MODULE D: REPORT OF THE TECHNICAL ASSESSOR/EXPERT

(EN ISO/IEC 17025:2017)

# Audit data

|  |  |  |  |
| --- | --- | --- | --- |
| Function | ****Name**** assessor/expert | Activities see assessment plan | Date(s) + location(s) of the assessment office/witness; am/pm |
| TA/EX |  |  |  |

# Representatives of the body

|  |  |
| --- | --- |
| Function Can be changed according to the naming used by the body | Name |
| Responsible for the management system |  |
| Technical responsible |  |
| … |  |

# evaluation of the implementation of the corrective actions taken following the previous assessment

|  |  |
| --- | --- |
| ID code of the previous assessment |  |

The evaluation of the follow-up of the non-conformity is recorded as “+” when all elements have been sufficiently followed up and resolved and it can be closed.   
A new non-conformity XX-Ay or XX-By (XX = initials assessor, y = reference number of the non-conformity in this partial report), is defined if

* - some elements are not yet resolved; and/or
* - some elements are not OK; and/or
* - the implemented solution has given rise to a new non-conformity.

|  |  |  |
| --- | --- | --- |
| Non-conformity of the previous assessment | Evaluation of the follow-up and effectiveness of the corrective action(s) taken | Evaluation |
|  |  |  |
|  |  |  |

# Assessment report

Please indicate the evaluation after each standard element:

* + (evaluated and OK);
* XX-Ay or XX-By (evaluated, but with non-conformity: XX = initials assessor, y = number of the non-conformity in this partial report);
* ne (not evaluated);
* na (not applicable).

Text in blue is for explanatory purposes and should be removed.

## General findings (office and witness activities)

General findings will usually arise from the evaluation at the office (but can also arise from various witness activities).

### Standard requirements

#### ISO/IEC 17025:2017 § 4+5 : General and structural requirements

These standard requirements are normally covered in the lead auditor's report, but if relevant or desired, you can report your evaluation of these elements below (in relation to the technical domain for which you were appointed):

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4 | General requirements |  |
| 4.1 | Impartiality |  |
| 4.2 | Confidentiality |  |
| 5 | Structural requirements |  |
| 5.1-5.7 | Organizational structure and management, scope of activities, responsibilities and authorities |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

#### ISO/IEC 17025:2017 § 6: Resource requirements

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.1 | General |  |
| 6.1 | The laboratory shall have available the personnel, facilities, equipment, systems and support services  necessary to manage and perform its laboratory activities. |  |
| 6.2 | Personnel |  |
| 6.2.1 | Personnel shall act impartially, be competent and work in accordance with the laboratory's management system. |  |
| 6.2.2 | The laboratory shall document the competence requirements (education, qualification, training, technical knowledge, skills and experience) for each function influencing the results of laboratory activities |  |
| 6.2.3 | The laboratory shall ensure that the personnel have the competence to perform laboratory activities and to evaluate the significance of deviations |  |
| 6.2.4 | The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities. |  |
| 6.2.5 a-f | Procedures and retention of records related to the competence of the personnel |  |
| 6.2.6 a-c | Authorization of personnel to perform specific laboratory activities |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.3 | Facilities and environmental conditions |  |
| 6.3.1 | The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results |  |
| 6.3.2 | The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented |  |
| 6.3.3 | Monitoring, controlling and recording environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results |  |
| 6.3.4 | Measures to control facilities shall be implemented, monitored and periodically reviewed |  |
| 6.3.5 | Laboratory activities at sites or facilities outside its permanent  Control shall be conform the requirements of § 6.3 |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.4 | Equipment |  |
| 6.4.1 | Access to equipment |  |
| 6.4.2 | Requirements for equipment outside the permanent control of the laboratory shall meet the requirements of §6.4 |  |
| 6.4.3 | Procedure for handling, transport, storage, use and planned  maintenance of equipment |  |
| 6.4.4 | Verification that equipment conforms to specified requirements before being placed or returned into service |  |
| 6.4.5 | The equipment used for measurement shall be capable of achieving the required measurement accuracy and/or measurement uncertainty |  |
| 6.4.6 | Calibration of measuring equipment |  |
| 6.4.7 | Calibration programme |  |
| 6.4.8 | Identification of the calibration status or period of validity |  |
| 6.4.9 | Management of equipment that produces questionable results |  |
| 6.4.10 | Procedure for intermediate checks |  |
| 6.4.11 | Reference values and correction factors |  |
| 6.4.12 | Measures to prevent unintended adjustments |  |
| 6.4.13 a-h | Retention of records |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.5 | Metrological traceability |  |
| 6.5.1 | Metrological traceability of measurement results shall be established and maintained by means of a documented unbroken chain of calibrations |  |
| 6.5.2 – 6.5.3 | Measurement results are traceable to the International System of Units (SI)  When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.6 | Externally provided products and services |  |
| 6.6.1 a-c | Suitable externally provided products and services |  |
| 6.6.2 a-d | Procedure and records for external providers of products or services |  |
| 6.6.3 a-d | Communication of requirements to external providers |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

#### ISO/IEC 17025:2017 §7 : Process requirements

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.1 | Review of requests, tenders and contracts |  |
| 7.1.1 a-d | Procedure for the review of requests, tenders and contracts |  |
| 7.1.2 | Informing the customer when the method requested by the customer is considered to be inappropriate or out of date |  |
| 7.1.3 | Defining the decision rule for statements of conformity |  |
| 7.1.4 | Differences between the request or tender and the contract |  |
| 7.1.5 | Informing the customer of any deviation from the contract |  |
| 7.1.6 | If a contract is amended after work has commenced, the contract review shall be repeated and communication of amendments to all affected personnel. |  |
| 7.1.7 | Cooperation with customers |  |
| 7.1.8 | Retention of records regarding contract review |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.2 | Selection, verification and validation of methods |  |
| 7.2.1 | Selection and verification of methods |  |
| 7.2.1.1 | Appropriate methods and procedures for laboratory activities, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. |  |
| 7.2.1.2 | All methods, procedures and supporting documentation shall be kept up to date and shall be made readily available to personnel |  |
| 7.2.1.3 | Using the latest valid version of a method |  |
| 7.2.1.4 | Selection of an appropriate method and informing the customer |  |
| 7.2.1.5 | Verify that the required performance of a method can be achieved + retention of records of the verification |  |
| 7.2.1.6 | Method development shall be a planned activity and shall be assigned to competent personnel |  |
| 7.2.1.7 | Deviations from methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer |  |
| 7.2.2 | Validation of methods |  |
| 7.2.2.1 | Validation of non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified |  |
| 7.2.2.2 | The influence of changes on a validated method shall be determined and where they are found to affect the original validation a new method validation shall be performed |  |
| 7.2.2.3 | Performance characteristics of validated methods |  |
| 7.2.2.4 a-e | Retention of records regarding validation |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.3 | Sampling |  |
| 7.3.1 – 7.3.2 | Sampling plan and method |  |
| 7.3.3 | Retention of records of sampling data |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.4 | Handling of test or calibration items |  |
| 7.4.1 | Procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items  Precautions to avoid deterioration, contamination, loss or damage to the item |  |
| 7.4.2 | System for the unambiguous identification of test or calibration items |  |
| 7.4.3 | Deviations from specified conditions shall be recorded.  Indicating which results may be affected by the deviation in the test or calibration report |  |
| 7.4.4 | Environmental conditions shall be maintained, monitored and recorded |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.5 | Technical records |  |
| 7.5.1 | Technical records contain sufficient information to facilitate or enable the repetition of the laboratory activity under conditions as close as possible to the original |  |
| 7.5.2 | Amendments to technical records can be tracked to previous versions or to original observations  Both original and amended data and files shall be retained |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.6 | Evaluation of measurement uncertainty |  |
| 7.6.1 | Identification of contributions to measurement uncertainty that are of significance |  |
| 7.6.2 | Measurement uncertainty for calibrations |  |
| 7.6.3 | Evaluation/estimation of measurement uncertainty for testing |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.7 | Ensuring the validity of results |  |
| 7.7.1 a-k | Procedure for monitoring the validity of results |  |
| 7.7.2 a-b | Data shall be recorded in such a way that trends are detectable |  |
| 7.7.3 | Monitoring performance by comparison with results of other laboratories (proficiency testing or other interlaboratory comparisons) |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.8 | Reporting of results |  |
| 7.8.1 | General |  |
| 7.8.1.1 | The results shall be reviewed and authorized prior to release |  |
| 7.8.1.2 – 7.8.1.3 | The results shall be provided accurately, clearly, unambiguously and objectively and shall include all the information agreed with the customer and necessary for the interpretation of the results and all  information required by the method used. All issued reports shall be retained as technical records. When agreed with the customer, results may be reported in a simplified way |  |
| 7.8.2 | Common requirements for reports (for testing, calibration or sampling) |  |
| 7.8.2.1 | Contents of the report |  |
| 7.8.2.2 | Responsibilities for all information provided in the report - Information supplied by the customer |  |
| 7.8.3 | Specific requirements for test reports |  |
| 7.8.3.1 a-e | Additional requirements where necessary for the interpretation of the test results |  |
| 7.8.3.2 | Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements of § 7.8.5 |  |
| 7.8.4 | Specific requirements for calibration certificates |  |
| 7.8.4.1 | Requirements for calibration certificates |  |
| 7.8.4.2 | Requirements for calibration certificates in case of sampling (see §7.8.5) |  |
| 7.8.4.3 | Recommendation on calibration interval is not allowed |  |
| 7.8.5 | Reporting sampling – specific requirements |  |
| 7.8.5.1 a-f | Additional information necessary for the interpretation of results |  |
| 7.8.6 | Reporting statements of conformity |  |
| 7.8.6.1 | Document the decision rule for the statement of conformity |  |
| 7.8.6.2 | The statement clearly identifies the results on which the statement of conformity is applied, the specifications and the applied decision rule |  |
| 7.8.7 | Reporting opinions and interpretations |  |
| 7.8.7.1 | Documenting the basis upon which the opinions and interpretations have been made and authorization of personnel for the expression of opinions and interpretations |  |
| 7.8.7.2 | Opinions and interpretations expressed in reports shall be based on results obtained from the tested or calibrated |  |
| 7.8.7.3 | Retention of records of communication/dialogue with the customer |  |
| 7.8.8 | Amendments to reports |  |
| 7.8.8.1 | Any change of information shall be clearly identified |  |
| 7.8.8.2 | Amendments to a report shall be made only in the form of a further document, or data transfer with appropriate mention |  |
| 7.8.8.3 | New report shall be uniquely identified and shall contain a reference to the original that it replaces |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.9 | Complaints |  |
| 7.9.1 – 7.9.7 | Process and responsibilities related to receiving, handling, assessing, following up and deciding on complaints |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.10 | Nonconforming work |  |
| 7.10.1 – 7.10.3 | Procedure and records relating to the management and follow-up of nonconforming work |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.11 | Control of data and information management |  |
| 7.11.1 | Access to the data and information needed to perform laboratory  activities |  |
| 7.11.2 | Validation of the functionality of the laboratory information management system (including interfaces) used to collect, process, record, report, store or retrieve data. Authorization, documentation and validation prior to implementation of changes (including laboratory software configuration or modifications to commercial off-the-shelf software) |  |
| 7.11.3 a-e | Requirements for the laboratory information management system |  |
| 7.11.4 | Requirements for off-site systems or systems managed/maintained through external providers |  |
| 7.11.5 | Instructions, manuals and reference data are readily available to personnel |  |
| 7.11.6 | Calculations and data transfers shall be checked |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

#### ISO/IEC 17025:2017 §8 : Management system requirements

These standard requirements are normally covered in the lead auditor's report, but if relevant or desired, you can report your evaluation of these elements below (in relation to the technical domain for which you were appointed):

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 8.1 – 8.3 | Management system documentation |  |
| 8.4 | Control of records |  |
| 8.5 | Actions to address risks and opportunities |  |
| 8.6 | Improvement |  |
| 8.7 | Corrective actions |  |
| 8.8 | Internal audits |  |
| 8.9 | Management reviews |  |

###### Main documents subject to evaluation:

###### Overall description of the findings, including the reference to any detected non-conformities:

### Additional requirements of BELAC

|  |  |  |  |
| --- | --- | --- | --- |
| Reference | Evaluation | Conclusion | |
| BELAC 2-001 (reference to accreditation) |  |  | |
| BELAC 2-002 (accreditation scope : fixed versus flexible – dormant activities) |  |  | |
| BELAC 2-101 (accreditation scope of a test laboratory: description + evaluation) |  |  | |
| BELAC 2-110 (accreditation scope of a calibration laboratory: description + evaluation) |  |  | |
| BELAC 2-003 (policy and guidelines regarding traceability of measurement results) |  |  | |
| BELAC 2-106 (proficiency tests (PT): guidelines for participation and performance evaluation) |  |  | |
| BELAC 2-107 (expression of measurement uncertainty in calibration) |  |  | |
| BELAC 2-108 (expression of measurement uncertainty in quantitative testing) |  |  | |
| BELAC 2-404 (EA - 2/17 Notified Body) |  |  | |
| BELAC 2-405-DOSI (Specific provisions for the accreditation of laboratories recognized as dosimetric service by the Federal Agency for Nuclear Control (FANC)) |  |  | |
| BELAC 2-405-DNA JUST (requirements for accreditation of forensic DNA laboratories) |  |  | |
| BELAC 2-405-CPR (requirements for accreditation of bodies notified in the framework of Regulation No 305/2011) |  |  | |
| BELAC 2-405-WADA (requirements for accreditation of WADA anti-doping laboratories) |  | |  |

## Evaluation of specific activities (IncLuding witness)

Please report any activity followed. For several activities, you must copy and complete the passage below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Evaluated activity/group of activities: |  | | | |
| Spoken with: |  | | | |
| Documents reviewed? |  | Yes |  | No |
| Main documents reviewed: |  | | | |
| Followed/witnessed during an 'on-site' execution? |  | Yes |  | No |
| Assessed standard requirements: | | | | Evaluation: |

|  |  |  |
| --- | --- | --- |
| 5 | Structural requirements |  |
| 6.1 | General |  |
| 6.2 | Personnel |  |
| 6.3 | Facilities and environmental conditions |  |
| 6.4 | Equipment |  |
| 6.5 | Metrological traceability |  |
| 6.6 | Externally provided products and services |  |
| 7.1 | Review of requests, tenders and contracts |  |
| 7.2 | Selection, verification and validation of methods |  |
| 7.3 | Sampling |  |
| 7.4 | Handling of test or calibration items |  |
| 7.5 | Technical records |  |
| 7.6 | Evaluation of measurement uncertainty |  |
| 7.7 | Ensuring the validity of results |  |
| 7.8 | Reporting of results |  |
| 7.9 | Complaints |  |
| 7.10 | Nonconforming work |  |
| 7.11 | Control of data and information management |  |

###### Overall description of the findings, including the reference to any detected non-conformities:

## Conclusion

1. Summary of assessment findings concerning conformity with the accreditation conditions

Please give a general summary of all the findings made during the assessment. The summary should include elements of the following themes, **where relevant**: impartiality and independence/confidentiality, competence and management of activities, effectiveness of the management system.

* 1. Recommendation(s):
     1. With regard to granting, maintaining or renewing the accreditation(s):

Granting [[1]](#footnote-1)/ maintaining / renewing of the accreditation certificate please delete as appropriate

|  |  |  |
| --- | --- | --- |
|  | positive recommendation | Explanation required if several standards |
|  | positive recommendation with reservation | Explanation required |
|  | negative recommendation | Explanation required |

In case of transition to a new version of an accreditation standard:

|  |  |  |
| --- | --- | --- |
|  | positive recommendation for transition to | Accreditation standard+year |
|  | negative recommendation for transition | Explanation required |

Other information:

* + 1. With regard to the activities covered by the accreditation(s)

The detailed accreditation scope as approved by the assessment team can be found in the Excel file in attachment.

You received an Excel file with a scope proposal: please indicate in this file which activity/group of activities has been subject to evaluation, whether on a documentary basis or in practice. Also indicate your agreement on the formulation of each activity within your sector. If you do not agree with the formulation proposed in the working version of the accreditation scope, you must explain the correction in the column “agreement on formulation” and adapt it in this working version. Please send this file together with this module D and the evaluated module E to the lead assessor and belacdossiers@economie.fgov.be.

With regard to the activities already covered by the accreditation:

|  |  |
| --- | --- |
|  | The presentation of the accreditation scope(s) can be maintained |
|  | The presentation of the accreditation scope(s) has to be adapted (for details cfr the scope(s) in attachment) |
|  | Not applicable (initial accreditation) |

The requested extensions/changes of the activities:

|  |  |  |
| --- | --- | --- |
|  | can all be granted | |
|  | can partially be granted | Explanation required |
|  | can’t be granted | Explanation required |
|  | not applicable (no extensions/changes requested) | |

1. Additional information

In this section, any additional information can be added information that does not belong under the other titles, but which is worth mentioning e.g. planned changes in a firm’s organizational structure or activities, points of interest for the next assessment,…When no additional information is to be mentioned, please indicate ‘not relevant’.

|  |  |
| --- | --- |
| Date of creation of the report | xx/xx/xxxx |

1. For initial assessment or for an additional accreditation standard [↑](#footnote-ref-1)