1.INTRODUCTION

The purpose of this guideline is to guide laboratories in the implementation of ISO/IEC 17025:2017 standard. In assessments to be performed according to the previous version of ISO/IEC 17025, practices coming with the new revision will not be taken into consideration.

The laboratory that applies for accreditation presents the documents and records specified in Form FR-7-01-8, Documents Requested from Laboratories on Application, to New Business Education Foundation-NBE.

Assessment of laboratories are planned to cover activities carried out at their premises, site activities and mobile activities, including testing, calibration and sampling. The purpose of the assessment is to decide whether the laboratory has a system that meets the requirements of ISO/IEC 17025 standard and applicable guidelines

Information obtained before, during and after the assessment will be kept strictly confidential by the members of the New Business Education Foundation-NBE assessment team and case officers, and will not be communicated to third parties.

2.RELATED DOCUMENTS

In the implementation of this guideline, matters in ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories, and the documents related to laboratory activities on the NBE website should be taken into consideration.

3.APPLICATION

The procedures related to the receipt of the application are carried out as specified in NBE PR-7-01 Procedure for the Accreditation of Conformity Assessment Bodies, section 3.1.3 Receipt and Review of the Application. In addition to these;

a)Test, calibration, sampling and internal calibration fields for which the applying laboratory requests accreditation are confirmed by contacting the organization. The confirmation process also includes the compliance of the scope requests in the applied field with the field documents specified in the relevant scope declaration. If the organization is performs internal calibration, the field/range/method for which internal calibration is performed must be declared in the application form.

Note 1: Internal calibration is a calibration activity which is not included in the accredited scope of the laboratory but only provides its own metrological traceability and does not distribute traceability further. The assessments of the organizations performing internal calibration activities are carried out by adding a calibration specialist in the relevant field to the assessment team.

Note 2: When applied solely for the sampling activity, the sampling activity for which accreditation is requested will be accepted only if it is related to a subsequent testing or calibration. For sampling, requirements under Article 3b heading must also be considered.

b)The scope of accreditation applied by the organization is assessed in terms of its accreditability. This assessment includes, but is not limited to, the following steps:
i. Is the scope applied a testing, calibration or sampling activity?
ii. Is there a domestic/foreign accreditation implementation in the field applied?

The assessment of the application is recorded by FR-7-01-85 Application Review Form. If needed, expert opinion in the relevant field can be taken.

When determining the laboratory scope, the matters above and the matters specified in Article 4.1 are taken into consideration.

The laboratory is required to be carrying out its activities in the scope requested by the first accreditation application, and is required to have carried out the laboratory activities related to these scopes. In special cases (e.g., when there is an obligation to get the approval of the relevant ministries to start operations, and when there is no actual client), it is required to work with a sample.

Laboratories applying for the initial accreditation perform internal audit and management review for the entire system, and submit their records to NBE.

Before the assessment, the laboratory informs NBE about its activities carried out on the site. Case officer and NBE lead assessor (team leader) responsible for the assessment plan the assessment, and on the basis of the laboratory activities covered by the scope applied, consider all factors necessary for reliable assessment of the laboratory's competency. During the planning process, the selection of the sample sites for site assessment, laboratory's personnel to be assessed, and whether there is a need for additional technical assessors for this purpose will be decided.

4.IMPLEMENTATION OF ISO/IEC 17025 IN LABORATORY ACCREDITATION

In laboratory implementations; organizations that want to be accredited or are already accredited by NBE according to ISO/IEC 17025 standard must comply with the following matters.

4.1 Determination of Laboratory Scope

The laboratory specifies in its documentation the methods (procedures) of testing, calibration and sampling that it declares to comply with the requirements of ISO/IEC 17025 standard and the related documents. Calibration activities performed internally should also be included in this declaration. Accreditation assessment is planned based on the declaration of the laboratory.

If the application is made with an in-house method or a modified method, the organization should

give acceptable justifications for applying with such a non-standard method.

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 declare compliance with ISO/IEC 17025 standard for testing, calibration and sampling activities that are constantly outsourced.

4.2 Matters Related to Impartiality and Confidentiality

The laboratory carries out its laboratory activities in a way to assure matters related to impartiality and confidentiality. In order to ensure the impartiality of its activities. the laboratory conducts risk assessment on an on-going basis.

Risk assessment is not tied to any methodological condition in the standard, and is carried out in accordance with the level of impartiality (first, second and third parties) declared by the laboratories, the legislation and other mandatory documents to which they are subjected to, and the risk caused by impartiality hazard. The laboratory designs the system as a whole by assessing the dangers that could affect its impartiality and risks that could occur.

The risk assessment identifies potential dangers/scenarios/threats related to impartiality, control measures in place to prevent the occurrence of such circumstances, and how to manage the process in the event of a danger, and specifies these in relevant documents. It must determine how to eliminate the identified danger related to impartiality or how to minimize the risk in all cases.
Risk assessment related to impartiality should at least consider the dangers that may arise from situations such as property, administration, management, personnel, shared resources, financial transactions, contracts, marketing (including branding), sales commission payments or other incentives for the guidance of new customers.

The laboratory is responsible for the management of all information obtained or generated during the course of its activities in line with legal obligations. The laboratory secures the matters related to customer confidentiality by a method that can hold it legally accountable, such as a contract with the customer. However, when the requirements of law, legislation etc. conflict with the requirements of the standard, legislative provisions apply. If the legal authority requests to access customer information without notifying the customer, the customer will not be informed about the fact that the information was shared. This should be specified in customer contracts.

4.3 Matters related to Structural Requirements

Organizations should define managerial functions responsible for laboratory activities. This definition can be expressed as top 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 part of a legal entity that can be held legally responsible for its activities. In accordance with the purpose of this standard, a public laboratory is considered to be a legal entity with public status. In the assessment of the laboratories with public legal entity status, reviewing the document showing the public legal entity status such as the institutional act, regulation, Decree-Law etc. is considered adequate. Organizations with public legal entity status are required to make declaration of assurance instead of professional liability insurance.

The laboratories with private law legal entity status must be registered according to the Commercial Codes. Associations, foundations and professional chambers can establish enterprises to perform laboratory activities that are registered according to the Commercial Codes. 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 having such legal entity status are required to have a professional liability insurance to cover the scope of activities for which they are requesting accreditation or for which they are already accredited.

4.4 Staff-related Matters

The laboratory employs all personnel (internal or external personnel) in accordance with its 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. For personnel employed abroad, a contract including the above-mentioned matters is done in writing that takes into consideration the local legislation of the relevant country. Impartiality, confidentiality and conflict of interest contacts (notifications) 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 made available for the assessment teams. Social security notifications made by taking into account the work period of the personnel in charge of managerial functions (technical management, quality management) should be available 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 keeps records related to social security indicating the other working relationships of the personnel in question to show to the assessment teams during assessment. The laboratory specifies the arrangements to secure these matters in the contracts.

There is no difference in the evaluation of internal and external personnel in the laboratory with regards to competence, monitoring etc. All personnel should be monitored. Contributions due to personnel performance should be included in verification or validation studies, regardless of internal or external personnel difference. When a different case is concerned, the reasons should

be presented to the assessment team. As far as the CMC value for calibration laboratories is concerned, assessments in question should be made more carefully.

Competency monitoring should be determined in accordance with the status of the laboratory activity (risk, frequency, etc.).

ISO/IEC 17025 standard specifies the requirements that need to be fulfilled for quality management and technical management. There is no difference between the assignment of these tasks to a single person and naming that person "quality manager, technical director, etc.", and the division of duties and the fulfilment of the activities in question by multiple personnel. It should be considered that if a division of duties is made, an additional control element must be defined in the system to check whether the activities are carried out consistently.

ISO/IEC 17025 standard can be applied to any kind of laboratory regardless of the number of personnel. However, outsourcing may be required when the requirements of the standard for confidentiality and impartiality (such as handling of complaints, internal audits, etc.) cannot be satisfied through internal resources. Legal arrangements related to impartiality and confidentiality that the laboratory must conform to should be considered.

The laboratory can identify its personnel in critical positions for activities for which they are accredited. In cases where critical personnel are identified, personnel taking part in technical management and quality management should be considered. Communication channels should be established to ensure continuous access to this personnel. Appointment of appropriate agents is also an option to ensure the continuity of these functions. When the laboratory identifies critical personnel, it should also consider personnel whose absence may cause an activity in the scope of accreditation to stop (e.g., a single test person authorized in a scope).

The laboratory should write down its competence requirements within the scope of planning, implementation, control and prevention functions that affect the results of its activities. For example, as the demand, proposal, contract process is part of planning, internal audit is part of control.

In all cases, as stated in Article 4.1.10 of the Accreditation Agreement, personnel changes affecting activities within the scope of accreditation is notified in writing to NBE within the time period specified in the contract. After this notification, NBE assesses the status of the laboratory, and depending on the content of the change, NBE may not make any changes in accreditation status, may partially or completely suspend the accreditation or withdraw it; can request in-place assessment.

4.5 Equipment

ISO/IEC 17025 standard requires access to equipment that is necessary and sufficient for laboratories. Under normal circumstances, the organization should only use the equipment it owns, or the equipment that was leased or loaned to the organization on a long-term basis. If the

organization has to use different equipment, the compliance of the equipment used in the accredited activity must be shown, and it should be demonstrated that the equipment used was considered in verification/validation studies (if necessary).

In all cases, as stated in Article 4.1.10 of the Accreditation Agreement, changes (equipment change, equipment location change, etc.) affecting activities within the scope of accreditation is notified in writing to NBE within the time period specified in the contract. After this notification, NBE assesses the status of the laboratory, and depending on the content of the change, may not make any changes in accreditation status, may partially or completely suspend the accreditation or withdraw it; can request in-place assessment.

ISO/IEC 17025 does not mandate the laboratories to keep backup equipment used for testing, calibration and sampling, but laboratories can choose to keep backup of some equipment depending on the risk status of the activities they perform.

4.6 Outsourced Products and Services

A laboratory may outsource an activity for a temporary period of time due to unpredictable reasons (e.g., workload, temporary capacity loss, etc.). Laboratories cannot constantly outsource for the scope of activities for which they are accredited.
The laboratory, except for compelling reasons, procures the outsourced laboratory activity from an organization accredited in the requested activity by NBE, or as the case may be, by an accreditation body with a recognition agreement in testing, calibration and sampling to which NBE is a party. Compelling reasons are cases such as legal provisions, non-existence of another accredited organization in the same field, etc. In such cases, the laboratory receiving the external service assures the compliance of the services received. This assurance may be provided by an assessment of the external supplier laboratory or by other laboratory-developed procedures. In such cases, in order to see the compliance of the laboratory receiving the service, NBE may supervise assessments performed by the laboratory receiving the service in relation to assuring the compliance of the external service received. The laboratory receiving external services includes the necessary provisions in its contract that will allow the external supplier to ensure the above mentioned supervision in the laboratory. The laboratory receiving the service must ensure the compliance of the external supplier for the work to be done in all cases. The fact that the external supplier is accredited is an important criterion to ensure this assurance, but whether this assurance is enough or not should be determined by the organization receiving the service.

If an external laboratory activity service is used, necessary information including the identity of the external supplier is shared with the customer during the demand-offer process. The laboratory may reject the external supplier specified by the customer except where legally required. The laboratory should also consider matters related to impartiality while determining the external supplier.

Since the accreditation status of the laboratory that actually performs the calibration is considered as evidence for metrological traceability in the calibration field, laboratory receiving the service

presents the report prepared by the external supplier laboratory to the customer as an appendix to its own report.

The laboratory should communicate with the external supplier about the outsourced services as specified in the standard, and notify the external supplier of its conditions on subjects such as the competence and the matters which should be included in the report (e.g., uncertainty of measurement in the sampling activity etc.) The laboratory specifies in its contract that the outsourced laboratory activity given to the external supplier cannot be transferred to another laboratory.

The laboratory informs NBE about the outsourced laboratory activities that fall within the scope of laboratory activities for which it is accredited. This notification is done in writing on a document basis during the accreditation process as it was done during the initial application.

4.7 Sampling

It is possible for laboratories to be accredited only for the sampling activity. In this case, the sampling activity should be related to the testing or calibration activity. It is not possible to get accreditation according to ISO/IEC 17025 for a sampling activity that is not related to any testing or calibration activity and that is intended for production processes with no subsequent testing or calibration operation.
In cases where the accreditation will be granted only for the sampling activity, the laboratory must ensure that the sampling activity is intended for the performance of a subsequent testing/calibration operation.

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

- The laboratory calculates the uncertainty of measurement in sampling activities where it is accredited.
- If the testing/calibration method for which the laboratory is accredited refers to the sampling method in itself or if the sampling activity is performed by the laboratory, then the laboratory should calculate the uncertainty of measurement due to sampling.
- In the above cases, if the sampling activity is outsourced, the laboratory receiving the service should demand in the contract that it signs with the external supplier the information necessary to evaluate the uncertainty of measurement due to sampling (which may be the uncertainty of measurement itself).
- When the sample is supplied by the customer; the laboratory specifies in its report that the sample was supplied by the customer, that the contribution of uncertainty of measurement due to sampling is not included, and that the sample has been subjected to testing/calibration the way it was received (if the sample is suitable for the relevant testing).

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

4.8 Proficiency Tests and Inter-Laboratory Comparison

As a minimum, laboratories perform the internal and external quality control activities prescribed by the standard that are suitable for their activities. As an external quality control activity, proficiency testing or participation in inter-laboratory comparisons are carried out according to the requirements of PR-7-04 Procedure for Proficiency Testing and Inter-Laboratory Comparison Programs.

In order to evaluate the performed quality control activity as an external quality control activity, it is necessary that the evaluation criteria for the results are predetermined and that an assessment outside of the laboratory is performed as much as possible. The studies and assessments performed by the laboratory after the final external quality control activity report is submitted are not considered as external quality control activity.

Laboratories should evaluate their plans in fields where they would like to demand a scope extension by the methods specified in PR-7-04 Procedure for Proficiency Testing and Inter-Laboratory Comparison Programs and include them in the relevant NBE form.

4.9 Assessment of Risks and Opportunities

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

Although the assessment of risks and opportunities has not been tied to a methodological condition in the standard, it should be performed in accordance with the goals of the laboratories, the level of complexity of the management system, and the legislation and other mandatory documents to which they are subject to.

The assessment of risks and opportunities includes the identification, analysis and assessment of risks/opportunities. The aim of risk assessment is to decide, depending on the outcome of risk assessment, whether it is necessary to reduce the risks and/or to first improve them.

This is the most basic level of management expected from the implementation of risk and opportunity assessment. The laboratory can execute an advanced risk assessment process. In all cases, the laboratory should practically determine how the risks and opportunities associated with testing, calibration and sampling activities will be managed in a reactive and proactive manner.

Questions such as "what is the depth in the assessment of risks and opportunities", or "what cases are defined as risk", and things like the organizational structure of the laboratory, personnel structure and competence level, infrastructure etc. may vary from laboratory to laboratory. By considering the quality management system in its entirety, the laboratory can assess the risks and opportunities based on the scope for which it is accredited. When conducting risk and opportunity

assessment, the laboratory can also go over the articles of the standard focusing on the laboratory activity. There are no constraints on laboratories to specify similar/the same risk monitoring/prevention methods for laboratories' process approach or for risks that may be common for multiple laboratory activities (multiple tests).

The risk assessment is a process that needs to be updated according to changing circumstances and involves continuous monitoring and re-evaluation of actions for improvement. Risk management is not a one-time only activity.

4.10 Quality System Documentation

The laboratories should set up their systems by choosing from Option A and B, the one that best suits their structure. In both options, the main objective is to establish a management that allows the management of the requirements of the standard in a repeatable manner. Expectation from Option B is to assure at least the requirements specified in Option A. There is no difference between the options in terms of accreditation assessments. For both options, the assessment team will check to see if a management system has been established that meets at least the requirements specified in Option A.

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

Laboratories can submit documentation that they will prepare to ensure the integrity of the quality management system and to demonstrate compliance with ISO/IEC 17025 standard as a Quality Handbook.

Laboratories should establish their management systems in accordance with ISO/IEC 17025 and accreditation rules, and should document their procedures as necessary to consistently apply their quality management systems in accordance with the standard. When establishing the boundaries of documentation, organizations should also consider that the above-mentioned compliance can be shown to the assessors of the accreditation body, and also ensure the auditability of their systems. For example, as a requirement of the standard, the laboratory management should communicate with the personnel about their duties, powers and responsibilities, but although the standard does not define a method for this communication, it should demonstrate that this requirement is fulfilled, and it should specify the suitable method of recording (in writing etc.) for this part of the system to be auditable.

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 makes "Assessment Schedule" for each CAB taking into account activities and personnel. In accordance with the PR-7-01 Procedure for the Accreditation of Conformity Assessment Bodies, an accreditation cycle program is prepared for each CAB to be assessed at the relevant locations in a manner that represents all of the activities in the scope of accreditation (scope in the annex to the accreditation certificate) together with the management system.

The risk based assessment approach is taken into consideration when making the cycle program. Risk factors to be considered when planning assessments may include, but are not limited to

- The non-conformities found in previous assessment, observation and / or focus of the subsequent assessment
- The changes in personnel
- The changes in scopes
- The changes in equipment
- Outsourced products and services
- Unsatisfactory PT/ ILC results
- Revised standards related to accredited scopes
- Feedback or complaints
- Changes in requirements of regulation, legislation etc. (if applicable)
- Corrective actions made by laboratory for nonconforming work and preventive actions within the scope of accreditation
- Frequency of conformity assessment activities and number of test/sampling report/calibration certificate

In the initial accreditation assessments, all locations and all scopes applied by the CAB are assessed. The activities and locations of the laboratory are evaluated according to risk-based approach and assessed at least once within the 48-month period during which the accreditation is valid.

For the samplings in the relevant accreditation program shall be taken into account together with the following issues.

5.1 Important Activities

Important activities are processes that affect CAB's competency and are considered in this framework such as policy development, process and/or procedure development and review of the contract as appropriate, planning of conformity assessment activities, review of the results of conformity assessment activities, approval and decision, etc. So, all activities to meet the requirements of ISO / IEC 17025 standard are considered as important activities. For example, evaluation of impartiality, assurance of personnel competence and metrological traceability,

sampling, selection of appropriate methods for activities, reporting of results, complaint processes etc. The compliance of important activities with the requirements is confirmed by various assessment techniques.

5.2 Personnel Sampling

For the selection of the personnel to perform assessed activity during the assessment, "Personnel Competency Monitoring Chart/Matrix" presented to NBE, shall be taken as a basis. This document should indicate which personnel are authorized in each method and function (such as test, calibration, sampling, report writing, etc.).

Accordingly, in the initial accreditation assessment, the performance of the most competent personnel (taking into account experience, graduation, etc.) are witnessed. Then, if possible, the performance of the personnel, who are lastly authorized or have the lowest level of competency (taking into account experience, graduation, etc.) are 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. Lastly authorized personnel can be preferred here. If deficiencies due to personnel performance are identified in the witnessed activities, an appropriate sampling is performed in order to be able to witness the performance of the personnel who can perform adequately within the organization (the most competent personnel after the inadequate personnel etc.).

5.3 Scope Sampling

In the case of extensive scope, methods can be selected by using sampling method. In this case, before conducting the assessment, it is important to select as many and various activities and locations as necessary to prove technical competency in the relevant scope.

In scope sampling, the risks that may be created by the conformity assessment activity are taken into account (analysis results being critical for human health, animal health, and the environment etc., considered to be critical in the relevant legislation, and given a legal limit, etc.). Sampling can be done if:

- The device used for the test is shared
- The test method is similar
- Matrices of the samples being tested are similar.

Furthermore, when sampling, the frequency of testing, the experience of the laboratory, the experience of the staff conducting the test, the findings of the previous assessment, CAB's results in the proficiency tests should be taken into account.