MODULE D: REPORT OF THE TECHNICAL ASSESSOR/EXPERT

(EN ISO/IEC 17043:2010)

# 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).

## 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 17043:2010 §4 Technical requirements

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.1 | General |  |
| 4.1 | General competence and access to expertise within the fields of items and properties measured |  |
| 4.2 | Personnel |  |
| 4.2.1 | Availability, authority and competence of managerial and technical personnel |  |
| 4.2.2 | Defining and ensuring qualifications and experience for key positions |  |
| 4.2.3 | Status of personnel (employed or under contract) – Competence and supervision |  |
| 4.2.4  4.2.4 a) | Authorisation of personnel for specific tasks :  Selection of PT items |  |
| 4.2.4 b) | PT scheme planning |  |
| 4.2.4 c) | Sampling |  |
| 4.2.4 d) | Operating equipment |  |
| 4.2.4 e) | Determination of stability, homogeneity, assigned values and associated uncertainties |  |
| 4.2.4.f) | Preparation, handling and distribution of PT items |  |
| 4.2.4 g)-h) | Data processing and statistical analysis |  |
| 4.2.4 i) | Evaluation of performance of PT participants |  |
| 4.2.4.j) | Opinions and interpretations |  |
| 4.2.4 k) | Authorisation and issuing PT reports |  |
| 4.2.5 | Personnel records including records of competence to perform tasks assigned to personnel (employed or under contract) |  |
| 4.2.6 | Policy and procedure for identifying training needs and providing training |  |
| 4.2.7 | Adequacy of training and evaluation of effectiveness of training activities |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.3 | Equipment, accomodation and environment |  |
| 4.3.1 | Appropriate facilities and equipment  (manufacturing, handling, calibration, testing, storage and despatch, for data processing, for communications, and for retrieval of materials and records) |  |
| 4.3.2 | Documented requirements for accommodation and environmental conditions |  |
| 4.3.3 | Control of access to facilities |  |
| 4.3.4 | Control, monitoring and registration of environmental conditions that can significantly influence the quality of the PT items and any testing and calibration |  |
| 4.3.5 | Separation of incompatible activities and prevention of cross-contamination |  |
| 4.3.6 | Appropriate validation and maintenance of performance characteristics of methods and equipment used to confirm the content, homogeneity and stability of PT items |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.4 | Design of proficiency testing schemes |  |
| 4.4.1 | Planning |  |
| 4.4.1.1 | Process identification, planning, description & execution |  |
| 4.4.1.2 | No subcontracting of planning |  |
| 4.4.1.3  4.4.1.3 a)-b) | Documented plan addressing objectives, purpose and basic design including:  Name and address of PT provider and name, address, affiliation of the coordinator and any other relevant personnel |  |
| 4.4.1.3 c) | Information on subcontracted activities |  |
| 4.4.1.3 d) | Participation criteria |  |
| 4.4.1.3 e) | Number and type of expected participants |  |
| 4.4.1.3 f)-g) | Selection of measurands/characteristics including information on what is to be identified, measured or tested and description of expected range of values/ characteristics to be expected |  |
| 4.4.1.3 h) | Identification of potential error sources |  |
| 4.4.1.3 i) | Requirements for production, QC, storage and distribution |  |
| 4.4.1.3 j) | Prevention of collusion or falsification and procedures if collusion or falsification is suspected |  |
| 4.4.1.3 k) | Information to be supplied to participants including global time schedule |  |
| 4.4.1.3 l) | For continuous proficiency testing schemes : distribution dates/frequency, deadlines for returning results and test or measurement date when relevant |  |
| 4.4.1.3 m) | Information related to preparation and testing/measuring of PT items |  |
| 4.4.1.3 n) | Methods for homogeneity and stability testing including biological viability testing when relevant |  |
| 4.4.1.3 o) | Preparation of reporting format for participants |  |
| 4.4.1.3 p) | Description of statistical analysis |  |
| 4.4.1.3 q) | Origin, traceability and measurement uncertainty of assigned values |  |
| 4.4.1.3 r) | Evaluation criteria of participant performance |  |
| 4.4.1.3 s) | Description of data, interim reports or information to be returned to participants |  |
| 4.4.1.3 t) | Publication policy of participants results |  |
| 4.4.1.3 u) | Actions in case of lost or damaged PT items |  |
| 4.4.1.4 | Technical expertise and experience / advisory group |  |
| 4.4.1.5  4.4.1.5 a) | Use of technical expertise for:  Planning requirements (see §4.4.1.3) |  |
| 4.4.1.5 b) | Identification/resolution of potential difficulties related to PT items |  |
| 4.4.1.5 c) | Instructions for participants |  |
| 4.4.1.5 d) | Comments on issues or remarks raised in previous PT rounds |  |
| 4.4.1.5 e) | Advice on participant performance evaluation methods |  |
| 4.4.1.5 f) | Comments on PT results and participants performance |  |
| 4.4.1.5 g) | Advice to participants |  |
| 4.4.1.5 h) | Response to feedback from participants |  |
| 4.4.1.5 i) | Technical meetings with participants |  |
| 4.4.2 | Preparation of proficiency test items |  |
| 4.4.2.1 | Procedures for appropriate PT item preparation |  |
| 4.4.2.2 | Procedures for appropriate PT item acquisition, collection, preparation, handling, storage, disposal in line with regulatory/ethical requirements |  |
| 4.4.2.3 | Matching of PT items with routine type of items/materials |  |
| 4.4.2.4 | Instructions for returning PT items after preparation or manipulation when applicable |  |
| 4.4.3 | Homogeneity and stability |  |
| 4.4.3.1 | Criteria for adequate homogeneity and stability |  |
| 4.4.3.2 | Procedure for assessment of homogeneity and stability with appropriate statistical design |  |
| 4.4.3.3 | Timing of homogeneity assessment |  |
| 4.4.3.4 | Demonstrated stability throughout the conduct of the PT including storage and transport conditions |  |
| 4.4.3.5 | Use of PT items from previous rounds : confirmation of property values |  |
| 4.4.3.6 | Procedures used to collect, produce, package and distribute the  proficiency test items are fit for purpose when homogeneity and stability testing are not feasible |  |
| 4.4.4 | Statistical design |  |
| 4.4.4.1 | Statistical design in accordance with the objectives of specific PT scheme |  |
| 4.4.4.2 | Documented and justified statistical design and data analysis methods |  |
| 4.4.4.3  4.4.4.3 a) | Elements to be considered in the statistical design:  Required or expected accuracy (trueness and precision) and measurement uncertainty |  |
| 4.4.4.3 b) | Minimum number of participants and alternative approaches for performance assessment in case of insufficient number of participants |  |
| 4.4.4.3 c) | Relevance of significant figures to reported results, number of decimal places |  |
| 4.4.4.3 d) | Number of PT items to be tested and repetitive tests |  |
| 4.4.4.3 e) | Procedure to establish evaluation criteria |  |
| 4.4.4.3 f) | Procedure to identify and/or handle outliers |  |
| 4.4.4.3 g) | Procedure for evaluation of excluded values |  |
| 4.4.4.3 h) | Objectives for design and frequency of PT rounds |  |
| 4.4.5 | Assigned values |  |
| 4.4.5.1 | Procedure for determination of assigned value(s) |  |
| 4.4.5.2 | Calibration PT schemes: metrological traceability and measurement uncertainty |  |
| 4.4.5.3 | Other PT scheme areas : consideration of relevance, needs and feasibility for traceability and measurement uncertainty |  |
| 4.4.5.4 | Justified use of consensus value as assigned value and estimation of uncertainty |  |
| 4.4.5.5 | Policy on disclosure of assigned values |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.5 | Choice of method or procedure |  |
| 4.5.1 | Test methods, calibration or measurement procedures to be used |  |
| 4.5.2 a)-b) | Considerations to be made in case of participants’ choice of method  (Procedure and policy for comparison of results obtained by different methods - Awareness of technically equivalent methods and of assessment of results accordingly) |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.6 | Operation of proficiency testing schemes |  |
| 4.6.1 | Instructions for participants |  |
| 4.6.1.1 | Prior notice on despatch and arrival of test items |  |
| 4.6.1.2  4.6.1.2 a) | Detailed instructions to all participants on:  - Routine testing on PT items |  |
| 4.6.1.2 b) | - Factors influencing the PT items |  |
| 4.6.1.2 c) | - Procedure for preparation and conditioning prior to testing |  |
| 4.6.1.2 d) | - Handling and safety instructions |  |
| 4.6.1.2 e) | - Specified environmental conditions |  |
| 4.6.1.2 f) | - Instructions on recording and reporting results and associated uncertainties |  |
| 4.6.1.2 g) | - Latest reception date for PT or measurement results |  |
| 4.6.1.2 h) | - Information on contact details of PT provider |  |
| 4.6.1.2 i) | - Instructions on return PT items |  |
| 4.6.2 | Proficiency test items handling and storage |  |
| 4.6.2.1 | Appropriate identification, segregation and protection from contamination or degradation prior to despatch |  |
| 4.6.2.2 | Secure storage facilities preventing damage or deterioration – procedures for authorizing despatching to and reception from storage facilities |  |
| 4.6.2.3 | Periodic deterioration testing of stored PT items, chemicals and materials |  |
| 4.6.2.4 | Handling, decontamination and disposal of hazardous PT items, chemicals and materials |  |
| 4.6.3 | Packaging, labelling and distribution of proficiency test items |  |
| 4.6.3.1 | Conformity of packaging and labelling processes to safety and transport requirements |  |
| 4.6.3.2 | Specifying environmental conditions for transport, monitoring during transport and assessment of impact on PT item |  |
| 4.6.3.3 | Documented instructions for transport of PT item by participants |  |
| 4.6.3.4 | Appropriate labelling of PT items |  |
| 4.6.3.5 | Procedure for confirmation of delivery of PT item |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.7 | Data analysis and evaluation of proficiency testing scheme results |  |
| 4.7.1 | Data analysis and records |  |
| 4.7.1.1 | Validation, maintenance and operational checks of data processing equipment and software |  |
| 4.7.1.2 | Recording and analysis of results – procedures for validity checks of data entry, data transfer, statistical analysis, and reporting |  |
| 4.7.1.3 | Generation of summary and performance statistics consistent with statistical design |  |
| 4.7.1.4 | Detection of statistical outliers |  |
| 4.7.1.5 | Procedure and criteria for dealing with gross errors |  |
| 4.7.1.6 | Criteria and procedures to identify and manage PT items found to be unsuitable after distribution |  |
| 4.7.2 | Evaluation of performance |  |
| 4.7.2.1 | Documented, valid and fit-for-purpose evaluation methods – no subcontracting of performance evaluation |  |
| 4.7.2.2  4.7.2.2 a) | Expert commentary on participants’ performance with regard to:  Overall performance against prior expectations |  |
| 4.7.2.2 b) | Variation within and between participants and comparison with previous or similar PT-results or published precision data |  |
| 4.7.2.2 c) | Variation between methods and procedures |  |
| 4.7.2.2 d) | Error sources and suggestions for performance improvement |  |
| 4.7.2.2 e) | Advisory and educational feed-back for continual improvement |  |
| 4.7.2.2 f) | Cases of impossible result and performance evaluation |  |
| 4.7.2.2 g) | Suggestions, recommendations, comments |  |
| 4.7.2.2 h) | Conclusions |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.8 | Reports |  |
| 4.8.1 | Clear and comprehensive PT reports covering global as well as individual performance - no subcontracting of final report authorization |  |
| 4.8.2  4.8.2.a) | Content of PT-scheme reports:  - Name and contact details PT provider |  |
| 4.8.2.b) | - Name and contact details PT coordinator |  |
| 4.8.2.c) | - Identification of persons authorizing the report |  |
| 4.8.2.d) | - Indication of subcontracted activities |  |
| 4.8.2.e) | - Issue date and status of PT report |  |
| 4.8.2.f) | - Page numbering and indication of the end of PT report |  |
| 4.8.2.g) | - Confidentiality statement |  |
| 4.8.2.h) | - Report number and PT-scheme identification |  |
| 4.8.2.i) | - Description of PT-items used |  |
| 4.8.2.j) | - Participants’ results |  |
| 4.8.2.k) | - Statistical data and summaries |  |
| 4.8.2.l) | - Applied procedure for establishment of assigned value |  |
| 4.8.2.m) | - Metrological traceability and measurement uncertainty of assigned value |  |
| 4.8.2.n) | - Procedure for establishing PT- standard deviation or other evaluation criteria |  |
| 4.8.2.o) | - Assigned values and summary statistics for grouped results |  |
| 4.8.2.p) | - Comments on participants’ performance |  |
| 4.8.2.q) | - Information about PT design and implementation |  |
| 4.8.2.r) | - Applied statistical procedures for data analysis |  |
| 4.8.2.s) | - Advise on interpretation of statistical analysis |  |
| 4.8.2.t) | - Comments and recommendations on PT outcome |  |
| 4.8.3 | Timescale for reporting – provision of preliminary or anticipated results in sequential PT schemes and in case of perishable PT items |  |
| 4.8.4 | Policy for use of reports |  |
| 4.8.5 a)–c) | Requirements for newly issued or amended reports (identification – traceability - reason for re-issue or amendment) |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.9 | Communication with participants |  |
| 4.9.1 | Specific information made available by PT provider  (Scope of PT scheme - Participation fee - Eligibility criteria for participation - Confidentiality arrangements - Application details) |  |
| 4.9.2 | Advice to participants in case of changes in PT scheme design or operation |  |
| 4.9.3 | Communication on documented appeal procedures |  |
| 4.9.4 | Communication records |  |
| 4.9.5 | Issuing statements of participation or performance |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 4.10 | Confidentiality |  |
| 4.10.1 | Confidentiality of participants’ identity |  |
| 4.10.2 | Confidentiality of information supplied by participants |  |
| 4.10.3 | Awareness of revealing PT results to third parties |  |
| 4.10.4 | Written notification of providing PT results directly to regulatory authorities |  |

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

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

#### ISO/IEC 17043:2010 §5 Management 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 |
| 5.1 | Organization |  |
| 5.2 | Management system |  |
| 5.3 | Document control |  |
| 5.4 | Review of requests, tenders and contracts |  |
| 5.5 | Subcontracting services |  |
| 5.6 | Purchasing services and supplies |  |
| 5.7 | Service to the customer |  |
| 5.8 | Complaints and appeals |  |
| 5.9 | Control of nonconforming work |  |
| 5.10 | Improvement |  |
| 5.11 | Corrective actions |  |
| 5.12 | Preventive actions |  |
| 5.13 | Control of records |  |
| 5.14 | Internal audits |  |
| 5.15 | 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 2-109 (accreditation scope of a PT provider : 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) |  |  |

## 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: |

|  |  |  |
| --- | --- | --- |
| 4.1 | General |  |
| 4.2 | Personnel |  |
| 4.3 | Equipment, accommodation and environment |  |
| 4.4 | Design of proficiency testing schemes |  |
| 4.5 | Choice of method or procedure |  |
| 4.6 | Operation of proficiency testing schemes |  |
| 4.7 | Data analysis and evaluation of proficiency testing scheme results |  |
| 4.8 | Reports |  |
| 4.9 | Communication with participants |  |
| 4.10 | Confidentiality |  |
| 5 | Management requirements |  |

###### 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)