# **PART 1—GENERAL INFORMATION**

## **Laboratory Information**

|  |  |  |
| --- | --- | --- |
| **Name** | **:** |  |
| **Address** | **:** |  |
| **City** | **:** |  |
| **Postal Code** | **:** |  |
| **Country** | **:** |  |

## **Application Information**

|  |  |
| --- | --- |
|  | Flexible Scope |
|  | Notified Body |
|  | Internal Calibration |

## **Assessment Information**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Assessment start and end day** | **:** | **Start** | **-** | **End** | | | | | |
| **Assessment Number** | **:** |  | | | | | | | |
| **Assessment Type** | **:** | **Assessment Type** | | | | | | | |
| **Assessed Location Information** | **:** | **Type** | | | **Name:** | **Address:** | **City:** | **Postal Code:** | **Country:** |
| Assessed Location | | |  |  |  |  |  |
| Assessed Location | | |  |  |  |  |  |
| Assessed Location | | |  |  |  |  |  |
| Assessed Location | | |  |  |  |  |  |
| Assessed Location | | |  |  |  |  |  |

## ***Assessment Team Information***

|  |  |  |  |
| --- | --- | --- | --- |
| ***Assignment*** | ***Name-Surname:*** | ***Assessment Start Date*** | ***Assessment End Date*** |
| *Assignment* |  | *Start* | *End* |
| *Assignment* |  | *Start* | *End* |
| *Assignment* |  | *Start* | *End* |
| *Assignment* |  | *Start* | *End* |

# **PART 2 – GENERAL EVALUATION**

## **Requested Scope of Accreditation (This part will be filled in by the laboratory).**

The requested scope of the laboratories should be entered in accordance with NBE's "Guidelines for Scope of Declaration to be Accredited". In the box for scopes, select the corresponding status.

The assessor / technical expert should indicate the analysis performed by asterisks (\*). In addition, the scope requested by the organization must be checked to ensure that the scope of extensions, withdrawals, and changes are made correctly.

The Lead Assessor should verify the accuracy of the scope controlled by the Assessor / Technical Expert.

Approved "Scope" image can be added.

### **For Calibration Laboratories**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Please select appropriate if there is a difference in current scope** | **Measured Quantity**  **Instrument or Gauge** | **Measurement Range** |  | **Measurement Conditions** | **Calibration and Measurement Capability (Expanded Measurement Uncertainty k = 2) (±)** | **/ Explanations** |
| *Is there a difference?* |  |  |  |  |  |  |
| *Is there a difference?* |  |  |  |  |  |  |
| *Is there a difference?* |  |  |  |  |  |  |
| *Is there a difference?* |  |  |  |  |  |  |
| *Is there a difference?* |  |  |  |  |  |  |

### **For Testing Laboratories**

|  |  |  |  |
| --- | --- | --- | --- |
| **Please select appropriate if there is a difference in current scope** | **Tested**  **Materials / Products** | **Name of the Test / Category of the Test, Analyte Characteristics** | **Testing Method**  **(National, International standards,**  **in house methods), Testing Technique, Measured Characteristic** |
| *Is there a difference?* |  |  |  |
| *Is there a difference?* |  |  |  |
| *Is there a difference?* |  |  |  |
| *Is there a difference?* |  |  |  |
| *Is there a difference?* |  |  |  |

## **Assessed Areas and Person Responsible**

* The persons interviewed during the assessment should be processed into the table. Please list the interviewees, their positions, the assessment technique, the areas assessed at the previous assessment, and the persons interviewed at the previous assessment into the table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Persons interviewed during the assessment** | **Positions** | **Assessment Technique (Performance, Interview, Document Validation etc.)** | **Persons interviewed in previous assessment** |
| *Quality Management Representative Names* | Quality Management Representative | Document review, Interview |  |
| *Information Technologies Resposible Names* | IT Responsible | Interview |  |
| *Test/ Calibration Responsible Names* | Test/Calibration Responsible | Performance |  |
| *Sampling Responsible Names* | Sampling Responsible | Performance, Interview |  |
| *Purchasing Responsible Names* | Purchasing Responsible | Interview |  |

* Indicate how the persons who performed test, persons interviewed and the methods assessed are determined. For this purpose, you can benefit from the I-7-01-13 Assessment Team Working Instructions. During sampling, the risks that can arise from the method under test are also taken into consideration. For example; the test apparatus is common, the test method is similar, and the matrices of the tested samples are similar. Specify the sampling method.

|  |
| --- |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert.* |

## **Evaluation of the Nonconformities Found in the Previous Assessment and Compliances with the Accreditation Contract**

* Comments on the nonconformities (U) and observations (G) found in the previous assessment should be written.

|  |  |  |  |
| --- | --- | --- | --- |
| **Previous Assessment Number** | **Nonconformity and Observation Number** | **Actions Taken for the nonconformity** | **Nonconformity Cancelled?** |
|  |  |  | *Y / N* |
|  |  |  | *Y / N* |
|  |  |  | *Y / N* |

* Suitable use of NBE Mark should be checked.

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences.* | | |

* *Financial Liabilities (Professional Liability Insurance and NBE Mark usage fee etc.)*

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

# **PART 3 – EVALUATION OF STANDARD CLAUSES**

* Form FR-7-01-20 should be filled in at least 1 month prior to the laboratory's assessments (initial assessment, surveillance, scope extension, re-assessment, etc.) in the form of red italics.
* The items specified in FR-7-01-20 shall be filled in by lead assessor and / or assessor / technical expert. During the assessment, the assessment team must confirm the documentation information that the organization has declared in this form (such as document number, revision number, revision date, etc.) is up-to-date. The records / evidence examined during the assessment must be stated under each item.

## **4 General Requirements**

*\*Laboratory management activities related to impartiality \*Identification of risks to impartiality on an on-going basis and realization of related activities \*Legally binding commitments of the organization on confidentiality \*Informing the customer before disclosing customer information to the public*

### **4.1 Impartiality**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **Confidentiality**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

## **5 Structural Requirements**

\*Being a legal entity or a defined part of a legal entity (commercial registry gazette, ministry authorization, establishment law etc.) \*Identification of the laboratory management \*Identification of the laboratory activity except for the activities provided from the external supplier continuously \*Locations where the laboratory activities are carried out (temporary, mobile,customer facilities) \* Responsibilities and authorities of the personnel \* Documentation of the procedures in a necessary manner \* Establishment of appropriate communication processes \* Ensuring efficiency of laboratory activities

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

## **6 Resource Requirements**

\* Laboratory has impartial and competent personnel \* Existence of documented education, qualification, training, technical knowledge, skill, experience and competence requirements of personnel \* Personnel authorized laboratory activities \* Personnel competence monitoring \* Appropriate environmental requirements \* Access to necessary equipment \*Establishment of metrological traceability via an unbroken chain of calibration / reference \* Conformity of external provider personnel to personnel competence criteria defined by the laboratory, if external provider is used

### **6.2 Personnel**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert. Please specify the documents and records examined* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **6.3 Facilities and environmental conditions**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **6.4 Equipment**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **6.5 Metrological traceability**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **6.6 Externally provided products and services**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

## **7 Process requirements**

\* When external provider is used, informing the customer and obtaining the customer's approval \* Choosing the appropriate method \* Verification reports for standard methods and validation reports for non-standard methods and records of measurement uncertainty \* Update of reports and their suitability for proper use \* Working with appropriate matrix \*sampling plan, identity of sampling personnel and contribution of sampling to uncertainty of measurement \* Protection of confidentiality and integrity of data \* Realization of internal and external parameters to ensure validity of results \*Compliance of external parameters to PR-7-04 \* Rationale of decision rule based on risk level \* the expression of opinions and interpretations by authorized personnel and documentation of their basis \* Documented complaints process \* Evaluation of complaints by independent persons who are not related to the activity of complaint \* Bringing non-conforming work to risk level and defining responsibles \* Access to information and data

### **7.1 Review of requests, tenders and contracts**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory* | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert. Please specify the documents and records examined* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.2 Selection, validation and verification of methods**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory.* | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.3 Sampling**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *İncelenen referans dokümanlar, kayıtlar/kanıtlar / Reviewed reference documents, records/evidences* | | |

### **7.4 Handling of test or calibration items**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.5 Technical records**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.6 Evaluation of measurement uncertainty**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.7 Ensuring the validity of results**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined.* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.8 Reporting of results**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert. Please specify the documents and records examined* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.9 Complaints**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert. Please specify the documents and records examined* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.10 Nonconforming Work**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert. Please specify the documents and records examined* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **7.11 Control of data and information management**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Assessor / Technical Expert. Lead Assessor can give comments. Please specify the documents and records examined* | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

## **8 Management System Requirements**

\* Implementation of the appropriate management system according to Option A or Option B \* Establishment of policies and objectives \* Related documentation; control and periodic review of this documentation \* Creation and maintenance of readable and accessible records \* Evaluation of actions related to risks and opportunities \* Activities of improvement \* Activities carried out for the review of identified non-conformities, determination of causes, corrective actions and review of the possibility of future realization \* Internal audit records showing the applicability and sustainability of the requirements defined in the quality system \* Management review activities and records

### **8.1 Options**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **8.2 Management System Documentation ( Option A)**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **8.3 Control of management system documents ( Option A)**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **8.4 Control of records ( Option A)**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **8.5 Actions to address risks and opportunities (Option A)**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **8.6 Improvement (Option A)**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **8.7 Corrective Actions ( Option A)**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **8.8 Internal Audits (Option A)**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

### **8.9 Management Reviews (Option A)**

|  |  |  |
| --- | --- | --- |
| *This part will be filled in by the laboratory*. | | |
| Reference Documents | | |
| *This part will be filled in by Lead Assessor. Assessor/ Technical Expert can give comments. Please specify the documents and records examined*. | U | G |
|  |  |
| *Reviewed reference documents, records/evidences* | | |

# **PART 4 – Objective Evidence for On-Site Assessment**

Fill in for the performed test / calibration / sampling activities. Fill in a separate page for each performance (you can duplicate the page if necessary). In standard methods, please write the method number; in in-house methods please write the laboratory SOP number.

**Abbreviations : Y** (*Satisfactory*), **YD** (*Unsatisfactory*), **UD** (*Not Applicable*)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Assessed Unit and Site****►** | |  | | | |
| **Assessed Method**  **▼** | | **Standard No/SOP No2**  **▼** | | **Standard Date/SOP Rev. No**  **▼** | |
| Standard | In-house |  | |  | |
| **Test/Sampling/Calibration Staff and Functions** ► | |  | | | |
| **Description** | | | **Related Document and/or Comments** | | **Status** |
| Evaluation of the competence of personnel who perform laboratory activities (6.2)  *(knowledge on the practice, correct practice)* | | |  | | *Status* |
| Facilities and environmental conditions related to test/calibration/sampling performed (6.3)  *(can include, but are not limited to temperature, humidity, cross-contamination)* | | |  | | *Status* |
| *Equipment/, reference standard/material used in test/calibration/sampling (6.4)*  *(conformity, name, manufacturer, serial number)* | | |  | | *Status* |
| *Metrological traceability source, conformity to G-1-12 (6.5)*  *(calibration provider, reference material manufacturer etc.)* | | |  | | *Status* |
| *Explanations on sampling (if applicable) (7.3)*  *(sampling existance, correct application of method, records etc.)* | | |  | | *Status* |
| *Test/calibration sample (7.4) (name, manufacturer, model, serial number etc).* | | |  | | *Status* |
| *Handling of test and calibration items (transportation, receipt, handling, protection, storage, retention, disposal and return)* | | |  | | *Status* |
| *Internal quality control activities (7.7)*  *(conformity, frequency, success, actions taken when non-conforming)* | | |  | | *Status* |
| *Reporting of results and archiving (7.8)*  *(whether the information requested by the standard is in the test report or calibration certificate, compliance with NBE G-1-06, G-2-18)* | | |  | | *Status* |
| **Notes** | | | | | |
|  | | | | | |

# **PART 5 – ASSESSMENT FINAL EVALUATIONS**

## **Focus of the Subsequent Assessment**

The items and areas that need to be examined further in the next assessment should be stated.

|  |
| --- |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert.* |

## **Comments of the Assessor and Recommendation for Accreditation**

### **Comments**

\* Strengths and weaknesses of the laboratory \* Areas where the laboratory may have potential for improvement \* Suitability of the quality system \* General impressions \* Mark the appropriate box for the accreditation recommendation in the final part.

|  |
| --- |
| *This part will be filled in by Lead Assessor and Assessor/Technical Expert.* |

### **Recommendation**

Check the accreditation recommendation after the corrective actions has been completed and the nonconformities have been successfully closed. (Multiple boxes can be ticked.)

Initial Accreditation

Maintainance of Accreditation

Renewal of Accreditation

Full Suspension of Accreditation

Full Withdrawal of Accreditation

Acceptance of Scope Change (including scope extension)

Suspension of Some Scopes

Withdrawal of Some Scopes

Removal of Suspension

Name / Address Change

No Accreditation

English Scope

# **This Report is Prepared by;**

|  |  |  |
| --- | --- | --- |
| **Name and Surname** | : |  |
| **Date** | : | *Report Date* |
| **Signature** | : |  |