1. PURPOSE

The purpose of this document is to guide testing and calibration laboratories in the implementation of the ISO/IEC 17025:2017 standard. The accreditation processes for testing and calibration laboratories are defined in the "PR.017-NAC Procedure for the Accreditation of Conformity Assessment Bodies." The accreditation of laboratories is carried out considering the additional requirements listed in the table attached to the same procedure. PR.017-NAC and the additional requirement guidelines are published on NAC's website (www.nac-us.org) for public access.

2. SCOPE

This guideline applies to all testing and calibration laboratories seeking accreditation or maintaining accreditation under the ISO/IEC 17025:2017 standard through NAC. It encompasses the processes and requirements for initial accreditation, scope extensions, and ongoing compliance, including the determination of laboratory scope, impartiality and confidentiality measures, structural and personnel requirements, equipment and external services management, proficiency testing, risk and opportunity evaluations, and quality system documentation.

3. DEFINITIONS

Definitions related to this guideline are provided in INST.001-NAC Instruction for Definitions and Abbreviations Used in NAC Documentation.

4. RELATED DOCUMENTS

The implementation of this document uses the ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories standard and the guidelines created for laboratories available on the NAC website.

PR.017-NAC Procedure for the Accreditation of Conformity Assessment Bodies

5. IMPLEMENTATION

5.1 Receipt and Review of Applications

The processes related to the receipt of applications are carried out as specified in the "PR.017-NAC Procedure for the Accreditation of Conformity Assessment Bodies" section on Receipt and Review of Applications. In addition:

- The accreditation requests of the applicant laboratory are verified by contacting the CAB. If the CAB performs internal calibration, it must provide information about the areas/ranges/methods of internal calibration in the application.

- The scope of accreditation requested by the CAB is evaluated for its accreditable eligibility.

- The application is evaluated and recorded using the NAC Application Review Form. Laboratories applying for initial accreditation must be conducting activities in the scopes they apply for and, if applying for a system-wide accreditation, must have conducted an internal audit and management review meeting and submitted their records to NAC.

- Before the assessment, laboratories must inform NAC of the activities (sampling, fieldwork, etc.) conducted by their current personnel. NAC uses this information in the assessment plan preparation phase.

5.2 Fees

The application fee is a fixed fee requested by NAC to accept and record the applicant CAB's application, taken upon NAC's acceptance of the application. This fee is non-refundable unless the assessment is not conducted due to reasons arising from NAC. Other fees are determined in accordance with the GL.001-NAC Guideline on Accreditation Service Fees.

5.3 Implementation of ISO/IEC 17025:2017 In Laboratory Accreditation

In laboratory practices, organizations wishing to be accredited or already accredited by NAC according to the ISO/IEC 17025:2017 standard must comply with the following points:

5.3.1 Determination of Laboratory Scope

For testing laboratories, the accreditation scope defines the materials and/or products being tested; the components/parameters or characteristics tested; and, if necessary, the techniques, methods, and/or equipment used. Similarly, for calibration laboratories, it defines the measurement parameter, measurement range, Calibration Measurement Capability (CMC) uncertainty, and the method or procedure used for CMC.

The accreditation test/calibration scope is typically defined in terms of standard test methods prepared by international, national, and professional standards writing organizations. Laboratories applying for accreditation for the first time use the current version of the standard test method. Laboratories that have been previously accredited may use the previous version following the current version for one year from its publication date. Test methods currently under revision or in "draft" status cannot be used in the accreditation scope. The accreditation assessment is planned based on the laboratory's declaration.

If a laboratory applies for accreditation with an in-house or modified method, it must explain the reasons and present validation records of the method to NAC before the assessment.

Laboratories requesting accreditation solely for sampling activities must demonstrate that the sampling method is followed by a subsequent testing or calibration activity.

Laboratories cannot request accreditation for testing, calibration, and sampling activities continuously provided externally according to the ISO/IEC 17025:2017 standard.

Laboratories applying for initial accreditation must already be performing activities within the requested scopes and have conducted laboratory activities related to those scopes. In addition to the above points, the guidelines (GL.019-NAC.TCL, GL.022-NAC.TCL, GL.023-NAC.TCL, GL.025-NAC) are considered in determining the laboratory's scope.

5.3.2 Matters Related to Impartiality and Confidentiality

Laboratories must conduct their activities ensuring impartiality and confidentiality. To achieve this, they must conduct a risk assessment. The laboratory evaluates potential hazards and risks that could affect its impartiality and documents how to manage these situations in practice. The laboratory must define how to eliminate identified hazards or minimize risks in every situation.

The laboratory secures matters related to customer confidentiality through legally binding methods, such as contracts with the customer. However, in cases where the legal requirements of the CAB's country conflict with the standard's requirements, legal provisions apply. If a legal authority requests access to customer-related information without the customer's knowledge, the laboratory does not

inform the customer about the sharing of this information. This situation must be stated in the customer contracts.

5.3.3 Structural Requirements

Organizations must define the senior management responsible for laboratory activities. The individual or individuals who provide the necessary resources for the laboratory, initiate the resource procurement process, and are responsible for laboratory activities should be accepted as the laboratory management. The laboratory must be a legal entity or a defined part of a legal entity that can be held legally responsible for its activities.

According to this standard, a public laboratory is considered a legal entity based on its public status. In the assessment of public laboratories, it is sufficient to see the establishment law, regulation, or decree as a document and record showing the public legal entity status according to the legislation of the country where the institution is located. Organizations with public legal entity status are required to make a statement of assurance instead of professional liability insurance.

Laboratories with private legal entity status must prove this status according to the legislation of the country they are located in. Associations, foundations, and professional chambers can establish enterprises to perform laboratory activities. Organizations with such legal entity status must document their legal status. Organizations with such legal entity status must have professional liability insurance.

5.3.4 Personnel Requirements

Laboratories must employ personnel (internal or external) in accordance with the management system and make written employment contracts according to the Labor Law of the country they are in. For work types not required to be in writing by the relevant Labor Law, a written contract specifying the working conditions is made between the laboratory and the relevant personnel. Confidentiality, impartiality, and conflict of interest agreements (commitments) must be made in writing between the personnel and the laboratory and signed by both parties. These agreements must be directly made with the personnel and recorded to be shown to the assessment teams. For personnel in management positions (technical management, quality management), insurance notifications made according to the country's regulations must be prepared to be shown to the assessment team.

In situations where the laboratory does not take responsibility for the social security of its personnel, it must keep records showing the social security status of the personnel for presentation to the assessment teams. The laboratory must specify these arrangements in its contracts to secure these points.

Evaluations such as competency and monitoring are carried out for both internal and external personnel without discrimination and included in validation or verification studies. If there is a different situation, the reasons must be presented to the assessment team. For calibration laboratories, when considering the CMC value, these evaluations must be conducted more carefully. Competency monitoring must be determined according to the risk and frequency of the laboratory activity performed.

The ISO/IEC 17025:2017 standard applies to all types of laboratories regardless of the number of personnel. However, where the requirements of the standard related to confidentiality and impartiality (e.g., handling of complaints, internal audits, etc.) cannot be met with internal resources, external resources may need to be used. Legal regulations to which the laboratory is subject must be considered concerning confidentiality and impartiality.

Laboratories must define critical personnel for the accredited activities and maintain continuous access communication channels with these personnel or appoint suitable deputies. When defining critical personnel, the laboratory must consider personnel whose absence would halt an accredited activity (e.g., the only authorized testing personnel in a scope). The laboratory must document competency requirements related to planning, implementing, controlling, and preventing functions that affect the results of laboratory activities.

In any case, changes affecting personnel involved in accredited activities must be reported to NAC in writing within the periods specified in the Accreditation Agreement. Following this notification, NAC will evaluate the laboratory's status and depending on the nature of the change, may not make any changes to the accreditation status, may partially or fully suspend, or withdraw the accreditation, or may request an on-site assessment.

5.3.5 Equipment

The ISO/IEC 17025:2017 standard requires laboratories to have access to the necessary and sufficient equipment. The CAB should only use equipment it owns or has obtained long-term from external sources. If the CAB must use different equipment from that used during the accreditation assessment, it must demonstrate the suitability of the equipment for the accredited activity and that it has been considered in validation/verification studies (if necessary).

Changes affecting equipment used in accredited activities (e.g., equipment changes, relocation of equipment) must be reported to NAC in writing within the periods specified in the Accreditation Agreement. Following this notification, NAC will evaluate the laboratory's status and depending on the nature of the change, may not make any changes to the accreditation status, may partially or fully suspend or withdraw the accreditation, or may request an on-site assessment.

The ISO/IEC 17025:2017 standard does not mandate having backups of equipment used in testing, calibration, and sampling. However, laboratories may consider having backups of some equipment based on the risk of their activities.

5.3.6 Externally Provided Products and Services

A laboratory may temporarily outsource work to an external supplier due to unforeseen reasons (e.g., workload, temporary capacity reduction). Laboratories cannot continuously use external suppliers for activities within their accredited scopes.

Except for force majeure, laboratories must obtain laboratory activity services from an accredited organization that is accredited by NAC or by an accreditation body recognized in agreements to which NAC is a party in the areas of testing, calibration, and sampling.

Force majeure includes legal requirements, the absence of another accredited organization in the same field, etc. In such cases, the laboratory obtaining external services must ensure the suitability of the services. This assurance can be provided through an audit at the external supplier's laboratory or through other methods developed by the laboratory. NAC may oversee audits conducted by the laboratory to ensure the suitability of external services. The laboratory must include provisions in its contracts to allow for such oversight. In all cases, the laboratory obtaining external services must ensure the suitability of the external supplier for the work. The accreditation of the external supplier is an important criterion for this assurance but is not sufficient on its own and must be determined by the laboratory obtaining the service.

When obtaining laboratory activity services externally, necessary information, including the identity of the external supplier, must be shared with the customer during the request-offer process. The laboratory may reject an external supplier specified by the customer, except in legally mandatory situations. The laboratory must also evaluate impartiality considerations when determining the external supplier.

In the field of calibration, since the accreditation status of the laboratory performing the calibration is considered proof of metrological traceability, the laboratory obtaining the service must present the report issued by the external supplier as an appendix to its report to the customer.

The laboratory must communicate with the external supplier regarding competency and reporting requirements specified in the standard (e.g., measurement uncertainty in sampling activities) and other conditions. The laboratory must state in its contract that the external supplier cannot transfer the laboratory activity to another laboratory.

The laboratory must inform NAC about laboratory activities outsourced for activities within its accredited scope. This information must be provided in writing during the initial application and throughout the accreditation process.

5.3.7 Sampling

Laboratories can be accredited solely for sampling activities, provided that the sampling activity is intended for subsequent testing/calibration. Accreditation cannot be granted for sampling activities related to production processes without subsequent testing or calibration.

In cases where accreditation is granted solely for sampling activities, the laboratory must ensure that the sampling activity is intended for subsequent testing/calibration.

The following criteria are considered when calculating the measurement uncertainty arising from sampling:

- Laboratories must calculate measurement uncertainty for sampling activities within their accredited scope.

- If the accredited testing/calibration method refers to or describes the sampling method and the sampling activity is performed by the laboratory, the laboratory must calculate the measurement uncertainty arising from sampling.

- If the sampling activity is performed by an external supplier in the above cases, the laboratory obtaining the service must request the necessary information (including the measurement uncertainty itself) from the external supplier to evaluate the measurement uncertainty arising from sampling.

- In cases where the sample is provided by the customer, the laboratory must state in the report that the sample was provided by the customer, that the measurement uncertainty does not include the contribution from sampling, and that the sample was subjected to testing/calibration as received (if suitable for the relevant test).

If the characteristics (e.g., class, density) of the sample are specified by the customer, the laboratory must state in the report that the testing process was selected according to the customer's declaration.

5.3.8 Proficiency Testing and Interlaboratory Comparisons

Laboratories must perform internal and external quality control tests suitable for their activities, at a minimum as specified by the standard. Participation in proficiency testing or interlaboratory comparison

tests as external quality control activities must be conducted according to the "PR.019-NAC Proficiency Testing and Interlaboratory Comparison Programs Procedure."

When requesting scope expansion, laboratories must fill out and upload the NAC form to the NAC QM, considering the points specified in the "PR.019-NAC Proficiency Testing and Interlaboratory Comparison Programs Procedure."

5.3.9 Evaluation of Risks and Opportunities

Laboratories must identify, evaluate, and document risks and opportunities related to laboratory activities. Actions arising from these evaluations must be proportionate to the impact of the risks and opportunities on the validity of laboratory results.

Although the standard does not prescribe any specific methodology for risk and opportunity evaluation, laboratories must perform these evaluations according to their objectives, the complexity of their management system, applicable regulations, and other mandatory documents.

Risk and opportunity evaluation involves identifying, analyzing, and assessing risks/opportunities. The purpose of risk assessment is to determine whether it is necessary to reduce or prioritize improvements based on the results of risk analysis.

This risk and opportunity evaluation practice is expected to be the most basic level of management. Laboratories can operate a more advanced risk assessment process. In any case, laboratories must practically determine how to manage identified risks and opportunities, both reactively and proactively, for testing, calibration, and sampling activities.

The depth of risk and opportunity evaluation, or the circumstances under which risks are identified, varies depending on the laboratory's organizational structure, personnel structure, competency level, infrastructure, etc., and can differ from one laboratory to another. Laboratories can evaluate risks and opportunities for their entire quality management system and the scope of their accreditation. When conducting risk and opportunity evaluation, laboratories can focus on laboratory activities and go through the standard's clauses. There are no restrictions on specifying similar/same risk monitoring/prevention methods for risks common to multiple laboratory activities (multiple tests).

Risk assessment is a process that must be updated according to changing circumstances, including continuous monitoring and reassessment of actions for improvement. Risk management is not a one-time activity.

5.3.10 Quality System Documentation

Laboratories establish their systems according to their structure by choosing either Option A or B. In both options, the primary goal is to create a management system that allows for the repeatable management of the standard's requirements. The expectation for Option B is to ensure the minimum requirements specified in Option A are met. There is no difference between the options in terms of accreditation assessments. For both options, the assessment team will check whether a management system meeting at least the requirements of Option A has been established.

There is no different assessment in accreditation assessments for organizations certified by an accredited certification body or self-operating ISO 9001:2015 under Option B.

Laboratories can present their documentation for maintaining the integrity of their quality management system and demonstrating compliance with ISO/IEC 17025:2017 through a Quality Manual.

Laboratories must establish their management systems in compliance with ISO/IEC 17025:2017 and accreditation rules and must write procedures necessary to consistently implement their quality management systems according to the standard. When determining the extent of writing procedures, organizations must consider showing compliance with the above-mentioned requirements to accreditation body assessors and ensuring the assessability of their systems. For example, laboratory management must communicate duties, authorities, and responsibilities to personnel as required by the standard, but there is no specified method in the standard for this communication. However, laboratories must demonstrate that this requirement has been met and determine an appropriate record-keeping method (e.g., written) to ensure this part of the system is assessable.

Internal audits must be planned and conducted at most 12-month intervals, including laboratory activities, by persons independent of the work being audited and possessing the necessary competency. Management review processes must be planned and conducted at 12-month intervals.

5.4 Risk-Based Planning and Sampling Approach In Assessments

To ensure more regular and effective surveillance assessments, the accreditation officer prepares an "Assessment Plan" for each CAB, considering the accredited activity areas and personnel. An accreditation cycle program is prepared to ensure that all activities listed in the accreditation scope (scope in the annex of the accreditation certificate) are assessed at relevant locations according to the "PR.017-NAC Procedure for the Accreditation of Conformity Assessment Bodies."

The risk-based assessment approach is used when preparing the cycle program. Risk factors to consider when planning assessments may include but are not limited to:

- Nonconformities identified in the previous assessment
- Changes in personnel performing the analysis or hiring of new personnel
- Changes in scope
- Changes in equipment
- Externally supplied products and services
- Unsatisfactory PT/ILC results
- Revised accredited standards
- Feedback and complaints
- Changes in legal requirements, regulations, etc., when applicable
- Corrective and preventive actions taken by the organization for nonconformities
- Frequency of issuing Test Reports/Calibration Certificates/Sampling Reports

During initial accreditation assessments, all scopes and locations applied for by the organization are assessed. During the 48-month validity period of the accreditation, the laboratory's activities and locations are evaluated based on a risk-based approach and assessed at least once.

The following points, along with the relevant accreditation program rules, are considered during sampling.

5.4.1 Significant Activities

Processes affecting the CAB's competence and considered in this context are defined as significant activities. Thus, all activities performed by the laboratory to meet the ISO/IEC 17025 standard requirements are considered significant activities. Examples include impartiality assessment, ensuring personnel competence and metrological traceability, sampling, selecting appropriate methods for activities, reporting results, and complaint processes. The suitability of significant activities is verified through various assessment techniques.

5.4.2 Personnel to be Sampled

The selection of personnel performing the assessed activity is based on the "Personnel Competence Monitoring Schedule/Matrix" provided by the CAB to NAC. This document shows which personnel are authorized for which methods and functions (testing, calibration, sampling, report writing, etc.).

During initial accreditation assessments, the performance of the most competent personnel (considering experience, graduation, etc.) is observed first, followed by, if possible, the performance of the most recently authorized or least experienced personnel. During surveillance assessments, the performance of personnel not observed in previous assessments must be evaluated based on the authorizations in the above-mentioned document. Recently authorized personnel may be preferred. If any inadequacies are identified in personnel performance during witnessed activities, the assessment continues by evaluating the performance of the next most competent personnel (e.g., the next most competent personnel after the inadequate personnel).

5.4.3 Scope to be Sampled

If the scope for which accreditation is requested is broad, the methods applied for by the laboratory are selected through sampling. In this case, the key is to select a sufficient number of methods within the relevant scope to prove technical competence and conduct the assessment. The risks associated with the test method must also be considered when selecting the sample (e.g., the critical importance of the analysis result for human, animal, or environmental health, criticality determined by the relevant regulation with a legal limit).

Sampling can be done under the following conditions:

- The same device is used for the tests.

- The test methods are similar.

- The matrices of the samples tested are similar.

Additionally, when sampling, the frequency of the test, the laboratory's experience, the experience of the personnel performing the test, the findings of the previous assessment, and the results obtained by the CAB in proficiency testing must be considered.

6. REVISION TABLE

Date	Section	Amendment
19.03.2020	Header	Logo is changed.
22.03.2024	Header & all sections	New document code is used. Editorial changes are made, including re-numbering of sections.