



# GLOBAL LABORATORIES ACCREDITATION BOARD

## PROFICIENCY TESTING REQUIREMENT

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## 1. Scope

- 1.1. Organizations seeking or maintaining accreditation shall participate in proficiency testing. The purpose of this requirement is to provide interested parties with objective evidence of an organization's capability to produce data that is both accurate and repeatable for the activities listed in its scope of accreditation. Favorable proficiency testing data can be used to demonstrate an organization's competence to clients, potential customers, accreditation bodies and other external entities. Participation in proficiency testing activities also provides invaluable feedback in the internal monitoring of an organization's quality system. Through these activities, an organization can verify its competence to perform specific tests.
- 1.2. This document outlines GLAB's general requirements in regards to proficiency testing. This document is designed based upon requirements of ISO/IEC 17025:2005, ISO/IEC 17011:2004.

## 2. PROFICIENCY TESTING SPECIFIC REQUIREMENTS 17025:2017 TESTING LABORATORIES

- 2.1. Two terms which appear frequently in the discussion of proficiency testing are **Discipline** and **Sub-discipline**. The following definitions for these terms have been established by GLAB to apply to all procedures and documents, both internal and external, wherein an organization's testing capabilities are stated or referenced. This applies as well to all procedures and documents, both internal and external, from organizations accredited by GLAB. In order to maintain consistency of interpretation of procedures, documents, and requirements to which these terms relate, any questions regarding their use will be decided at the discretion of GLAB's technical staff having given due consideration to any opposing points of view from all interested parties.

## 3. Definitions:



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- 3.1. **Testing “Discipline”**: A category of test intended to quantify or evaluate common or related parameters of a unit, device or substance submitted for test.
- 3.2. **Testing “Sub-discipline”**: At a minimum a sub discipline is an element of an associated test discipline for which the magnitude of a stated parameter has been defined as a measurement objective and will be determined by a specified method using appropriate skills and equipment. A sub-discipline may be composed of one or more such elements where the organization has determined that the measurement objective, the specified method and the appropriate equipment are either identical or similar to such a degree that they can be considered as mutually representative. In addition the organization shall have determined that the successful performance of either would be satisfactory objective evidence of the technical competence necessary to successfully perform the other. The organization must document the basis for its decision to group multiple elements of a discipline into a single composite sub discipline. Such documentation shall be available for review by an assessor at the time of assessment or at other times as requested by GLAB.

## **4. GLAB currently accredits organizations in the following disciplines:**

- 4.1. **Testing:**
  - 4.1.1. Chemical
  - 4.1.2. Biological
  - 4.1.3. Microbiological

## **5. PROFICIENCY TESTING REQUIREMENTS: APPLICANT ORGANIZATIONS**

- 5.1. Prior to accreditation by GLAB, an applicant organization must provide objective evidence of proficiency testing activity for at least one item included in its desired scope of accreditation. The item that the organization chooses for proficiency testing must be one that is suitable to demonstrate the competence of the organization for the main field of activities in testing. The results of this proficiency testing must be meaningful, in that the organization not only needs to perform the proficiency testing, the resulting data must demonstrate the organization’s



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competence in performing the specified test. Proficiency testing data utilized for the adherence of this section shall be dated no more than 12 months from the initial assessment date.

- 5.2. Upon achieving accreditation by GLAB, Organizations are required to perform proficiency testing annually. Even if an organization finishes its proficiency testing in a single year, proficiency testing activities must occur every year. Results of this testing shall be monitored during the organization's subsequent surveillance or reaccreditation assessment. At minimum organizations are required to have objective evidence of favorable proficiency testing results for each discipline in their scope of accreditation within a four year cycle. GLAB may choose to shorten the interval for proficiency testing should there be any significant changes to the organization's staff or scope of accreditation. This decision will be made on a case-by-case basis.
- 5.3. If an organization is accredited for only one discipline and that discipline has no sub disciplines then the lone discipline would be the subject of proficiency testing on an annual basis at a minimum.
- 5.4. If an organization is accredited for only one discipline and that discipline has two sub disciplines then the more comprehensive of the two should be selected for proficiency testing the first year and the remaining sub discipline will be scheduled for the following year. After two years the plan repeats these two sub disciplines in years three and four.
- 5.5. If an organization is accredited for only four disciplines and two have no sub disciplines while the other two disciplines have multiple sub disciplines, all four disciplines must be represented on the four year plan at least once during the four years in which the plan is active. The sub disciplines chosen are to be from the more challenging of those available. During the next four year plan those disciplines represented by selected sub disciplines will be represented by different sub disciplines selected again from the more challenging of those remaining. Barring changes to the scope or the proficiency testing requirements, this process of selection would continue until all sub disciplines have been the subject of proficiency testing at least once and



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all disciplines of the scope have been addressed at least once in each successive four year period.

- 5.6. Organizations seeking accreditation shall develop a 4 year PT plan prior to initial assessments. This plan will be reviewed by the assessment team during the onsite visit for compliance to this policy. Any deviations from the mandatory requirements as outlined in this policy shall be submitted to headquarters for approval. Headquarters will notify the assessment team and the client of any such approvals for deviations to this policy.
- 5.7. PT plans must address all disciplines of the scope at least once during the time interval covered by the four year plan. Where a discipline is composed of several sub disciplines the sub discipline chosen shall be from among the more challenging and comprehensive within the specific discipline. Each successive sub discipline chosen in subsequent proficiency tests shall be from the more challenging of the sub disciplines remaining. This process shall continue until all disciplines and sub disciplines have been included at least once. Within the period of time when any four year plan is active not all sub disciplines may be selected for proficiency testing, however all disciplines shall be represented at least once during each successive four year period.
- 5.8. Organizations are responsible for updating 4 year PT plans prior to expiration of any current plan. A copy of current plans will be kept in client assessment files. All organizations shall monitor their proficiency testing activity and performance through the use of documented plans or schedules. The documentation which defines the manner in which an organizations proficiency testing program is managed and any information regarding results or evaluation of performance shall be made available to GLAB or its assessors during assessments or upon request. Failure to produce meaningful, acceptable results shall necessitate an investigation and, if required, corrective action by the organization. An approved means of proficiency testing activity shall be conducted upon implementation of corrective action to demonstrate the organization's competence and the effectiveness of the corrective action taken. Records of such activity shall be provided to GLAB assessments or upon request. In the case that an



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organization fails to investigate or take appropriate corrective action for proficiency testing that produces unacceptable results, GLAB will initiate its policy for removal of the affected test activity from the scope of accreditation of the organization involved.

5.9. All accredited organizations shall monitor their proficiency testing activity and performance through the use of documented proficiency testing plans or schedules, which shall be made available to GLAB during surveillance and reassessments or upon request. These plans or schedules, however specified or written, should address the requirement for testing of each discipline over a four year period. Accredited organizations wishing to expand their scope shall modify the 4 year plan as necessary in order to include the capabilities being added as a result of the scope expansion.

5.10. Changes in an organization's staffing, the methods by which tests are performed, equipment available to the laboratory etc. may render current PT policies and procedures inadequate. ISO/IEC 17025:2005 requires review of policies and procedures as a mandatory activity during management review. Accredited organizations shall be able to provide objective evidence that their policies and procedures related to proficiency testing are reviewed for suitability. The review as well as any conclusions or actions resulting from it shall be recorded in the minutes of the management review. The record shall indicate the conclusion of any such review and the action taken if the policies and procedures related to proficiency testing are found to no longer be adequate. Additional reviews may occur at other times as deemed necessary by the organizations management or at the request of GLAB. Any such reviews and conclusions or actions resulting from them shall be recorded.

## **6. APPROVED MEANS OF PROFICIENCY TESTING**

- 6.1. The following activities (listed in their order of preference and acceptability) have been approved by GLAB for the purpose of demonstrating proficiency:
- 6.2. Participation in proficiency testing programs sponsored by a third party accredited provider or participation in proficiency testing programs sponsored by a third party provider, and inter-laboratory comparisons.



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- 6.3. When use of the above approved methods is considered by the organization as being impractical as a means of demonstrating proficiency the following activities, listed in their order of preference, may be used pending prior approval by GLAB: Intra-laboratory comparisons and; repeatability studies.
- 6.4. Note: If an organization wishes to proceed with one of the above mentioned means, they must state in writing why third party or inter laboratory comparisons are not feasible and how they plan to conduct the test and analyze the data. This document shall be submitted to GLAB headquarters for review and approval.

## **6.5. Third Party Programs**

- 6.5.1. GLAB promotes third party proficiency testing and strongly encourages its accredited or applicant organizations to participate in proficiency testing programs sponsored by third party providers whenever such programs exist. Some of the advantages to participating in this type of program are: assurance that the proficiency testing takes place at appropriate and regular intervals; complete objectivity on the part of the proficiency testing sponsor; statistical analysis and reporting of the resultant data by the provider, and; direct reporting of the results to GLAB by the provider on behalf of the organization upon availability.
- 6.5.2. If a third party sponsored program does not exist for a particular scope, the proficiency testing requirement may be satisfied through the employment of inter laboratory / intra laboratory comparisons, repeatability studies or a combination thereof, or the analysis of particular program specific reference materials or standards, provided that the program is documented and approved by GLAB.

## **6.6. Inter-laboratory Comparisons**

- 6.6.1. An acceptable inter laboratory comparison is one in which two or more organizations perform testing on the same or similar artifact, using compatible methods, under specified conditions. The resulting data from each organization should be in agreement with that of the other participants. Organizations should be accredited or in the applicant stages of accreditation whenever practicable. However, in cases where the participating laboratories



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are not accredited then evidence of traceability must be proven as required in GLAB's Traceability Policy. Evidence of traceability shall be documented on GLAB's Traceability Acceptance Criteria form (GLF-14).

6.6.2. For certain organizations, in extraordinary circumstances with proprietary activities or highly specialized scopes, an inter laboratory comparison may not be feasible. In such cases, the proficiency testing requirement may be satisfied through the use of intra laboratory comparisons.

## **6.7. Intra-laboratory Comparisons**

6.7.1. An intra-laboratory comparison is conducted when several analysts or technicians within an organization perform testing on the same or similar artifact, using the same method, under specified, controlled conditions. The data resulting from this activity shall be analyzed for statistical validity.

## **6.8. Repeatability Studies**

6.8.1. If none of the aforementioned proficiency testing activities are feasible, as in the case of a specialized organization employing a single technician, proficiency may be demonstrated through repeatability studies with the prior approval of GLAB.

6.8.2. Repeatability studies consist of a number of tests or measurements (generally at least 8) performed on the same or similar artifact, using the same method, under specified, controlled conditions. The results of these studies shall be analyzed for statistical validity by appropriate means.

6.9. If laboratories utilize other means of PT, (i.e., not an accredited provider), then an approval for these activities must be submitted along with objective evidence for acceptability to GLAB for review and approval.

6.10. If laboratories utilize other means of PT (i.e., not an accredited provider), then an approval for these activities must be submitted along with other objective evidence for acceptability to GLAB for review and approval.





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6.11. Prior to accreditation all sub-disciplines shall undergo a PT. The results submitted for these studies shall be no more than 6 months from the initial assessment date. Additionally, a PT plan shall be developed including all sub disciplines, dates of expected participation and type of PT (i.e. third party, inter lab, inter-laboratory comparison, repeatability). Prior to receiving accreditation PT results shall have a passing score. GLAB will evaluate the PT plan during the initial assessment and determine whether the plan is suitable. GLAB has the authority to require more (PTs) for each sub-discipline based on factors such as the risk, sector of operation, and methodology used, history of former results or staff turnover.

6.12. Failure to meet GLAB's PT policy requirements will result in nonconformity, possibly resulting in the reduction or suspension of the scope of accreditation.

## 7. REFERENCES

7.1. ILAC-P9:11/ 2010 ILAC Policy for Participation in Proficiency Testing Activities.

7.2. ISO/IEC 17011 Conformity assessment – General requirements for accrediting Conformity assessment bodies