MODULE D: REPORT OF THE TECHNICAL ASSESSOR/EXPERT

(EN ISO 17034:2016)

# 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.

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| --- | --- | --- |
| 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

#### EN ISO 17034:2016 § 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 | Contractual matters |  |
| 4.2 | Impartiality |  |
| 4.3 | Confidentiality |  |
| 5 | Structural requirements |  |
| 5.1-5.4 | Definition of the organization and management structure, activities, responsibilities and authorities |  |

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 5.1 | The RMP shall be (part of) a legal entity that can be held responsible for its activities |  |
| 5.2 | Organized and operated in such a way that the applicable requirements of EN ISO 17034 are met |  |
| 5.3 a)-g) | Definition of the organization and management structure. Establishing responsibilities, authority and interrelations between personnel. |  |
| 5.4 a)-c) | Adequate communication mechanisms (for internal use and for use with customers) |  |

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

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

#### EN ISO 17034:2016 § 6: Resource requirements

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.1 | Personnel |  |
| 6.1.1 | All personnel are supervised and competent and work in accordance with the RMP’s management system |  |
| 6.1.2 | Management of confidential information |  |
| 6.1.3 | Sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions |  |
| 6.1.4 | Identifying training needs and providing training of personnel |  |
| 6.1.5 | Records of job descriptions |  |
| 6.1.6 | Records of authorizations, competence, educational and professional qualifications of personnel |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.2 | Subcontracting |  |
| 6.2.1 | Procedures to ensure that the subcontractors’ experience and technical competence are sufficient for their assigned tasks |  |
| 6.2.2 | Selection of subcontractors on the basis of their ability to meet the requirements stipulated by the RMP. |  |
| 6.2.3 | No subcontracting allowed for critical processes |  |
| 6.2.4 | Procedures to assess that all tasks performed by subcontractors comply with the requirements set by the RMP |  |
| 6.2.5 | Evidence of the subcontractor’s competence |  |
| 6.2.6 | Evaluation of the competence of the subcontractor or supervising of the operations carried out by the subcontractor. |  |
| 6.2.7 | Results and the descriptions of procedures used by subcontractors are available to allow the technical evaluation of data |  |
| 6.2.8 | Sufficient knowledge of the subcontractor’s task to evaluate the subcontractor’s activity |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.3 | Provision of equipment, services and supplies |  |
| 6.3.1 | Procedures for the selection of equipment, services and supplies |  |
| 6.3.2 | Specified requirements for equipment, services and supplies |  |
| 6.3.3 | Inspection, calibration or verification of equipment and consumable materials |  |
| 6.3.4 | Records of purchases of equipment, services and supplies, including records of the selection criteria used, confirmation of acceptance, and any commissioning data |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 6.4 | Facilities and environmental conditions |  |
| 6.4.1 | Suitable and adequate laboratory facilities and calibration and testing areas |  |
| 6.4.2 | Monitoring of environmental conditions |  |
| 6.4.3 | Other environmental factors (incompatible activities, vibration, dust, …) |  |
| 6.4.4 | Access to and use of areas shall be controlled appropriately |  |

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

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

#### EN ISO 17034:2016 § 7: Technical and production requirements

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.1 | General requirements |  |
| 7.1 | Addressing the requirements for the production of RM and CRM |  |
| 7.2 | Production planning |  |
| 7.2.1 | Identification and planning of processes that directly affect the quality of RM production and documented production plan |  |
| 7.2.2 | Technical input of subcontractors involved shall be specified and documented and regularly reviewed. |  |
| 7.2.3 a)-u) | Points to address during the planning stage |  |
| 7.2.4 | Adequate verification in case of production of multiple batches of RM with equivalent properties. |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.3 | Production control |  |
| 7.3 | The RMP shall verify that the production plan has been implemented as specified, and deviations from the plan shall be documented and approved |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.4 | Material handling and storage |  |
| 7.4.1 | Arrangements to ensure the integrity of its candidate RM and RM throughout the production process. |  |
| 7.4.2 | Identification, preservation and separation of candidate RM and RM |  |
| 7.4.3 | Adequate packaging and secure storage areas/stock rooms |  |
| 7.4.4 | The condition of all RM shall be assessed at appropriate intervals throughout the storage period |  |
| 7.4.5 | Control of packaging and labelling processes to ensure conformity with safety and transport requirements. Procedures for transport to the customer shall be defined. |  |
| 7.4.6 | Measures to ensure integrity of each individual RM unit up to the point when first used. |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.5 | Material processing |  |
| 7.5.1 a)-i) | Procedures to ensure that the material has undergone adequate processing for its intended use |  |
| 7.5.2 | Equipment used in material processing shall be operated in accordance with documented procedures. |  |

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

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

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| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.6 | Measurement procedures |  |
| 7.6 | Relevant requirements of ISO/IEC 17025 are met with respect to calibration and testing |  |
| 7.7 | Measuring equipment |  |
| 7.7 | Measuring equipment used in RM production is used in compliance with the relevant requirements of ISO/IEC 17025 |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.8 | Data integrity and evaluation |  |
| 7.8.1 | All calculations and data transfers are subject to appropriate checks |  |
| 7.8.2 a)-d) | Validation of computer software, procedures for protecting the integrity of data, maintenance of software and equipment, procedures for maintenance of data security |  |
| 7.8.3 | Appropriate statistical procedures for monitoring, testing, calibration or value assignment of RM |  |

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

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

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| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.9 | Metrological traceability of certified values |  |
| 7.9.1 | Metrological traceability of the certified values shall be established in compliance with the relevant requirements of ISO/IEC 17025 |  |
| 7.9.2 | The stated reference shall be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit, or a measurement standard |  |
| 7.9.3 | Where it is technically possible, the stated reference is traceable to the International System of Units (SI). |  |
| 7.9.4 | Where metrological traceability to the SI units is not technically possible, the RMP shall demonstrate metrological traceability to an appropriate reference |  |
| 7.9.5 | For studies in which the values need to be traceable to a higher order reference system, it shall be ensured that the measurements are calibrated with standards with metrologically traceable values |  |
| 7.9.6 | Secondary parameters that have a significant influence on the certified value or its uncertainty shall have evidence of metrological traceability |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.10 | Assessment of homogeneity |  |
| 7.10.1 | Assessment of the homogeneity of any candidate RM in its final packaged form |  |
| 7.10.2 | Homogeneity requirements for multiple batches |  |
| 7.10.3 | Validated measurement procedures so that the precision and selectivity are fit for the purpose required. |  |
| 7.10.4 | Determination of homogeneity for every property of interest |  |
| 7.10.5 | Homogeneity shall be quantified as an uncertainty contribution (unless it has a negligible contribution) |  |

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

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

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| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.11 | Assessment and monitoring of stability |  |
| 7.11.1 a)-f) | Assessment of stability under storage conditions and under conditions of transport.  Advice on adequate storage and use.  Scheme for monitoring stability,  Precautions when the stability of a certified value cannot be ensured.  Assessment of possible effects on the stability of the material where repeated use is permitted |  |
| 7.11.2 | Experimental assessment of stability before release |  |
| 7.11.3 | For multiple batches the stability of a sufficient number of different batches shall be experimentally verified |  |

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

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

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| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.12 | Characterization |  |
| 7.12.1 | When assigning property values, characterization of the RM is required |  |
| 7.12.2 | Quantitative or qualitative properties |  |
| 7.12.3 a)-e) | Selection of a characterization strategy that is appropriate for the intended use |  |
| 7.12.4 | Characterization of properties of interest with appropriate traceability and sufficient reliability |  |
| 7.12.5 | Technical evaluation of the data and documents involved in the characterization |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.13 | Assignment of property values and their uncertainties |  |
| 7.13.1 | documented procedures for the assignment of property values |  |
| 7.13.2 a)-e) | Requirements to be included in the procedures for assignment of property values |  |
| 7.13.3 | Take due account of technical information on test methods and equipment when assigning the property values |  |
| 7.13.4 | Investigation of outliers |  |
| 7.13.5 | Uncertainty contributions need to be included in the assigned uncertainty |  |
| 7.13.6 a)-d) | Uncertainty contributions to be considered (at a minimum) |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| 7.14 | RM documents and labels |  |
| 7.14.1 | RM certificate for CRMs and product information sheet for other RMs. |  |
| 7.14.2 a)-l) | Contents of RM certificates and product information sheets |  |
| 7.14.3 a)-e) | Additional information on RM certificates |  |
| 7.14.4 | Requirements for RM labels |  |
| 7.14.5 | RM labels for RM’s with reduced physical size |  |

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

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

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| --- | --- | --- |
| 7.15 | Distribution service |  |
| 7.15.1 | Distribution process, including precautions needed to avoid deterioration of the RM |  |
| 7.15.2 | Records of all RM sales and distribution |  |
| 7.15.3 | Guidance and technical support related to the RMs |  |
| 7.15.4 | Notify users of any change to the property value or uncertainty for any RM within the validity period of the RM |  |
| 7.15.5 | Ensuring an effective post-distribution service for RMs, subject to resale through a distributor |  |

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

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

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| --- | --- | --- |
| 7.16 | Control of quality and technical records |  |
| 7.16.1 | procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records |  |
| 7.16.2 | recording information that might be needed in a future dispute situation |  |
| 7.16.3 | All records shall be readily retrievable and in facilities that provide a suitable environment |  |
| 7.16.4 | Handling mistakes in records |  |
| 7.16.5 | Records shall be held securely and in confidence |  |
| 7.16.6 | Procedures to protect electronically held data |  |
| 7.16.7 | Defining an appropriate retention period for technical records |  |
| 7.16.8 | Calibration or measurement results shall be reported in accordance with ISO/IEC 17025. |  |

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

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

|  |  |  |
| --- | --- | --- |
| 7.17 | Management of non-conforming work |  |
| 7.17.1-3 | Procedures for non-conforming work and decision on recall of RM |  |

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

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

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| --- | --- | --- |
| 7.18 | Complaints |  |
| 7.18.1-10 | Process and responsibilities related to receiving, handling, evaluating, following up and deciding on complaints. |  |

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

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

#### EN ISO 17034:2016 § 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):

|  |  |  |
| --- | --- | --- |
| 8.1 | Options |  |
| 8.2 | Quality policy (Option A) |  |
| 8.3 | General management system documentation (Option A) |  |
| 8.4 | Control of management system documents (Option A) |  |
| 8.5 | Control of records (Option A) |  |
| 8.6 | Management review (Option A) |  |
| 8.7 | Internal audit (Option A) |  |
| 8.8 | Actions to address risks and opportunities (Option A) |  |
| 8.9 | Corrective actions (Option A) |  |
| 8.10 | Improvement (Option A) |  |
| 8.11 | Feedback from customers (Option A) |  |

###### 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 2-111(accreditation scope of a producer of reference materials : 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 | General requirements |  |
| 5 | Structural requirements |  |
| 6.1 | Personnel |  |
| 6.2 | Subcontracting |  |
| 6.3 | Provision of equipment, services and supplies |  |
| 6.4 | Facilities and environmental conditions |  |
| 7.1 | General requirements |  |
| 7.2 | Production planning. |  |
| 7.3 | Production control |  |
| 7.4 | Material handling and storage |  |
| 7.5 | Material processing |  |
| 7.6 | Measurement procedures |  |
| 7.7 | Measuring equipment |  |
| 7.8 | Data integrity and evaluation |  |
| 7.9 | Metrological traceability of certified values |  |
| 7.10 | Assessment of homogeneity |  |
| 7.11 | Assessment and monitoring of stability |  |
| 7.12 | Characterization |  |
| 7.13 | Assignment of property values and their uncertainties |  |
| 7.14 | RM documents and labels |  |
| 7.15 | Distribution service |  |
| 7.16 | Control of quality and technical records |  |
| 7.17 | Management of non-conforming work |  |
| 7.18 | Complaints |  |

###### 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)