



Support for the National Accreditation Centre MOLDAC  
to successfully undergo the EA peer evaluation process  
Twinning Project MD14/ENPI/TR/20



## ACTIVITY 1.4

TRAININGS OF MOLDAC PERSONNEL INVOLVED IN  
ACCREDITATION PROCESS INCLUDING THE ISSUE REGARDING THE  
REQUIREMENTS OF THE NEW VERSIONS OF THE EA, IAF, ILAC  
DOCUMENTS

# ILAC-P9:06/2014

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## REFERENCES

- **ISO/IEC 17025:2005** General Requirements for the competence of testing and calibration laboratories
- **ISO/IEC 17011:2004** Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies
- **ISO/IEC 17043:2010**, Conformity assessment – General requirements for proficiency testing
- **ILAC-P9:06/2014**, ILAC Policy for participation in Proficiency Testing activities
- **EA-1/17A-S1 2014**, Supplement 1 to EA/1-17 Criteria for Membership





## TERMINOLOGY

**PROFICIENCY TESTING (PT)** : Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (*ISO/IEC 17043:2010*)

**INTER-LABORATORY COMPARISON (ILC)** : Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories or inspection bodies in accordance with predetermined conditions (*ISO/IEC 17043:2010*)

**PROFICIENCY TESTING PROVIDER (PTP)** : organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme (*ISO/IEC 17043:2010*)

**PARTICIPANT**: laboratory, organization or individual, that receives proficiency test items and submits results for review by the proficiency testing provider

**NOTE** In some cases the participant may be an inspection body (*ISO/IEC 17043:2010*)





## §1. INTRODUCTION

- According to **ISO/IEC 17025** a **laboratory** shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the **participation in interlaboratory comparisons or proficiency testing programmes.**
- ISO 15189 also requires that **medical laboratories** seek confirmation for confidence in their results through **participation in suitable interlaboratory comparisons**
- ISO/IEC 17011 requires **accreditation bodies** to take into account during **assessment** and the **decision making process participation and performance in proficiency testing**





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ISO/IEC 17025:2005 General Requirements for the competence of testing and calibration laboratories



### 5.9 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

*The laboratory shall have quality control procedures for **monitoring the validity of tests and calibrations undertaken**..... This **monitoring shall be planned and reviewed** and may include, but not be limited to, the following:*

- a) regular use of certified reference materials and/or internal quality control using secondary reference materials;*
- b) **participation in interlaboratory comparison or proficiency-testing programmes;***
- c) replicate tests or calibrations using the same or different methods;*
- d) retesting or recalibration of retained items;*
- e) correlation of results for different characteristics of an item.*

*Note The selected methods should be appropriate for the type and volume of the work.*



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ISO/IEC 17011:2004 Conformity assessment — General requirements for accreditation bodies  
accrediting conformity assessment bodies



### 7.15 PROFICIENCY TESTING AND OTHER COMPARISONS FOR LABORATORIES

*“The **AB** shall establish procedures to take into account, during the assessment and the decision-making process, the **laboratory's participation and performance in proficiency testing.**”*

*“The **AB** may **organize proficiency testing** or other comparisons itself, or may **involve another body judged to be competent.**”*



**EA 1/17A-S1 2014**

*“The **AB** shall ensure that its accredited laboratories **participate in proficiency testing** or other comparison programs, where available and appropriate, and that corrective actions are carried out when necessary. The **minimum amount of proficiency testing** and the **frequency of participation** shall be specified in cooperation with interested parties and shall be appropriate in relation to other surveillance activities.”*

*NOTE 1 It is recognized that there are particular areas where proficiency testing is impractical.”*



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### ***EA-1/17A-S1 - EA Criteria for Membership***

2.1 The table below lists the specific criteria with which **Full Members and Associate Members have to comply, and how and when EA will check the compliance**

Membership Specific Criteria	Applicable to: Full Members	Applicable to: Assoc. Members*
5. Not own shares in or otherwise have a financial or managerial interest in a conformity assessment body	YES	YES
<b>6. Not providing proficiency testing (PT) services (see Note 2)</b>	<b>YES</b>	<b>YES</b>
7. Not competing with other national accreditation bodies in accordance with the applicable legal, EA, IAF and ILAC rules	YES	YES

**Note 2: Measurement audit activities that are conducted as part of a specific accreditation assessment are not considered as conformity assessment activities if being an integral component of the on-site assessment.**





ILAC-P9:06/2014

ILAC Policy for Participation in Proficiency Testing Activities

## §2.SCOPE

This policy sets out the **requirements** for, and gives **guidance to accreditation bodies, on the use of proficiency testing activities in the accreditation process** of laboratories and where relevant, inspection bodies.

It also aims to **assist accreditation bodies to consistently define and apply relevant PT policies, thereby providing a tool for harmonization in the process of establishing multilateral and bilateral agreements** .  
In the context of this document, “laboratories” implies all laboratory types – i.e., testing, calibration and medical laboratories.







## ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.1 - ABs ... seeking to sign or to maintain their status as a **signatory** to the **ILAC MRA** shall **demonstrate the technical competence** of their accredited calibration and testing laboratories ....

One of the elements by which accredited laboratories can demonstrate technical competence is by **satisfactory participation in PT activities** where such activities are **available and appropriate**.

Technical competence can also be demonstrated by successful participation in interlaboratory comparisons that have been organised for purposes other than PT in its strictest sense. For example:

- to evaluate the performance characteristics of a method;
- to characterise a reference material;
- to compare results of two or more laboratories on their own initiative;
- to support statements of equivalence of measurement of NMIs (CMC).





## ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

**§4.2** - The minimum PT activity according to a laboratory's scope is:

- evidence of satisfactory participation **prior to gaining accreditation** where PT is available and appropriate;
- **further and ongoing activity** that is appropriate to the scope of accreditation and consistent with the PT participation plan. (The main elements of a PT participation plan are provided in 4.3 below.)

***Note:** ABs should **support the use of appropriate PT programmes which meet the essential requirements of ISO/IEC 17043, where applicable.***





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### ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.3 - ABs shall have a **policy on the use of PT activities in the assessment and accreditation process**. This policy shall include the following:

- a reference to the importance of PT as a tool to **demonstrate laboratory and inspection body competence** (where relevant) and to assist in **maintaining the quality** of the laboratory or inspection body performance;
- requirements regarding the **minimum level and frequency** of participation in PT by accredited laboratories, including the need for a **PT participation plan** which has been formulated by the laboratory or inspection body (where relevant) and is regularly reviewed;
- **how PT participation and performance** (in particular consistent poor performance), **will be reviewed and utilised during the assessment and accreditation decision-making process**;
- **expectations** regarding action by laboratories in response to **poor performance in PT, and any requirements for notification of this performance to the AB...**



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## ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.3 - ABs shall have a **policy on the use of PT activities in the assessment and accreditation process**. This policy shall include the following:

- requirements regarding the **minimum level and frequency** of participation in PT by accredited laboratories, including the need for a **PT participation plan** which has been formulated by the laboratory or inspection body (where relevant) and is regularly reviewed;

ACCREDIA-DT Policy is described in the document **RT-36 rev.0**

***“Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “***

The Laboratory shall prepare a suitable program of participation at comparisons, review it periodically, update it and monitor its performance so as to demonstrate that **the scope of accreditation has been covered throughout the accreditation cycle**.





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### ACCREDIA Policy: RT-36 “*Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department*”

For the preparation and revision of the program the Laboratory shall consider, for each metrological sector (All1 –DA-05), at least, the following factors:

- the minimum frequency of participation** given in the present document, in the general regulations, in the national and international technical standards and in the applicable EA and ILAC rules;
- the results obtained from previous participations at comparisons;**
- the frequency and the entity of actions deriving from internal controls of the management system of technical activities**, in particular those permitting the identification, quantification and monitoring of any systematic deviation (such as nonconformities, corrective actions, preventive actions deriving from calibrations and metrological confirmation).



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### **ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “**

For the preparation and revision of the program the Laboratory shall consider, **for each metrological sector**, at least, the following factors:

- the results of assessments by second or third parties;**
- circumstances or factors of the Lab which could justify a modification to the usual frequency of participations;**
- the availability of providers of PTs and/or ILCs.**

[Example of ACCREDIA-DT accreditation form – PT/ILC program form](#)



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## ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.3 - ABs shall have a **policy on the use of PT activities in the assessment and accreditation process**. This policy shall include the following:

- **how PT participation and performance** (in particular consistent poor performance), **will be reviewed and utilized during the assessment and accreditation decision-making process;**

ACCREDIA-DT Policy is described in the document **RT-36 rev.0**

***“Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “***

For Calibration Labs positive results of participations **are used by ACCREDIA-DT to confirm the Calibration and Measurement Capabilities (CMCs)**. Therefore, each time the calibrated item and the measurement method permit it, in providing the results, **the Laboratory shall not declare an uncertainty value which is greater than the accredited or required CMCs.**





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### ACCREDIA Policy: RT-36 “*Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department*”

Participation at a PT and/or ILC is necessary, **with an indication that the performance was positive** (absolute normalized error  $|E_n| \leq 1$  for all measurement points and/or suitable and effective CAs) **for each metrological sector:**

- during the phase of **first accreditation and of extension, before they are granted;**
- at least once during the accreditation cycle**, before the granting of **renewal**; except for the sector of ionized radiations for which participation at PTs and/or ILCs is expected at each surveillance;
- on the request of ACCREDIA-DT during the resumption of activities following self-suspension**, as described in RG-13.



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## ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.3 - ABs shall have a **policy on the use of PT activities in the assessment and accreditation process**. This policy shall include the following:

- expectations regarding **action by laboratories in response to poor performance in PT**, and any requirements for notification of this performance to the AB





## ACCREDIA Policy: RT-36 “*Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department*”

### §7 COMPARISONS INDICATING AN UNSATISFACTORY PERFORMANCE

If the results of a Laboratory are not satisfactory (with normalized error  $|En| > 1$  in one or more measurement points) in a PT or ILC, it shall act as set down in its own internal procedure **for the management of NCs** and, if applicable and/or necessary, **proceed with a self-suspension regarding the specific metrological sector**

The Lab shall also evaluate the **impact with respect to past activities** and **transmit to ACCREDIA-DT within 3 months** from receipt of the results, **the evidence of the treatment, the implemented CAs and the modalities for verifying their effectiveness.**





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## ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “

### §7 COMPARISONS INDICATING AN UNSATISFACTORY PERFORMANCE

As a verification of the effectiveness of implemented CAs, **ACCREDIA-DT recommends participation at the first due PT and/or ILC, and it reserves the right to oblige the Lab to participate** if the evidences provided were not satisfactory or the modality planned for the verification of effectiveness was not adequate.

**If this is the case**, during the phase for the maintenance of accreditation, **the CSA-DT is informed of the negative outcome and it decides regarding any subsequent actions to be taken** (e.g. modification of the periodicity of the surveillances).

**Ineffective treatment of unsatisfactory results is a cause of suspension of accreditation of the Laboratory in the specific metrological sector.**



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## ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

### § 4.4

**ABs shall fully document their policies and procedures** in relation to the use of PT in accreditation.

In particular, **they must be able to evaluate**, through the accreditation process, that the **participation in PT activities** of laboratories accredited by them is **effective, and that corrective actions are carried out when necessary.**

ABs shall also **review the PT plans** prepared by the laboratory with regard to their suitability in relation to the scope of accreditation.

Where these plans are not considered to be suitable it may be necessary for the accreditation body **to provide guidance in identifying the required PT coverage**





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**ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “**

**The program is considered an integral part of the technical documentation annexed to the application for accreditation/renewal/ extension and it is evaluated by ACCREDIA-DT as an additional part of the document analysis. For this assessment the Laboratory shall provide to ACCREDIA-DT the elements as described in the next slide.**

**The evaluation and any changes to a previous program (and positively evaluated by ACCREDIA-DT) is not a part of maintenance activities.**



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**ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “**

**Example of elements that shall be provided to ACCREDIA-DT by Calibration Labs.**

Type of comparison		Elements to be given to ACCREDIA by the Lab	
		Programming phase	Application phase
1	PTs / ILCs proposed by independent providers	<ul style="list-style-type: none"> <li>– Name of provider of PTs / ILCs</li> <li>– item of the PT / ILC</li> </ul>	<ul style="list-style-type: none"> <li>– Name of provider of PTs / ILCs</li> <li>– Item of the PT / ILC</li> </ul>
2	PTs / ILCs organized by EA, by APLAC, or provided within the ambit of regional and international cooperation	<ul style="list-style-type: none"> <li>– Identification of the PT / ILC</li> </ul>	<ul style="list-style-type: none"> <li>– Identification of the PT / ILC</li> <li>– Evidence of participation and/or results</li> </ul>



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**ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “**

**Example of elements that shall be provided to ACCREDIA-DT by Calibration Labs.**

Type of comparison		Elements to be given to ACCREDIA by the Lab	
		Programming phase	Application phase
3	Measurement Audit	An indication of the planned application to ACCREDIA-DT is sufficient	<ul style="list-style-type: none"> <li>– Evidence of the records of research carried out by the Lab showing the unavailability of PT / ILCs.</li> <li>– Instrument chosen by the Lab to be used for the measurement audit.</li> <li>– Provider of the certificate of calibration for the instrument chosen and/or copy of the certificate of calibration of the instrument.</li> </ul>



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**ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “**

**Example of elements that shall be provided to ACCREDIA-DT by Calibration Labs.**

Type of comparison		Elements to be given to ACCREDIA by the Lab	
		Programming phase	Application phase
4	On-site experimental assessment	An indication of the planned application to ACCREDIA-DT is sufficient	<ul style="list-style-type: none"> <li>– Evidence of the records of research carried out by the Lab showing the unavailability of PT / ILCs.</li> <li>– Instrument chosen by the Lab to be used for the on-site experimental assessment.</li> <li>– (if available) provider of the certificate of calibration for the instrument chosen</li> <li>– (if available) copy of the certificate of calibration of the instrument</li> </ul>



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### ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.5 - ABs may **provide information that can assist laboratories** in identifying and formulating their PT participation needs and plans. Annex C of ISO/IEC 17043 provides useful information to assist ABs in this task.

Assistance may for example include:

- listings or direction to possible sources of PT, and considerations for selecting suitable programs;

*For example in ACCREDIA possible sources of PT are published on the reserved area of ACCREDIA's website for calibration Labs (the list can also be obtained on request to the ACCREDIA-DT Secretariat)*

- [reserved area ACCREDIA's web site for Calibration Lab;](#)
  - [list managed by the EA LC working group on ILCs for calibrations.](#)
- guidance on how to analyse and formulate the particular PT needs of the laboratory.
  - *ACCREDIA-DT's application form DA-05*
  - [ACCREDIA-DT's list of documents LS-09 rev.05](#)



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### ILAC-P9:06/2014, ILAC Policy for participation in Proficiency Testing activities

§ 4.6 - It is recognized that there are areas of testing and calibration for which suitable PT **does not exist** or **is not practical**. In such cases, the AB and the laboratory **shall discuss and agree on suitable alternative means** by which performance can be assessed and monitored. This would need to be considered as part of the planned PT and/or related activities.

*According to ACCREDIA-DT Policy **RT-36 rev.0** suitable alternatives are:*

- Measurement audit:** calibration of a measurement standard or measurement instrument, whose calibration parameters are known, by a laboratory exclusively and entirely in the presence of the technical assessor during the on-site assessment.*
- On-site experimental assessments:** assessment involving one or more calibrations in the presence of the technical assessor who verifies the proper application of technical procedures, knowledge of the state of the art and the capacity of the laboratory to apply correct professional practices. If possible, the results of the calibrations are compared with the results of previous ones on the same measurement standard or instrument.*



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## ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “

### §5 DIFFERENT TYPES OF COMPARISONS

#### 1. PTs and/or ILCs proposed by independent and competent organizations;

ACCREDIA-DT accepts the following organizations as providers of PTs and/or ILCs:

- Providers of proficiency testing (PTPs) accredited by ABs signatory to the EA or ILAC agreements of mutual recognition for calibration and testing scopes;
- National Metrological Institutes and Designated Institutes signatory of the CIPM MRA agreements (e.g., in Italy, INRIM and ENEA-INMRI).

ACCREDIA-DT also accepts other providers, if they have been qualified by the Laboratory in conformity with the requirements of ISO/IEC 17043, such organizations are present:

- on the EPTIS website at the address <https://www.eptis.bam.de/en/index.htm>;
- on the list managed by the EA LC working group on ILCs for calibrations and published in the reserved area of ACCREDIA’s website for calibration Labs. (the list can also be obtained on request to the ACCREDIA-DT Secretariat).





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## ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “

### §5 DIFFERENT TYPES OF COMPARISONS

#### 2. PTs and/or ILCs organized by EA, by APLAC or offered within the ambit of regional and International co-operation

ACCREDIA-DT, following EA-2/14 M:2008 or equivalent APLAC documents, chooses one or more Labs on the basis of the metrological sectors for participation at regional and international ILCs.



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## ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “

### §5 DIFFERENT TYPES OF COMPARISONS

#### 3. Measurement Audit

If there are no providers of PTs and/or ILCs available for certain metrological sectors, the Laboratories shall nevertheless keep records of research conducted so as to be able to prove their unavailability. **In such circumstances ACCREDIA-DT accepts the request for a measurement audit.**

Note: Labs may request a measurement audit to verify the effectiveness of corrective actions (CAs) resulting from negative results of participation at PTs and/or ILCs.





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## ACCREDIA Policy: RT-36 “Proficiency Testing (PT) and Interlaboratory Comparison (ILC) for the Calibration Laboratories Department “

### §5 DIFFERENT TYPES OF COMPARISONS

#### 4. On-site experimental assessments

In cases where the performance modalities of a laboratory turn out to be the most relevant for a correct calibration and in cases where the calibration uncertainty of the measurement instruments or systems have a calibration uncertainty due basically to the instrument or system itself, ACCREDIA-DT accepts the request for an on-site experimental assessment.

[...]

Participation at PTs and/or ILCs cannot be replaced systemically by the conduct of measurement audits.



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## ***Examples of ACCREDIA-DT forms where information on PT is utilized during the assessment and the accreditation decision-making process***

- [DT-Mod-006 rev.11](#)
- [Modello RC rev.0](#)
- [Modello RT rev 0](#)
- [Tabella riassuntiva x CSA rev.07](#)
- [Modello RV rev.02](#)





## Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process



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### **EA-1/17A-S1 - EA Criteria for Membership**

#### **2 CRITERIA FOR MEMBERSHIP**

2.1 The table below lists the specific criteria with which **Full Members and Associate Members have to comply, and how and when EA will check the compliance.**

Membership Specific Criteria	Applicable to: Full Members	Applicable to: Assoc. Members*
1. Appointed by the Member State as the single national accreditation body	YES	YES*
2. Operate accreditation as a public authority activity with formal recognition by the Member State	YES	YES*
3. Have clearly distinguished tasks and responsibilities from other national authorities	YES	YES
4. Operate on a not-for-profit basis	YES	YES

\*Note 1: for Associate Members, read 'country or economy' instead of 'Member State' in the criteria/requirement



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## Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

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### ***EA-1/17A-S1 - EA Criteria for Membership***

2.1 The table below lists the specific criteria with which **Full Members and Associate Members have to comply, and how and when EA will check the compliance**

Membership Specific Criteria	Applicable to: Full Members	Applicable to: Assoc. Members*
5. Not own shares in or otherwise have a financial or managerial interest in a conformity assessment body	YES	YES
<b>6. Not providing proficiency testing (PT) services (see Note 2)</b>	<b>YES</b>	<b>YES</b>
7. Not competing with other national accreditation bodies in accordance with the applicable legal, EA, IAF and ILAC rules	YES	YES

**Note 2: Measurement audit activities that are conducted as part of a specific accreditation assessment are not considered as conformity assessment activities if being an integral component of the on-site assessment.**



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### ***EA-1/17A-S1 - EA Criteria for Membership***

#### **2 CRITERIA FOR MEMBERSHIP**

2.1 The table below lists the specific criteria with which **Full Members and Associate Members have to comply, and how and when EA will check the compliance.**

Membership Specific Criteria	Applicable to: Full Members	Applicable to: Assoc. Members*
8. Only operate across national borders, within the territory of another Member State, when the circumstances set out in the applicable legal, EA, IAF and ILAC documents are met	YES	YES*
9. When operating across border, under the exceptions foreseen, it shall inform the national accreditation body of that Member State and offer him to participate as observer	YES	YES

\*Note 1: for Associate Members, read 'country or economy' instead of 'Member State' in the criteria/requirement



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## ***EA-1/17A-S1 - EA Criteria for Membership***

### **2 CRITERIA FOR MEMBERSHIP**

2.1 The table below lists the specific criteria with which **Full Members and Associate Members have to comply, and how and when EA will check the compliance.**

Membership Specific Criteria	Applicable to: Full Members	Applicable to: Assoc. Members*
10. Publish audited annual accounts prepared in accordance with generally accepted accounting principles)	YES	YES
11. Make publicly available information on the outcome of the peer-evaluations	YES	YES

\*Note 1: for Associate Members, read 'country or economy' instead of 'Member State' in the criteria/requirement

