

<b>Prepared By: Quality Manager Assessment Policy</b>	<b>Assessment Policy</b>	<b>Doc. No. : ABIS/AP/01</b>
<b>Approved By: CEO</b>		<b>Rev. No. : 03 / 20.08.2020</b>

## Assessment Policy

### 1. Purpose

This document describes the policy of Accreditation Committee in relation to the evaluation of the conformity assessment bodies like testing and calibration laboratories, certification bodies of quality systems, products and personnel and inspection bodies as well.

### 2. References

ISO/IEC 17011 “General requirements for accreditation bodies which accredit the conformity assessment bodies”, paragraph. 7.3.1

### 3. Assessment criteria

The assessment criteria which are used for assessment of the technical competence of the conformity assessment bodies are:

No	Type of Organization	Criteria	EA/ILAC guides
1	Testing Laboratories	S SH ISO/IEC 17025:2017	EA: 4/05, 4/07, 4/09, 4/10, 4/14, 4/15, 4/16, 4/17 ILAC: G9:2005, G2 1994 G8:1996
2	Calibration Laboratories	S SH ISO/IEC 17025:2017	EA: 04/02
3	Medical Laboratories	S SH ISO/IEC 15189:2007	EA: 04/12
4	Inspection Bodies	S SH EN 17020:2022	IAF/ILAC – A4:2004, EA: 5/03
5	Management System Certification Bodies	S SH ISO 17021:2020	IAF-GD 2:2005 and IAF GD 6:2006 EA: 7/04, 7/05
6	Product Certification Bodies	S SH EN 45011:1998	IAF GD 5:2006 EA: 6/02, 6/03
7	Personnel Certification Bodies	S SH ISO 17024:2012	IAF GD 24:2004
8	Bodies for Certification of Food Safety Management System	S SH ISO 17021:2006 ISO/TS 2200:2007	IAF MD1:2007 IAF MD2:2007 IAF MD3:2008 IAF MD4:2008

#### 3.2 Use of witnessing during site assessments

Throughout the 4 year accreditation cycle, all analysis and accredited services must be witnessed during the process of assessment and surveillance.

The expected number of witnesses in cases of initial accreditation of laboratories shall depend on the number of analysis.

<b>Number of analysis required to be accredited</b>	<b>Number of witnesses recommended for the first assessment visit</b>
Up to 10 analysis	70% of the analysis
From 11-20 analysis	50% of the analysis
From 21-50 analysis	40% of the analysis
From 51-100 analysis	30% of the analysis
Over 100 analysis	25% of the analysis

The rest of the analysis which has not been assessed during the first assessment visits, shall be witnessed during the surveillance visits.

For services from certification and inspection bodies the number of recommended witnesses shall be 50-100% of the service list for which accreditation is being sought by the conformity assessment body. The number shall not depend on the accreditation field but from technical assessors, inspectors and controllers involved in the inspection.

The selection of the list of analysis or services which will be witnessed shall be done by the technical assessor in cooperation with lead assessor. The criteria to be taken into account during selection shall be but limited at:

1. Importance and complexity of service
2. Persons authorized to perform it
3. The environment conditions and methods selected to perform the service
4. Unsuccessful participation in the inter-laboratory comparisons
5. Changes of staff, methodology and environmental conditions

### 3.3 Accreditation of opinions and interpretations

The Accreditation Committee recognizes and performs the accreditation of opinions and interpretations or extension of accreditation for opinions and interpretations. The accreditation of opinions and interpretations as a separate activity is not allowed. It is the responsibility of the Laboratory (its own policy), whether or not to make interpretations of the results obtained by the consumers.

Should the laboratory seek accreditation for issuing opinion and interpretation, it must submit to ABIS all the documentation related to opinions and interpretations as well as any other document required for accreditation. The assessment on opinions and interpretations carried out by the technical assessor shall become part of the assessment plan.

The laboratory is required to have a procedure for description of the whole process for involvement of opinions and interpretations in the testing report of calibration certificate. It

depends on the laboratory whether or not to make interpretation of the results. Yet it depends on the laboratory whether to seek or not accreditation for interpretation and opinions. Such decision of the laboratory must be stated in the documentation of its management system.

The Accreditation Committee requests laboratory to determine the criteria to which the authorized persons must comply, in order to express interpretation and opinions. The laboratory must have records of qualifications, experience, training and authorization.

### 3.4 Including the opinions and interpretations in the testing report

The consumers of the accredited laboratory may require the inclusion of the opinions and interpretations in the testing reports which bear the accreditation symbol. In accordance with ISO / IEC 17025:2005 the laboratory may include the opinions and interpretations in the testing report provided that:

1. The laboratory has been accredited to provide opinions and interpretations requested by the consumer.
2. The opinion and interpretation was based in the results deriving from the analysis from which the laboratory has been accredited with the method for which he was accredited.

If the laboratory has not been accredited for providing opinions and interpretations, it is recommended their release in a separate report and not together with the results obtained from the analysis for which the lab has been accredited.

### 3.5 Accreditation of bodies which realize only sampling or sample processing. The

Accreditation Committee does not recognize or perform accreditation of laboratories which realize only sampling or sample processing but not testing it.

## 4. Assessment

4.1 Accreditation Committee must provide the accreditation service with professionalism, integrity and appropriateness.

4.2 The assessment is based on the criteria established in point 3.

4.3 In order to provide accreditation services with the right quality, the team of assessors must fulfill the requirements of the code defined in the point 5. The team of assessors is composed by the lead assessor, technical assessors and experts. The number of technical assessors is determined depending on the number of fields as well as number of services for which accreditation is being sought. Experts are used for very specific fields of assessment based on their technical competence. Observers authorized by ABIS may be included in the assessment team. The number of observers should not exceed two for each assessment visit.

4.4 The requirements of the assessors' code (see point 5) must be fulfilled from the assessors during the time of performing assessment/surveillance/reassessment visits in the bodies.

4.5 Accreditation Committee is entitled to effectuate additional not notified visit in order to monitor the effectiveness of the implementation of the management system from the conformity assessment bodies. These additional and not notified visits are not related to complaints or changes which might occur in the organization and that might influence the compatibility of the management system with the requirements of standards.

## **5. The code of assessors**

5.1 The assessor should be conscious that he/she represents the Accreditation Committee and perform assessment in full compliance with criteria set by ABIS.

5.2 Every clarification related to ABIS policies and procedures should be directly required to ABIS. If the clarifications are needed during the assessment visits, they must be arranged only with the DA representative and without the presence of representatives of the body being assessed.

5.3 They should communicate in a professional, friendly and controlled manner with the staff of the body which is being accredited as well as with the assessment team.

5.4 Findings and the non-conformities must be presented in a quiet and justified fashion.

5.5 Every misunderstanding with the staff of the body which is being accredited should be solved in a quiet and reasonable manner. In cases of persisting misunderstanding, the assessor should explain to the body the ABIS procedure of appeals.

5.6 The assessor should keep in mind that if he/she provides any advice they must not become a consultancy.

5.7 He/she should keep in mind the time planned for the assessment visit and manage it according to the plan. If it is necessary the extension of the assessment time, this should only happen after consulting the technical staff of the body being accredited.

5.8 Keep also in mind that the purpose of the visit is to assess the technical competence of the conformity assessment bodies. The assessment visit should not be used to demonstrate the competence and knowledge of the assessors.

5.9 Assessors must be very attentive.

5.10 He/she should not keep contacts with the conformity assessment bodies, for accreditation matters, without the permission in writing from ABIS other than those during the assessment visits.

5.11 Advantages from the relationship with the clients are not permitted, including the

acceptance of gifts, commissions, discounts or profits of any other nature, from the assessed conformity assessment body.

5.12 He/she should respect all the deadlines defined by Accreditation Committee for the submission of reports and forms. He/she must maintain the confidentiality and secrecy of all the documentation received from ABIS and requests the permission from ABIS should there be need to photocopy or duplicate ABIS documents.

5.13 All the information included in the documents obtained while performing the task on behalf of ABIS, must be treated as confidential and must not be disclosed to any other person or organization (including his own staff) neither in that moment in time nor in the future, without prior written authorization from ABIS and the organization which was assessed.

5.14 The information obtained during assessment must not be used for personal purposes.

5.15 Invitations to speak on behalf or represent ABIS must not be accepted, without getting prior consent from ABIS.



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