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

Table of contents

[**Name of the assessed CAB** 2](#_Toc29542547)

[Assessment plan 3](#_Toc29542548)

[Attendance list opening meeting/closing 6](#_Toc29542549)

[Summaries and conclusions of assessment 7](#_Toc29542550)

[Team leader: NAME First name 7](#_Toc29542551)

[Technical assessor: NAME First Name 11](#_Toc29542552)

[Finding n°: initials + x/y 15](#_Toc29542553)

[Corrective action sheet for finding n°: initials + x/y 16](#_Toc29542554)

[Scope of accreditation validated for a medical laboratory 17](#_Toc29542555)

# **Name of the assessed CAB**

Type of assessment

(ex: P1S1+E1)

According to standard ISO 15189: 2012

*« Medical laboratories -- Requirements for quality and competence »*

(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:** |  |

**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 | |

|  |
| --- |
| 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 |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

| **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 leader  Please 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 (§ 4.1) | | | | |
|  | | | | |
| Ethical conduct (§ 4.1.1.3) | | | | |
|  | | | | |
| Laboratory director (§ 4.1.1.4) and Management responsibility (§ 4.1.2) | | | | |
|  | | | | |
| Communication (§ 4.1.2.6) | | | | |
|  | | | | |
| General and functional organisation (organization chart, positioning in the structure, management, job descriptions, substitution) (§ 4.1.2.5) | | | | |
|  | | | | |
| Management of staff competence (contract, training, qualification, authorization, competence and performance, records…) (§ 5.1) | | | | |
|  | | | | |
| Accommodation and environmental conditions (access, ambient conditions, maintenance) (§ 5.2) | | | | |
|  | | | | |
| Purchase (purchase data, supplier, services and good selection and evaluation, purchase, storage and record control …) (§ 4.6 et § 5.3) | | | | |
|  | | | | |
| Equipment (identification, calibration and monitoring of measurements *(A016)*, reference standards of measurements, computer or automated equipment, defective equipment, equipment files …) (§ 5.3) | | | | |
|  | | | | |
| Laboratory information management (in-house software, record transfer, data protection and safeguard, software version management …) (§ 5.10) | | | | |
|  | | | | |
| Examination by referral laboratories (competent/accredited, contract + confidentiality and impartiality, information of clients, records) (§ 4.5) | | | | |
|  | | | | |
| Resolution of complaints (§ 4.8) | | | | |
|  | | | | |
| Requirements with regard to process realization  *(please indicate list of assessed files – vertical traceabiliy)* | | | | |
| * *Service agreements:* (§ 4.4) * *Advisory services:* (§ 4.7) * *Pre-examination processes:* (§ 5.4) * *Examination processes:* (§ 5.5) * *Management of flexible scopes (if applicable):* (Annexe A012) * *Post-examination processes :* (§ 5.7) * *Reporting of results and release of results:* (§ 5.8 et § 5.9) * *Ensuring quality of examination results:* (§ 5.6) | | | | |
| Requirements with regard to Management System of the CAB | | | | |
| * *Policies and objectives:* (§ 4.1.2.3 et § 4.1.2.4) * *Management system and document control:* (§ 4.2 et § 4.3) * *Record control:* (§ 4.13) * *Evaluation and audits:* (§ 4.14) * *Management review:* (§ 4.15) * *Internal audit:* (§ 4.14.5) * *Identification and control of non-conformities:* (§ 4.9) * *Improvement and corrective/preventive actions:* (§ 4.10 - § 4.11 - § 4.12) | | | | |
| Respect of applicable EA, IAF and ILAC requirements: ***see annex A006 – applicable standards and guidelines*** | | | | |
|  | | | | |
| 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*** | | | | |
|  | | | | |
| 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 : |
| - | | |  |  |
| Additionnal comments (if signifiant) : | | | | |
|  | | | | |
| 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:  *Thank you for* ***specifying changes*** *of the accreditation scope, if applicable.* | | | | |
|  | | | | |
| Persons encountered: | | | | |
| NAME- First name | Function - Service | | | |
|  | |  | | |
|  | |  | | |
|  | |  | | |
|  | |  | | |
|  | |  | | |
|  | |  | | |
| List of assessed files (vertical traceability): | | | | |
|  | | | | |

***Do not forget to complete the summary sheet of all verified criteria (F017)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 proofs*.  *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…) (§ 5.1) | | | | |
|  | | | | |
| Accommodation and environmental conditions (access, ambient conditions, maintenance) (§ 5.2) | | | | |
|  | | | | |
| Equipment (identification, calibration and monitoring of measurements *(A016)*, reference standards of measurements, computer or automated equipment, defective equipment, equipment files …) (§ 5.3) | | | | |
|  | | | | |
| Examination by referral laboratories (competent/accredited, contract + confidentiality and impartiality, information of clients, records) (§ 4.5) | | | | |
|  | | | | |
| Service agreements – Advisory services (§ 4.4 et § 4.7) | | | | |
|  | | | | |
| Pre-examination processes (§ 5.4) | | | | |
|  | | | | |
| Examination processes (§ 5.5) | | | | |
|  | | | | |
| Method verification and validation (§ 5.5.1.3) *(A011)*. | | | | |
|  | | | | |
| Measurement uncertainty of measured quantity values (§ 5.5.1.4). | | | | |
|  | | | | |
| Post-examination process (§ 5.7) | | | | |
|  | | | | |
| Reporting of results and release of results (§ 5.8 et § 5.9) | | | | |
|  | | | | |
| Participation for inter laboratory comparisons, frequency of participation, results obtained, corrective actions and other proofs of their competence in case of non-participation (§ 5.6) *(A015 et F023)*. | | | | |
|  | | | | |
| Laboratory information management (§ 5.10) | | | | |
|  | | | | |
| Observation on realization of analyses and/or on-site sampling | | | | |
| * *Tests/calibration or observed sampling :* * *Observed personnel :* * *Statement of observation :* | | | | |
| Management of flexibility of the accreditation scope (if applicable) *(A012)*. | | | | |
| * *Management of the list 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 – applicable standards and guidelines*** | | | | |
| 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 : | |
| - |  | |  | |
| Additionnal comments (if signifiant) : | | | | |
|  | | | | |
| 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 over in the accreditation scope.** | | | | |
| Name – First name | | Function - Service | | Technical domain(s) ***(see A005)*** |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
| List of assessed files (vertical traceability): | | | | |
|  | | | | |

***Do not forget to complete the summary sheet of all verified criteria (F017)***

|  |  |
| --- | --- |
| **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 medical laboratory**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Description: OLAS_MAIN_Logo** | | | | | |
| **Laboratory:** |  | | | **Standard: ISO/IEC 15189** | |
| **Contact:** |  | | | **Accreditation no:** | |
| **Street:** |  | | | **Version:** | |
| **Town:** |  | | |  | |
| **Country:** |  | | |  | |
| **Telephone:** |  | | |  | |
| **Fax:** |  | | |  | |
| **E-mail:** |  | | |  | |
| **Accreditation scope for a medical 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) |
|  | |  |  | |  |