MODULE C: REPORT OF THE LEAD ASSESSOR

(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

#### ISO/IEC 17043:2010 §4 Technical requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### ISO/IEC 17043:2010 §5 Management requirements

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| Clause | Description | Evaluation |
| **5.1** | **Organization** |  |
| 5.1.1 | Legal identity and accountability |  |
| 5.1.2 | Responsibilities of PT provider in carrying out its proficiency testing operations |  |
| 5.1.3 | Extent of the management system |  |
| 5.1.4 | Key personnel responsibilities: identification of potential conflicts of interest – procedures to ensure impartiality |  |
| 5.1.5  5.1.5 a) | Requirements related to personnel, confidentiality, impartiality and management:  Availability of managerial and technical personnel with adequate authority and resources |  |
| 5.1.5 b) | Free from any undue pressure |  |
| 5.1.5 c) | Policies and procedures with regard to confidentiality |  |
| 5.1.5 d) | Policies and procedures to ensure confidence in competence, judgement, impartiality and operational integrity |  |
| 5.1.5 e) | Organizational structure and relationships |  |
| 5.1.5 f) | Function descriptions |  |
| 5.1.5 g) | Awareness of personnel with regard to their responsibilities towards the objectives of the management system |  |
| 5.1.5 h) | Adequate supervision |  |
| 5.1.5 i) | Technical Management – responsibilities and authority |  |
| 5.1.5 j) | Quality manager – responsibilities and authority |  |
| 5.1.5 k) | Deputies for key positions |  |
| 5.1.6 | Appropriate internal communication on the management system ensured by top management |  |

###### 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 |
| **5.2** | **Management system** |  |
| 5.2.1 | Set-up, implementation, and maintenance of management system in accordance with its extent |  |
| 5.2.2 | Adequate documentation of the management system – information to personnel, availability and implementation |  |
| 5.2.3 a-e | Quality policy statement issued by top management - overall objectives |  |
| 5.2.4 | Commitment of top management for continual improvement |  |
| 5.2.5 | Importance of meeting customer, statutory and regulatory requirements emphasized by top management |  |
| 5.2.6 | Quality manual - structure of the documentation of the management system |  |
| 5.2.7 | Roles and responsibilities of technical- and quality managers |  |
| 5.2.8 | Change control and integrity maintenance ensured by top management |  |

###### 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 |
| **5.3** | **Document control** |  |
| **5.3.1** | **General** |  |
| 5.3.1 | Control of internal and external documents |  |
| **5.3.2** | **Document approval and issue** |  |
| 5.3.2.1 | Document review and approval prior to issue - Master list of approved documents |  |
| 5.3.2.2 a)-d) | Procedures shall ensure :  availability of appropriate documents  periodical review of documents  assurance against unintended use of invalid or obsolete documents  maintenance of suitably marked obsolete documents |  |
| 5.3.2.3 | Unique identification of documents |  |
| **5.3.3** | **Document changes** |  |
| 5.3.3.1 | Review and approval of changes |  |
| 5.3.3.2 | Identification of changes |  |
| 5.3.3.3 | Procedures related to manual changes |  |
| 5.3.3.4 | Procedure related to control of changes in computerised systems |  |

###### 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 |
| **5.4** | **Review of requests, tenders and contracts** |  |
| 5.4.1 | General policies and procedures ensuring:  Adequate definition, documentation and understanding of requirements  Presence of capability and resources to meet requirements  Technically appropriate PT scheme |  |
| 5.4.2 | Records of reviews and changes |  |
| 5.4.3 | Review of contracts including subcontracted work |  |
| 5.4.4 | Deviations in contracts or PT design – information to participants/customers |  |
| 5.4.5 | Review and communication of contract amendments |  |

###### 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 |
| **5.5** | **Subcontracting services** |  |
| 5.5.1 | Demonstration of subcontractors’ experience and technical competence |  |
| 5.5.2 | No-subcontracting of PT scheme planning, performance evaluation and authorization of final report |  |
| 5.5.3 | Notification of subcontracting in advance and in writing |  |
| 5.5.4 | Responsibility for subcontracted work |  |
| 5.5.5 | Register of subcontractors, scope of subcontracting and records of competence assessment |  |

###### 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 |
| **5.6** | **Purchasing services and supplies** |  |
| 5.6.1 | Policy and procedures for selection of services and supplies – procedures for purchase and handling of reagents and materials |  |
| 5.6.2 | Records of inspection of purchased critical supplies, equipment, materials |  |
| 5.6.3 | Review and approval of purchasing documents for critical services and supplies |  |
| 5.6.4 | Records of evaluation of suppliers of critical supplies and services - list of approved suppliers |  |

###### 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 |
| **5.7** | **Service to the customer** |  |
| 5.7.1 | Cooperation with participants/customers – assurance of confidentiality |  |
| 5.7.2 | Customer feedback |  |

###### 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 |
| **5.8** | **Complaints and appeals** |  |
| 5.8 | Policy and procedure for resolution of complaints and appeals – records of complaints and appeals, investigations, 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 | Description | Evaluation |
| **5.9** | **Control of nonconforming work** |  |
| 5.9.1  5.9.1 a) | Policy and procedure for control of non-conforming activities ensuring:  Designation of responsibilities and authorities |  |
| 5.9.1 b) | Evaluation of significance of non-conforming work |  |
| 5.9.1 c) | Decision taking on actions, timescale, acceptability of non-conforming work |  |
| 5.9.1 d) | Information to participants/customers – recall or disregard of non-conforming PT items or reports already sent |  |
| 5.9.1 e) | Responsibility for authorization of work resumption |  |
| 5.9.2 | 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 | Description | Evaluation |
| **5.10** | **Improvement** |  |
| 5.10 | Continuous improvement of the effectiveness of the management system |  |

###### 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 |
| **5.11** | **Corrective actions** |  |
| 5.11.1 | General - Policy and procedures - Designation of personnel |  |
| 5.11.2 | Cause analysis |  |
| 5.11.3  5.11.3.1 | Selection and implementation of corrective actions  Identification, selection and implementation of corrective actions |  |
| 5.11.3.2 | Corrective action appropriate to the extent and risk |  |
| 5.11.3.3 | Documentation and implementation of required changes |  |
| 5.11.4 | Monitoring of corrective actions |  |
| 5.11.5 | Additional audits |  |

###### 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 |
| **5.12** | **Preventive actions** |  |
| 5.12.1 | Identification – development, implementation and monitoring of action plans |  |
| 5.12.2 | Procedure including initiation of actions and verification of effectiveness |  |

###### 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 |
| **5.13** | **Control of records** |  |
| **5.13.1** | **General** |  |
| 5.13.1.1 | Procedure for managing records |  |
| 5.13.1.2 | Storage, preservation and retention times of records |  |
| 5.13.1.3 | Security and confidentiality of records |  |
| 5.13.1.4 | Protection and back-up of electronically-held data |  |
| **5.13.2** | **Technical records** |  |
| 5.13.2.1 a)-f) | Requirements for retaining records of different types of technical data |  |
| 5.13.2.2 | Traceability of and responsibility for observations, raw data and calculations |  |
| 5.13.2.3 a)-c) | Alterations of records (identification, dating, traceability) |  |

###### 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 |
| **5.14** | **Internal audits** |  |
| 5.14.1 | Procedure and preset schedule for periodic internal audits – planning and organization by quality manager- Trained and qualified internal auditors |  |
| 5.14.2 | Corrective actions – notification of customers/participants when relevant |  |
| 5.14.3 | Audit records |  |
| 5.14.4 | Follow-up audits – verification of effectiveness of 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 | Description | Evaluation |
| **5.15** | **Management reviews** |  |
| 5.15.1 | Procedure and preset schedule for periodic MR & items to be included |  |
| 5.15.2 | Records of results and actions which are to be discharged within an appropriate and agreed timescale |  |

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

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

### Additional requirements of BELAC

|  |  |  |
| --- | --- | --- |
| Reference | Evaluation | Conclusion |
| BELAC 2-001 (reference to accreditation) |  |  |
| BELAC 2-002 (accreditation scope : fixed versus flexible – dormant activities) |  |  |
| BELAC 2-109 (accreditation scope of a PT provider : description + evaluation) |  |  |
| BELAC 2-003 (policy and guidelines regarding traceability of measurement results) |  |  |
| BELAC 2-106 (proficiency tests (PT): guidelines for participation and performance evaluation) |  |  |
| BELAC 2-107 (expression of measurement uncertainty in calibration) |  |  |
| BELAC 2-108 (expression of measurement uncertainty in quantitative testing) |  |  |