

# **EGAC Transition Policy** *for* **ISO/IEC 17025: 2017**

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1. Introduction

On November 2017 the standard ISO/IEC 17025: 2017 Conformity assessment — General criteria for the operation of various types of Laboratories performing Calibration / Testing has been published by ISO.

On December 2017 International Laboratory Accreditation Co-Operation (ILAC) ISO/IEC 17025:2017 published their resolution GA.20.15 on the transition period of three (3) years with the final date of transition as November 2020, please see ILAC Secretariat communication below.

***" 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 transition period , accreditation of a laboratory to ISO /IEC 17025:2005 will not be recognized under the ILAC agreement . "***

***In this regard, the standard was published on November 2017, therefore the three year transition period will conclude on November 2020."***

The outcome of the ballot and the agreed resolution is also available in the News section of the ILAC website <http://www.ilac.org/news.html> .

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## **2. Transition to ISO/IEC 17025:2017**

### **2.1 General**

For the CAB's Accredited for Calibration / Testing, the arrangement includes the following:

- EGAC start to implement assessments against the new standard ISO/IEC 17025: 2017 from 01 Jul. 2018.
- Between 01 January to 30 June 2018 EGAC will use ISO/IEC 17025: 2005 for the new applicant CAB's or for ISO/IEC 17025: 2017 by a CAB request , then their first assessment will be according to ISO/IEC 17025: 2017
- Between 01 Jul. 2018 to 31 Oct. 2018, EGAC shall conduct *surveillance* visit only for its CAB's of Calibration / Testing Laboratories against the ISO/IEC 17025:2005 or against ISO/IEC 17025:2017 standard by a CAB request before scheduling the assessment.
- Between 01 Jul. 2018 to 31 Oct. 2018, EGAC shall accept *Initial and Re assessment* applications for its CAB's of Calibration / Testing Laboratories against the 17025:2017 standard.
- From 01 Nov. 2018 all EGAC CAB's " *Initial and Re assessment* applications, surveillance for (Calibration / Testing) Laboratories shall implement assessments against the new standard ISO/IEC 17025: 2017.
- All non-conformances raised during the transition period before 01 Jul. 2018 to 31 Oct. 2018 will have a corrective action against requirements in the standards (ISO/IEC 17025: 2005) and ISO/IEC 17025:2017
- From 01 Nov. 2018 non-conformances raised during the transition period will have a corrective action against requirements in the new standard (ISO/IEC 17025: 2017).
- EGAC shall issue a new accreditation certificate according to (ISO/IEC 17025: 2017) only after having confirmed compliance with ISO/IEC 17025: 2017 and a decision is taken on this (refer to 2.5).
- It is important that Calibration / Testing Laboratories that have not yet started transition to the new standard (ISO/IEC 17025: 2017), shall start transition process as soon as possible. EGAC expect Calibration / Testing Laboratories to establish an action plan for implementation. The plan shall be sent to EGAC before 01 May 2018. Based on this action plan EGAC will, for each Calibration / Testing Laboratories, decide on the assessment method to verify compliance with the new standard (refer to 2.2).

For all Calibration / Testing Laboratories which accredited by EGAC have to end transition and complying with ISO/IEC 17025: 2017 new standard by 1 July 2020

### **2.2 The action plan of the Calibration / Testing Laboratories**

Before 01 May 2018 the Calibration / Testing Laboratories shall provide EGAC with an action plan which demonstrates that they have analyzed the new standard and its implications for their management system operations and that they have drafted a plan to effectively implement all changes needed to comply before the date set by EGAC, namely **1 July 2020**.

As a minimum the plan shall include:

1. All specific actions to be taken to implement the changes introduced by ISO/IEC 17025:2017,
  - The risk-based thinking applied that has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements,
  - The greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities,
  - a definition of "laboratory" has been added

2. The time lines and milestones for completion of actions,
3. The persons responsible for the actions,
4. Ways to monitor progress and completion of the actions.

### **2.3 EGAC assessment for the purpose of transition**

The assessment to verify the implementation of the new standard, ISO/IEC 17025: 2017 shall consist of:

#### **2.3.1 Review of the changes in documentation:**

The review of the action plan of the Calibration / Testing Laboratories shall be conducted at the EGAC site to verify that the Calibration / Testing Laboratories has analyzed the impact on their system and have drafted the plan for implementation (refer to 2.2). During the first surveillance assessment after 01 July. 2018, EGAC will review the changes ( for the transitioned CAB ) in the documented systems and the progress made towards implementation of the action plan. When the Calibration / Testing Laboratories has performed an internal audit to assess the effectiveness of the changes and its implementation. The internal audit report shall report clearly and positively on the findings related to implementing ISO/IEC 17025: 2017. Starting from 1 Nov. 2019 ,If such an internal audit report cannot be demonstrated, EGAC will raise a finding that the Calibration / Testing Laboratories will need to respond to within a specific time table as per EGAC Regulation R05G.

#### **2.3.2 Assessment at the site of the Calibration / Testing Laboratories.**

During the first Surveillance assessment from 01 Nov. 2018, EGAC will review records concerning the implementation of the new standard. As a minimum these records shall demonstrate:

- Analysis of impact on system when drafting the action plan;
- Internal audit finding;
- If the Calibration / Testing Laboratories has multiple sites the implementation at all sites;
- Personnel records reflecting "competence" rather than only meeting qualification requirements;

### **2.4 Non conformities against new requirements**

- Before 1 Jul. 2018 Non-conformities issued against clauses of ISO/IEC 17025 : 2005 will implement corrective actions and provide EGAC with the corrective action report according to ISO/IEC 17025 : 2005 in the identified time as EGAC regulation R05G.

- Start 1 Jul. 2018 to 31 Oct. 2018 Non-conformities issued against clauses of ISO/IEC 17025 : 2005 or ISO/IEC 17025 : 2017 , CAB"s will implement corrective actions and provide EGAC with the corrective action report according to ISO/IEC 17025 : 2005 or ISO/IEC 17025 : 2017 in the identified time as EGAC regulation R05G,

- Start 1 Nov. 2018 , CAB"s Non-conformities issued against clauses of ISO/IEC 17025 : 2017 , CAB"s will implement corrective actions and provide EGAC with the corrective action report according to ISO/IEC 17025 : 2017 in the identified time as EGAC regulation R05G,

- EGAC shall in due time revise its current explanatory documents applicable for Calibration / Testing Laboratories Accreditation. Until revision has taken place the documents remain in force. References to the previous standards should be read as references to the new standard.

**The modified EGAC Requirements (information Pack ) will be available on the EGAC website and it is the responsibility of Calibration / Testing Laboratories to download the documents from the EGAC Website.**

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### **2.5 Accreditation certificate and related Scope**

- The Accreditation certificate and Scope of Accreditation will be adapted start by 1 July. 2018 to reflect accreditation against ISO/IEC 17025: 2017 after its related assessment against the new standard has been successfully completed and a decision for initial / maintenance "surveillance" / renewal of accreditation will be taken.

- The accreditation certificate and scope of accreditation valid date will be adapted for( initial /reassessment) of CAB's from Nov. 2017 to 1 July. 2018 will reflect accreditation against ISO/IEC 17025: 2005 until Nov. 2020 and it will be transferred to reflect ISO/IEC 17025: 2017 on their first surveillance visit , then the new issued accreditation certificate and scope valid date will be ended to complete the same accreditation cycle which started from the ( initial /reassessment ) accreditation date.

- It is important to note that the four year assessment cycles will remain unchanged, i.e. a new four year cycle will not automatically commence on the date of transition to ISO/IEC 17025:2017, this will only happen in the case of initial and renewal "reassessment" of accreditation.

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