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P002

Performing assessments and definitions

Modifications: p. 4, 5, 11, 17-20

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Purpose of the procedure

The purpose of this procedure is to describe the process of performing an assessment in the context of accreditation of Conformity Assessment Bodies (CABs). This procedure is intended in priority to the assessors and experts, to the clients and the OLAS staff.

Definitions

Conformity assessment body

A conformity assessment body (CAB) can be:

- a testing laboratory,
- a calibration laboratory,
- a medical laboratory,
- an inspection body,
- a certification body.

Quality assessor / team leader (TL), junior quality assessor, technical assessor, technical expert

See Procedure “P004 – Qualification of assessors and technical experts and monitoring of their competences and performances”.

Accreditation assessment

Systematic, independent and documented process allowing the evidence of the compliance of a CAB, to clearly defined accreditation criteria.

Assessment to grant accreditation (Initial)



First assessment following an application to grant accreditation.

The assessment consists of:

- assessing the compliance of the CAB’s quality management system with all the requirements of the standards and with other normative documents on the national, European and international level concerning accreditation and all other document issued by European and international bodies and organizations in the area of accreditation,
- checking that the arrangements described in the quality management system are effectively and efficiently applied,
- assessing, on the basis of this information, the CAB’s technical competence to perform tests or calibrations as well as the inspections or certifications covered by the application.

During a granting assessment, all the fields of activities included within the scope of accreditation must be assessed. Nevertheless, OLAS can choose not to assess all the techniques of each area if their number is very important. The remainder will be controlled during the surveillance assessments throughout the entire accreditation cycle.

During the witness assessments of a **system certification body**, OLAS makes the choice of the domains to be assessed considering their representativeness, (number of certificates issued by EA code, critical aspect of the domain), and the availability of witness assessments.

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Extension assessment

Assessment performed following an application to extend a CAB's scope (area) of accreditation.

The assessment consists of:

- assessing the competence of the CAB for the area covered by the extension with all the requirements of the standards or other applicable documents on the national, European and international level concerning accreditation and with all other document issued by European and international bodies and organizations in the area of accreditation,
- checking compliance and application of specific documents to these elements,
- ensuring that all the arrangements relating to the area covered by the application to extend the scope are subject to the general rules in force for the CAB.

During an extension assessment, OLAS assesses at least the area concerned by the extension.

Surveillance assessment

Assessment intended to check if the conditions required to maintain a CAB's accreditation are met.

The assessment consists of:

- assessing the implementation of corrective action, which the CAB was committed to take following findings established during the previous assessment, with all the requirements of the standards or other normative documents on the national, European and international level concerning accreditation and with all other document issued by European and international bodies and organizations in the area of accreditation,
- confirm maintaining of technical competence of the CAB for areas of activity contained in the technical annex to the certificate, and covered by the surveillance,
- assessing changes, which have occurred in the CAB since the previous assessment,
- checking the compliance of the quality management system since the last assessment.



During a surveillance assessment, OLAS can proceed to sample its fields of activities in order to assess the complete accreditation scope during an entire accreditation cycle.

Reassessment

Audit intended to reevaluate every 5 years compliance of the CAB with the accreditation criteria for all activities covered by the area (scope) of accreditation. Like the assessment to grant accreditation, this is a full assessment of the CAB.

The assessment consists of:

- assessing the compliance of the CAB's quality management system with all the requirements of the standards or other applicable documents on the national, European and international level concerning accreditation and with all other document issued by European and international bodies and organizations in the area of accreditation,
- checking the application of the quality management system,
- validating the continued technical competence of the CAB for the items indicated in the scope of accreditation to the certificate,
- ensuring the implementation of corrective action, which the CAB was committed to after the non-compliances found during the last assessment.

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During a reassessment, all the fields of activities inscribed in the scope of accreditation must be assessed. Nevertheless, OLAS can choose not to assess all the techniques of each area if their number is very important. The remainder will be controlled during the surveillance assessments throughout the entire accreditation cycle.

During the witness assessments of a **system certification body**, OLAS makes the choice of the domains to be assessed considering their representativeness, (number of certificates issued by EA code, critical aspect of the domain), and the availability of witness assessments.

Additional assessment

Assessment performed, on the opinion of the Accreditation Committee and on the decision of the head of OLAS department, following an initial, extension, surveillance or reassessment. OLAS specifies the objectives and conditions of the assessment.

Office assessment

An office assessment is generally performed by the team/leader. The objective of this assessment is to verify, among others, the conformity of the quality management system, the traceability of the records, the staff folders (competences, trainings, etc.), the closing of the findings and the implementation of corrective actions.

When the team leader does not have enough competences to check the technical competences of the CAB's staff, OLAS calls a technical assessor/expert.

Witness assessment

A witness assessment is organized for all accredited or applying CABs in the frame of a granting, surveillance, extension or a renewal assessment. It corresponds to the following by the OLAS assessors of:

- an inspection of a building or premises performed by an inspection body;
- a certification assessment (products or systems) performed by a certification body;
- a sampling activity performed by a laboratory.

The witnesses assessment can be organized before or during the quality assessment. If witness assessments have to be performed after the quality assessment, they have to be planned within a 6-month delay.

Document review



A documentary review is carried out systematically, prior to the organization of an initial assessment. It is intended to verify the compliance of the management system of the CAB to the requirements of / the standard (s) of for which he is a candidate for accreditation.

This review is performed by the team leader.

For the accreditation of a testing laboratory, calibration laboratory or of medical biology, who are developing their own methods, the review of the validation records is carried out by technical assessor in charge of the assessment of the concerned domain.

Document assessment

The document assessment is an assessment based on an examination of documents submitted by the CAB.

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Remote assessment

Assessment of the physical location or virtual site of a conformity assessment body, using electronic means.

Virtual site

A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.

Suspension

Temporary invalidation of a part or all the areas for which accreditation has been granted.

Reduction

Invalidation of a part of the areas for which accreditation has been granted.

Retirement

Decision of a CAB to put an end to its accreditation.

Withdrawal

Decision of OLAS to put an end to the accreditation of a CAB.

Major non-conformity

Major gap detected in the CAB's organization presenting a serious risk to the reliability of results and/or decisions.

Non-conformity

Gap detected in the CAB's organization resulting from a requirement in the frame of reference, which has not or has only partially been dealt with, but which does not have any direct impact on the reliability of the results and/or decisions.

Comment

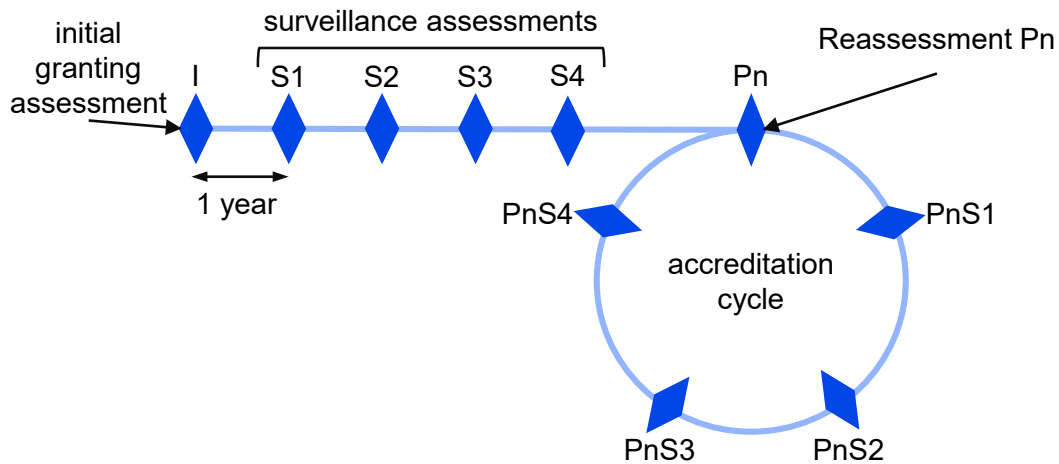
Concerns an arrangement needing to be more formalized or specified.

Closing of a non-conformity

Result of the verification by OLAS of the implementation and effectiveness of all actions provided in the action plan, the relevance of it has been validated by the audit team.

Accreditation cycle of CAB's

General



Accreditation is granted for a 5 years period and can be renewed. The accreditation or renewal date is the date of decision taking for accreditation taken by the head of department.

Accreditation renewal takes effect on the date of expiry of the previous certificate of accreditation. If the decision is only taken after the expiry of the previous accreditation certificate, the accreditation takes effect on the date of the decision.

In case of suspension of accreditation, the accreditation renewal date corresponds to the date of the decision taking for accreditation by the head of department.

OLAS may organize supplementary assessments to the 4 surveillance assessments planned in the accreditation cycle, if for instance important elements within the accredited bodies organization have been modified or following complaints.

Extension assessments are organized according to the needs of the CABs, either at the same time as a surveillance assessment or reassessment, or at any other moment of the accreditation cycle.

Surveillance



Surveillance assessments are scheduled in order to respect the anniversary date of the initial granting or renewal assessment, within a limit of 2 months before or after this date.

Surveillance assessments are organized by OLAS about 6 months before their realization to ensure that of all people involved in the process are available.

The assessment program containing the domains to be assessed, is established by means of forms *F021A* and *F021B*. The choice of activities to assessed takes into account the risks identified in the forms *F021A* and *F021B*.

An intermediary report (*form F037 – Intermediary report*) indicating, for each comment and non-conformity raised, the applied corrective action and the date on which the corrective action has been closed, is sent to OLAS within 6 months after the concerned office assessment.

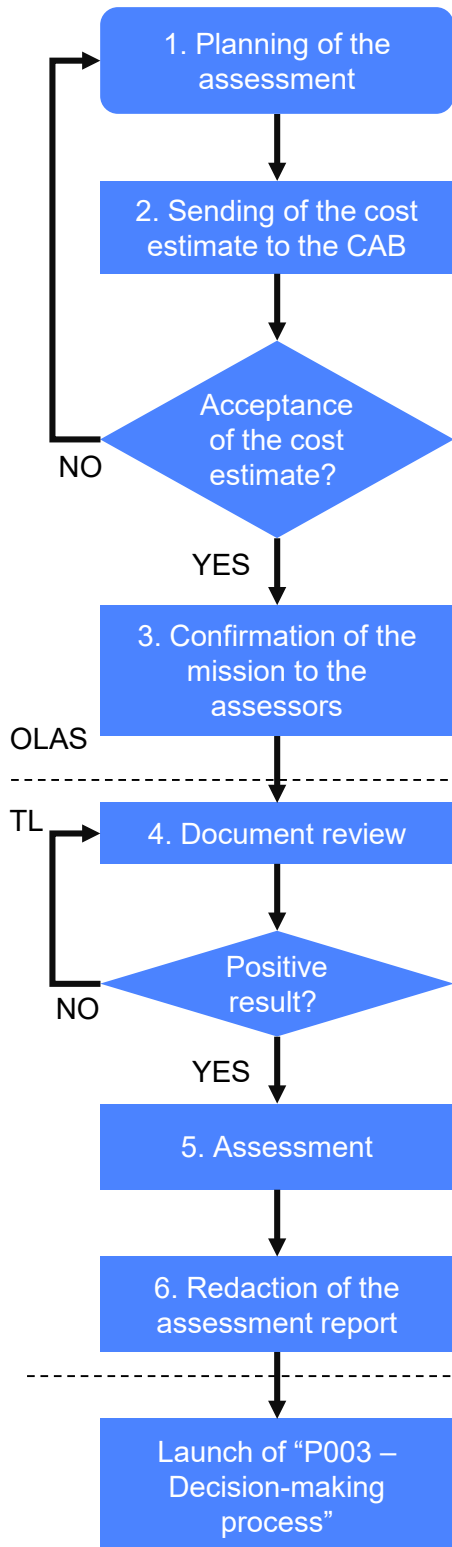
For laboratories, the *F023* form, summarizing participation in interlaboratory comparisons, is sent to OLAS when the following assessment is planned.

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For management system certification bodies, the form *F030 – indicateurs de performance annuelle des OEC accrédités* is sent to OLAS when the following assessment is planned.

If during an accreditation cycle, the date of the S4 surveillance assessment is shifted for more than 6 months with respect to the anniversary date of the granting assessment, for instance following a voluntary suspension, this S4 surveillance assessment is omitted. The reason is that the reassessment must be organized with respect to the anniversary date, in order to issue the new accreditation certificate before the expiration date of the previous certificate.

Assessment process



Step 1. Planning of assessments.

The OLAS case accreditation manager is responsible to plan granting, extension, surveillance, reassessment and additional assessments. Planning includes selecting the domains and sites to be assessed, designating the assessment team, calculating the number of assessment days and setting the assessment date. The planning is detailed in Chapter 5.

Step 2. Preparation and acceptance of the cost estimate by the CAB.

The case accreditation manager prepares the cost estimate for the assessment, which includes the composition of the assessment team, the dates and the duration of the assessment. The CAB must accept or reject the quotation, the duration of the assessment, and the composition of the assessment team. Any refusal must be motivated (see § 5.3).

Step 3. Confirmation of the assessor's mission.

When the cost estimate is accepted by the CAB, the case accreditation manager sends a mission order to each member of the assessment team indicating the nature and the duration of the assessment, the dates, references of the CAB as well as the composition of the assessment team. Each member has to return the appendix 1 of this letter to OLAS, dated and signed in order to formalize the acceptance the mission.

The case accreditation manager has to ensure that the assessors and experts have all the documents necessary for the proper conduct of the assessment.



Step 4. Document review.

Before each assessment to grant accreditation, the team leader must review the documents at his disposal to check compliance with the provisions of the applicable standards and guides (cf. Appendix A006 – applicable standards and guides). He records the date of this review in the assessment plan F003S

Step 5. Realization of the assessment.

The team leader contacts the assessment team and the CAB applying for accreditation to elaborate the assessment plan detailing the main phases of the

assessment and sends it to OLAS at least 2 weeks before the assessment for final verification and validation. If a technical assessor acts alone, he has to establish his own assessment plan applying the same principles. OLAS sends the final assessment plan to the CAB and assessors at least 5 working days prior to the assessment.

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The assessment consists of at least four phases:

- an opening meeting ;
- the evaluation of the quality management system and the technical competences of the staff of the CAB, realized in conformity with the principles defined in the standard ISO 19011 ;
- a consultation meeting of the assessment team ;
- a closing meeting.

The form *F003P – Short assessment report* is completed by the assessment team on site and preferably delivered to the audited CAB before leaving, or sent within 24 hours after the assessment. Proceeding of the assessment is detailed in Chapter 6.

Step 6. Assessment report writing

The team leader then prepares the audit report on the basis of the form *F003 – Audit report (F003A, F003B, F003C, F003D, F003F, F003H)*. He sends the complete final report to OLAS by e-mail within 30 working days after the assessment. OLAS sends the final report to the CAB within 40 working days after the assessment. Prescriptions concerning the audit report are detailed in Chapter 7.

Planning of assessments

Planning of assessments is triggered either by:

- the notification of the identification number,
- the planning of surveillance assessment of the accredited CAB in conformity to the accreditation cycle,
- the verification of the application for extension of the applicant CAB,
- the decision of the head of OLAS department to perform an additional assessment following the opinion of the Accreditation Committee.

It finishes with the sending of the cost estimate to the accredited or candidate to an accreditation CAB.

Appointment of the assessment team



Assessment team

The case accreditation manager selects the areas and sites to be assessed. He identifies in the National Register of Technical and Quality Assessors the quality assessors team leaders, technical assessors as well as the experts competent to perform the assessments. The team leader can participate in selecting the other members of the team.

An assessment team always consists of an assessor for the evaluation of the quality management system, and at least one assessor for the evaluation of the technical aspects. For an extension assessment organized between two assessments, OLAS can decide to only call a technical assessor, if the quality management system has been assessed positively during the previous assessment.

The quality assessor (or one of them) is the team leader. He represents the assessment team in relation to the management of the assessed CAB and is responsible for the presentation of the final assessment report. He is, in the last resort, responsible for all phases of the assessment.

If they have the competence, some quality assessors can intervene be authorized as technical assessor.

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A technical assessor can perform alone a witness assessment, without the presence of the team leader.

A technical expert does not perform witness assessments without the presence of the team leader.

Change of an audit team: In general, an audit team is in charge of the accreditation of a case during 3 years. Beyond that period the team leader is replaced. As far as possible, the technical assessors and the experts are also replaced.

Junior quality assessor:

The case accreditation manager can appoint a junior quality assessor to accompany the assessment team, subject to his acceptance by the client. The team leader is free to entrust him with part of the quality assessment as well as the writing of potential findings under his supervision.

OLAS observer:

For each of the assessments to grant accreditation, a member of OLAS accompanies the assessment team as an observer. For other assessments, his presence is depending on the need of the CAB or OLAS.

OLAS may invite the competent authorities concerned by the assessed domain to participate in the accreditation audits as an observer, in accordance with the modified law of 4th of July 2014, reorganizing ILNAS.

The CAB is informed sufficiently in advance of the presence of any OLAS observer (OLAS team, authority, etc.) during an assessment.

Fixation of the duration and date of the assessment

After appointing the assessment team, the case accreditation manager sets the duration of the assessment, in consultation with the assessment team if necessary. The date of the assessment is fixed in consultation with the CAB and the assessment team.

Calculation of the number of assessment days:

The calculation of the necessary number of person-days for an **initial or renewal assessment** is based on factors that may influence the duration such as:



- the diversity and complexity of activities in the scope,
- the diversity of reference languages,
- the logistical complexity (multiple sites for the activities covered by the application),
- the complexity of the applied regulations (in domains such as health, nuclear, etc.),
- IT complexity,
- results from previous assessments, if applicable.

The calculation of the necessary number of person-days for a **surveillance assessment** is based on factors that may influence the duration such as:

- the same factors than for initial or renewal assessments,
- the domains assessed during the previous assessments.

For an **extension assessment**, the number of assessment days is calculated on a case-by-case basis, depending on the modifications of the accreditation scope.

If the CAB voluntarily withdraws part of the existing accreditation scope before the assessment, the application of corrective actions in response to possible non-conformities or major non-conformities of the previous audit is nevertheless verified for the part that is withdrawn from the scope.

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Acceptance of the cost estimate by the CAB

The CAB must accept or refuse the cost estimate, the duration of the assessment and the composition of the assessment team by transmitting the signed document filled up to OLAS.

In case of refusal it must be motivated.

For OLAS, acceptable reasons to refuse a cost estimate can be:

- problems of confidentiality or impartiality of the assessor or expert works or any other conflict of interest,
- prior professional relations with the assessor or expert,
- eventual errors in the calculation of the audit cost,
- differences in understanding with regard to the accreditation scope.

If the CAB accepts the cost estimate, the organization of the assessment continues as stated in the present procedure.

If the CAB refuses the cost estimate, the relevant accreditation manager will review the reason and seek the advice of the department head or this deputy.

If the refusal is justified, the assessment planning will be reviewed taking into account the reason for refusal and the CAB will be informed.

In case of cancellation of the assessment within 10 working days prior to the scheduled date, the cost of the assessment preparation and the drafting of the report will be charged to the CAB. If appropriate, 20 % of the costs associated with the planned assessment days may also be charged to the CAB.



Documents for the preparation of the assessment

The case accreditation manager has to ensure that the assessors and experts have all the documents necessary for the smooth running of the assessment, such as:

- a project of the assessment plan – form F003S – Assessment plan
- ~~a version of the quality manual in force (if any),~~
- form F059 – List of documents for the preparation of an assessment as well as the relevant quality system documents;
- if applicable, a copy of the application for accreditation for the assessment to grant, extend and renew accreditation, including the draft scope of accreditation,
- the current scope of accreditation for surveillance or additional assessments,
- if applicable, a copy of the previous assessment report,
- if applicable, the form F023 – *Program of inter laboratory comparisons,*
- if applicable, the OLAS regulatory database or annex A022 – *Medical laboratories – presentation of the national legislation,*
- if applicable, the form F037 – *Intermediary Report,*
- if applicable, the form F017 – *Summary sheet of all criteria verified during the assessment,*
- if applicable, the form F045 – *Assessment preparation – laboratories* or F047 – *Assessment preparation – inspection bodies* or form F056 – *Assessment preparation – certification bodies,*
- if applicable, the form F030 – *Indicators of management system conformity assessment bodies' performance,*
- any other document necessary to achieve the assessment of the CAB.

If necessary, the assessors may contact directly the CAB to ask for additional information or documents needed to prepare the audit.

If necessary, OLAS can provide a document sharing platform ("OTX").

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Realization of the assessment

Document review

Before each assessment to **grant accreditation**, the team leader must review the documents at his disposal to check compliance with the provisions of the applicable standards and guides (cf. Appendix *A006 – applicable standards and guides*). He records the date of this review into the assessment plan of the report template.

The document review preceding the initial assessment is realized on the basis of the following documents:

- Quality manual (if any)
- List of documents that are in force
- Organisation chart(s) (legal, hierarchical, functional)
- Procedure(s) for control of documents and records
- Procedure(s) for authorization and maintaining qualifications of personnel
- Procedure for contract review
- Procedure for control of non-conformities
- Procedure for internal audits
- Record of the last internal audit (covering both quality and technical parts)
- Record of the last management review
- Template of a report or certificate

For laboratories, validation files must be sent to the concerned technical assessors, in order to allow them to analyze the files in the context of their preparation.

If this review of documentation reveals major non-conformities, the OLAS head of department may decide not to proceed to the assessment. In this case, the applicant CAB receives a preliminary report of the review of documents set up by the form “*F003N – Review of documents preliminary to the granting assessment*” and the non-conformity reports issued. The costs for the redaction of the preliminary report are 435 € (half audit day) per implicated assessor and have to be covered by the applicant CAB.

The accreditation procedure will only restart after all major non-conformities were closed by the CAB and after validation by the team leader.

Assessment



Phase I – the opening meeting

The opening meeting is intended to:

- present the assessment team to the CAB clarifying the roles and responsibilities,
- remind the objectives and criteria for accreditation,
- control the range of the field of accreditation,
- validate the assessment program,
- confirm the rules for confidentiality.

The opening meeting is conducted by the team leader.

Where, for reasons of availability or unequal audit duration, staggered audit dates one or more technical assessors start the assessment before or after the team leader, they also start their assessment with a short meeting to validate the scope of accreditation and the logistical aspects concerning them.

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Phase II - evaluation of the system and the technical skills

Evaluation of the quality management system and the technical skills of the staff of the CAB is realized in conformity with the principles defined in the standard ISO 19011.

If needed, the team leader can, over the course of the assessment, make changes to the assessors' and experts' missions and to the assessment program, but only with the approval of the assessed CAB and/or their client visited during the witness assessments.

During the assessment, the assessment team must ensure that:

- the quality management system of the CAB complies with the standards and guides (OLAS, EA, IAF and ILAC) listed in Appendix *A006 – Applicable Standards and Guides* and the references stated in the scope of accreditation,
- the corrective actions based on non-conformities or comments, identified during the previous assessment, are efficiently closed,
- the use of the OLAS logo is part of the accredited CAB's rights and obligations as described in appendix *A003 – Guidelines for the use of the OLAS logo*. The control must be done on certificates, internet sites, informative, commercial or publicity documents,
- the test results subject to the interlaboratory comparison programme obtained by the form *F023 – Program of inter laboratory comparisons* demonstrate the competence of the laboratory in the areas concerned in the application,
- the situation of the laboratories with regard to the traceability of measurements, the reference materials and measurement equipment is defined,
- the laboratories have installed an approach for evaluation of the uncertainty calculations presented in the scope of accreditation
- the quantities that are followed up by metrology and the measuring range are defined.

In order to assure the competence of all the personnel of the CAB, OLAS performs witness assessments. The definition of a witness assessment is available in the chapter 2 of the present procedure. The policy applied to plan a witness assessment is defined in chapter 5.2 of the present procedure.

The assessment team has to document any findings recorded in the course of the assessment, based on the definitions for major non-conformity, non-conformity and comment, as defined in this document. All findings have to be documented in a clear and precise way and supported by evidence. The findings are identified in relation to the specific requirements of the accreditation standard or any other normative document covered in the application for accreditation. For all findings the assessors and experts have to fill out the box "Motivation of the classification of the finding...". For major non-conformities, the assessors and the experts also have to provide a clear description of the risk associated with this type of finding on form *F003E – Non-conformity report*.



Phase III – consultation meeting of the assessment team

A consultation meeting of the assessment team enabling any *F003E – Non-Conformity report* to be completed.

If the assessment team does not reach a conclusion regarding a finding, it shall refer to the accreditation body for clarification.

Phase IV – the final meeting

A final meeting with the team leader, the technical assessors, experts and, insofar as possible, the management of the assessed CAB and the managers of the departments concerned, which enables:

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- to present at least the findings recorded during the assessment to the management of the CAB,
- to sign the approval or rejection of the findings recorded on F003E forms. In case of refusal of a finding by the CAB, the Accreditation Committee takes a decision,
- to give a clear statement concerning the granting, the extension, the maintaining or the renewal of the accreditation, as to be sent to the Accreditation Committee,
- to set a date for reception of corrective actions, which must not exceed 15 working days after the assessment,
- to define the changes to be done by the CAB on its accreditation scope,
- to inform the CAB about the next steps of the accreditation procedure.

Where, for reasons of availability or unequal audit duration, staggered audit dates or not all assessors are present at the final closing meeting, intermediate closing meetings shall be held so that each assessor, after having finished his part of the assessment, can present his or her conclusions and any findings.

Finally, form F003P is completed by the assessment team on site and preferably delivered to the audited CAB before leaving, or sent within 24 hours after the assessment. This form gives a summary of information on conformity of the quality management system, on competence of personnel and a recommendation from the team leader regarding the accreditation decision. It has also to be sent to OLAS not later than 24 hours after the assessment.

Once the closing meeting completed, the classification of the identified non-conformities and the recommendation of the audit team (granting, maintaining, extending,... of accreditation) cannot be modified any more.

In case of a witness assessment of a management systems certification body, the auditor shall complete form *F003R – Résumé du rapport d'audit terrain ISO/CEI 17021-1* after the assessment and return it to the body no later than 48 hours after the assessment. At the same time, the report is transferred to the OLAS.

Before leaving the premises of the CAB, the assessors and experts are obliged to return all documents that belong to the assessed, except the documents expressly necessary to write the assessment report. The originals of the finding reports and attendance lists are stored by the lead assessor.

Proposals of corrective actions by the CAB



After the assessment, the CAB provides an analysis of the extent and cause of the findings and proposes corrective actions on the form *F003E*. The description of the extent of the finding shall take into account the services concerned, the precedence and the possible impact (sending of erroneous results or not).

The electronic version of this form is then transmitted to the team leader and/or the technical assessor and/or the expert for validation. If the responses are considered insufficient, the assessors or the experts ask supplementary information. If the responses stay insufficient, the Committee takes a decision.

The team leader, the technical assessor or the expert can limit the time required to take a corrective action in accordance with the severity or degree of risk of the non-conformity.

Major non-conformities

Before being closed, the major non-conformities must be subject to corrective actions applied effectively within 3 months that follow the assessment. For this reason, proofs of the implementation of corrective actions shall be sent to the assessors and the experts having

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written the findings, for closing them from a documentary point of view. The effectiveness of corrective actions is automatically verified during the next audit of the concerned domain.

During this period of 3 months, an accreditation file cannot be presented to the Accreditation Committee as long as the proofs have not been validated. After the period of 3 months, the file is presented to the Accreditation Committee for opinion. If one / or several major non conformities are not closed, the Committee will give his opinion in accordance with the provisions of the OLAS procedure P003.

Non-conformities and comments

The application of the corrective actions must be done within 3 months following the assessment. 6 months after the end of the assessment, the CAB sends to OLAS an intermediary report indicating, for each comment and non-conformity raised the applied corrective action and the date on which the corrective actions have been closed.

In case of a delay in closing a corrective action, the CAB must specify in this report the reasons of the delay and the action plan meant to assure the closure.

If OLAS does not receive the intermediary report or if the corrective actions have not been implemented without valid reason, OLAS can ask the opinion of the Accreditation Committee for further actions to undertake.

Assessment report writing

The team leader draws up the assessment report. He chooses the appropriate template of audit report among those available on the OLAS website:

- *“F003A – Rapport d’audit ISO/IEC 17025, 17020 et 17065”;*
- *“F003B – Rapport d’audit ISO 15189”;*
- *“F003C – Rapport d’audit ISO/IEC 17021-1”;*
- *“F003D – Rapport ISO/IEC 17021-1-17065”;*
- *“F003F – Rapport ISO/IEC17025-15189”.*
- *“F003H – Rapport d’audit ISO/IEC 17025*



which must contain

- Form *“F003S – Assessment plan”*,
- Form *“F003E - Finding and corrective action”*,
- if applicable, supporting documents for the corrective action proposed by the accredited CAB,
- the adapted scope of accreditation validated by the team leader.

OLAS's expectations with regard to the redaction of assessment reports are detailed in Appendix *“A025 – Audit Report Writing Guide”*.

The form *“F017 - Summary sheet of all criteria verified during the assessment”* has to be completed by every assessor.

The team leader must include in his statement as to the granting, maintaining, withdrawing, etc. of accreditation status, the conclusions of all technical assessors and experts who were involved in the assessment.

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It is imperative that the assessment report contains the result of the control of corrective action from the previous assessment. Findings recorded during the previous assessment where corrective action has proved to be unsatisfactory must be recorded as new findings. In the event of a difference of opinion on a finding or the closing of a finding, the assessment team has to refer to OLAS, which can call on an expert in the area to propose a solution. This solution will be submitted to the Accreditation Committee together with the final report.

The team leader sends the complete final report to OLAS and to the assessed CAB by e-mail **30 working days** after the assessment has been performed. The originals of the “Attendance list for opening and closing meetings” and of the *F003E* must be kept by the team leader for **at least 2 years** before being destroyed.

The team leader sends the form “*F003M – Follow-up of accreditation assessments*” to OLAS to give a feedback concerning the duration of the assessment, the number of technical assessors and experts involved in the mission, and the points of the standard or the technical areas to control in priority during the next assessment.

OLAS remains responsible for the contents of the final report, including recorded findings.

If applicable, the team leader must complete Form “*F011A Evaluating the services of a technical assessor or an expert*” for each technical or junior assessor or expert, who accompanied him during the assessment.

Each team leader is evaluated at least every 3 years. In that case, the OLAS observer must complete Form “*F011B Evaluating the services of a quality assessor or junior quality assessor*” for the monitoring the evaluation of the lead assessor.

Form “*F010 – Customer satisfaction with regard to the accreditation procedure*” has to be completed and sent to OLAS by the assessed CAB after the accreditation decision.

Specific policies for organizing assessments

For the organization of assessments, OLAS has defined the following policies:



- **Granting or renewal assessments:** during a granting or a renewal of accreditation, a witness assessment of each general domain of the scope of accreditation is systematically organized.
- **Extension assessments:** for an extension of accreditation, a witness assessment of each new activity concerned by the extension is systematically organized.
- **Surveillance assessments:** during surveillances, each of the areas of the scope of accreditation is subject to a witness assessment at least once during the accreditation cycle. The choice of the assessed areas, during each surveillance, is defined on case by case, together with the concerned CAB in order to assure that the whole scope of accreditation has been covered during a complete accreditation cycle.

The forms *F021A* and *F021B* –allow planning the organization of all assessments over a complete cycle of accreditation.

Whenever possible, the witness assessments are done before the office assessments.

Accreditation of multi-site organizations is described in appendix “*A013 – Accreditation of multi site organizations*”.

Assessment of parameters added within the context of a flexible scope is detailed in appendix “*A012 – Management of fixed and flexible accreditation scopes*”.

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8.1 Special cases:

8.1.1 Medical laboratory – Sample collection sites

As part of their activities, some medical laboratories may use sample collection centres (blood, urine, stool ...) or other collection sites (company, retirement home, home etc.). This sampling activity is an integral part of activities covered by accreditation.

During the first accreditation cycle, OLAS plans to visit a maximum number of collection centres. If the results of the audits are satisfactory, the number of sample collection centres to be visited per accreditation cycle can be reduced to 10 + 20% of the rest (= 10 + (n-10) / 5) from the first renewal.

When other collection sites exist (company, retirement home, home etc.), one witness is planned at each assessment.

To carry out assessment of sample collection sites, OLAS uses technical (or quality and technical) assessors with the necessary competences to cover the activities related to sampling.

8.1.2 Inspection bodies

For granting accreditation assessment, insofar as possible, a minimum of two inspections by technical assessor or expert are to be witnessed. The “Inspection du Travail et des Mines” (ITM) is invited to assist, as an external observer, to the assessment of the CABs that are authorized by the Minister of Labour, in the fields of his competence.

8.1.3 Certification bodies of quality management systems

The team set up for office and witness assessment of a certification body of management systems consist of at least a team leader whose initial training and professional experience are compatible with the area concerned by accreditation.

For the ISO 9001 certification scheme and “non-critical” EA codes, a quality assessor may perform witness assessments without the presence of a technical assessor or expert in the field concerned, in accordance with this procedure.



For other certification schemes, where the technical assessor or expert does not have training in ISO 14001, ISO 45001 or ISO 27001 standards, the team leader must be trained in this standard. He supports the technical assessor or expert during the witness assessment.

During a witness assessment of a certification body, the team acts only as an observer, unless it identifies a risk that could endanger the health and safety of people, the health and welfare of animals or the environment. In this case, the team informs the certification body, which must inform the audited client if necessary, as well as OLAS.

For all certification schemes, the provisions of this document are applicable to the organisation of the initial, extension, surveillance and extension assessments, as well as to the sampling of the areas to be witnessed. For all certification schemes, specific provisions concerning the organisation of witness and sampling of areas to be assessed are established in document IAF MD17.

8.1.3.1 For ISO 9001, ISO 14001 and ISO 45001 certification schemes

For the extension of the accreditation scope to new areas/ new EA codes scope, as well as for the sampling of areas to be witnessed, OLAS applies the provisions of document EA MD17.

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Recording of assessed EA codes is carried out in F021B form. It is based on the assessment plan, defined in collaboration with the CAB and the assessors, as well as on the consideration of risk factors listed in the form.

When, during an accreditation cycle, the full accreditation scope cannot be covered by one of the means described above, OLAS reduces the accreditation scope in order to guarantee full coverage during the following accreditation cycle.

~~EA codes identified as "critical", the assessment team needs to be strengthened by a technical auditor or expert whose training and/or professional experience covers the concerned domain.~~

~~For SMQ1, the "non-critical" EA codes, the team leader (quality assessor) can carry out witness assessments without the presence of a technical assessor or an expert in the concerned domain, in accordance with this procedure.~~

~~For the domains SMQ4 (environmental management system), SMQ5 (occupational health and safety management systems) and SMQ3 (information security Management Systems): The witness assessment is performed by at least one technical assessor or an expert. An analysis is performed to define their competence. The elements of this analysis are recorded. When a technical assessor or an expert is not qualified according to ISO 14001, ISO 45001 or ISO 27001 standards, the team leader shall necessarily be trained on this standard. He has to accompany them during the witness assessment.~~

Specific approach for sampling of EA codes:

~~For sampling of witnessing activities of EA codes covering QMS and EMS domains, OLAS refers to the requirements of document IAF MD17:2015 for domains SMQ1 and SMQ4 which groups the EA codes into clusters.~~

~~For sampling of witnessing activities of EA codes covering the domain of ISO 45001, OLAS is referring to the document IAF MD22 for the domain SMQ5 which groups the EA codes into clusters.~~

For an initial assessment or extension of accreditation:

~~All critical EA codes (as defined in chapters 5 and 6 of IAF document MD17 for the domains SMQ1 and SMQ4 and in annex E of the IAF document MD22 for the domain SMQ5) shall be witnessed.~~

For the first accreditation cycle:

~~All EA codes covered by accreditation shall be assessed at least once during an accreditation cycle.~~



~~A witness assessment shall be performed in each cluster.~~

For the following cycles:

~~All EA codes covered by accreditation shall be assessed at least once during an accreditation cycle. If the concerned CAB was able to demonstrate its stability, a witness assessment shall be performed in each cluster during two successive accreditation cycles.~~

Policy regarding the required competence for the organisation of specific assessments:

For accreditation of organisms active in certification of information security management systems (ISO 27001), the knowledge and competences of the personnel responsible for organisation, assessment (office and witness assessment) and decision taking are aligned with the requirements of the document IAF MD13 :2015.

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Management policy of a CAB's move

Inspection and certification bodies

The CAB must inform OLAS of its move by mail. The accreditation certificate and its technical appendix are updated with respect to the new address of the CAB. The former accreditation certificate is no longer valid and must be returned to OLAS.

Testing, calibration and medical laboratories

The laboratory must inform OLAS of its move by mail and request the suspension of its accreditation from the date when the laboratory stops its activities in its former premises.

The audit for lifting of the suspension after the move is used to verify in particular the environmental conditions and the qualification of equipments. It is similar to a renewal audit, covering all the areas of activity listed in the scope of accreditation. This audit is the beginning of a new accreditation cycle.

The suspension of the accreditation lasts until the decision is made following the audit carried out in the new premises. During this period of suspension, the laboratory cannot issue reports covered by accreditation (OLAS logo). On the OLAS website, the laboratory will keep on appearing in the National Accreditation Register, bearing the mention "voluntary suspension of accreditation".

Exception:

For tests, calibrations or analyses carried out on-site (e.g. pH or electrical conductivity of water using portable equipment), voluntary suspension of accreditation is not required.

Special provisions for carrying out audits in cases of force majeure

When the organisation of an on-site assessment has to be cancelled in the short term, OLAS always favours the reorganisation of a new on-site assessment at a later date.

However, the following examples of situations can be considered as cases of force majeure:

- If the moving of one or more assessors becomes impossible for an indefinite period of time, such as border closures or lockdown ;
- If the postponement of the assessment leads to an exceeding of the validity date of the accreditation certificate (reassessment);
- If the number of assessments affected by a cancellation is significant and a reorganisation at later dates hinders the functioning of OLAS and the AC.



The "force majeure" assessment is then a combination of document assessment and remote assessment (via tele- or videoconference, if possible provided by the CAB concerned) to replace the office and/or witness assessment.

In order to justify the "force majeure" assessment, the accreditation manager in charge of the file carries out an analysis on the basis of form F040.

Types of assessment concerned

The "force majeure" assessments apply to:

- Surveillance and renewal assessments ;
- Scope extension assessments in areas where technical competence has already been demonstrated on similar activities;

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- Transition assessments to a new version of an accreditation standard (e.g. ISO/IEC 17025:2017).

No on-site witness assessment will be organised in addition to the "force majeure" assessment, unless major non-conformities in the operation of the organisation are identified by the assessment team. In this case, OLAS reserves the right to take any decision in accordance with procedure P003 - Decision-making process.

For initial assessments and extension assessments to activities where technical competence has not yet been demonstrated on similar activities, the organisation of an on-site assessment is mandatory.

Assessment planning

As far as possible, OLAS tries to maintain the planned dates for the office and witness assessment to carry out the "force majeure" assessment.

OLAS also maintains the assessment durations initially planned for the assessors, including the planned durations for witnessing, assessment preparation and report writing.

If a request for extension is postponed, the assessment duration is re-evaluated.

The team leader organises the remote interviews in consultation with the CAB and the assessment team in order to cover the needs of each. He sends the F003S assessment plan detailing the main phases of the assessment at least 2 weeks before the assessment (if possible) to OLAS for verification and final validation.

OLAS encourages CABs and assessors to give priority to remote assessments, as opposed to document assessments, in order to facilitate communication as much as possible. Depending on the size of the CAB and the number of assessors in the team, OLAS recommends staggering the interviews in time to ensure the availability of each participant.

Carrying out the assessment

The remote assessment includes the phases described in point 6.2, with the exception of the "witness" part.

After the closing meeting, the CAB has a period of 3 additional working days to review and accept/refuse findings identified by the assessors. During this 3-day period, the CAB may provide additional information to the assessors to avoid any misunderstanding.

Finding sheets are signed by the CAB and the assessors concerned. A scanned version of the signed finding sheets is sent to OLAS for information. Electronic signatures on PDF documents are also accepted.

Projected timetable for the granting or renewal of accreditation of a CAB

This projected timetable is only given by the way of indication to help the client to plan the proceeding of the granting or renewal of an accreditation.

Month	OLAS	CAB
0	Registration of the CAB Notification following acceptance of the application	Sends the application for accreditation Sends (if necessary) complementary documents
0.5	Planning of the assessment (client and assessors)	
2	Sending of the cost estimate to the CAB Sending of the mission orders to the assessors Document review (only for initial assessments)	Acceptation of the cost estimate
3	Initial assessment (office and witness)	Proposals for corrective actions
5	Sending of the assessment report	
6		Maximum delay to implement corrective actions for major non-conformities
6 – 7.5	Accreditation Committee and notification of the decision by the head of OLAS department	

It doesn't take into account the supplementary delays due to the unavailability of the client or the assessors, the refusal of an assessor, the major non-conformities identified during the document review or the delay in the reception of corrective actions or the assessment report.