ETHIOPIAN ACCREDITATION SERVICE **Guidelines for Proficiency Testing and Inter-Laboratory Comparison for Calibration Laboratories**	**Copy No.** **Page 1 of 21** **Document No. GD07 /05** **Revision no. 1.1** **Effective Date. 2023-02-07**

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Contents

1. PURPOSE

This Guideline used to accreditation bodies for of Inter Laboratory Comparison activity.

2. SCOPE

This is applicable to accreditation process for Calibration Laboratories where the formal Proficiency Testing Programs are not possible. This also provides a tool for harmonisation in the accreditation process of testing and calibration laboratories.

3. GENERAL

The interlaboratory comparison (ILC) is defined by the standard ISO/IEC 17043:2010 as the organization, performance, and evaluation of calibration/test results for the same or similar item by two or more laboratories in accordance with predetermined conditions. ILC represents very effective means to demonstrate technical competence of the participant and also serves as a technical base for accreditation. Furthermore, it is a critical element for monitoring of quality of measurement results as required by ISO/IEC 17025:2017.

This guideline of Inter Laboratory Comparison is for Calibration laboratories which are accredited by Ethiopian National Accreditation Organisation (EAS) or applicant to EAS for accreditation. This procedure can be used as an alternative in the absence of formal Proficiency Testing programs to meet the requirements of standard. Calibration Laboratories have to demonstrate their competence by successful participation in inter laboratory comparisons between two or more laboratories to implement quality control activities for monitoring the validity of calibration undertaken as per ISO/IEC 17025:2017. ISO/IEC 17025:2017 requires labs to participation in PT/ILC, where available and appropriate. An interlaboratory comparison does not require the use of co-ordinating body and participant

laboratories are only comparing performance amongst the group of participating members, whereas proficiency testing is an ILC which is managed by an independent third party and additionally proficiency testing includes the participation of reference laboratory and uses its results to determine performance. The selection of reference laboratory, artifact and evaluation of performance etc are critical as this procedure expects these activities from the participant laboratory.

EAS shall encourage participation in ILC and provide to calibration laboratories general information related to participation in ILCs.

4. INTERLABORATORY COMPARISON SCHEMES:

Successful participation in an interlaboratory comparison is one of the mandatory requirements of the accreditation bodies to obtain and maintain accreditation (ISO/IEC 17025:2017). Accreditation body require a laboratory's participation in interlaboratory comparisons at least once before the initial accreditation and at least once during the reassessment visits in each of the larger sub-areas within the laboratory's scope of accreditation.

Various types of ILC schemes are available such as:

- Participation in Self Organized ILC with permission from EAS.
- Participation in ILC Organized by NMI, Regional or International Organization.
- Participation in Self Organized Small ILC.
- Participation in Measurement Audit

5. PARTICIPATION IN SELF ORGANISED ILC WITH PERMISSION FROM EAS:

5.1. The interlaboratory comparison (ILC) means organization, implementation and evaluation of results of measurements and calibration of the same or similar artifacts /samples carried out by two or more than two laboratories in

conformity with predetermined conditions.

To carry out the ILC, the participating laboratory may follow the following steps

5.2. The participating laboratory must prepare and communicate to EAS the information containing details of the artifact / parameters along with the range to be calibrated and reference laboratory selected for inter comparison in the reporting Format-A (Annexure A). The laboratory shall select the artifact and calibration points in a manner to cover the entire range of the accredited scope or applied scope.

5.3. The participating laboratory has to select a reference laboratory which should be either NML, Ethiopia or any other accredited laboratory having a better CMC than the participating laboratory at a calibration point in that particular parameter. The laboratory shall ensure that the reference laboratory is preferably not under the same top management.

5.4. The artifacts used shall maintain homogeneity and stability throughout the ILC exercise/process otherwise results could contain errors and become invalid to use. Further the artifacts shall have range as per scope, sufficient resolution, to allow the participant laboratory to report an uncertainty approximately equal to their CMC as defined in their scope of accreditation or in the application. The laboratory shall not report uncertainty better than their accredited /claimed CMC. The reported uncertainty for participating and reference laboratory shall be close to or equal to their CMC.

5.5. The participating laboratory shall communicate the calibration results of the selected artifact and other information regarding CMC of reference laboratory to EAS in Format A along with calibration certificate of artifact for approval of

the program before sending the artifact for calibration to Reference Laboratory, analyse the data and calculate normalised error i.e E_n ratio as per the following and submit the results to EAS.

5.6. Evaluation of Inter Laboratory Comparison Results - Normalized error is a statistical evaluation used to compare inter laboratory comparison results between the participant and the reference laboratory where the uncertainty in the measurement result is included.

Typically, it is the first evaluation used to determine conformance or nonconformance (i.e. Satisfactory/Unsatisfactory) in inter laboratory comparison.

When determining whether a participant's results are satisfactory or unsatisfactory, the following rules are used;

- When the value of |En| ≤ 1 (i.e. between -1 and +1), the results are considered satisfactory.
- When the value of |En| > 1 (i.e. greater than +1 or less than -1), the results are considered unsatisfactory.

To calculate normalized error, use the equation provided below:

$$E_n = \frac{x_{Lab} - x_{Ref}}{\sqrt{U_{Lab}^2 + U_{Ref}^2}}$$

$$E_n = \frac{x_{Lab} - x_{Ref}}{\sqrt{U_{Lab}^2 + U_{Ref}^2}}$$

Where,
x_{Lab} = measurement result of participating lab
x_{Ref} = measurement result of reference lab
U_{Lab} = Expanded Uncertainty (i.e. 95%) of participating lab
U_{Ref} = Expanded Uncertainty (i.e. 95%) of reference lab

If the participating laboratory is not able to understand the above equation, use the step-by-step instructions below to calculate normalized error (i.e. En);

- Subtract the result from the participating laboratory by the result of the reference laboratory (i.e. laboratory bias).
- Calculate the root sum of squares for both laboratories' reported estimates of measurement uncertainty.

– Divide the value calculated in step 1 and by the value calculated in step 2

In short, laboratory participating in ILC should follow the steps as given below:

i. Selection of suitable artefact, range/parameter, calibration points
ii. Calibration of artefact at selected points by participating laboratory.
iii. Selection of the reference laboratory having better CMC than participating laboratory.
iv. Communication of above information in suitable format to EAS for permission to carry out inter laboratory comparison.
v. After go ahead from the Accreditation body, submit the artefact to reference laboratory for calibration at the same selected points.
vi. After getting results of comparison from the reference laboratory evaluate the normalized error En value and analyze inter laboratory comparison results
vii. Submission of inter laboratory comparison results to EAS.

Note:

i. The formulae in equations are correct only if x and X are independent
ii. Measurement results and reported uncertainty shall be in same unit.
iii. Minimum three calibration points to be selected in a range.
iv. Furthermore, it is always a good idea to double check your ILC results.
v. In case the result of inter-laboratory comparison is not satisfactory i.e |En| > 1, then lab has to perform root cause analysis and take necessary corrective action with information to accreditation body EAS.
vi. In cases where the reference laboratory has reported uncertainty coarser than the participating laboratory the purpose of ILC is defeated. Hence it shall not be considered as a valid inter laboratory comparison.

5.7. Example of Inter Laboratory Comparison and En Value Calculation

Let us consider a lab 1 (say ABC Calibration Laboratory) a participating laboratory conducting inter laboratory calibration with lab 2 (say XYZ Calibration Laboratory) a reference laboratory in thermal parameter.

- Name of the artifact: Temperature Indicator with RTD sensor
- Range: 0°C to 250°C
- Least Count: 0.1°C
- Reference: Temperature Indicator with PRT sensor with least count 0.01°C
- Temperature Calibration Points: 100°C & 200°C

Inter laboratory Comparison Measurement Results

(1) At a temperature of 100°C

- Measurement result of participating lab, X_{Lab} = 100.5°C
- Expanded uncertainty of participating lab, U_{lab} = ± 0.2°C @ confidence level of approximately 95% with coverage factor *k*=2.
- Measurement result of reference lab, X_{Ref} = 100.55°C
- Expanded uncertainty of reference laboratory, U_{Ref} = ± 0.15°C @ confidence level of approximately 95% with coverage factor *k*=2.

$$E_n = \frac{100.5 - 100.55}{\sqrt{(0.3)2 + (0.21)2}} = \frac{-0.05}{\sqrt{0.0625}} = \frac{-0.05}{0.25} = -0.2$$

$|E_n|$ = 0.2, which is less than 1, Hence result of ILC at 100°C is satisfactory.

(2) At a temperature of 200°C

- Measurement result of participating lab, X_{Lab} = 200.5°C

- Expanded uncertainty of participating lab, U_{lab} = ± 0.3°C @ confidence level of approximately 95% with coverage factor *k*=2.
- Measurement result of reference lab, X_{Ref} = 200.25°C
- Expanded uncertainty of reference lab, U_{Ref} = ± 0.21°C @ confidence level of approximately 95% with coverage factor *k*=2.

$$E_n = \frac{200.5 - 200.25}{\sqrt{(0.3)2 + (0.21)2}} = \frac{0.25}{\sqrt{0.1341}} = \frac{0.25}{0.3662} = 0.68$$

$|E_n|$ = 0.68, which is less than 1, Hence result of ILC at 200°C is satisfactory.

6. PARTICIPATION IN ILC ORGANISED BY NMI, REGIONAL OR INTERNATIONAL ORGANISATION:

6.1. Organisation: One of the participating laboratory or reference laboratory invites laboratories for participating in the ILC for parameter. Then a questionnaire of basic information and calibration & measurement capabilities is sent to these laboratories. Based on information provided by them database is prepared. Depending upon the number of participants and their geographical location, the number of artifacts, their distribution plan, time management for carrying out ILC and reporting of results is planned.

6.2. Selection of Artifacts and Initial Inspection: Measurement equipment /artifacts are decided and initial checks are done and their stability is determined after initial tests.

6.3. M*easurement Points:* Protocol predefines the calibration points in the calibration range of inter-comparison. Environmental conditions are deciding at which calibration must be carried out by reference laboratory/participating laboratory.

6.4. Assigned Value & Uncertainty of Measurement: The assigned value is defined by reference laboratory which is a highest authority for the particular measurement. In case of more than one reference laboratories are involved in calibration of the artifacts, then weighted mean of the value and uncertainty are taken as assigned values.

6.5. Results: Results of the participants are kept anonymous (each laboratory with different code). The data analyses coordinators only know the coding system. On the basis of the participating laboratories reported measured values and uncertainty of measurement values, the results are evaluated on the basis of calculation of En number.

6.6. Conclusion: Conclusion shows that if the participant laboratory agrees within declared uncertainty thus supporting declared measurement capabilities. If the participant is not an accredited laboratory in accordance with ISO/IEC 17025:2017, then it can use the result in support of the process of accreditation.

7. PARTICIPATION IN SELF ORGANISED SMALL INTERLABORATORY COMPARISON:

7.1. In this method laboratories have to organise or participate in a small ILC for one of the following reasons.

- Where there is no suitable PT scheme available because of fast technical advancement or in fields where laboratories are performing very specific measurements or in areas where PT is not practical.
- Where PT poses an unreasonable burden on the laboratory.
- Where in any particular parameter number of existing laboratories are low.

In view of the above a laboratory or small group of laboratories may decide to organise an ILC among themselves. Participation in small ILC involves in most of the cases two to four participant laboratories. The maximum size in the group is up to seven participants. The requirements of ISO/IEC 17043 "General Requirements of Proficiency Testing" are applied on small ILC, but it is not necessary to fulfil all the requirements for a small ILC. This helps to provide trust to the participants of small ILC. The assessment of suitability of these small ILCs will be a part of normal laboratory accreditation audit.

7.2. Scope**:** These guidelines are meant for assessors from accreditation bodies about the elements of ISO/IEC 17043 to be considered, when assessing the results from small ILC. These guidelines are also applicable to small ILCs.

7.3. Evaluation of Performance:

From a metrological point of view in the small ILC, use of assigned value based on an external reference (scenario1) should be preferred over an assigned value based on participant results (scenario 2) which in turn should be preferred over not using any assigned value (scenario 3).

In order to establish an evaluation of performance, the small ILC organiser should define pre assessment criteria before the start of small ILC.

- Scenario1: The organizer has used an assigned value based on an external reference. In this case the evaluation of results from small ILC if the assigned value and reported values have stated uncertainties, use of En number should be preferred. The assigned value may stem from a suitable reference standard e.g certificate of measurement standard or instrument in the field of calibration performed by an expert laboratory.
- Scenario 2: The organizer has used assigned value based on participant results. The participants are experienced laboratories having taken part in earlier similar small ILC or one of the participants operate at a higher

metrological level and more over have used more advanced equipment. Its measurement results could be taken as reference/ assigned value. Results may be evaluated on the basis of normalized error i.e. En value.

- Scenario 3: The organizer has not used any assigned value and the performance score is not calculated. The reproducibility of results/variance among the participants, type of distribution, difference between the extreme values and reported uncertainty of measurements are few parameters on the basis of which performance of an individual participant may be established.

7.4. Assessing Participant Results of Small ILC by EAS:

The appropriateness of participation in small ILC is evaluated by the assessors while assessing the ILC of a laboratory. The assessment depends upon the following two situations.

- The laboratory assessed has organized and participated in the small ILC.
- The laboratory assessed has only participated in small ILC.

In the first situation assessor has to evaluate the plan, report and organisation of the small ILC to conclude upon the relevancy of small ILC.

In the second situation assessor should check the details how results have been evaluated and then decide upon the fitness of the small ILC.

7.5. Conclusion: For the organisation of small ILC, the management system of accredited laboratory or laboratory in the process of being accredited is included. So the assessor while assessing the outcome of small ILC should verify management requirement, technical requirements as described in the document EA 4/21 “Guidelines for the assessment of the appropriateness of small ILC within a process of lab accreditation”.

8. MEASUREMENT AUDITS:

8.1. Introduction: ISO/IEC 17025:2017 requires that laboratories shall plan and perform quality assurance procedures for monitoring the validity of tests and

calibrations undertaken. The laboratories shall participate in interlaboratory comparison or proficiency testing programmes where available and appropriate. EAS may provide audit measurement artefacts as part of the technical assessment process. This applies to calibration laboratories and also to testing laboratories that conduct internal calibrations. These guidelines also provide EAS policy and other relevant details for participation in measurement audit.

The EAS Measurement Audit service is a valuable tool that supports the technical assessment of calibration laboratories. Its purposes are:

i. To provide confirmation that the Calibration and Measurement Capability (CMC) can be supported by “real” measurements. This gives both EAS and the participating laboratories confidence in calibration results;
ii. To enable EAS to assess the way in which results are reported to customers.

EAS requires applicant calibration laboratories to participate in measurement audit or equivalent activity i.e PT/ILC as part of the initial assessment process. EAS also has an ongoing programme of measurement audits for accredited laboratories following the four-year assessment plan.

8.2. Policy- EAS recognizes the measurement audit as an effective assessment tool in the laboratory accreditation process and their results can provide clear evidence of technical competence and will form an important part of the assessment for all testing and calibration laboratories.

8.3. Measurement Audit Activity: If a laboratory already has in place arrangements for PT/ILCs that are at least equivalent to those that could be provided by EAS then such arrangements may be an acceptable substitute. Decisions regarding the acceptance of these arrangements shall be

technically based. EAS measurement audit artefact shall be used when alternative arrangements are not acceptable.

8.4. **Analysis of Measurement Audit Results:** EAS compares laboratories' results with "reference values" that are obtained from the NMI or from other equivalent organisations. The comparison takes into account the difference between laboratories' results and the reference values, as well as the uncertainties associated with both. The Normalised Error Ratio (EN ratio) is usually employed for this analysis.

8.5. The EN ratio should usually be within the range ± 1. If the analysis reveals that it lies outside this range, EAS may request investigation of the results and requires that any necessary corrective and preventive actions are undertaken. The assessment team will assess the activities of the laboratory in resolving any issues.

8.6. **Costs for Conducting Measurement Audits:** The provision of measurement audits offered by EAS may be a chargeable service and the cost will take into account:

- Purchase cost and depreciation of the artefacts;
- Costs of maintaining traceability of measurement and maintenance/repair of the equipment;
- Costs associated with production of measurement instructions and analysis of the results;
- Costs of storage, inspection, packaging and transport.

8.7. It should be noted that the provision of measurement audits is not a commercial service. It is only available to applicant and accredited laboratories as a support tool for technical assessment of these organisations.

8.8. Confidentiality: EAS shall undertake not to divulge a laboratory's identity and results to any other party and Technical Assessors involved in this exercise shall also be bound by the same rules of confidentiality.

Note: It is essential to maintain homogeneity and stability of the artifact throughout the measurement audit process. Otherwise, the results could contain errors and become invalid for use.

Example –

Example of Inter Laboratory Comparison and En Value Calculation

Let us consider a lab 1 (say ABC Calibration Laboratory) a participating laboratory conducting inter laboratory calibration with lab 2 (say XYZ Calibration Laboratory) a reference laboratory in thermal parameter after taking permission from the accreditation body.

- Name of the artifact: Temperature Indicator with RTD sensor
- Range: 0°C to 250°C
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- Reference Standard Used: Temperature Indicator with PRT sensor with least count 0.01°C
- Temperature Calibration Points: 100°C & 200°C

Inter laboratory Comparison Measurement Results:

At a temperature of 100°C

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- Measurement result of reference lab, X_{Ref} = 100.55°C

- Expanded uncertainty of reference laboratory, U_{Ref} = ± 0.15°C @ confidence level of approximately 95% with coverage factor *k*=2.

100.5 – 100.55 = - 0.05

$$E_n = \frac{-0.05}{\sqrt{(0.3)2 + (0.21)2}}$$

$$= \frac{-0.05}{\sqrt{0.0625}} = -0.2$$

$|E_n|$ = 0.2, which is less than 1, Hence result of ILC at 100°C **is satisfactory.**

At a temperature of 200°C

- Measurement result of participating lab, X_{Lab} = 200.5°C
- Expanded uncertainty of participating lab, U_{lab} = ± 0.3°C @ confidence level of approximately 95% with coverage factor *k*=2.
- Measurement result of reference lab, X_{Ref} = 200.25°C
- Expanded uncertainty of reference lab, U_{Ref} = ± 0.21°C @ confidence level of approximately 95% with coverage factor *k*=2.

$$E_n = \frac{200.5 - 200.25}{\sqrt{(0.3)2 + (0.21)2}}$$

$$= \frac{0.25}{}$$

$$= \frac{\text{----------}}{\sqrt{0.1341}} = 0.68$$

$|E_n| = 0.68$, which is less than 1, Hence result of ILC at 200°C is satisfactory8

REFERENCES:

i. ISO/IEC 17025:2017, General Requirements for the Competency of Testing and Calibration Laboratories.

ii. ILAC P9:06/2014, ILAC Policy Participation in Proficiency Testing Activities.

iii. EA-4/21, Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation.

Annexure A

Format 'A'

Inter Laboratory Comparison

ARTIFACT DETAILS and CALIBRATION RESULTS TO EAS FOR APPROVAL:

Details of Artifact: (Name, Make, Model, Sr.No., Least Count and Range):

Standard Used for Calibration: (Identity & Calibration Status):

Parameter(s) selected: (Range, SI Unit)

Participating Laboratory (Name and Address)					**Reference Laboratory (Name and Address)**
Calibration Point	Observed/ Standard Reading	DUC Reading	Reported Uncertainty (±)	Accredited /Claimed CMC (±)	Accredited CMC (±)

Signature of Authorised Lab Representative

Date:

APPROVAL FROM EAS

APPROVED: (Yes or No)

Remarks:

Name & Signature of EAS official

Date:

REFERENCE LABORATORY RESULTS:

Calibration Point	Observed /Standard Reading	DUC Reading	Reported Uncertainty (±)

RESULTS:

Parameters (Calibration Point)	Normalised Error, |En|

Revision No.	Date approved	Revision History
1	2022-05-10	• The document is revised due to the name ENAO change to EAS and new logo developed.
1.1	2023-02-07	• Correction done on page 1 that, this document was prepared by Meseret Tessema replaced by Zewdu Ayele (new quality manager). • Former director general was resigned and replaced by Mrs. Meseret Tessema.