MODULE C: REPORT OF THE LEAD ASSESSOR

(EN ISO/IEC 17025:2017 + EN ISO 17034:2016
+ EN ISO/IEC 17043:2010)

# 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

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| --- | --- |
| 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 |
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# 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

##### MANAGEMENT REQUIREMENTS : CHAPTER 4, 5, 8 OF EN ISO/IEC 17025:2017

#####  CHAPTER 5 OF EN ISO/IEC 17043:2010

#####  CHAPTER 4, 5, 8 OF EN ISO 17034: 2016

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §4.1 Impartiality** **§4.2 Confidentiality,**  **§ 5 Structural requirements****EN ISO/IEC 17043:2010 §4.10 Confidentiality** **§5.1. Organization** **EN ISO17034:2016 § 4.2 Impartiality**  **§4.3 Confidentiality**  **§5 Structural requirements** |
| 4.1.1 | 5.1.4 5.1.5 d) | 4.2.1 | Structured and managed so as to safeguard impartiality |  |
| 4.1.2 |  | 4.2.2 | The management shall be committed to impartiality |  |
| 4.1.3 | 5.1.5 b) | 4.2.2 | No commercial, financial or other pressures that compromise impartiality. |  |
| 4.1.4-5 |  | 4.2.2 | Identify risks to its impartiality on an on-going basis. (risks that arise from its activities, or from its relationships, or from the relationships of its personnel). Demonstrate how such risk are eliminated or minimized |  |
| 4.2.1 | 4.10.2 5.1.5 c) | 4.3.16.1.2 | Management of all information obtained or created including confidential information |  |
| 4.2.2 | 4.10.3 | 4.3.2 | Notification of release of confidential information  |  |
|  | 4.10.1 |  | Confidentiality of participants’ identity |  |
|  | 4.10.4 |  | Written notification of providing PT results directly to regulatory authorities |  |
| 4.2.3 |  |  | Information about the customer obtained from sources other than the customer |  |
| 4.2.4 |  |  | Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law  |  |
| 5.1 | 5.1.1 | 5.1 | Shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its activities |  |
| 5.2 |  |  | Identification of the management that has overall responsibility  |  |
| 5.3 |  | 5.3 b) | Definition and documentation of the range of activities (Specifically emphasized in ISO/IEC 17025:2017 §5.3 : Subcontracting of the laboratory activities on an ongoing basis not allowed.) |  |
| 5.4  | 5.1.25.1.3 | 5.2 | Activities shall be carried out in such a way as to meet the requirements of the applicable standard and of the laboratory’s customers, regulatory authorities and organizations providing recognition. Includes activities performed in permanent facilities as well as at other sites (including temporary or mobile facilities) |  |
| 5.5 a)-c) | 5.1.5 e) f) | 5.3 a) c) | Definition of the organization and management structure. Specifying the responsibility, authority and interrelationship of personnel |  |
| 5.6 a)-e) | 5.1.5 a) i) j) | 5.3 d) e) f) | Availability of authorized personnel and resources needed to carry out their duties |  |
|  | 5.1.5 k) |  | Deputies for key positions |  |
| 5.7 a) | 5.1.65.2.5 | 5.4 a)-c) | Management shall ensure that appropriate communication takes place including on the importance of meeting customers' and other requirements. |  |
| 5.7 b) | 5.2.8 |  | Management shall ensure that the integrity of the management system is maintained in case of changes |  |
|  |  | 5.3 g | Have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its activities |  |

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

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

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §8.1 Options management system**  **§8.2 Management system documentation (option A)**  **§8.3 Control of management system documents (Option A)****EN ISO/IEC 17043:2010 §5.2 Management system**  **§5.3. Document control** **EN ISO 17034:2016 §8.1 Options management system**  **§8.2 Quality policy (option A)**  **§8.3 General management system documentation (Option A)**  **§8.4 Control of management system documents (Option A)** |
| 8.1.1 |  | 8.1.1 | General  |  |
| 8.1.2 |  | 8.1.2 | Option A  |  |
| 8.1.3 |  | 8.1.3 | Option B : Establishment and maintenance of 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 |  |
|  | 5.2.1 |  | Set-up, implementation, and maintenance of management system in accordance with its extent |  |
| 8.2.1 | 5.2.3 a)-e) | 8.2.2 | policies related to quality shall be documented under the authority of the top management |  |
| 8.2.3 | 5.2.4 | 8.2.3 | Commitment of top management to the development and implementation of the management system and continuous improvement of the effectiveness of the management system |  |
|  |  | 8.2.3 | Policies shall include commitments related to : production of RM to conform to EN ISO 17034, testing and calibration in support of the production of RM to conform to ISO/IEC17025, implementation of policies and procedures,improvement of effectiveness of the MS,good professional practive and quality of the produced RM |  |
| 8.2.2 |  |  | The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory |  |
|  | 5.2.3 a)-e) |  | Policy shall include : management's commitment to the quality of its proficiency testing services, management's statement of the standard of service, purpose of the management system related to quality, commitment to implementation of policies and procedures, management's commitment to comply with this International Standard and to continually improve theeffectiveness of the management system. |  |
| (8.9.2 b)) |  | 8.2.4 | Overall objectives shall be reviewed during the management review |  |
|  | 5.2.6 |  | Quality manual outlining the structure of the documentation of the management system |  |
| (5.5 - 5.6) | 5.2.7 | 5.3 d) e) f) | Roles and responsibilities of technical- and quality managers |  |
| 8.2.1 | 5.2.1 | 8.2.18.3 | Policies and objectives are established, documented, maintained, acknowledged and implemented |  |
| 8.2.4 | 5.2.25.3.2.2 |  | All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system |  |
| 8.2.5 | 5.2.2 | 8.3 | All personnel involved shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities |  |
| 8.3.1 | 5.3.1 | 8.4.1 | Internal and external documents are controlled |  |
| 8.3.2 a)-f) | 5.3.2. 5.3.3 | 8.4.2 | Requirements for control of documents  |  |

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

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

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| --- | --- | --- | --- | --- |
| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §7.1 Review of requests, tenders and contracts** **EN ISO/IEC 17043:2010 §5.4. Review of requests, tenders and contracts** **EN ISO 17034:2016 §4.1: Contractual matters** |
| 7.1.1 a)-d) | 5.4.1 | 4.1.1 | Procedure for the review of requests, tenders and contracts |  |
|  | 5.4.3 | 4.1.2 | Review of contracts including subcontracted work |  |
| 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 |  |
|  | 5.4.4 |  | Deviations in contracts or PT design – information to participants/customers |  |
| 7.1.5 |  |  | Informing the customer of any deviation from the contract |  |
| 7.1.6 | 5.4.5 |  | Management of contract amendments |  |
| 7.1.7 | 5.7.1 |  | Cooperation with customers |  |
| 7.1.8 | 5.4.2 | 4.1.3 | Retention of records regarding contract review |  |

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

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

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| --- | --- | --- | --- | --- |
| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §5.3 Range of laboratory activities**  **§6.6 Externally provided products and services** **EN ISO/IEC 17043:2010 §5.5. Subcontracting services** **§5.6 Purchasing services and supplies****EN ISO 17034:2016 §6.2: Subcontracting** **§ 6.3 Provision of equipment, services and supplies** |
| (6.6.2 a)-d)) | 5.5.1 | 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 production planning, selection of subcontractors, assignment of property values and their uncertainties, authorization of property values and their uncertainties, authorization of RM documents. |  |
|  | 5.5.2 |  | No-subcontracting of PT scheme planning, performance evaluation and authorization of final report |  |
| 5.3 |  |  | Definition and documentation of the range of laboratory activities. for which it conforms.. Subcontracting of the laboratory activities on an ongoing basis not allowed |  |
|  |  | 6.2.4 | Procedures to assess that all tasks performed by subcontractors comply with the requirements set by the RMP |  |
| (6.6.2 a)-d)) | 5.5.5 | 6.2.5  | Evidence of the subcontractor’s competence |  |
|  |  | 6.2.6  | Evaluation of the competence of the subcontractor or supervision 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 |  |
| 7.1.1 c | 5.5.3 |  | Notification of subcontracting |  |
|  | 5.5.4 |  | Responsibility for subcontracted work |  |
| 6.6.1 a-c | 5.6.2 | 6.3.2 | Suitable externally provided products and services  |  |
| 6.6.2 a)-d) | 5.6.15.6.25.6.35.6.4 | 6.3.16.3.36.3.4 | Procedure and retention of records for externally provided products and services and 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:

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 § 8.6.2 Improvement (Option A) (Feedback from customers)** **EN ISO/IEC 17043:2010 § 5.7. Service to the customer**  **§ 4.9 Communication with participants** **EN ISO 17034:2016 §8.11 Feedback from customers (Option A)** |
| 8.6.2 | 5.7.2 | 8.11 | Feedback from the customer |  |
|  | 4.9.1 |  | Specific information made available by PT provider |  |
|  | 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:

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §7.9 Complaints****EN ISO/IEC 17043:2010 §5.8 Complaints & appeals** **EN ISO 17034:2016 §7.18: Complaints** |
| 7.9.1 | 5.8 | 7.18.1 | Documented process to receive, evaluate and make decisions on complaints. |  |
| 7.9.2 7.9.3 |  | 7.18.27.18.6 | Process for handling for complaints : requirements & availability to any interested party |  |
| 7.9.2 |  | 7.18.3 | Reception and confirmation of complaints |  |
| 7.9.4 |  | 7.18.7 | Responsible for gathering and verifying all necessary information to validate the complaint |  |
| 7.9.2 |  | 7.18.4 | Responsible for all decisions at all levels of the handling process for complaints |  |
|  |  | 7.18.5 | No discriminatory actions |  |
| 7.9.5 |  | 7.18.8 | Acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome. |  |
| 7.9.6 |  | 7.18.9 | The outcomes to be communicated shall be made by, or reviewed and approved by impartial person |  |
| 7.9.7 |  | 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:

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §7.10.Nonconforming work,** **EN ISO/IEC 17043:2010 §5.9 Control of nonconforming work** **EN ISO 17034:2016 §7.17: Management of nonconforming work** |
| 7.10.1 | 5.9.1 a)-e) | 7.17.1 7.17.2 | Procedure for the management of non-conforming work including responsibilities & authorities |  |
| 7.10.2 |  |  | Records of nonconforming work and actions |  |
| 7.10.3 | 5.9.2 | 7.17.2 | Implementation of corrective actions in case nonconforming work could recur |  |
|  | 5.9.1 d) | 7.17.3 | decision on recall  |  |

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

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

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §8.7 Corrective actions (Option A),** **EN ISO/IEC 17043:2010 §5.11 Corrective actions** **EN ISO 17034:2016 §8.9: Corrective action (Option A)** |
| 8.7.1 a)-f) | 5.11.1 | 8.9.1 | Policy and procedure(s) for implementing corrective actions |  |
| 8.7.1 b) | 5.11.2 | 8.9.2 | Investigation to identify the root causes  |  |
| 8.7.2 | 5.11.3 | 8.9.3 | Selection and implementation of appropriate corrective actions |  |
| 8.7.1 d) | 5.11.4 | 8.9.4 | Monitoring of effectiveness of the corrective actions |  |
|  | 5.11.5 | 8.9.5 | Additional audits whenever there is doubt |  |
| 8.7.3 a)-b) |  |  | Retention of records of nonconformities and corrective actions |  |

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

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

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §8.6.1 Improvement (option A)****EN ISO/IEC 17043:2010 §5.10 Improvement**  **§5.12 Preventive actions** **EN ISO 17034:2016 §8.10 Improvement (option A)** |
| 8.6.1 | 5.10 + 5.12.1 | 8.10.1 8.10.2 | Identify and select opportunities for improvement and develop, implement and monitor any necessary actions |  |
|  | 5.12.2 | 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:

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §7.5 Technical records**  **§8.4 Control of records (Option A)****EN ISO/IEC 17043:2010 §5.13 Control of records** **EN ISO17034:2016 §7.16: Control of quality and technical records**  **§ 8.5 Control of records (Option A)** |
|  | 5.13.1.1 | 7.16.1 | Procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of records |  |
|  | 5.13.1.2 | 8.5.2 | Procedures for retaining records, including confidentiality arrangements |  |
| 8.4.2 |  | 8.5.1 | Controls needed for the identification, storage, backup, protection, archive, retrieval, retention time and disposal of its records |  |
| 8.4.1 |  |  | Establishment and retention of legible records to demonstrate fulfilment of the requirements of ISO/IEC 17025 |  |
| 7.5.1 | 5.13.2.2 |  | Technical records contain sufficient information to facilitate or enable the repetition of the laboratory activity under conditions as close as possible to the original. Observations, data, checking and calculations shall be recorded at the time they are made and shall be identifiable to the specific task and to the personnel responsible |  |
|  |  | 7.16.2 | recording information that might be needed in a future dispute situation |  |
|  | 5.13.2.1 |  | Requirements for contents of technical records related to PT rounds |  |
| 8.4.2 | 5.13.1.2 | 7.16.3 | All records shall be readily retrievable  |  |
| 7.5.2 | 5.13.2.3 | 7.16.4 | Management of mistakes/amendments of records |  |
| 8.4.2 | 5.13.1.3 | 7.16.5 | Records shall be held securely and in confidence |  |
| 7.11.3 | 5.13.1.4 | 7.16.6 | Procedures to protect electronically held data |  |
| 8.4.2 | 5.13.1.2 | 7.16.7 | Defining retention period for records |  |
| (7.8) |  | 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:

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §8.5.: Actions to address risks and opportunities (option A)** **EN ISO 17034:2016 §8.8.: Actions to address risks and opportunities (option A)** |
| 8.8.1 |  | 8.5.1 a-d | Consider the risks and opportunities associated with the activities |  |
| 8.8.2 |  | 8.5.2 a-b | Plan actions to address these risks and opportunities |  |
| 8.8.3 |  | 8.5.3 | Actions taken shall be proportional to the potential impact  |  |

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

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

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 § 8.8 Internal audit (option A)** **EN ISO/IEC 17043:2010 § 5.14 Internal audits** **EN ISO 17034:2016 § 8.7 Internal audits (option A)** |
| 8.8.1+8.8.2 | 5.14.1 | 8.7.1 | Audit programme (predetermined schedule and procedures) |  |
| 8.8.2 | 5.14.2 | 8.7.2 | Corrective actions |  |
| 8.8.2 | 5.14.3 | 8.7.3 | Records |  |
| 8.8.2 (+8.7) | 5.14.5 (+5.11) | 8.7.4 | Follow up of the corrective actions |  |

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

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

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 § 8.9 Management reviews (option A)** **EN ISO/IEC 17043:2010 § 5.15 Management reviews** **EN ISO 17034:2016 § 8.6 Management reviews (option A)** |
| 8.9.1+8.9.2 | 5.15.1 | 8.6.1 | Procedure, preset schedule, periodicity, content |  |
| 8.9.3 | 5.15.2 | 8.6.2 | Records, actions and timescale |  |

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

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

##### TECHNICAL REQUIREMENTS : CHAPTER 6,7 OF EN ISO/IEC 17025:2017

#####  CHAPTER 4 OF EN ISO/IEC 17043:10

#####  CHAPTER 6, 7 OF EN ISO 17034:2016

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §6.1 General**  **§6.2 Personnel** **EN ISO/IEC 17043:2010 §4.1General**  **§4.2 Personnel** **EN ISO 17034:2016 §5.2: Personnel** |
| 6.1 | 4.1 |  | Availability of competent personnel (including subcontractors) |  |
| 6.1 |  |  | Availability of facilities, equipment, systems and support services necessary to manage and perform its activities |  |
| 6.2.1 | 4.2.3 | 6.1.1 | Personnel shall act impartially, be competent and work in accordance with the management system. |  |
| 6.2.2 | 4.2.2  4.2.6 | 6.1.36.1.4 | Competence requirements (education, qualification, training, technical knowledge, skills and experience) for each function influencing the activities shall be documented |  |
|  | 4.2.7 | 6.1.4 | Ensuring necessary training and evaluation of effectiveness of training activities |  |
| 6.2.3 | 4.2.1 |  | Personnel shall have the competence to perform the activities and to evaluate the significance of deviations |  |
| 6.2.4 | 4.2.55.1.5 g) | 6.1.6 | Communication of duties, responsibilities and authorities to personnel. |  |
| 6.2.5 a-f | 4.2.55.1.5 h) | 6.1.56.1.6 | Procedures and retention of records related to selection, training, supervision, authorization and monitoring competence of the personnel |  |
| 6.2.6 a)-c) | 4.2.4 | 6.1.6 | Authorization of personnel to perform specific activities |  |

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

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

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §6.3 Facilities and environmental conditions** **EN ISO/IEC 17043:2010 §4.3: Equipment, accommodation and environment****EN ISO 17034:2016 §6.4: Facilities and environmental conditions** |
| 6.3.1 | 4.3.1 | 6.4.1 | The facilities and environmental conditions shall be suitable for the activities |  |
| 6.3.2 | 4.3.2 |  | The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented |  |
| 6.3.3 | 4.3.4 | 6.4.2 | Monitoring, controlling and recording the environmental conditions  |  |
| 6.3.4 | 4.3.34.3.5 | 6.4.3 6.4.4 | Measures to control facilities (access, environmental factors, incompatible activities…) |  |
| 6.3.5 | 4.3.2 |  | Activities at sites or facilities outside its permanent control |  |

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

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

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| --- | --- | --- | --- | --- |
| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §7.2 : Selection, verification and validation of methods****EN ISO/IEC 17043:2016 §4.3.6 Validation and maintenance of performance characteristics of methods and  equipment**  **§4.5: Choice of method or procedures****EN ISO 17034:2016 §7.6: Measurement procedures** |
| 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 unless it is not appropriate or possible to do so |  |
| 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 |  |
|  |  | 7.6 | Relevant requirements of ISO/IEC 17025 are met with respect to calibration and testing |  |
|  | 4.3.6 |  | Appropriate validation and maintenance of performance characteristics of methods and equipment |  |
|  | 4.5.1 |  | Test methods, calibration or measurement procedures to be used |  |
|  | 4.5.2 |  | Considerations to be made in case of participants’ choice of method |  |

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

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

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| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §6.4 Equipment****EN ISO/IEC 17043:2010 §4.3 Equipment, accommodation and environment****EN ISO 17034:2016 §7.7 Measuring equipment** |
| (6.4) |  | 7.7 | Measuring equipment used in RM production is used in compliance with the relevant requirements of ISO/IEC 17025 |  |
| 6.4.1 | 4.3.1 | 7.7 | Access to appropriate equipment |  |
| 6.4.2 |  | 7.7 | Requirements for equipment outside the permanent control of the laboratory shall meet the requirements of §6.4 |  |
| 6.4.3 |  | 7.7 | Procedure for handling, transport, storage, use and planned maintenance of equipment |  |
| 6.4.4 | 4.3.6 | 7.7 | Verification that equipment conforms to specified requirements before being placed or returned into service |  |
| 6.4.5 | 4.3.6 | 7.7 | The equipment used for measurement shall be capable of achieving the required measurement accuracy and/or measurement uncertainty |  |
| 6.4.6 | 4.3.6 | 7.7 | Calibration of measuring equipment  |  |
| 6.4.7 |  | 7.7 | Calibration programme |  |
| 6.4.8 |  | 7.7 | Identification of the calibration status or period of validity |  |
| 6.4.9 |  | 7.7 | Management of equipment that produces questionable results |  |
| 6.4.10 |  | 7.7 | Procedure for intermediate checks |  |
| 6.4.11 |  | 7.7 | Reference values and correction factors |  |
| 6.4.12 |  | 7.7 | Measures to prevent unintended adjustments |  |
| 6.4.13 a-h |  | 7.7 | Retention of records |  |

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

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

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| --- | --- | --- | --- | --- |
| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §6.5 : Metrological traceability****EN ISO 17034:2016 §7.9: Metrological traceability of certified values** |
| 6.5.1 |  | 7.9.1 | 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 |  | 7.9.1 | 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 |  |
|  |  | 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:

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| --- | --- | --- | --- | --- |
| Clause EN ISO/IEC 17025:2017 | Clause EN ISO/IEC 17043:2010 | Clause EN ISO 17034:2016 | Description | Evaluation |
| **EN ISO/IEC 17025:2017 §7.11 Control of data & information management****EN ISO/IEC 17043:2010 §4.7 Data analysis and evaluation of proficiency testing scheme results (§4.7.1.1 +  §4.7.1.2)****EN ISO 17034:2016 §7.8 Data integrity and evaluation** |
| 7.11.1 |  |  | Access to the data and information needed to perform laboratory activities |  |
| 7.11.2 |  |  | The laboratory information management system shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction.  |  |
| 7.11.2 |  | 7.8.2 a) | Software developed in-house or changes or modifications to commercial off-the-shelf software shall be validated |  |
|  | 4.7.1.1 |  | Validation, maintenance and operational checks of data processing equipment and software |  |
| 7.11.3 a)-d) |  | 7.8.2 b)c)d) | Protection from unauthorized access, protecting and maintaining integrity of data, data security, safeguarding the accuracy of data (recording and transcription) |  |
| 7.11.3 e) |  |  | Records of system failures of the laboratory information management system and appropriate immediate and corrective actions. |  |
| 7.11.4 |  |  | Requirements for off-site systems or systems maintained through external providers |  |
| 7.11.5 |  |  | Instructions, manuals and reference data are readily available to personnel |  |
| 7.11.6 | 4.7.1.2 | 7.8.1 | Calculations and data transfers shall be checked |  |
|  |  | 7.8.3 | Appropriate statistical procedures for monitoring, testing, calibration or value assignment of RM’s |  |

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

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

##### TESTING AND CALIBRATION :

##### SPECIFIC PARTS OF CHAPTER 7 OF EN ISO/IEC 17025:2017

|  |  |  |
| --- | --- | --- |
| Clause EN ISO/IEC 17025:2017 | 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 EN ISO/IEC 17025:2017 | 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 itemsPrecautions 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 EN ISO/IEC 17025:2017 | 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 EN ISO/IEC 17025:2017 | 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 EN ISO/IEC 17025:2017 | Description | Evaluation |
| **7.8** | **Reporting the 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 allinformation 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:

##### PROVIDING PROFICIENCY TESTING :

##### SPECIFIC PARTS OF CHAPTER 4 OF EN ISO/IEC 17043:2010

|  |  |  |
| --- | --- | --- |
| Clause EN ISO/IEC 17043:2010 | 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 |  |
| 4.4.1.34.4.1.3 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 |  |
| 4.4.1.54.4.1.5 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 theproficiency 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 |  |
| 4.4.4.34.4.4.3 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:

|  |  |  |
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| Clause EN ISO/IEC 17043:2010 | 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 |  |
| 4.6.1.24.6.1.2 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:

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| Clause EN ISO/IEC 17043:2010 | 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  | See above |
| 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 |  |
| 4.7.2.24.7.2.2 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:

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| Clause EN ISO/IEC 17043:2010 | 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 |  |
| 4.8.24.8.2.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:

##### PRODUCTION OF REFERENCE MATERIALS :

##### SPECIFIC PARTS OF CHAPTER 7 OF EN ISO 17034:2016

|  |  |  |
| --- | --- | --- |
| Clause EN ISO 17034:2016 | 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:

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| --- | --- | --- |
| Clause EN ISO 17034:2016 | 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 EN ISO 17034:2016 | 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 EN ISO 17034:2016 | 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 EN ISO 17034:2016 | 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 EN ISO 17034:2016 | 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 EN ISO 17034:2016 | 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 EN ISO 17034:2016 | 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 EN ISO 17034:2016 | 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:

|  |  |  |
| --- | --- | --- |
| Clause EN ISO 17034:2016 | Description | Evaluation |
| **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:

### 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 2-109 (accreditation scope of a PT provider : description + evaluation) |  |  |
| BELAC 2-110 (accreditation scope of a calibration laboratory: description + evaluation) |  |  |
| 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) |  |  |
| 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) |  |  |