



International Association for Assessment Board Inc. (IAAB)

**Requirements for accreditation bodies
for GLA Assessment for Testing and Calibration Laboratories**

IAAB 17011 – 6: 2024 - Issue 1

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0. Introduction

This document defines the requirements for accreditation bodies accrediting Testing and Calibration Laboratories according to ISO 17025 standards.

1. Scope

- ISO 17011 all requirements will be applicable in addition to specific IAAB Requirements.
- IAAB 17011 - 6 activities covered by accreditation process for Accreditation Bodies which provide accreditation for testing and calibration Laboratories according to ISO 17025.

2. Normative references

- References: ISO/IEC 17000, Conformity assessment — Vocabulary and general principles.
- ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories.

3. Terms and definitions

Accreditation	third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks
Accreditation body	authoritative body that performs accreditation
Accreditation process	activities from application through to granting and maintenance of accreditation as defined by the accreditation scheme

4. General Requirements

4.1	Legal Entity	No additional requirements
4.2	Accreditation Agreement	The accreditation body shall establish a legally enforceable arrangement with each Testing and Calibration Laboratories. Agreement shall include - not to act manner as their activities bring disputation to IAAB & accreditation body - use of logo as per the IAAB guideline and policy
4.3	Use of Accreditation Symbols and Other Claims of Accreditation	The accreditation body shall provide the logo with unique identification number for each accredited Testing and Calibration Laboratories. The accreditation body shall sign the agreement with the testing and calibration laboratories for the determine conditions for the use of logo. AB shall make the use of logo policy is publicly available.
4.4	Impartiality Requirements	Accreditation body shall select the - competent impartial committee personnels - the impartiality committee must consist of member from business association, technical areas, or from relevant sectors applicable. - One person should be a subject matter expert of Testing and Calibration Laboratories.

		- One person must have knowledge of accreditation assessment and processes - One person should have knowledge of the local statutory and regulatory bodies. All impartiality committee members will choose the chairperson of the impartiality committee. AB shall make the competency matrix for the impartially committee. AB shall provide the training for impartiality committee on their related roles and responsibilities AB shall conduct the impartial committee meeting once a year, and record shall be maintained. AB shall ensure impartially committee members are free from financial, commercial, political and other pressures Impartiality committee persons will not recommend clients for accreditation or Testing and Calibration Laboratories. In case of deviation, the member shall be removed form the impartiality committee. Top management will not be having voting rights, top management may participate as an observer. Top management should be a chairperson for the committee. Impartiality committee recommendations are bindings for an accreditation body. AB shall - make available all the data of Testing and Calibration Laboratories including applicants - including all suspended, cancelled and withdrawn Testing and Calibration Laboratories data.
4.5	Financing and Liability	Accreditation body shall have risk assessment for financial activity and liability. Accreditation body shall have insurance policies covering - Accreditation activities liability - health and safety of assessors & personnels involved in accreditation activities including accident risk cover - the result of risk assessment
4.6	Establishing Accreditation Schemes	While developing the accreditation scheme, AB shall ensure: • the applicable legal, statutory & regulatory requirements of national & international compliance; • Calibrate the Laboratories with national & international

		parameters at least once in 6 months, records shall be maintained by laboratory; - Decide the competency criteria of each function in Laboratory; - the latest equipment's & technology (i.e. self-testing kit & Machine) for testing & calibration shall be covered in the scheme; - objective of accreditation scheme & intended outcome that meet the expectation of stakeholders; - Impartiality of accreditation scheme; - Scheme development person or committee shall be competent as per annexure 5; - Shall be publicly available; - man-days are calculated based on the annexure 3 of this document.
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5. Structural Requirements

5.1 to 5.8	Structural requirements	The accreditation body can delegate the responsibilities to the competent person.
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6. Resource Requirements

6.1	Competence of Personnel	Annexure 1 specifies the type of knowledge and skills that the AB shall define for - application review - documentation review - review report - assessment team - decision team Accreditation body shall conduct mock assessment to demonstrate the competence of assessment team, technical expert and observer prior to the assignment.
6.2	Personnel Involved in the Accreditation Process	Accreditation body shall have agreement for confidentiality, impartiality and code of ethics for - Assessors - Technical expert - Interpreters - Observers - Guide - Any other person participates in assessment Annexure 2 specifies required qualification and work experience for personnel involved in Accreditation activities.

6.3	Personnel Records	Accreditation body shall maintain emergency contact details of personal involved in accreditation scheme of management system. Accreditation body shall maintain the continual professional development records of personal involved in accreditation scheme of management system.
6.4	Outsourcing	Accreditation body shall sign an agreement with outsourced body / organization for confidentiality, impartiality and code of ethics. Accreditation body shall conduct risk assessment for the outsourced activities. Records shall maintain.

7. Process Requirements

7.1	Accreditation Requirements	AB shall prepare the assessment scheme requirement in line with technical sectors or based on industrial classification such as high, medium or low risk industries.
7.2	Application for Accreditation	Accreditation body shall identify applicant testing and calibration laboratories outsourced processes or activities in the application form. AB shall review the outsourced process if required necessary.
7.3	Resource Review	Accreditation body shall review its capacity to carry out the assessment international during the application review.
7.4	Preparation for Assessment	Accreditation body shall send the mutually agreed plan and schedule prior to the assessment with Testing and Calibration Laboratories, considering - Availability of resources - Suitable environmental conditions - Any cultural celebrations Initial assessment • AB shall prepare the accreditation scheme for the full cycle <i>(which includes application review to laboratory approval and surveillance and recertification audit process.)</i> • AB shall prepare the rules for suspension, cancellation and withdrawal of Laboratory. Accreditation Bodies shall demonstrate minimum one mock assessment for the full cycle of accreditation scheme before accredited any testing and calibration laboratories. AB shall maintain the record of mock assessment.
7.5	Review of Documented Information	No additional requirements
7.6	Assessment	Prior to or during the assessment: • the accreditation body shall verify the competence of the persons involved in the assessment process of Testing and Calibration of Laboratories

		- the assessment team shall ensure the documented report shall include - positive points; - findings such as Major, Minor Nonconformities; - any observations; - comments on capability of laboratories. The assessment team shall inform the laboratory about the appeal and complaint process of Accreditation body. Accreditation body shall calculate the man-days for laboratory office assessment as per Annexure 3. Requirements of Accreditation body for assessment of laboratory “Applied Scope Risk Category” as per Annexure 4.
7.7	Accreditation Decision-making	No additional requirements
7.8	Accreditation Information	The accreditation certificate shall indicate the scope of accreditation which should clearly specify the Technical Areas where applicable.
7.9	Accreditation cycle	- Surveillance and reassessment activities, which may include - on-site, remote or a combination of assessment methods. - Frequency of surveillance assessment conducted at least once a year or as per statutory and regulatory bodies guidelines.
7.10	Extending Accreditation	No additional requirements
7.11	Suspending, Withdrawing or Reducing Accreditation	No additional requirements
7.12	Complaints	Accreditation body shall ensure Complainee not a part of the complaint handling team. Accreditation body shall handle the complaint considering the impartiality, while conducting investigation and also validating the decision on complaint.
7.13	Appeals	Accreditation body shall ensure Appellee not a part of the appeal handling team. Accreditation body shall handle the appeal considering the impartiality, while conducting investigation and also validating the decision on appeal.
7.14	Records on Testing and Calibration Laboratories	AB shall maintain record of complaint, appeal and feedback and related actions. AB shall maintain record of laboratories minimum 5 years or as per

		statutory and regulatory requirements. AB shall maintain record of active, suspended, withdrawn and cancelled laboratories.
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8. Information Requirements

8.1	Confidential Information	No additional requirements.
8.2	Publicly Available Information	AB shall make the publicly available information regarding the - accreditation scheme; - includes office assessment; - Rule & procedures of accreditation scheme; - Accreditation fee.

9. Management System Requirements

9.1	General	No additional requirements.
9.2	Management System	No additional requirements.
9.3	Document Control	No additional requirements.
9.4	Records Control	No additional requirements.
9.5	Nonconformities and Corrective Actions	No additional requirements.
9.6	Improvement	No additional requirements.
9.7	Internal Audits	No additional requirements.
9.8	Management Reviews	Input to management Review shall include: - Assessor's performance review - Personnel involved in accreditation program - Number of active, suspended, withdrawn and cancelled Testing and Calibration Laboratories

Annexure 1: Required types of knowledge and skills for personnel involved Accreditation activities

The following table specifies the type of knowledge and skills that an AB shall define for specific functions.

Knowledge and skills	Accreditation functions				
	Application review	Document review	Assessment team	Reviewing assessment reports and accreditation decisions making	Accreditation scheme development team
Principles and applications of ISO/IEC 17011 / IAAB 17011-1		X	X	X	
Understanding of applicable ISO/IEC 17011 / IAAB 17011-5 documents			X		
Understanding of Applicable testing and calibration laboratories requirements			X	X	
Understanding of general regulatory & Statuary requirements			X	X	
Understanding of AB's Processes			X		
Understanding of Testing and Calibration Laboratories processes.					X
Identification of complexities, technologies, intended use and risk classifications in assessment process.			X		
Deployment of assessor competences and requirements.	X				X
Knowledge on identifying and evaluating factors that impact an appropriate Testing and Calibration standard's			X		
Understanding of ISO/IEC 17021-1 & IAAB Relevant Guideline for CB's.	X	X	X	X	X

Note: technical Expert may have understanding of general regulatory & statutory requirements.

Annexure 2: Required Qualification and Work experience for personnel involved in Accreditation activities

Qualification and Work experience	Accreditation functions						
	Application reviewer	Document reviewer	Assessor	Assessor (TL)	Technical Expert	Assessment reports and accreditation decision maker	Accreditation scheme development team
Education (i.e. Graduate or equal qualification)	X	X	X	X		X	X
Work experience in Testing and Calibration Laboratories {High-Risk 4+years Medium-Risk 3+years Low-Risk 2+years}			X	X	X*		X
Assessor / Lead Assessor Certificate or Similar qualification			X	X			
Industry specific knowledge	X	X	X	X	X	X	X
Assessment experience	X	X	X	X		X	X

*Technical Expert must have more then 5 Year work experience.

Annexure 3: Requirements of Man-days for Testing and Calibration Laboratories Assessment

Man-days CB Personal	Low Risk	Medium Risk	High Risk
1-10	1.5	2	3
11-20	2	2.5	3.5
21-50	2.5	3	4
51-100	4	4.5	6
101-200	6	7	8
201-500	10	12	15
501-1000	12	15	20
1001 & above	20	25	35

Note: Ab shall maintain the justification of Man-day for CB Assessment.

Annexure 3 A: Additional man-day with number of tests performs per month

Man-days Test Perform per month	Low Risk	Medium Risk	High Risk
500 to 1,000	0	0	0.5
1001 to 5000	.5	.75	1
5001 to 10000	1	1.5	2
10001 to 15000	1.5	2	2.5
15001 to 20000	2	2.5	3
20001 to 35000	2.5	3	3.5
35001 to 80000	3	3.5	4
80001 & above	4	4	5

Note: Ab shall maintain the justification of Man-day for CB Assessment.

Annexure 4: Requirements of Accreditation body for witnessing of Testing and Calibration Laboratories Applied Scope Risk Category

Risk Category	Client Witness Requirements for CB
High	Mandatory
Medium	Mandatory
Low	Optional

Note: In case, AB witnessed the CB in High-risk category, AB can award low risk category (i.e. Medium & Low Risk) without witnessing. AB shall maintain the records for decision.

IAAB identifies three primary complexity categories of compliance risks based on the nature and severity of an organization that fundamentally affect the auditor time.

These are:

- **High** – organizations operations with significant nature and severity (typically the construction industry, heavy manufacturing or processing type organizations),
- **Medium** – organizations operations with medium nature and severity (typically light manufacturing organizations with some significant risks), and
- **Low** – organizations operations with low nature and severity (typically small organizations).

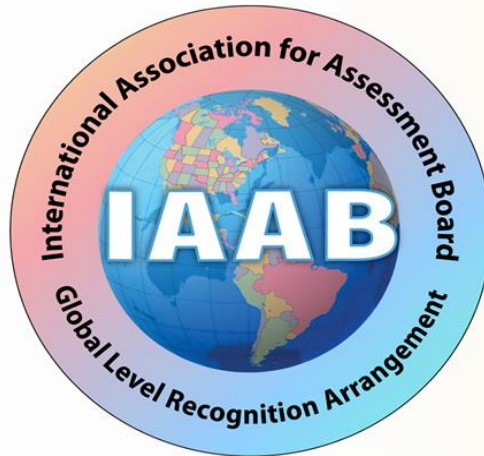
Business Sector	Complexity category
• mining and quarrying • manufacture of coke and refined petroleum products • oil and gas extraction • pulping part of paper manufacturing including paper recycling processing • oil refining • chemicals (including pesticides, fabrication of batteries and accumulators), and pharmaceuticals • gas production, storage and distribution • electricity generation and distribution • nuclear • storage of large quantities of hazardous material • non-metallic processing and products covering ceramics, concrete, cement, lime, plaster, etc. • primary productions of metals • hot and cold forming and metal fabrication • manufacturing and assembly of metal structures • shipyards (depending on the activities could be medium) • aerospace industry • automotive industry • manufacturing of weapons and explosives • recycling of hazardous waste • hazardous and non-hazardous waste processing e.g. incineration etc. effluent and sewerage processing • industrial and civil construction and demolition (including building completion with electrical, hydraulic and air conditioning installation activities)	High

• slaughter houses • transport and distribution of dangerous goods (by land, air and water) • defense activities/crisis management • telecommunications • healthcare/hospitals/veterinary/social works • corporate activities and management, HQ and management of holding companies • financial institutions, advertising agency • food, beverage and tobacco – processing • hotels, leisure services and personal services excludes restaurants	
• aquaculture (breeding, rearing, and harvesting of plants and animals in all types of water environments) • fishing (offshore fishing is high) • farming/forestry (depending on the activities could be high) • textiles and clothing except for dyeing • leather and leather product except for tanning • manufacturing of wood and wooden products including manufacturing of boards, treatment/impregnation of wood • paper production and paper products excluding pulping • non-metallic processing and products covering glass, ceramics, clay, etc. • general mechanical engineering assembly • manufacturing of metallic products • surface and other chemically based treatment for metal fabricated products excluding primary production and for general mechanical engineering (depending on the treatment and the size of the component could be high) • production of bare printed circuit boards for electronics industry • rubber and plastic injection molding, forming and assembly • electrical and electronic equipment assembly • manufacturing of transport equipment and their repairs - road, rail and air (depending on the size of the equipment, could be high) • recycling, composting, landfill (of non-hazardous waste) • water abstraction, purification and distribution including river management (note commercial effluent treatment is graded as high) • fossil fuel wholesale and retail (depending on the amount of fuel, could be high) • transport of passengers (by air, land and sea) • transport and distribution of non-dangerous goods (by land, air and water) • research & development in natural and technical sciences (depending on the business sector could be high). Technical testing and laboratories • education services (depending on the object of teaching activities could be high or low) • public administration, local authorities • manufacturing of fiberglass • dyeing of textiles and clothing • tanning of leather and leather products • fishing (offshore, coastal dredging and diving)	Medium
• wholesale and retail (depending on the product, could be medium or high, e.g. fuel) • general business services include industrial cleaning, hygiene cleaning & dry cleaning. • engineering services (could be medium depending on type of services)	Low

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|--|--|
| <ul style="list-style-type: none">• post office services• restaurants• commercial estate agency, estate management• all repair products & Service (non-critical products),• Training service | |
|--|--|

Additional Manday Consideration:

In case of high-risk AB shall calculate additional man days if needed based on the complexity / legal requirements and calculated effective number of personnel, AB shall maintain the records of justification.



FURTHER INFORMATION

**For further information
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