MODULE C: REPORT OF THE LEAD ASSESSOR

(EN ISO/IEC 17025:2017)

# 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 17025:2017 § 4.: General requirements

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| Clause | Description | Evaluation |
| **4.1** | **Impartiality** |  |
| 4.1.1 | Laboratory activities shall be undertaken impartially |  |
| 4.1.2 | The laboratory management shall be committed to impartiality |  |
| 4.1.3 | No commercial, financial or other pressures that compromise impartiality. |  |
| 4.1.4-5 | Identification of 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). The laboratory shall be able to demonstrate how it eliminates  or minimizes such risk |  |

###### 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 |
| **4.2** | **Confidentiality** |  |
| 4.2.1 | Management of all information obtained or created during the performance of laboratory activities. |  |
| 4.2.2 | Notifying the customer when the laboratory is required to release confidential information (unless prohibited by law) |  |
| 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 |  |

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

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

#### ISO/IEC 17025:2017 § 5: Structural requirements

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| Clause | Description | Evaluation |
| 5.1 | The laboratory 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 for the laboratory |  |
| 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. |  |
| 5.4 | Laboratory activities (performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer’s facility) shall be carried out in such a way as to meet the requirements of the standard and of the laboratory’s customers, regulatory authorities and organizations providing recognition. |  |
| 5.5 a-c | Definition of the organization and management structure of the laboratory. Specifying the responsibility, authority and interrelationship of personnel. Documenting procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results |  |
| 5.6 a-e | Availability of authorized personnel and resources needed to carry out their duties |  |
| 5.7 | Laboratory management shall ensure that communication takes place regarding the management system and that the integrity of the management system is maintained in case of changes |  |

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

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

#### ISO/IEC 17025:2017 § 6: Resource requirements

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| Clause | Description | Evaluation |
| **6.1** | **General** |  |
| 6.1 | The laboratory shall have available the personnel, facilities, equipment, systems and support services  necessary to manage and perform its laboratory activities. |  |
| **6.2** | **Personnel** |  |
| 6.2.1 | Personnel shall act impartially, be competent and work in accordance with the laboratory's management system. |  |
| 6.2.2 | The laboratory shall document the competence requirements (education, qualification, training, technical knowledge, skills and experience) for each function influencing the results of laboratory activities |  |
| 6.2.3 | The laboratory shall ensure that the personnel have the competence to perform laboratory activities and to evaluate the significance of deviations |  |
| 6.2.4 | The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities. |  |
| 6.2.5 a-f | Procedures and retention of records related to the competence of the personnel |  |
| 6.2.6 a-c | Authorization of personnel to perform specific laboratory 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 |
| **6.3** | **Facilities and environmental conditions** |  |
| 6.3.1 | The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results |  |
| 6.3.2 | The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented |  |
| 6.3.3 | Monitoring, controlling and recording environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results |  |
| 6.3.4 | Measures to control facilities shall be implemented, monitored and periodically reviewed |  |
| 6.3.5 | Laboratory activities at sites or facilities outside its permanent  Control shall be conform the requirements of § 6.3 |  |

###### 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 |
| **6.4** | **Equipment** |  |
| 6.4.1 | Access to equipment |  |
| 6.4.2 | Requirements for equipment outside the permanent control of the laboratory shall meet the requirements of §6.4 |  |
| 6.4.3 | Procedure for handling, transport, storage, use and planned  maintenance of equipment |  |
| 6.4.4 | Verification that equipment conforms to specified requirements before being placed or returned into service |  |
| 6.4.5 | The equipment used for measurement shall be capable of achieving the required measurement accuracy and/or measurement uncertainty |  |
| 6.4.6 | Calibration of measuring equipment |  |
| 6.4.7 | Calibration programme |  |
| 6.4.8 | Identification of the calibration status or period of validity |  |
| 6.4.9 | Management of equipment that produces questionable results |  |
| 6.4.10 | Procedure for intermediate checks |  |
| 6.4.11 | Reference values and correction factors |  |
| 6.4.12 | Measures to prevent unintended adjustments |  |
| 6.4.13 a-h | 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 | Description | Evaluation |
| **6.5** | **Metrological traceability** |  |
| 6.5.1 | 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 | 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 |  |

###### 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 |
| **6.6** | **Externally provided products and services** |  |
| 6.6.1 a-c | Suitable externally provided products and services |  |
| 6.6.2 a-d | Procedure and records for 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:

#### ISO/IEC 17025:2017 §7 : Process requirements

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| Clause | Description | Evaluation |
| **7.1** | **Review of requests, tenders and contracts** |  |
| 7.1.1 a-d | Procedure for the review of requests, tenders and contracts |  |
| 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 |  |
| 7.1.5 | Informing the customer of any deviation from the contract |  |
| 7.1.6 | If a contract is amended after work has commenced, the contract review shall be repeated and communication of amendments to all affected personnel. |  |
| 7.1.7 | Cooperation with customers |  |
| 7.1.8 | 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 | Description | Evaluation |
| **7.2** | **Selection, verification and validation of methods** |  |
| **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 |  |
| 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 |  |

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

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

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| Clause | Description | Evaluation |
| **7.3** | **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:

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| Clause | 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 items  Precautions 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:

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| Clause | Description | Evaluation |
| **7.5** | **Technical records** |  |
| 7.5.1 | Technical records contain sufficient information to facilitate or enable the repetition of the laboratory activity under conditions as close as possible to the original |  |
| 7.5.2 | Amendments to technical records can be tracked to previous versions or to original observations  Both original and amended data and files shall be retained |  |

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

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

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| Clause | Description | Evaluation |
| **7.6** | **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:

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| Clause | 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:

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| Clause | Description | Evaluation |
| **7.8** | **Reporting of 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 all  information 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:

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| Clause | Description | Evaluation |
| **7.9** | **Complaints** |  |
| 7.9.1 | Documented process to receive, evaluate and make decisions on complaints. |  |
| 7.9.2 – 7.9.3 | A description of the handling process for complaints shall be available to any interested party |  |
| 7.9.4 | Responsibility for gathering and verifying all necessary information to validate the complaint |  |
| 7.9.5 | Informing the complainant van de klager (acknowledging receipt, providing progress reports and outcome) |  |
| 7.9.6 | The outcomes made by, or reviewed and approved by impartial person |  |
| 7.9.7 | 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 | Description | Evaluation |
| **7.10** | **Nonconforming work** |  |
| 7.10.1 a-f | Procedure for the management of non-conforming work |  |
| 7.10.2 | Retention of records of nonconforming work and actions |  |
| 7.10.3 | Implementation of corrective actions in case nonconforming work could recur |  |

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

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

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| Clause | Description | Evaluation |
| **7.11** | **Control of data and information management** |  |
| 7.11.1 | Access to the data and information needed to perform laboratory  activities |  |
| 7.11.2 | Validation of the functionality of the laboratory information management system (including interfaces) used to collect, process, record, report, store or retrieve data. Authorization, documentation and validation prior to implementation of changes (including laboratory software configuration or modifications to commercial off-the-shelf software) |  |
| 7.11.3 a-e | Requirements for the laboratory information management system |  |
| 7.11.4 | Requirements for off-site systems or systems managed/maintained through external providers |  |
| 7.11.5 | Instructions, manuals and reference data are readily available to personnel |  |
| 7.11.6 | Calculations and data transfers shall be checked |  |

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

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

#### ISO/IEC 17025:2017 §8 : Management system requirements

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| Clause | Description | Evaluation |
| **8.1** | **Opties** |  |
| 8.1.1 | General |  |
| 8.1.2 | Option A (cfr 8.2 to 8.9) |  |
| 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, fulfils the management system clause requirements in 8.2 to 8.9. |  |

###### 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 |
| **8.2** | **Management system documentation (option A)** |  |
| 8.2.1 | Policies and objectives are established, documented, maintained, acknowledged and implemented |  |
| 8.2.2 | The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory |  |
| 8.2.3 | Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness |  |
| 8.2.4 | 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 | All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities |  |
| **8.3** | **Control of management system documents (Option A)** |  |
| 8.3.1 | Internal and external documents are controlled |  |
| 8.3.2 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:

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| Clause | Description | Evaluation |
| **8.4** | **Control of records (Option A)** |  |
| 8.4.1 | Establish and retain legible records |  |
| 8.4.2 | Controls needed for records including confidentiality commitments |  |

###### 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 |
| **8.5** | **Actions to address risks and opportunities (Option A)** |  |
| 8.5.1 a-d | Consider the risks and opportunities associated with the laboratory activities |  |
| 8.5.2 a-b | Plan actions to address these risks and opportunities |  |
| 8.5.3 | Actions taken shall be proportional to the potential impact on the validity of laboratory results. |  |

###### 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 |
| **8.6** | **Improvement (Option A)** |  |
| 8.6.1 | Identify and select opportunities for improvement and implement any necessary actions |  |
| 8.6.2 | Feedback from customers is sought, analysed and used to improve the management system, laboratory activities and customer service |  |

###### 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 |
| **8.7** | **Corrective actions (Option A)** |  |
| 8.7.1 a-f | Management of corrective actions |  |
| 8.7.2 | Corrective actions shall be appropriate |  |
| 8.7.3 a-b | Retain 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 | Description | Evaluation |
| **8.8** | **Internal audits (Option A)** |  |
| 8.8.1 | Objective and planning of internal audits |  |
| 8.8.2 a-e | Management of internal 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 |
| **8.9** | **Management reviews (Option A)** |  |
| 8.9.1 | Objective and planning of management reviews |  |
| 8.9.2 a-o | Requirements and records concerning the input for the management review |  |
| 8.9.3 a-d | Requirements and records concerning the output of the management review (decisions and actions) |  |

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

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

### Additional requirements of BELAC

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| **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 2-110 (accreditation scope of a calibration laboratory: 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) |  | |  |