



GLOBAL LABORATORIES ACCREDITATION BOARD

GENERAL PROCEDURE FOR ACCREDITATION

Introduction

This Manual describes the detailed procedure of accrediting testing laboratories under the GLAB Policy and Procedures for Accreditation of Laboratories. It sets forth the duties and obligations of the parties involved and the necessary evaluation and monitoring procedures required to ensure compliance with provisions of the accredited bodies, ISO/IEC 17025/ISO 15189 and other requirements contained in this document. GLAB is organized and ensures to safeguard the objectivity and impartiality of its activities. Assessment of the competence of accreditation bodies is carried out at the accreditation body head office (and other locations if applicable), assessment of the test facilities (where applicable), and witness assessment. This document explains how GLAB plans and executes initial assessment, surveillance, follow-up, and reassessment to accreditation bodies in accordance with GLAB accreditation requirements and ISO 17025/ISO 15189 on a two-year accreditation cycle.

Step 1: Preliminary Letter of Application for Accreditation

Upon receipt of a request for information of GLAB accreditation, GLAB staff shall provide the requirements for accreditation along with instructions for submitting a Preliminary Letter of Application. To determine the eligibility of a CAB to apply for GLAB accreditation, GLAB shall request that the CAB body shall submit a letter of preliminary application for accreditation with information of its CAB, and attach the following information confirmation of third party status, proof of ownership of the CAB, copy of publicly available documents describing the CAB's program, brief description of the laboratory scheme, including a list of the standard(s) utilized and the identity of the testing body.





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Within 30 days of receipt of a preliminary letter of application for accreditation and the required information, GLAB staff shall review and issue a written report determining the eligibility of the program(s) for GLAB accreditation. If GLAB finds, on the basis of the information submitted by the prospective applicant, that the CAB meets the eligibility requirements contained in section 5.2, GLAB shall provide the inquirer with an application form and instructions for completing and submitting the application. If GLAB finds, on the basis of the information submitted by the prospective applicant, that the certification body does not meet the eligibility requirements contained in section 5.2, the applicant shall be advised in writing.

GLAB makes its services available to all (CABs) whose requests are concurrent with GLAB's scope of activity. In the event the applicant requests accreditation services in unfamiliar areas, GLAB utilizes a technical expert to assist with allocation of assessment days, assessor competency, committee competency needs etc. If the technical resources cannot be formulated, then GLAB has the right to reject the application.

Step 2: Application for Accreditation

The application for accreditation shall be signed by an authorized representative and a non-refundable application fee shall be submitted to GLAB. The following information is required in conjunction with the application scope of the desired accreditation (Description of testing/calibration performed, including a description of activities performed at the organization's facility, customer locations, and in-house calibrations performed as applicable), number of sites of CAB and number of persons who work in each site and the types of activities that the site conducts regarding the conformity assessment a signed contract agreement provided by GLAB to the applicant (GLF-01). The Accreditation Program application form requires that the applicant include the following information: general characteristics of the applicant such as corporate entity, its relationship in a larger corporate entity if any, name,

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addresses, legal status, relevant staff contacts, and technical resources; description of the CAB's activities including copies of its charter and/or constitution and bylaws; organizational chart, a listing of names of all management persons who will be involved in the conformity assessment scheme (s) disclosure of the relationship of the CAB to all program licensees, description of how the applicant manages any real or apparent conflicts of interest between parties involved in the CAB, identity of the body(s) conducting surveillance, and a copy of the contract agreement between the CAB and the body (ies) conducting surveillance, specific details on the evaluation process including sampling methods, inspection levels, and acceptance criteria, any other available material which will aid GLAB in evaluating the application

With the acquired information from the application, GLAB formulates a quotation which covers the accreditation cost and subsequent visits. Also the number of days and man power for assessment is decided based on the application information. Hence the quote provided is purely based on the information and is subjected to change on inadequate or incomplete information.

If the applicant wishes to proceed with the accreditation, the agreement of accreditation shall be signed by the applicant and provided to GLAB, denoting that GLAB can take further steps to process. On finalizing the agreement, a proposed scope is created based on the information retrieved from the application. The template scope shall be shared to the assessment committee and the CAB to confirm their readiness on the requirements.

Step 3: Assessment Confirmation

Upon confirmation of the assessment by CAB, GLAB staff intimates to the accreditation committee regarding the event which reviews for the availability of assessors, technical experts with appropriate competencies to perform in due schedule. The stipulated period and time shall be discussed within the committee and decided with approval of management board. A preliminary visit shall be conducted





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before the initial assessment with the agreement of CAB. The competencies and the deficiencies of the CAB shall be identified. GLAB shall exercise due care to avoid consultancy in pre assessment visits.

If an assessor has already involved twice in the preliminary assessments of accreditation of the client or gives an impression of conflict of interest with the applicant, the same assessor will not be assigned. Assessors and the team shall sign the impartiality and confidentiality agreements of GLAB to avoid such conflict of interest. The list of assigned assessment team shall be provided by GLAB to CAB. The CAB has the right to object any member of assigned team. If GLAB finds any conflict of interest as informed by CAB, GLAB shall change the member and appoint a new member in the team. Even at such durations GLAB assures for the integrity and impartiality of assessment.

Step 4: Document review and assessment

GLAB shall request for the base documents from CAB to initiate documentation review at least prior to 30 days of assessment. This might include documents viz legal status, Organisation chart, Quality manual, performed and completed proficiency test/inter lab comparisons, measurement uncertainty budgets etc. Based on the accreditation scheme requirement by CAB, the additional documents might vary.

On receiving of documentation, the assessor will be notified and will begin the documentation review. The assessors review the document and will be filed in CABs file of GLAB. If any non conformities are there, assessor shall ask for more documents or further explanations. If severe non conformities arises assessor shall decide for further postponing of assessment and shall inform the same to CAB. However if GLAB feels that the CAB is not completely developed or complies, GLAB has the right to amend on the assessment schedule until CAB complies the non conformity.

Over review of the documentation if appropriate, a recommendation is made to proceed with on site assessment and the lead assessor develops the plan. The plan shall include and not limited to the scope





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of CAB, appropriate standards and references, location, date and time of assessment, names of the management representatives, names of the assessors and their tasks, confidentiality statement etc. CABs will receive the assessment plan at least 2 weeks before the assessment and shall communicate to lead assessor if any changes required. GLAB shall also have a copy of the plan to work within similar schedule.

Onsite assessment is carried to check whether CAB complies ISO 17025/ISO 15189. The assessment starts with an opening meeting with the top management of CAB. Opening meeting shall start with introduction of the assessment team and discusses the scope & purpose of the assessment, review of assessment plan, criteria for accreditation, reporting procedure etc. The CAB shall discuss on the proprietary information of the organization and the levels of possible non conformities and observations during the visit. The meeting disperses with signature of the attendance sheet for detailed evaluation.

Evaluation of the CAB starts with personnel assessment, interviews of personnel, document review. Witness assessment in the field site shall be assessed when CAB and GLAB schedules it. The competency of the CAB is ensured by interviewing the staff about the desired scope, in house calibrations, measurement of traceability etc. The methods followed in technical competency, environmental conditions, equipment, traceability, reporting of the results, measurement uncertainty, records and method validation are assessed. The (CAB) is obligated to assist the assessment team by ensuring that all facilities related to the scope of accreditation are accessible. Members of CAB shall be with the assessment team explaining the process and provide supporting documentation for the corresponding activity. The assessor on evaluation will record the non conformities or observations. They may be of major, minor non conformities or just observations. Observations shall not be necessarily complied with corrective action whereas non conformities should be. On time of assessment, any difficulties or scope deviations or not meeting GLAB policy, assessor shall contact GLAB for clarification.

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Closing meeting is sessioned after detailed evaluation and examination of the documents. The meeting discuss the performance of the CAB against the standard, non conformities if any, observations and a detailed report. The assessment team shall inform the timeline for the corrective actions and responses. If CAB does not agrees the non conformities GLAB's appeal and dispute procedure shall be followed to register the non acceptance. A final review of the scope will be reviewed and approved between the assessors and CAB with attendance signed prior to the end of the meeting. A witness assessment shall be scheduled and agreed between the lead assessor and the CAB to ensure all assessment activities are witnessed over a 6 year period.

Step 5: Decision on Accreditation

CAB should submit the corrective actions raised on assessment at least within 60 days and that should give confidence to assessment team that the non conformities are closed. Objective evidence for statements or activities completed due to corrective action taken should coincide with the nonconformity and should be clearly identifiable to the assessment team. CAB shall submit as in GLAB procedure/form.

If CAB fails to submit the corrective action in scheduled time frame, GLAB has the right to abrogate the accreditation and might require for CAB to apply again for the accreditation. In addition to corrective actions to nonconformities, CAB shall take corrective actions in response to complaints received, and to record the actions taken and their effectiveness.

On completion and resolution of the assessment material including acceptable corrective action, the lead assessor makes a recommendation to grant or deny the accreditation. Once the accreditation is recommended by the lead assessor the assessment material will be reviewed by GLAB accreditation committee and submitted to the final decision making committee.





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The accreditation committee is the final decision maker for the accreditation either to grant or deny accreditation without undue delay. Members of the GLAB accreditation committee are members who have no conflict of interest with the CAB. Members are selected based on their fields of expertise aligning with the scope accreditation of the CAB. More than one committee member or technical expert may be selected to complete the final review. The final review consists of a complete assessment report review that should provide committee members confidence that the CAB is fully complying with the standard assessed and GLAB policies and have adequately responded to all non-conformities. If requirement is not fulfilled the accreditation committee may reject the assessment and shall request additional information at its prudence. In such cases, the top management viz President and/or board of directors will instruct the lead assessor to retrieve more information from the laboratory or the laboratory may be communicated directly from GLAB.

CABs shall respond to any rejections or comments made by the accreditation committee. If the accreditation is not recommended by the lead assessor or the accreditation committee, then GLAB will communicate this to CAB which requires complete reapplication by CAB for accreditation or extensive follow ups. If the accreditation committee grants accreditation, GLAB issues a Certificate of Accreditation. Certificates are developed based on the scope received from the assessment team.

On development, a draft is reviewed by a peer review committee for adequacy against GLAB policies for certificates of accreditation. Any questions or comments derived from this review will be provided to the CAB or assessor for clarification. Prior to release all the certificates shall be provided to CAB for further clarifications if any. Certificate shall contain an initial accreditation date, an issue date, an expiry date, a unique accreditation number and certificate number. The accreditation number remains the same for the CAB as the certificate number is adjusted on an ongoing basis. Revision dates are also issued as necessary. The certificate contains the scope of accreditation which includes the scope statement from the CAB along with a supplementary certificate that contains the activities, the CAB is

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accredited. The GLAB symbol is provided on each certificate. The accreditation certificates on acceptance by the CAB, a final certificate shall be provided to CAB via email in a non-editable format, hard copy via mail and also posted on the GLAB website. CABs shall adhere to the policy of GLAB on use of the accreditation symbols, the ILAC Mark and accreditation language. Assessors will review CAB's utilization of the accreditation symbol during on-site assessments and have full authority to document non-conformities for improper utilization. GLAB also has full authority to initiate a non conformance against use of logo if any misuse is found.

Surveillance of accreditation

Regular surveillance assessment within a year of initial accreditation shall be conducted for maintenance of the accreditation requirement. This is to ensure the compliance with accreditation requirement is typically followed. After first year surveillance, then GLAB shall schedule within two years interval for forthcoming years. The surveillance assessment is less comprehensive as compared to the assessment and the assessed aspects shall include but not limited to enquiries from GLAB to CAB on accreditation aspects, declaration by the CAB with respect to their operation, documents and records, including updates from the quality manual, clauses of both the quality system and the scope of accreditation activities etc.

Surveillance assessment though not full comprehensive, non conformities shall be detected by GLAB assessors hence forth CAB shall address the non conformities and send the report. The assessors report on the review shall decide to allow or deny the accreditation to be maintained. If major non conformity like scope change or system change is observed, then the review report shall be sent to accreditation committee for further decision. GLAB shall have the right to change the frequency of onsite visits. The frequency of the visit depends on the competency proved in the past accreditation visit. Based on necessity GLAB decides on off site assessment through the required documents.

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Reassessment of accreditation

On expiry of the accreditation period, GLAB organizes a complete reassessment as initial assessment. CABs shall schedule the reassessment within 2-3 months of the expiry to avoid lapse in the accreditation. GLAB shall schedule for a reassessment and surveillance depending on the proven stability of CABs. In case if CAB runs over its expiration the President shall grant an extension. An extension of the certificate shall be granted depending on the circumstance. On submission of reassessment report to the accreditation committee, committee works on the complete aspects of number of observations, nature of observations, comments etc. If the committee director feels that the assessor visits has extended, then director shall discuss with the management board for change in assessor. Otherwise also if GLAB feels to change the assessor at any time point, GLAB has rights to change the assessor and the team member.

Expansion of Scope

If CAB wishes to extend the scope of accreditation, then CAB shall fill the application and submit to GLAB for the assessment. GLAB reviews the application and provides the quote. Assessment for scope expansion shall be conducted separately or along with regular assessment depending on the nature of the expansion.

Assessors review's the required scope corresponding to the technical areas and documents and submits the report to the accreditation committee. If any non conformity found, corrective actions shall be submitted. The committee shall decide on granting or denying the accreditation for the required scope.

Suspension, withdrawal, reduction or cancellation of accreditation

GLAB has right to suspend, withdraw, reduce or cancel the accreditation at any time during the CAB's accreditation period as per the procedure. This shall happen when CAB persistently fails to conform to





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Standard and/or GLAB policies, CAB fails to complete corrective actions during the timeframe, CAB misused GLAB symbol, CAB convicts any offense or breaks laws leading to discredit the reputation and goodwill. GLAB reserves the right to publicize any actions it may take with respect to withdrawal, cancellation, reduction or suspension of CAB's accreditation. GLAB will also cancel accreditation upon the formal written request of CAB

Disputes & Appeals

CAB or any other interested party may dispute or appeal the decisions of GLAB as per the procedure described in with respect to: refusal to accept an applicant (CAB's) application for accreditation; failure to confer accreditation; suspension, withdrawal, reduction, or cancellation of accreditation; refusal to extend an applicant CAB's scope of accreditation; an appeal by a third party against GLAB's decision to grant accreditation; assignment of assessment team; nonconformities written by the assessment team; any other issue relevant to the accreditation process.

Proficiency testing

To ensure all CABs meet the GLAB Proficiency Testing Requirements (GLP-01), CABs are required to develop a 4 year Proficiency Testing Plan. This plan shall be evaluated during on-site assessments. Deviations from the specified requirements for PT shall be evaluated by GLAB peer review committee and communicated to the assessment team. Any changes to the 4 year PT plan shall be communicated to the GLAB assessment team.

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Fee Structure

A nominal fee structure is maintained which is uniform for all types of laboratories. The fee structure is quite simple and economical

Testing Laboratory Fee Structure:

S.No	Fee structure	India* & developing countries	Foreign countries USD
1.	Application Fee	20,000/discipline	300/discipline
2.	Accreditation fee	50,000/annum	1000/annum
3.	Surveillance & Re-assessment Fee	20,000	300
4.	Assessment fee		
	Assessor fee	5000/man day	400/man day

*To the above mentioned fees GST @18.0 % should be paid along with said fees

Assessment Charges

In addition to the above fee, laboratory shall bear the cost of following:

- Travel of the assessment team
- Boarding & Lodging

Guidelines for Travel, Boarding and Lodging:

- Travel to be made by Air in economy class (Apex fare) or by train in 2nd AC Class or by AC Bus.
- If the journey is made by own car, the re-imbusement will be as per company's rules or restricted to 2nd AC Class fare by train.
- The laboratory shall also make arrangements for boarding & lodging for the Assessment team. A single occupancy AC accommodation may be provided for each Assessor/ Observer in a reasonably good hotel/ guesthouse and arrangement for local transportation from temporary residence to the laboratory site and airport/ railway station/ bus stand.

Fee Payment:

All payments through Demand Draft/ Check/ Bank Transfer. For further details please contact Email : info@g-lab.us , Contact No : +91-9894770511

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