***Please update the table of contents before closing the document***

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# **Name of the assessed CAB**

Type of assessment

 (ex: P1S1+E1)

According to standard ISO/IEC 17025: 2017

*« General requirements for the competence of testing and calibration laboratories»*

 (File no 20xx/x/0xx)

***Please find all necessary information with regard to the type of audit and file noon your mission order***

## Assessment plan

|  |  |
| --- | --- |
| **Name of the CAB** |  |

**Assessment criteria and objectives**

|  |  |
| --- | --- |
| **Accreditation standard :** |  |
| **Type of assessment :** | [ ]  initial [ ]  renewal [ ]  surveillance [ ]  extension [ ]  additional |

*The above table is to be repeated for each accreditation standard concerned, cf. mission order.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Notified body:** | [ ]  yes[ ]  no | **Directive(s) / regulation(s) assessed:** |  |
| **Multisite CAB?** | [ ]  yes[ ]  no |

**Assessment scope, team, sites and dates**

| Name of the assessor | Function\* | Assessed activities | Site | Date | Flexible scope of accreditation? | Modifications of the scope (extensions, flexibility) | Findings to be closed and any other follow-up actions |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | [ ]  yes |  |  |
|  |  |  |  |  | [ ]  yes |  |  |
|  |  |  |  |  | [ ]  yes |  |  |
|  |  |  |  |  | [ ]  yes |  |  |
|  |  |  |  |  | [ ]  yes |  |  |
|  |  |  |  |  | [ ]  yes |  |  |
|  |  |  |  |  | [ ]  yes |  |  |
| TL = Team leader, TA = Technical Assessor, Expert = E, JA = Junior Assessor |

|  |  |
| --- | --- |
| For initial assessments : date of documentary review by the team leader |  |

**Schedule**

*Plan intermediate closing meetings if not all assessors are present at the final closing meeting.*

| Date and time : | Reference section: | Names of assessors: | Persons encountered: |
| --- | --- | --- | --- |
|  |  | Opening meeting - Presentation of assessors and participants,- Confirmation of rules of confidentiality ,- The audit objectives and criteria for accreditation,- Review of the scope of accreditation, - Approval of the audit plan,- Evolution since last assessment (organisation, MQS, equipment,…) | Form *F003G - Attendance list* to be completed |
|  |  |  | Team leader | Quality manager |
|  |  |  | Technical assessor | Technical manager and technicians |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  | If necessary, exchange of point of views of audit team members  | Audit team | / |
| Lunch Break |
|  |  | If necessary, exchange of point of views of audit team members  | Audit team | / |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  | Set up of possible findings, Preparation of the closing meeting | Audit team | / |
|  |  | Closing meeting - Presentation of findings and signature/approval of findings,- Presentation and comments with regard to the summary audit report,- Fix final date for reception of corrective actions (max. 15 work days),- Define changes to be realized to the scope of accreditation (if applicable) - Inform CAB of next steps with regard to accreditation procedure. | Form *F003G - Attendance list* to be completed |

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| Remark : Planning of the different phases of the management system audit and technical audit is likely to adjustments depending on constraints of the planning of the body which will be specified during the opening meeting |

## Attendance list opening meeting/closing

|  |  |  |  |
| --- | --- | --- | --- |
| **Opening meeting :** | [ ]  check the box | **Meeting date :** |       |
| **Closing meeting** | [ ]  check the box |

| **CAB’s audited personnel** | **Function** | **Signature** |
| --- | --- | --- |
|  |  | Original signed |
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| **Assessors** | **Function (TL, TA, E, JA) and technical domain** | **Signature** |
| --- | --- | --- |
|  |  | Original signed |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Summaries and conclusions of assessment

|  |
| --- |
| **Team leader: NAME First name** |
| Summary of the team leaderPlease fill out *all boxes below mentioning your* observations *and related assessment evidences*.*For all not examined or not applicable points, please state this clearly in the corresponding field.* |
| Important amendments since the previous assessment |
|  |
| Legal structure and description of the activities of the organization (§ 5.1 and 5.3 ISO/IEC 17025 :2017) |
|  |
| Impartiality (including the description of relations that could affect impartiality and means of control), independence and confidentiality (§ 4.1 and § 4.2 ISO/IEC 17025 :2017) |
|  |
| General and functional organization (organization chart, positioning in the structure, management, job descriptions, substitution) (§ 5.2 and 5.5.a ISO/IEC 17025 :2017) |
|  |
| Quality manager and technical manager (roles and responsibilities)(§ 5.5.b. and 5.6 ISO/IEC 17025 :2017) |
|  |
| Management of staff competence (contract, training, qualification, authorization, competence and performance, records…) (§ 6.2 ISO/IEC 17025 :2017) |
|  |
| Installations (access, ambient conditions if applicable, maintenance) (§ 6.3 ISO/IEC 17025 :2017) |
|  |
| Purchase (purchase data, supplier, services and good selection and evaluation, purchase, storage and record control …) (§ 6.6 ISO/IEC 17025 :2017) |
|  |
| Equipment (identification, calibration and monitoring of measurements *(A016)*, reference standards of measurements, computer or automated equipment, defective equipment, equipment files …)(§ 6.4 and § 6.5 ISO/IEC 17025 :2017) |
|  |
| Competence of service providers performing calibrations via the 3rd route (internal and/or external) *(A016)* (§ 6.5.2 ISO/IEC 17025:2017) |
|  |
| Subcontracting (competent/accredited, contract + confidentiality and impartiality, information of clients, records) (§ 7.1.1 c) and § 6.6 ISO/IEC 17025 :2017) |
|  |
| Complaints and appeals (§ 7.9 ISO/IEC 17025 :2017) |
|  |
| Requirements with regard to Management System of the CAB |
| * *Policies and objectives:* (§ 8.2.1 ISO/IEC 17025 :2017)
* *Management system and document control:* (§ 8.2 and 8.3 ISO/IEC 17025 :2017)
* *Record control:* (§ 8.4 ISO/IEC 17025 :2017)
* *Management review:* (§ 8.9 ISO/IEC 17025 :2017)
* *Internal audits:* (§ 8.8 ISO/IEC 17025 :2017)
* *Improvement and corrective/preventive actions:* (§ 8.6 and 8.7 ISO/IEC 17025 :2017)
 |
| Communication (§ 5.7.a ISO/IEC 17025 :2017) |
|  |
| Service to the customer (§ 7.1.7 ISO/IEC 17025 :2017) |
|  |
| Control of nonconforming testing and/or calibration work (§ 7.10 ISO/IEC 17025 :2017) |
|  |
| Technical records (§ 7.5 ISO/IEC 17025 :2017) |
|  |
| Control of data and information management (§ 7.11 ISO/IEC 17025 :2017) |
|  |
| Actions to address risks and opportunities (§ 8.5 ISO/IEC 17025 :2017) |
|  |
| Requirements with regard to process realization ***(please indicate list of assessed files – vertical traceabiliy)*** |
| * *Review of requests, tenders and contracts:* (§ 7.1 ISO/IEC 17025 :2017)
* *Selection, verification and validation of methods:* (§ 7.2 ISO/IEC 17025 :2017)
* *Management of flexible scopes (if applicable):* (Annex A012)
* *Sampling:* (§ 7.3 ISO/IEC 17025 :2017)
* *Handling of test and calibration items:* (§ 7.4 ISO/IEC 17025 :2017)
* *Assuring the quality of test and calibration results:* (§ 7.7 ISO/IEC 17025 :2017)
* *Reporting the results:* (§ 7.8 ISO/IEC 17025 :2017)
 |

|  |
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| Respect of applicable EA, IAF and ILAC requirements: *see annex A006 – applicable standards and guidlines* |
|  |
| Respect of the guidelines for the use of the OLAS accreditation symbol: ***see annex A003 – Guidelines for the use of the OLAS logo and accreditation symbol*** |
|  |
| For multisite CABs: Respect of the dispositions in *OLAS annex A013 – Accreditation of multi-site organizations*and its annex |
|  |
| Control of corrective actions of the previous assessment: *Please check also the intermediary report of the CAB regarding implementation of corrective actions.* |
|  |
| Only mention those findings ***which have not been closed in the table below:*** |
| Identification n° of the finding from the previous assessment | Identification n° of this assessment’s finding | Comment : |
| -  |  |  |
| Additional comments (if significant) : |
|  |
| Strong areas : |
|  |
| Sensitive areas : |
|  |
| Final conclusions of team leader on improving the efficiency of the quality system: |
|  |
| **Clear statement of the team leader** as to the granting, maintaining, withdrawing, etc. of accreditation status:: |
|   |
| **Validation of the accreditation scope** and the granted flexibility (if applicable) by the team in collaboration with the CAB before publication: *Please do* ***specify changes*** *of the accreditation scope, if applicable.* |
|  |

|  |
| --- |
| Persons encountered: |
| NAME- First name | Function - Service |
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| List of assessed files (vertical traceability): |
|  |

|  |
| --- |
| **Technical assessor: NAME First Name** |
| **Technical domain(s) assessed:**  |
| **Summary of the technical assessor:**Please complete *all boxes below, mentioning your* observations *and related assessment evidences*.*With regard to non-assessed points or if not applicable, please do state this clearly in the corresponding field.* |
| List of methods checked during this assessment |
|  |
| Management of staff competence (contract, training, qualification, authorization, competence and performance, records…) (§ 6.2 ISO/IEC 17025 :2017) |
|  |
| Subcontracting (competent/accredited, contract + confidentiality and impartiality, information of clients, records)(§ 7.1.1 c) et § 6.6 ISO/IEC 17025 :2017) |
|  |
| Installations (access, ambient conditions, if applicable, maintenance) (§ 6.3 ISO/IEC 17025 :2017) |
|  |
| Selection, verification and validation of methods (§ 7.2 ISO/IEC 17025 :2017) ***(A011)*** |
|  |
| Approach for evaluation of uncertainty measurements associated to the scope of accreditation (§ 7.6 ISO/IEC 17025 :2017) |
|  |
| Equipment (identification, calibration and monitoring of measurements ***(A016)***, reference standards of measurements, computer or automated equipment, defective equipment, equipment files …) (§ 6.4 ISO/IEC 17025 :2017) |
|  |
| Competence of service providers performing calibrations via the 3rd route (internal and/or external) ***(A016****)* (§ 6.5.2 ISO/IEC 17025:2017) |
|  |
| Sampling procedure and check the management of non-conform samples (§ 7.3 ISO/IEC 17025 :2017) |
|  |
| Handling of test and calibration items (§ 7.4 ISO/IEC 17025 :2017) |
|  |
| Participation for inter laboratory comparisons, frequency of participation, results obtained, corrective actions and other proofs of their competence in case of non-participation (§ 7.7 ISO/IEC 17025 :2017) ***(A015 et F023)*** |
|  |
| Result reporting (§ 7.8 ISO/IEC 17025 :2017) |
|  |
| Statements of conformity and decision rules (§ 7.8.6 ISO/IEC 17025 :2017) |
|  |
| Control of data and information management (§ 7.11 ISO/IEC 17025 :2017) |
|  |
| Actions to address risks and opportunities (§ 8.5 ISO/IEC 17025 :2017) |
|  |
| Observation of realisation of tests/calibration and/or on-site sampling |
| * *Tests/calibration and/or observed sampling:*
* *Observed personnel:*
* *Statement of observation:*
 |
| Management of flexibility of the accreditation scope (if applicable) ***(A012)*** |
| * *Management of the liist of accredited activities:*
* *Contract review:*
* *Design and implementation process:*
 |
| Elements to be examined for the **transition** of a fixed to a flexible scope |
| * *Stability of technical personal responsible for the activities relating to flexible scope :*
* *Complexity of the activities concerned :*
* *Knowledge of and compliance to the relevant standards and activities :*
* *Degree of understanding of the CAB in the rules and procedures for implementing and managing a flexible scope :*
* *Extent of controls proposed for managing a flexible scope :*
* *Planned frequency of use of the flexible scope :*
* *Location and geographical risks :*
 |
| Respect of applicable EA, IAF and ILAC requirements: *see annex A006 – Normes et guides applicables* |
| List of assessed EA, ILAC et IAF documents :Comment : |
| Control of corrective actions of the previous assessment: Please also check the intermediary report of the CAB, regarding the implementation of corrective actions. |
|  |
| Only mention those findings ***which have not been closed in the table below:*** |
| Identification n° of the finding from the previous assessment | Identification n° of this assessment’s finding | Comments : |
| -  |  |  |
| Additional comments (if significant) : |
|  |
| Strong areas : |
|  |
| Sensitive areas: |
|  |
| Final conclusion of the technical assessor regarding the technical competencies of the audited body |
|  |
| Persons encountered domains of the assessed scope : The below mentioned technical domains have to be taken from the accreditation scope. |
| Name – First name | Function - Service | Technical domain(s) *(see A005)* |
|  |  |  |
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|  |  |  |
|  |  |  |
| List of assessed files (vertical traceability): |
|  |

|  |
| --- |
| **Finding n°: initials + x/y** |
| **Accreditation standard:** |  |

**Comment:** concerns a provision which requires further definition or detail.

**Non-conformity:** gap detected in the organization of the laboratory or body resulting from a requirement from the frame of reference which has not been dealt with or partially dealt with, but which does not have a direct impact on the reliability of results or decisions

**Major non-conformity:** significant gap detected in the organization of the laboratory or body presenting a serious risk to the reliability of results or decisions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TECHNICAL OR QUALITY ASSESSOR | Finding: | - comment [ ]  | - non-conformity [ ]  | - major non-conformity [ ]  |
| Paragraph cited: | §  |
| This non-conformity relates to: | - application [ ]  | - documentation [ ]  |  |
| Description: |
|  |
| Motivation of the classification of the finding: *please describe the context associated with the finding* |
|  |
| Date:  | Assessor:  | Signature:  |
|  |
| assessed entity | Assessed entity approval: | - yes [ ]  | - no [ ]  |
| Remarks of the assessed entity: |
| Date:  | Assessed:  | Signature:  |

|  |
| --- |
| **Corrective action sheet for finding n°: initials + x/y** |

|  |  |
| --- | --- |
| assessed entity | Analysis of the extent of the finding: |
|  |
| Analysis of the cause (e.g. root cause analysis) of the finding: |
|  |
| Corrective action: |
|  |
| Deadline for application (cannot exceed three months after the date of the assessment): |  |
| Date:  | Assessed:  |
|  |
| QUALITY OR TECHNICAL ASSESSOR | Is the suggested corrective action appropriate? | - yes [ ]  | - no [ ]  |
| Remarks: |
| Date:  | Assessor:  |
|  |

**Remark: The recommended corrective action should be submitted by organizations to the appropriate Team Leader or Technical Assessor within 15 working days following the assessment.**

## Scope of accreditation validated for a testing laboratory

|  |
| --- |
| **Description: OLAS_MAIN_Logo** |
| **Laboratory:**  |  | **Standard: ISO/IEC 17025** |
| **Contact:**  |  | **Accreditation no:**  |
| **Street:**  |  | **Version:**  |
| **Town:**  |  |  |
| **Country:**  |  |  |
| **Telephone:**  |  |  |
| **Fax:**  |  |  |
| **E-mail:**  |  |  |
| **Accreditation scope for a testing laboratory** |
| **General domain:** (Please fill in one table for each general domain) |
| **Technical domains:**  |
| **Objects submitted to testing or analyse**(ex. products, materials, samples, matrix or equipment) | **Characteristics or** **measured properties** | **Measurement principles and equipment**(ex. manual or automatic measurement) | **Testing methods**(ex. published, adapted, internally validated) |
|  |  |  |  |

## Scope of accreditation validated for a calibration laboratory

|  |
| --- |
| **Description: OLAS_MAIN_Logo** |
| **Laboratory:**  |  | **Standard: ISO/IEC 17025** |
| **Contact:**  |  | **Accreditation no:**  |
| **Street:**  |  | **Version:**  |
| **Town:**  |  |  |
| **Country:**  |  |  |
| **Telephone:**  |  |  |
| **Fax:**  |  |  |
| **E-mail:**  |  |  |
| **Accreditation scope for a calibration laboratory** |
| **Technical domains:**  |
| **Objects submitted to calibration** | **Characteristics or measured properties** | **Calibration methods**(ex. published, adapted, internally validated) | **Measuring range** | **Calibration and Measurement Capability (CMC)**Enlarged uncertainty (k=2) |
|  |  |  |  |  |