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NAB-MALTA

TECHNICAL GUIDE

ATG15- Performance of in-house calibrations - Policy of the NAB-MALTA

Revision 3 October 2020

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FOREWORD

Accreditation is the mechanism to assure customers of the competence of laboratories and other types of conformity assessment bodies.

The National Accreditation Board of Malta (NAB-MALTA) is the single national accreditation body appointed as per Article 4 of Regulation (EC) 765/2008 with responsibility for accreditation in accordance with the relevant normative documents. It operates a management system which complies with the requirements established in EN ISO/IEC 17011.

International trade relies on certificates and reports issued by competent bodies. Confidence in certificates and reports is achieved by accreditation. Confidence in accreditation is based on a series of confidence building steps between the accreditation bodies and accredited conformity assessment bodies and the assurance given by the accreditation body that the accredited conformity assessment body constantly implements the relevant criteria and maintains and continuously develops its competence as defined in the relevant standard. This assurance is achieved through accreditation which includes regular on-site assessments and other types of accreditation activities.


The services of the NAB-MALTA are accessible to all applicants whose requests fall within the current activities as offered by the NAB-MALTA and which are in compliance with the cross-border accreditation requirements as stipulated in Article 7 of Regulation (EC) 765/2008. Access is not conditional upon the size of the applicant laboratory or membership of any association or group.

For the scope of this guide, the masculine gender shall also refer to the feminine gender.

SCOPE OF PUBLICATION


This publication describes the policy of the NAB-MALTA with regards to the metrological traceability requirements as established in the applicable accreditation standards including EN ISO/IEC 17025, EN ISO 15189 and EN ISO/IEC 17020. This policy shall also be applied to other conformity assessment activities where testing and calibration is involved (e.g. product certification).

This is a mandatory document which comes into effect from **1st July 2021**.

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1. Purpose


- 1.1 This technical policy statement outlines the requirements which have to be met by Conformity Assessment Bodies (CABs) opting to carry out in-house calibrations.
- 1.2 This policy applies to CABs that are carrying out in-house calibrations in support of their measurement activities
- for their own use within their own facilities; or
 - as a facility carrying out calibration for other accredited sections within their own organisation that have the same senior management and management system.

2. Related documents

- 2.1 **EN ISO/IEC 17025:2017** Clauses 6.4 and 6.5
- 2.2 **ATG10** – Proficiency Testing and Interlaboratory Comparisons
- 2.3 **ATG11** – NAB-MALTA Policy **Metrological Traceability of Measurement Results**

3. Introduction

- 3.1 It is recognised that accredited CABs may choose to carry out some calibration activities in-house to support their measurement activities rather than seek the services of an external accredited laboratory.
- 3.2 It is essential that in-house calibration activities in support of accredited measurement activities are carried out competently and provide **metrological** traceability, with determined measurement uncertainty.
- 3.3 NAB-MALTA publication **ATG11** (Policy on **Metrological Traceability of Measurement Results**), sets out the NAB-MALTA requirements for **metrological** traceability of measurement **results**.

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4. NAB-MALTA POLICY

4.1 This policy applies to calibrations in support of measurements e.g. balance calibration, temperature calibrations but excludes activities that could be used as a verification check on instrument performance before use, such as the calibration of chromatographs etc.


A **verification**, as defined in the **International Vocabulary of Metrology – Basic and General Concepts and Associated Terms - JCGM 200:2008**, is a provision of objective evidence that a given item fulfils specified requirements.

4.2 CABs carrying out in-house calibration are required to ensure that the **metrological** traceability of their calibrations meets the requirements of **ATG11** and the relevant requirements of **EN ISO/IEC 17025:2017** or **EN ISO 15189:2012**.


4.3 CABs shall ensure that the equipment used provides the uncertainty of measurement needed. Evaluation of the uncertainty of measurement shall be carried out in line with **EA4/02 (Evaluation of the Uncertainty of Measurement in Calibration)**.

4.4 It is reasonable to expect that in-house calibrations are subject to the same level of technical rigour that would be obtained if an external accredited laboratory or recognised NMI were used. To the end the following shall be in place:

- a) **the conditions of measurement (such as environmental conditions) are under sufficient control to provide a reliable result**
- b) trained and authorised personnel to both conduct the calibrations and to carry out any necessary checks;
- c) reference standards, certified reference materials or reference measuring instruments that are **metrologically** traceable with appropriate measurement uncertainties. Reference standards, certified reference materials or reference measuring instruments are to be for exclusive use in in-house calibration and they shall be owned by the conformity assessment body. The reference standards used should be in line with the requirements set out in NAB-MALTA policy **ATG11**;
- d) a controlled and documented validated procedure for each type of calibration;
- e) a means of recording and reporting the data and results of any calculations;
- f) a suitable level of quality control activities;
- g) a process for calculating the measurement uncertainty for each calibration (refer also to **EA-4/02**)

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- 4.5 CABs carrying out in-house calibrations in support of their accredited activities are required to maintain details of these calibrations. CABs shall:
- include in-house calibrations in their audit programme.
 - provide the NAB-MALTA with a list of instruments calibrated in-house.
 - provide the NAB-MALTA with a list of the reference standards and/or reference instruments used for in-house calibration.
- 4.5.1. The NAB-MALTA will use this information to ensure that the appropriate expertise is included in the assessment team to assess these activities.
- 4.6 Wherever possible the assessment of in-house calibrations will be covered as part of the **metrological** traceability and calibration aspects within normal assessment/surveillance activities.
- 4.7 Where significant additional assessment time or additional assessors are required, there will be an additional cost associated with this activity.
- 4.8 Specialist calibration assessors will be used if the in-house calibration is outside the area of expertise of the assessment team already involved in the assessment of the accredited activities. The assessment procedures used will include document review and on-site witnessing as appropriate.
- Note: On-site witnessing of in-house calibration activities can be expected at least during initial assessment and reassessments, however these may also be witnessed at any time during the accreditation cycle.
- 4.9 The ability to perform in-house calibrations will not be included in the published scope of accreditation.
- 4.10 CABs performing in-house calibrations shall not claim accreditation for calibration activities.
- 4.11 A CAB shall monitor the performance of its in-house calibrations by participating in an external PT/ILC programme (refer to NAB-MALTA policy **ATG10**) during the accreditation cycle.

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5. References

5.1 The following are important reference documents:

ILAC P10:07/2020

VIM

EA-4/02M:2013

EN ISO/IEC 17025:2017

EN ISO/IEC 17020:2012

EN ISO 15189:2012

ILAC-G24:2007

EN ISO 17034:2016

ILAC P14:09/2020

ILAC Policy on Metrological Traceability of Measurement Results

International Vocabulary of Metrology – Basic and General Concepts and Associated Terms, JCGM

Evaluation of the Uncertainty of Measurement in Calibration

General requirements for the competence of testing and calibration laboratories

Requirements for the operation of various types of bodies performing inspections

Medical laboratories – Particular requirements for quality and competence

Guidelines for the determination of calibration intervals of measuring instruments

General requirements for the competence of reference material producers.

ILAC Policy for Measurement Uncertainty in Calibration

5.2 Documents related to calibration and **metrological** traceability **of measurement results** are available for download from the following websites:

- **NAB-MALTA:** <http://www.nabmalta.org.mt>
- **EA:** <http://www.european-accreditation.org/documents.html>
- **ILAC:** <http://www.ilac.org>
- **BIPM:** <http://www.bipm.org>

5.3 National and International standards are available for purchase from the Malta Competition and Consumer Affairs Authority (MCCAA).

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