MODULE C: REPORT OF THE LEAD ASSESSOR

(EN ISO 17034:2016)

# 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).

### Standard requirements

#### EN ISO 17034:2016 § 4: General requirements

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| **4.1** | **Contractual matters** |  |
| 4.1.1 | Review of request, tender or contract concerning the production of RM |  |
| 4.1.2 | Review above includes subcontracted activities |  |
| 4.1.3 | Records of review |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| **4.2** | **Impartiality** |  |
| 4.2.1 | Structured and managed to safeguard impartiality |  |
| 4.2.2 | Personnel are free from any undue internal and external influencesIdentification of risks to its impartiality on an on-going basisElimination or minimization of identified risksTop management committed to impartiality |  |

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

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

|  |  |  |
| --- | --- | --- |
| Clause | Description | Evaluation |
| **4.3** | **Confidentiality** |  |
| 4.3.1 | All information (including confidential information) shall be treated in an appropriate manner  |  |
| 4.3.2 | Release of confidential information |  |

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

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

#### EN ISO 17034:2016 § 5: Structural requirements

|  |  |  |
| --- | --- | --- |
| 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:

|  |  |  |
| --- | --- | --- |
| 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:

|  |  |  |
| --- | --- | --- |
| 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:

|  |  |  |
| --- | --- | --- |
| 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:

|  |  |  |
| --- | --- | --- |
| 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:

|  |  |  |
| --- | --- | --- |
| **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:

|  |  |  |
| --- | --- | --- |
| **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 | Procedures for non-conforming work. |  |
| 7.17.2 a)-h) | Requirements for the procedures for non-conforming work. |  |
| 7.17.3 | Decision on recall of RMs shall be taken in a timely manner |  |

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

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

|  |  |  |
| --- | --- | --- |
| **7.18** | **Complaints** |  |
| 7.18.1 | A documented process for handling complaints |  |
| 7.18.2 | Description of the handling process for complaints is available to any interested party |  |
| 7.18.3 | Reception and confirmation of complaints |  |
| 7.18.4 | Responsibilities for complaint handling |  |
| 7.18.5 | No discriminatory actions |  |
| 7.18.6 | Requirements for the complaints handling process |  |
| 7.18.7 | Gathering and verifying all necessary information |  |
| 7.18.8 | Acknowledgement of receipt of the complaint, progress reports and outcome |  |
| 7.18.9 | Impartiality when handling complaints |  |
| 7.18.10 | Formal notice of the end of the complaint handling |  |

###### 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

|  |  |  |
| --- | --- | --- |
| **8.1** | **Options** |  |
| 8.1.1 | General  |  |
| 8.1.2 | Option A (cfr 8.2 to 8.11) |  |
| 8.1.3 | Option B: Establishing and maintaining a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of this International Standard (ISO 17034), fulfils the management system clause requirements in 8.2 to 8.11. |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.2** | **Quality policy (Option A)** |  |
| 8.2.1 | define and document its policy, objectives and commitment to ensure and maintain the quality of all aspects of RM production |  |
| 8.2.2 | policies related to quality shall be documented under the authority of the top management |  |
| 8.2.3 | Policies should state commitments with respect to ISO 17034 and relevant ISO/IEC17025, as well as implementation of the policies and procedures |  |
| 8.2.4 | Overall objectives shall be reviewed during the management review |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.3** | **General management system documentation (Option A)** |  |
| 8.3 | Extent of management system documentation.Management system documentation shall be communicated to, understood by, available to and implemented by all personnel concerned |  |
| **8.4** | **Control of management system documents (Option A)** |  |
| 8.4.1 | Control of documents (internal and external) |  |
| 8.4.2 a)-f) | Requirements for control of documents  |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.5** | **Control of records (Option A)** |  |
| 8.5.1 | Procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records |  |
| 8.5.2 | Procedures for retaining records, including confidentiality arrangements |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.6** | **Management review (Option A)** |  |
| 8.6.1 | Periodical review of the management system and production processes to ensure their continuing suitability and effectiveness |  |
| 8.6.2 )-k) | Actions arising from the management review |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.7** | **Internal audit (Option A)** |  |
| 8.7.1 | Goals and planning of the internal audit  |  |
| 8.7.2 | Corrective actions arising from internal audits |  |
| 8.7.3 | Records of findings and corrective actions from internal audits |  |
| 8.7.4 | Implementation and effectiveness of the corrective actions |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.8** | **Actions to address risks and opportunities (Option A)** |  |
| 8.8.1 | Risks and opportunities related to the activities are considered |  |
| 8.8.2 | Take actions to address risks and opportunities |  |
| 8.8.3 | Actions shall be proportionate to the potential impact |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.9** | **Corrective actions (Option A)** |  |
| 8.9.1 | Policy and procedure(s) for implementing corrective actions |  |
| 8.9.2 | Investigation to identify the root causes of the problem |  |
| 8.9.3 | Selection and implementation of corrective actions |  |
| 8.9.4 | Monitoring of effectiveness of the corrective actions |  |
| 8.9.5 | Additional audits whenever there is doubt |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.10** | **Improvement (Option A)** |  |
| 8.10.1 | Improvement of the effectiveness of its management system |  |
| 8.10.2 | Improvements shall be identified and action plans shall be developed |  |
| 8.10.3 | Verifying the effectiveness of the preventive actions |  |

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

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

|  |  |  |
| --- | --- | --- |
| **8.11** | **Feedback from customers (Option A)** |  |
| 8.11 | Seeking feedback from customers. Analysis of feedback to improve the management system, RM production activities and customer service. |  |

###### 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) |  |  |