relevant changes to the transition plan, i.e. those which may have an impact on the recognition transition assessments using the CERT/LRS/F02 -ISO/IEC 17025:2017 Transition Self-Assessment Template.

4.2. When implementing a transition plan, the following steps are recommended for laboratories using US ISO/IEC 17025: 2005.

a) Purchase a copy of US ISO/IEC 17025: 2017 from the UNBS Webstore and get to know the content and requirements of US ISO/IEC 17025: 2017. If you are a current user of **US ISO/IEC 17025:2005** you should focus on the changes in requirements. If you are a current user of **US ISO/IEC 17025:2005** you should focus on the gaps in your current system that need to be closed to meet requirements for US ISO/IEC 17025:2017.
b) Ensure that relevant personnel and all parties that have an impact on the effectiveness of your laboratory's quality management system is trained and understand the requirements of US ISO/IEC 17025: 2017 and key changes.

c) Develop an implementation plan, implement actions and update your management system to meet the new requirements.
d) Fill in the ISO/IEC 17025:2017 Transition Self-Assessment Template (CERT/LRS/F02) **at least 3 months** before the transition audit and get feedback from your assigned client case officer on adequacy.
e) Evaluate the effectiveness of implementation through internal audits and management reviews and define further actions where needed.

Contact us

For any further inquiries and questions about your transition plan and process, please contact us at:

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