Genel

1. **General**
2. Purpose: This guideline is to set forth the requirements for obtaining and maintaining National Accreditation Center accreditation for testing laboratories.
3. Reference Documents:
   ISO/IEC Standard 17025:2017, General requirements for the competence of testing and calibration laboratories.

   ILAC-P9, ILAC Policy for Participation in Proficiency Testing Activities
   ILAC-P10, ILAC Policy on Metrological Traceability of Measurement Results
   ILAC-G17, ILAC Policy for Measurement Uncertainty in Testing
   EPR 017 Procedure for the Accreditation of Conformity Assessment Bodies
   EK 016 Guidelines on Metrological Traceability
   EK 042 Guidelines on NAC Principles for Estimating Measurement Uncertainty in Calibration Laboratories

1. **Definitions**

General terms and definitions used in ISO/IEC 17000 series shall apply.

Other definitions related to metrological traceability and uncertainty:

calibration: a sequence of operations that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

combined standard measurement uncertainty: standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model

coverage factor: number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

expanded uncertainty: multiplication of the combined standard measurement uncertainty by a factor greater than one.

international system of units SI: a system of units based on the International System of Sizes, which is accepted in the General Conference on Measures and Weights (CGPM), including the names, symbols of basic units, prefixes of these names and symbols and their usage rules.

measurand: quantity intended to be measured.

measurement accuracy: closeness of agreement between a measured quantity value and a true quantity value of a measurand

measurement error: measured quantity value minus a reference quantity value

Metrological Traceability (VIM 3 Article 2.41): "Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibration each contributing to the measurement uncertainty".

Note: "For this definition, a 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard". In ISO/IEC 17025:2005 and ISO 15189:2007 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "traceability" is used throughout this Guideline.

Metrological traceability chain (VIM 3 Article 2.42): "Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference".

Metrological traceability to a measurement unit (VIM 3 Article 2.43): "Metrological traceability where the reference is the definition of a measurement unit through its practical realization".

Note: "The expression "traceability to the SI" means 'metrological traceability to a measurement unit of the International System of Units'". National Metrology Institute: National Metrology Institutes (NMIs) and Designated Institutes (DIs) are responsible for developing and maintaining national measurement standards in their countries or regions according to International Systems of Units (SI), ensuring equivalence to international measurement standards and providing metrological traceability to secondary (or less) level laboratories in the country. Throughout this Guideline, the term "National Metrology Institute" is used to cover both National Metrology Institutes as

well as Designated Institutes.

measurement precision: closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

measurement uncertainty: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

quantity: a property that belongs to a phenomenon, object, or substance, and the amount of which can be expressed as a number and reference.

testing laboratory: laboratory that performs testing according to ISO/IEC 17025.

verification: provision of objective evidence that a given item fulfils specified requirements validation: verification, where the specified requirements are adequate for an intended use

3. Accreditation Process

3.1 Application

Processes related to the receipt of an application is carried out as specified in "Receiving and Reviewing an Application" of the EPR 017 Procedure for the Accreditation of Conformity Assessment Bodies. In addition;

a. The testing, calibration, sampling and internal calibration areas for which the applicant laboratory requests accreditation are confirmed by contacting the body. The confirmation process also includes the compliance of scope requests in the area for which the body has applied with the field documents to be specified in the relevant scope declaration. If the body performs internal calibration, it will inform the area/range/method information of internal calibration in the application form.

Note 1: Internal calibration is a calibration activity that is not within the scope of a laboratory's accreditation but only provides laboratory's own metrological traceability and does not further distribute traceability. Assessments of bodies performing internal calibration activities are carried out by adding a calibration technician for the relevant field to the assessment team.

Note 2: When the application for accreditation is merely for sampling, the sampling activity in question is only accepted if it is related to a subsequent test or calibration to be performed. For sampling, requirements under Clause 4.7 must also be considered.

a. The scope of accreditation for which the body has applied is evaluated in terms of its accreditability. This evaluation includes, but is not limited to, the following stages:

- Is the application for scopes of testing, calibration or sampling activities?
- Is there a domestic/international accreditation implementation in the field of application?

Application evaluation is recorded with the Application Review Form. If necessary, expert opinion related to the field can be obtained.

In determining the scope of the laboratory, the above-mentioned considerations and the stated points are taken into account. The laboratory must be currently carrying out its activities within the scopes requested in the initial accreditation application and must have carried out laboratory activities related to these scopes.

Laboratories that apply for initial accreditation conduct internal audits and management reviews of the entire system and submit their records to NAC.

Prior to the assessment, the laboratories inform NAC about the laboratory activities (sampling, on-site activity, etc.) that their current personnel are in charge of and keep this information up-to-date. Defining the roles and responsibilities correctly and keeping them up to date is important for the creation of the assessment program.

Desired scope of accreditation detailing the calibration disciplines for which accreditation is sought must be submitted in the FR 055 Application Form for Testing Laboratories. As an example, the following format is recommended:

TEST CATEGORY	ITEMS, MATERIALS, OR PRODUCTS TESTED	SPECIFIC TESTS / PARAMETERS OR PROPERTIES, COMPONENTS, CHARACTERISTICS TESTED	SPECIFICATION, STANDARD TEST METHOD OR TECHNIQUE USED

NAC may at any time, in addition to the required documentation noted above, require other information.

3.2 Fees

Application fee is a fixed fee required by NAC for registering and filing the application of an applicant body. This fee shall be paid at the time of initial accreditation and shall not be refunded under any circumstances. Other fees shall be determined in accordance with EK 007 Guidelines on Accreditation Service Fees.

3.3 Assessment

After receiving the application form with required documents and fees, NAC shall review the submitted information. The assessment team shall conduct a document review and an assessment be scheduled if the review shows compliance with applicable requirements. The assessment periods are explained in "5.6 Accreditation Cycle" in EPR 017 Procedure for the Accreditation of Conformity Assessment Bodies. **The assessment may be conducted on-site or remotely depending on the circumstances.**

3.3.1 Corrective Actions

CABs shall response to nonconformities identified during the assessment within three months as of the conclusion of the assessment. The response must include objective evidence and root cause analysis to support CAR closures where appropriate. NAC reserves the right to conduct a follow-up assessment to determine if CARs and Concerns have been satisfactorily resolved. In cases where the CAB is not responsive within the specified period, the reason shall be justified; **otherwise NAC may decide not to grant accreditation to the laboratory.**

3.4 Accreditation Decision and Issuance of Certificate

All accreditation decisions (granting, maintenance, scope change, re-accreditation, suspension, scope reduction, withdrawal of accreditation etc.) shall be taken by the Accreditation Decision Committee and recorded in FR 042 Accreditation Decision Review Form.

NAC shall grant accreditation upon determination that based on the onsite/remote assessment and review of evidence submitted, the applicant has met all the accreditation requirements as a calibration laboratory for the calibration methods noted in the scope of accreditation certificate and available on the NAC website. The decision date shall be given in the accreditation certificate as the start date of the initial accreditation.

4. ISO / IEC 17025 Implementations in Laboratory Accreditation

In laboratory implementations, organizations that wish or are accredited from NAC according to the ISO/IEC 17025 standard must comply with the following matters.

4.1 Determining the Scope of a Laboratory

In its documentation, the laboratory specifies the methods of testing, calibration and sampling, which it states to work in accordance with the requirements of the ISO/IEC 17025 standard and related documents. Calibration activities performed internally should also be included in this statement. Accreditation assessment is planned based on the laboratory's statement. If an application has been made with an in-house method or modified method, the bodies must explain the acceptable reasons for applying with a non-standard method in this way. For laboratories that request accreditation only for the sampling activity, it is expected that they demonstrate that there is a testing or calibration activity to be performed subsequent to the sampling method. The laboratory cannot state that it works in accordance with the ISO/IEC 17025 standard in the testing, calibration and sampling activities it continuously provides from outside.

4.2 Impartiality and Confidentiality Requirements

The laboratory carries out its laboratory activities in a way that guarantees impartiality and confidentiality. The laboratory performs a risk assessment to ensure the impartiality of its activities and applies the assessment continuously. The risk assessment is not bound by any methodological conditions in the standard and is carried out in accordance with the level of impartiality stated by the laboratories (first, second and third party), the legislation and other mandatory documents they are subject to, and the risk that may arise from impartiality. The laboratory designs the entire system by evaluating the dangers that may affect its impartiality and the risks that may arise.

Risk assessment determines possible hazards/scenarios/threats related to impartiality, control measures in practice to prevent the occurrence of these situations and how the process will be managed in case of emergence of danger and specifies in its relevant documents. In each case, it must determine how to eliminate the identified danger associated with impartiality or how to minimize the risk.

At a minimum, the risk assessment for impartiality should take into account the dangers that may arise from situations such as ownership, administration, management, personnel, shared resources, financial transactions, contracts, marketing (including branding), payment of sales commissions, or other incentives to direct new customers.

The laboratory is responsible for the management of all information obtained or created during the implementation of its activities, in line with legal obligations. The laboratory guarantees issues related to customer confidentiality through a method that holds it legally responsible, such as a contract made with the customer. However, where requirements of law, legislation etc. coincides with the requirements of the standard, legal obligations are applied. If a legal authority wants to access information about the customer without the knowledge of the customer, the customer is not informed about the information being shared. This situation should be specified in the customer contracts.

4.3 Structural Requirements

Bodies should identify the managerial functions responsible for laboratory activities. This identification can be specified as senior management and laboratory management. No matter how it is expressed, the function that provides the resources needed by the laboratory, that initiates the final process for the procurement of resources, and that is responsible for laboratory activities should be accepted as the laboratory management.

The laboratory must be a legal entity or a defined section of a legal entity that can be held legally responsible for its activities. For the purposes of this standard, a public laboratory is considered a legal entity based on public status. In the assessment of laboratories with public legal entity, it is sufficient to see the establishment law and regulation as a document and record proving the public legal entity. Organizations with public legal entity qualifications are required to make a statement of assurance instead of professional liability insurance.

Laboratories that have a private law legal entity status must be registered in accordance with the relevant Commercial Code. Associations, foundations and professional chambers can establish enterprises registered in accordance with the relevant Commercial Law to perform laboratory activities. It is sufficient for organizations having such legal entity status to show their Trade Registry as document and record for their legal entity status. Organizations that have such legal entity status must have professional liability insurance to include their activities in the areas for which they request accreditation or are accredited.

4.4 Personnel Requirements

The Laboratory employs all its personnel (internal or external personnel) in accordance with the management system. Work contracts for all personnel must be written in all cases and must comply with the provisions of the Labor Laws. For the types of work that are not required in writing in the Labor Laws, a contract is signed in writing between the laboratory and the related personnel, indicating the working conditions. Contracts (notices) of impartiality, confidentiality and conflict of interest between the personnel and the laboratory are made in writing and signed by the parties. Contracts are made directly with the personnel, are recorded and available to the assessment teams. Insurance notifications made for the personnel working in managerial functions (technical management, quality management), taking into account the working time, are made available to be shown to the assessment team.

Apart from the cases mentioned above, in cases where the laboratory does not take responsibility for the social security of its personnel, it maintains the social security-related records showing the other working relations of the said personnel to be submitted to the assessment teams during the assessment. The laboratory specifies the arrangements to secure these issues in its contracts. There is no different evaluation in terms of competency, monitoring, etc. for the internal or external personnel in the laboratory. All personnel must be monitored. Contributions arising from personnel performance should be included in verification or validation work, regardless of internal and external personnel differences. In case of a different situation, the reasons should be presented to the assessment team. Considering the CMC value for calibration laboratories, these evaluations should be made more carefully.

Competence monitoring should be determined in accordance with the status of the laboratory activity (risk, frequency, etc.).□The ISO / IEC 17025 standard specifies the tasks that must be fulfilled in quality management and technical management. There is no difference between assigning these duties to a single person and naming them as "quality manager, technical manager, etc." and performing the said activities by more than one personnel by distributing the tasks. In case of distribution of tasks, it should be taken into consideration that an additional control element should be defined in the system regarding whether the activities are carried out consistently.

The ISO / IEC 17025 standard can be applied to any laboratory, regardless of the number of personnel. However, in cases where the requirements of the standard regarding confidentiality and objectivity (handling complaints, internal audits, etc.) cannot be provided by internal resources, it may be necessary to use outsourcing. Regarding impartiality and confidentiality, the legal regulations that the laboratory is bound by should be taken into consideration.

The laboratory can determine its personnel who are in a critical position for its accredited activities. In cases where critical

personnel are identified, personnel involved in technical management and quality management should be considered. Communication channels that can be accessed continuously for these personnel should be determined. It is also an option to appoint appropriate deputies to ensure the continuity of these functions. In identifying critical personnel, the laboratory should also consider personnel whose absence shall cause the cessation of an activity within the scope of accreditation (ex. the only testing personnel authorized within a scope). The laboratory should document the competency requirements within the scope of planning, implementation, control and prevention functions that affect the results of its activities. For example, as the request, proposal, contract processes are part of planning, the internal audit is part of control.

In all cases, the laboratory notifies NAC in writing of the personnel changes that affect the activities within the scope of accreditation as stated in the article of the Accreditation Agreement, within the periods specified in the agreement. After this notification, NAC evaluates the status of the laboratory and, depending on the content of the change, may not make any changes to the accreditation status, partially or completely suspend or withdraw accreditation, or request an on-site assessment.

4.5 Equipment

The ISO/IEC 17025 standard requires access to necessary and sufficient equipment for laboratories. Under normal circumstances, the body should use only equipment owned, leased or loaned to the body on a long-term basis. If the body has to use different equipment, it must prove the suitability of the equipment used for the activity accredited, demonstrate that it has been taken into account in the verification / validation studies (when necessary).

In all cases, the laboratory notifies NAC in writing of the changes (equipment change, equipment relocation, etc.) that affect the activities within the scope of accreditation as stated in the article of the Accreditation Agreement, within the periods specified in the agreement. After this notification, NAC evaluates the status of the laboratory and, depending on the content of the change, may not make any changes to the accreditation status, partially or completely suspend or withdraw accreditation, or request an on-site assessment.

In ISO / IEC 17025, there is no obligation to have backups of the equipment used in testing, calibration and sampling; however, laboratories may choose to have backups of some of their equipment depending on the risk status of their activities.

4.6 Outsourced Products and Services

A laboratory may temporarily outsource a work for unpredictable reasons (e.g work intensity, temporary capacity reduction, etc.). Laboratories may not consistently outsource for the activities within the scopes of their accreditation. Except for force majeure, the laboratory receives its outsourced laboratory activity, in accordance with the work to be performed, from a body accredited in the requested activity by NAC or by an accredited body that has a recognition agreement in the field of testing, calibration and sampling to which NAC is a party. Force majeure are situations such as legal obligations, absence of another accredited organization in the same field, etc. In such cases, the laboratory receiving outsourced service ensures the compliance of the services in question. This assurance can be provided by an assessment to be carried out in the external supplier's laboratory, or by other procedures developed by the laboratory. In such cases, NAC may supervise the assessments carried out by the laboratory receiving service to ensure the suitability of the outsourced service, in order to verify the competence of the laboratory receiving service. The laboratory receiving external services includes in its contract the provisions that will allow the above-mentioned supervision in the laboratory of the external supplier. In any case, the laboratory receiving service must ensure that the external provider is suitable for the work to be done. Accreditation of an external supplier is an important criterion for providing this assurance, but whether it is sufficient must be determined by the organization receiving the service.

In case of receiving external services for laboratory activities, the necessary information, including the identity of the external supplier, is shared with the customer during the request-proposal process. The laboratory may not accept the external supplier determined by the customer, except where it is a legal obligation. The laboratory should also evaluate issues related to impartiality in determining the external supplier. Since the accreditation status of the laboratory that actually performs the calibration for metrological traceability in the field of calibration is accepted as evidence, the laboratory that receives the service submits the report prepared by the external supplier laboratory to its customer in an annex to its report.

The laboratory should contact the external supplier with regard to the services it receives from outside, as specified in the standard, and inform the external supplier about its conditions such as competence and the issues that should be included in the report (for example, measurement uncertainty in sampling activity, etc.). The laboratory specifies in its contract that the outsourced laboratory activity may not be transferred to another laboratory.□

The laboratory informs NAC about the outsourced laboratory activities that fall within the scope of laboratory activities for which it is accredited. This information is carried out in writing on a document basis during the accreditation process as in the initial application.

4.7 Sampling

It is possible that laboratories can only be accredited for sampling activity. In this case, the sampling activity should be related to the testing or calibration activity. Accreditation is not granted according to ISO/IEC 17025 for sampling activities that are not related to any testing or calibration activities, and that is intended for production processes with no subsequent testing or calibration operation.

Only in cases where accreditation for the sampling activity is granted, the laboratory must guarantee that the sampling activity is intended for the subsequent testing/calibration operation.

The following criteria are taken into account when calculating the measurement uncertainty due to sampling:

- The laboratory calculates measurement uncertainty in accredited sampling activities.

- If the laboratory's accredited testing / calibration method refers to the sampling method in itself or describes the sampling, and the sampling activity is carried out by the laboratory, the laboratory must calculate the measurement uncertainty due to sampling.

- In the above-mentioned cases, if the sampling activity is outsourced, the laboratory receiving the service must request in the contract with the external supplier the necessary information (which may be the measurement uncertainty itself) to evaluate the measurement uncertainty due to sampling .

- In cases where the sample is provided by the customer, the laboratory states in its report that the sample is provided by the customer, that the contribution in the measurement uncertainty due to sampling is not included and the sample is tested / calibrated as it was taken (if the sample is suitable for the relevant test)

In cases where the class, density etc. of the sample to be tested / calibrated are specified by the customer, it is stated in the report that the applied test process is selected according to the customer statement.

4.8 Proficiency Testing and Inter-Laboratory Comparison

As a minimum, laboratories perform the internal and external quality control activity/activities prescribed by the standard that are suitable for their activities. As an external quality control activity, the laboratory performs proficiency tests or participates in inter-laboratory comparison according to the requirements of the Procedure for Proficiency Testing and Inter-laboratory Comparison Schemes. In order for the quality control activity to be evaluated as an external quality control activity, the evaluation criteria of the results should be determined in advance and an evaluation should be made outside the laboratory as much as possible. After the final report of external quality control activity is received, the studies and evaluations carried out by the laboratory are not considered as external quality control activity.

Laboratories should evaluate their planning in areas where they would like to request scope extension with the methods specified in the Procedure for Proficiency Testing and Interlaboratory Comparison Schemes and include them in the relevant NAC form.

4.9 Assessing Risks and Opportunities

Laboratories should address, assess and document risks and opportunities related to laboratory activities. The actions, risks and opportunities to be revealed as a result of these assessments should be proportional to the effect on the validity of the laboratory results.

Although there is no methodological requirement in the standard, the assessment of risks and opportunities should be carried out in accordance with the objectives of the laboratories, the level of complexity of the management system, the legislation and other mandatory documents.

Risk and Opportunity Assessment includes the identification, analysis and assessment of risks/opportunities. The purpose of risk assessment is to help decide whether there is a need to reduce risks and/or improve them primarily, depending on the results of risk analysis.

This is the most basic level of management expected from the implementation of risk and opportunity assessment. The laboratory may operate an advanced risk assessment process. In all cases, the laboratory should practically determine how the identified risks and opportunities related to testing, calibration and sampling activities are managed reactively and proactively.

The depth and definition of risks in the risk and opportunities assessment depend on the organizational structure, personnel and competency, infrastructure of the laboratory etc. and may vary from laboratory to laboratory. The laboratory can assess risks and opportunities on the basis of the scope for which it is accredited, taking into account the quality management system in its entirety. While carrying out the risk and opportunity assessment, the laboratory may go over the articles of the standard focusing on the laboratory activity. There are no restrictions on specifying a similar/identical risk monitoring/prevention method for the process approach of laboratories or for risks that may be common to multiple laboratory activities (multiple tests).□Risk

assessment is a process that needs to be updated according to changing situations, which includes continuous monitoring and re-evaluation of actions for improvement. Risk management is not a one- time activity.

4.10 Quality System Documentation

Laboratories should set up their systems by choosing the most appropriate option from Options A and B. In both options, the main goal is to create a management that allows the requirements of the standard to be managed in a repeatable manner. The expectation from Option B is, as a minimum, to assure the requirements specified in Option A. There is no difference between the options in terms of accreditation assessments. For both options, the audit team will, as a minimum, check whether a management system that meets the requirements set out in Option A has been established.

In Option B, there is no difference in accreditation assessments between the body being certified by an accredited certification body or operating ISO 9001 by itself.

Laboratories can present the documentation, which they will prepare to ensure the integrity of the quality management system and to demonstrate compliance with the ISO / IEC 17025 standard, with the Quality Manual.

Laboratories should establish their management systems in accordance with ISO / IEC 17025 and accreditation rules and document their procedures to the extent necessary to consistently implement quality management systems in accordance with the standard. When determining the limits of documentation, bodies should also take into account to demonstrate the above-mentioned compliance to assessors of the accreditation body and ensure the assessibility of their systems. For example, as a standard requirement, laboratory management should communicate with the personnel about their duties, authorities and responsibilities; however, although the standard does not specify a method for this communication, the laboratory should demonstrate that this requirement is fulfilled and a method (in writing, etc.) for record creation is determined in order for this part of the system to be assessible. By definition, the laboratories should plan and carry out internal audits in periods of at most 12 months for the whole system including the laboratory activities by persons who are independent of the work being assessed and have the competence required by the work. Management review processes should also be planned and carried out in periods of 12 months.

5. Risk-Based Planning And Sampling Approach In Assessments

In order for surveillance assessments to be more regular and effective, the case officer creates an “Assessment Program” for each organization, taking into account the areas of activity for which the organization is accredited and its personnel. In accordance with the "Procedure for the Accreditation of Conformity Assessment Bodies", an accreditation cycle program is prepared for each CAB to be assesssed at the relevant locations, representing all of the activities within the scope of accreditation (scope in the annex of the accreditation certificate) along with the management system throughout the cycle.

A risk-based assessment approach is used when creating a cycle program. Risk factors to be considered when planning assessments may include, but are not limited to, the following:

- Non-conformities detected in the previous assessment
- Change of personnel performing the analysis or recruitment of new personnel
- Changes in scope
- Changes in equipment
- Outsourced products and services
- Non-conforming PT/ILC results
- Revised accredited standards
- Feedback and complaints
- Changes in requirements of legal authority, regulation, legislation etc. (if applicable)
- Corrective actions carried out by the body for non-conforming work
- Frequency of preparing a test report / calibration certificate/ sampling report

In the initial accreditation assessments, all scopes and all locations for which the body has applied for accreditation are assessed. Within the 60-month period during which the accreditation is valid, the activities and locations of the laboratory are evaluated

within the framework of a risk-based approach and assessed at least once.

In the sampling, the rules in the relevant accreditation program are taken into consideration together with the following.

5.1 Important Activities

Processes that affect CAB's competency and are considered within this framework such as policy development, process and/or procedure development and review of the contract when appropriate, planning of conformity assessment activities, review of the results of conformity assessment activities, approval and decision, etc. are defined as important activities. Based on this, all activities carried out by the laboratory to meet the requirements of the ISO/IEC 17025 standard are considered as important activities. Examples: processes such as the evaluation of impartiality, assurance of personnel competence and metrological traceability, sampling, selection of appropriate methods for activities, reporting of results, complaint process, etc.. Compliance of important activities with the requirements is confirmed through various assessment techniques.

5.2. Personnel To Be Sampled

During the assessment, the selection of personnel to perform the assessed activity is based on the “Personnel Competence Monitoring Chart/Matrix” submitted by the body to NAC. This document should be prepared in a way to show which personnel are authorized in each method and function (test, calibration, sampling, report writing, etc.).□Accordingly, in the initial accreditation assessment, the performance of the most competent (taking into account experience, graduation, etc.) personnel is witnessed, and then, if possible, the performance of the personnel with the lowest level of competence (experience, graduation etc.)is witnessed. In surveillance assessments, the performance of the personnel whose performance have not been witnessed before are witnessed based on the authorizations specified in the above- mentioned document of the organization. Last authorized personnel can be preferred here. If deficiencies due to personnel performance are identified in the witnessed activities, the assessment is carried out by evaluating the personnel who can show sufficient performance within the organization (for example, the most competent personnel after the inadequate personnel).

5.3. Scope To Be Sampled

If the scope of accreditation requested is broad, the methods applied by the laboratory are selected by sampling. In this case, the important thing is to carry out the assessment by choosing a number of methods to prove that technical competence in the relevant scope is achieved. In sampling, risks that may arise from the method used in testing are taken into account (such as the fact that the result of the analysis is critical to the health of human, animal environment, etc, and that it is considered to be critical in the relevant legislation and a legal limit is given).

Sampling can be done if;

The device used for the test is shared,

The test method is similar,

The matrices of samples being tested are similar.

In addition, when sampling, the frequency of the test, the experience of the laboratory, the experience of the personnel conducting the test, the results of the previous assessment, and the results obtained by CAB in proficiency tests should be taken into account.

6. Metrological Traceability

The National Accreditation Center's policy on calibration of measurement instruments and metrological traceability of measurement results is described below. This policy is established to define NAC rules on how to fulfill metrological traceability requirements in accordance with ISO/IEC 17025:

a) In order to meet the metrological traceability requirements of the ISO/IEC 17025 standard, an organization receiving calibration service must ensure the metrological traceability of the equipment, which contributes significantly to the results of testing, calibration and sampling within the scope of accreditation, through the first and second route specified under Clause 6.

b) If an organization receiving calibration service has used non-calibrated equipment in the tests, calibrations and measurements within the scope of its accreditation, it must show to NAC that the contribution of the equipment in question to the measurement uncertainty of the results obtained is insignificant.

c) An organization receiving calibration services must keep records on the competence of the calibration provider.

d) An organization receiving calibration services must adopt a proactive approach to meet the requirements of the ISO/IEC 17025 standard for metrological traceability.

e) An organization receiving calibration services must submit its justification to NAC if it provides metrological traceability through Route-3 specified in this policy. Metrological traceability cannot be provided through Route-3, which is stated in Article f), only for economic or logistical reasons. Foreign service providers should also be contacted if there is no service provider in the same economy that can provide metrological traceability through the first and second routes. If it is shown that the requirements for competence are met in accordance with this Guideline, the use of Route-3 is allowed. An organization receiving calibration services must submit to NAC records of the search for a metrological traceability provider that comply with this Guideline.

f) An external service provider that provides metrological traceability in accordance with Route-3 must be evaluated by the laboratory that receives the calibration service for the relevant calibration and measurement capabilities (CMCs) in the context of the standard and this guideline, and its conformity must be ensured. This assurance must be provided by an assessment to be carried out by competent persons in the relevant field in the laboratory providing the service. In such cases, in order to ensure the suitability of the external service received, NAC may supervise assessments carried out by the laboratory receiving service to ensure that the laboratory receiving the service is competent. A laboratory receiving external services must include in its contract the provisions that will allow the above-mentioned supervision in the laboratory which provides services. All records of the evaluation process must be submitted to the NAC assessment team during the assessment process. In addition, where calibration cannot be performed according to the methods available in accredited laboratories (for example, when the equipment is too complex or only the producer has the appropriate infrastructure for calibration, etc.) use of Route-3 may be permitted.

g) Traceability evaluations are performed separately for each of the metrological traceability evidence claimed for all routes. If the first two routes are not possible, a laboratory that intends to provide metrological traceability through Route-3 must prove that the calibration provider from which it receives service meets the relevant requirements of the ISO / IEC 17025 standard with the minimum documents and records specified in Annex A.

h) An organization receiving calibration services must demonstrate evidence to NAC during the accreditation process that the external service provider providing metrological traceability through Route-3 is competent. For this purpose, NAC includes competent assessors/technical experts in the assessment team and evaluates the documented evidence and records demonstrating the competence of the external service provider used by the laboratory being assessed. An organization receiving calibration services must follow the hierarchy specified in Annex-B.

i) According to the Guidelines on Test Reports and Calibration Certificates with NAC Mark, a calibration laboratory accredited by NAC is required to use the accreditation mark in calibration certificates/reports as specified in this Guideline. ILAC P8 "Mutual Recognition Arrangement (Arrangement): As indicated in the General Requirements of "Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies", only reports/certificates that have the accreditation symbol/logo/mark may fully benefit from the recognition accorded by the ILAC MRA and Regional Arrangements (EA, APAC, IAAC etc.) recognized by ILAC.

Therefore, calibration certificates issued by calibration laboratories accredited by an accreditation body, other than NAC, which is covered by a recognition arrangement with ILAC or by one of the regional accreditation associations (EA, APAC, IAAC, etc.) recognized by ILAC must have the accreditation mark or reference information related to accreditation status in order for such certificates to be considered as evidence of traceability. In cases where the accreditation mark is not available, it is the responsibility of the party receiving service to show that the calibration in question has been performed by an accredited organization within the appropriate scope.

j) Reports / certificates issued by traceability providers who are not accredited in the field of calibration but have ISO 9001 certification, even if they are certified by an accredited certification body that provides traceability, cannot be accepted as traceability evidence.

k) In order to maintain the reliability of the calibration status of their calibrated equipment, organizations should regulate their calibration intervals, taking into account ILAC-G24 / OIML D 10 “Guidelines for the Determination of Calibration Intervals of Measuring Instruments”.

l) For organizations that conduct internal calibration, the clauses of this Guideline also apply to traceability.

6.1 Documentation on Metrological Traceability Routes, Selection and Process

Documentation on the selection and competence of the metrological traceability route must as a minimum include the following.

6.2 Metrological Traceability Routes

ILAC P10 has evaluated routes related to metrological traceability under three routes as follows.

Route-1: a national metrology institute that is a party to CIPM MRA Arrangement regarding the requested service and has calibration and measurement capability (CMC) published in the BIPM KCDB database. Services covered by CIPM MRA can be viewed in BIPM KCDB Annex C.

Route-2: A laboratory accredited according to ISO / IEC 17025 standard by an accreditation body covered by ILAC arrangement or regional

arrangements recognized by ILAC in the field of calibration and has the service requested within the scope of accreditation.

Route-3: a) A national metrology institute whose service is suitable for the intended need but is not a party of the CIPM MRA.

b) A calibration laboratory whose service is suitable for the intended need but is not accredited according to ISO/IEC 17025 by an Accreditation Body which is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

Note: Calibration activities of internal calibration organizations cannot be evaluated in the context of the routes specified in this guideline. The activities of organizations (organizations performing internal calibration) performing calibration, which is not covered by the accreditation, only to ensure their own metrological traceability are evaluated according to ISO/IEC 17025, this guideline and relevant documents.

Selection of Route-1 or Route-2

A laboratory must verify that the calibrations provided by the organization from which the calibration service is received are in accordance with the requirements of ISO / IEC 17025 regarding metrological traceability, that they have appropriate measurement uncertainties, and that they fulfill the requirements of this guideline for the required measurement areas and intervals.

A laboratory must verify that the calibration certificates issued by the organization from which the calibration service is received fulfill the requirements of ISO/IEC 17025 for calibration certificates.

Note: The scope of such a verification process may include the examination of a database located on the Web, the evaluation of accreditation documentation, and the examination of the scope of the calibration laboratory.

Selection of Route-3

Where metrological traceability is not possible through Route-1 and Route-2, a laboratory performing testing and sampling activities and seeking to provide metrological traceability through Route-3 is required to maintain stated activities and records of these activities so as to present to NAC in order to detect the competence of the calibration provider from which the laboratory intends to receive calibration service.

It is not possible for Calibration Laboratories to be accredited using Route-3. A calibration provider, which provides metrological traceability through Route-3, must as a minimum present the documents and records specified in Annex A to demonstrate its competence. NAC may request additional documents during the assessment process.

The laboratory must provide calibrations in accordance with the requirements of ISO/IEC 17025 for metrological traceability, with appropriate measurement uncertainties, for the measurement areas and intervals it needs.

The laboratory must ensure that the content of the calibration certificate issued by the calibration provider, which provides metrological traceability through Route-3, complies with the requirements of ISO/IEC 17025 for calibration certificates.

The laboratory must obtain and maintain the following documents and records:

- Records demonstrating that laboratories receiving calibration services from a calibration provider that provides metrological traceability through Route-3 has received this service by conducting research according to the hierarchy given in Annex-B.,
- Records of the metrological traceability of standard devices used by the calibration provider, which provides metrological traceability through Route-3,
- Records related to the evaluation with minimum documents and records specified in Annex-A, demonstrating the technical competence of the calibration provider providing metrological traceability through Route-3 and the claimed metrological traceability. The identity of the personnel should also be traceable in evaluations of personnel competence.

6.3 Traceability Requirements in the Absence of Direct Traceability to SI Units

Metrological traceability to SI units may not be possible in some cases. In this case, the reasons for not fulfilling the requirements specified in this guideline must be stated together with reasons. In this case, the selection of the route that will meet the requirements of ISO / IEC 17025 for metrological traceability is the responsibility of the laboratory receiving calibration service. The laboratory receiving calibration services must provide appropriate and documented evidence of this situation. Such situations are evaluated separately in accordance with the specific circumstances of laboratories in the assessment processes.

6.4 Metrological Traceability Requirements under the ILAC Arrangement in Testing

The ILAC Arrangement covers testing laboratories accredited according to ISO/IEC 17025 and medical laboratories accredited according to ISO 15189. Considering ISO/IEC 17025 and ISO 15189 standards, the following requirements must be taken into account.

- If the uncertainty components resulting from the calibration of the instruments used for the test significantly affect the combined measurement uncertainty of the test, the requirements in this guideline must be taken into account.

- In cases where the calibration of the instruments used for testing does not have a dominant effect on the test results, the laboratory should present quantitative evidence that the effect of uncertainty from the calibration on the measurement results is not significant.

NAC's policy on metrological traceability of certified reference materials (SRM) is as follows:

- The values assigned to CRMs produced by NMIs covered by CIPM MRA and included in the BIPM KCDB "Key Comparison Data Base" or produced by accredited reference material producers under its accredited scope of accreditation to ISO 17034 are considered to have established valid traceability (see ILAC General Assembly resolution ILAC 8.12).

- Certified reference materials entered into the JCTLM database are considered to provide valid metrological traceability of their certified values.

- Reference materials provided by other reference material producers can qualify as critical consumables. The laboratory must demonstrate that each reference material it uses is suitable for the intended use according to the ISO/IEC 17025 and ISO 15189 standards.

7. Measurement Uncertainty

Accredited calibration laboratories must estimate the relevant measurement uncertainty so that the results of all the calibrations they perform can be interpreted. Measurement uncertainties should generally be estimated and reported according to the method specified in the international document ISO/IEC Guide 98-3 published by BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML under the title "Guide to the Expression of Uncertainty in Measurement (GUM)" or the method described in the EA documents referring to this document.

The calculated uncertainty estimation should be documented and supported by evidence. Calibration Laboratories applying to become accredited must specify “calibration and measurement capability” for calibration studies included in their accreditation scope. The meaning of "Calibration and Measurement Capability" and the expression "Best Measurement Capability" previously used in the accreditation system is the same, and the detailed definition is given in the document ILAC P14:01/2013 "ILAC Policy for Uncertainty in Calibration". The difficulty of mathematical modeling used in estimating measurement uncertainty should be proportional to the desired degree of accuracy. At least the following information should be included in the presentation of measurement results;

- a clear description of the measurand,
- value found as a result of measurement,
- Expanded uncertainty at a confidence level of 95%,
- coverage factor, (k) and,
- unit of measurement of measurement result and expanded uncertainty ,

As the definition of CMC implies, accredited calibration laboratories shall not report a smaller measurement than the uncertainty described by the CMC for which the laboratory is accredited.

The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a specific coverage probability of approximately 95 %. The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand, e.g., percent.

For detailed information on measurement uncertainty calculations for calibration laboratories, please refer to EK 042 Guidelines on NAC Principles for Estimating Measurement Uncertainty in Calibration Laboratories.

Annex A (MANDATORY)

Minimum documents and records to be presented for the technical competence of the calibration service provider and claimed metrological

traceability:

- Validation records of calibration method
- Procedures and records used for measurement uncertainty
- Documentation and records for metrological traceability of measurements
- Documentation and records to ensure the quality of calibration results
- Documents and records related to personnel competence
- Documents and records related to accommodation and environmental conditions
- Documentation and records related to internal audit of the calibration laboratory

Other relevant documents and records requested in this guideline should also be submitted to NAC. NAC may request additional documents.

Annex B (MANDATORY)

If metrological traceability is provided through Route-3, the organization receiving calibration services must comply with the following hierarchy.

1. National metrology institute that is covered by CIPM MRA but does not have calibration and measurement capability published in KCDB for the requested calibration. In this case, the metrological traceability of the references used by the National Metrology Institute in the requested calibration service must be through Route-1 or Route-2.

2. A laboratory which is accredited to ISO/IEC 17025 Standard by an accreditation body signatory to the Recognition Arrangement with at least one of EA/ILAC/APAC/IAAC but does not provide the requested calibration service in the scope of accreditation. The metrological traceability of the references used in the requested calibration service of the calibration laboratory that provides the service must be through Route-1 or Route-2.

3. External service providers that provide metrological traceability of their services through Route-3, whose references used in the requested calibration service are metrologically traceable through Route-1 or Route-2. In this way, metrological traceability may be achieved in a few stages.

4. An external service provider that claims to provide metrological traceability to national standards and whose metrological traceability is provided through Route-3 must prove that these standards meet the properties of primary standards for the realization of SI units. The laboratory must keep records that the metrological traceability chain established in the said way meets the requirements of the standard.