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P003



Decision-making process

Modifications: p. 6,7

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1. Purpose of procedure

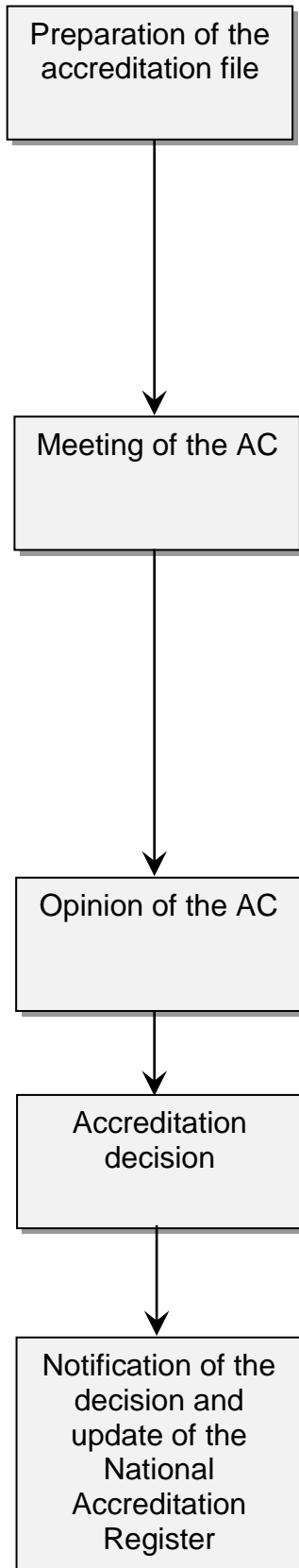
The purpose of this procedure is to formalize the decision-making process of OLAS in the frame of the accreditation of the conformity assessment bodies.

2. Definitions

Committee: the Accreditation Committee (hereinafter referred “CA”)

The other definitions necessary to the good comprehension of the present document are inscribed in the procedure *P002 – Performing assessments*.

3. Decision-making process



OLAS prepares the accreditation files and sends them to the members of the Accreditation Committee (hereafter AC) appointed to examine the new files as quickly as possible. All files are sent to the members of the AC at least 7 working days before the meeting date. An accreditation file includes at least the following documents:

- The written invitation on behalf of the Chairman,
- The agenda for the AC meeting,
- The minutes of the previous meeting,
- The assessment reports,
- When appropriate the application forms F001A, B or C,
- The scope of accreditation controlled by the assessors and experts.

The AC meets to give its opinion on each accreditation file. The AC examines:

- Assessment reports,
- Significant events regarding accreditation that have occurred since the prior meeting,
- When appropriate, cases of severe or repeated non-compliance concerning the applicable procedures by organizations or laboratories accredited by OLAS,
- When appropriate, cases of severe or repeated non-compliance concerning the applicable procedures by an assessor or an expert registered in the Registry of Quality and Technical Assessors,
- Any claims or complaints.

Opinions of the AC are given according to the guidelines defined in point 4.2.

In accordance to the article 5 of the law of the 4th July 2014 concerning the reorganisation of ILNAS, the head of OLAS department, or his deputy, takes the decision based on the opinion of the AC. The accreditation decision comes into effect with the signature of the form *F035 – Décisions relatives à l'accréditation*. A letter of notification of the decision is sent to the CAB.

The accreditation certificate is signed by the head of OLAS department, or his deputy. The accreditation scope for each granting, renewal or extension of accreditation is signed by the head of OLAS department, or his deputy.

After the notification of the decision by the head of OLAS department, or his deputy, the National accreditation register is updated if necessary.

4. Meeting of the Accreditation Committee (AC)

4.1. Organisation

The president convenes the AC upon request of the head of OLAS department, or his deputy, or upon request of at least three of the AC members. During each meeting, the AC approves the minutes of the previous meeting. The minutes are signed by the president or by the AC member who chaired the meeting.

The AC can only give an opinion if the quorum is reached. Therefore, the following conditions must be respected:

- The number of present members to the meeting must be superior to 50% of the members entitled to vote,
- Each of the members being counted for the calculation of the quorum must be free of all relation with the bodies to be accredited,

To check that the quorum is respected, the members of the AC inform the OLAS secretary of their absence, if possible 4 working days before the day of the meeting.

Before every AC meeting, OLAS verifies if the members who confirmed participation for the meeting do cover the competences required to treat the files, according to the annex A024 – *Analyse des domaines*, via le formulaire F042 – *Analyse des compétences présentes*.



The following situations may be possible:

		At least one AC member recognized competent for the relevant macro-domains is present at the meeting	
		Yes	No
Quorum respected	Yes	The AC gives his opinion during the meeting	File postponed to the next meeting or <i>Electronic voting</i> * with detailed opinion of competent members for the concerned macro-domain(s).
	No	Keep AC meeting	File postponed to the next meeting or <i>Electronic voting</i> * with detailed opinion of all AC members not present at the meeting.
		Cancel AC meeting	File postponed to the next meeting

* If a vote for one of the files is essential (e.g. renewal of assessment, etc.), electronic voting with detailed opinion can be organized by OLAS via form F033 – *Avis circonstancié des membres du CA*.

In case of an electronic voting, the AC's opinion is only valid under the following conditions:

- 1) Each electronic voting is justified by a detailed opinion;
- 2) The sum of votes expressed during the meeting and electronic votes must respect the quorum;

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- 3) If no competent member for the concerned macro-domains is present in a meeting, the majority (> 50%) of competent members entitled to vote, must have realized an electronic voting.

The AC secretary sets and specifies time limits (beginning and closing of electronic voting procedure). No vote will be accepted after the closing limit. The secretary records the votes cast and transmits the result with the comments to the AC members.

If electronic voting reveals major differences between the AC members and/or when important issues are identified in the record, OLAS reserves the right to postpone the file at the next AC meeting in order to allow a debate during a meeting or get additional information/explanations

If needed (ex: the quorum rule is not respected), the meeting can be cancelled by the president of the AC on demand of the head of OLAS department, or his deputy. In this case, the secretary informs the AC members 2 working days before the meeting accordingly.

Minutes are prepared for each meeting by the secretariat after every AC meeting. Approved minutes are sent to each AC member with the invitation for the upcoming meeting.

During the 4th quarter of the year, the AC fixes the dates of meetings for the following year. These dates are published on the OLAS website, as well as on the common platform (GovSpace). They can be modified, cancelled, or completed, if necessary

- **Extraordinary accreditation Committee**

When major non-conformities are identified and if they reflect a serious malfunctioning, or a non-compliance with the regulation, challenging the competence of the CAB to perform the activities, for which it is accredited, the president of the AC, upon request of the head of OLAS department, or his deputy, can convene the meeting of an extraordinary AC.

If the quorum is reached, the AC can take necessary decisions.

If the quorum is not reached, only a decision of total or partial suspension can be taken. This decision has to be validated during the next AC meeting.

4.2. Guidelines to give an opinion



The opinion of the AC must be motivated and enounce the facts (assessment reports, standards and applicable guides) and laws (ILNAS law and associated Grand-Ducal regulations) on which it is based, according to the Grand-Ducal regulation of June, 8th 1979 relating to the procedure to be followed by the administrations falling under the State and the communes. Positive opinions do not have to be motivated.

The opinion must indicate the composition of the AC, the names of the members who attended to the deliberation and the number of votes in favour of the expressed opinion. The possible different opinions must be annexed, anonymously.

The AC's opinions are based on a majority of the present members. In case of equality, the vote of the president is preponderant.

If there is any past, current or future relationship between them and a body seeking accreditation, the concerned AC members may not attend the deliberation or the vote. In case of an expert, he's not allowed to attend to the deliberations.

The opinion of the AC is prepared by the AC secretary and signed by its president or his designate.

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Positive opinion:

If during an initial (I), surveillance (S), extension (E), prolongation (P) or complementary (C) assessment, the CAB could demonstrate to the audit team and the AC the conformity of its quality system to the applicable standards, its technical competences in the domain covered by accreditation, and its capacity and reactivity to quickly raise the non-conformities identified during the assessment, the AC proposes a **positive opinion for...**

- granting (G)
- maintaining (M)
- extension (E)
- renewal (R)
- lifting of suspension (L)
- granting/ maintaining/ extension/ renewal (following a complementary assessment)

If during an initial (I), surveillance (S), extension (E) or prolongation (P) assessment, the audit team and the AC, despite the identification of non-conformities, have confidence in the quality system and the technical competences of the CAB, and if the CAB can demonstrate its capacity and reactivity to quickly raise the non-conformities identified during the assessment, the AC proposes a **positive opinion for...subject to...**

- granting subject to a complementary assessment
- maintaining subject to a complementary assessment
- extension subject to a complementary assessment
- renewal subject to a complementary assessment

If during a surveillance (S), prolongation (P) or complementary (C) assessment, the audit team observes that an accredited CAB is not totally in conformity to the requirements of accreditation, the AC proposes a **positive opinion for... subject to...**

- maintaining subject to a partial suspension (to be specified)
- renewal subject to a partial suspension (to be specified)
- lifting of suspension subject to a partial suspension (to be specified)

If during a surveillance (S), prolongation (P) or complementary (C) assessment, the audit team observes that part of the activities described in the accreditation scope of the CAB do not correspond anymore to the requirements of accreditation, the AC Committee proposes a **positive opinion for...subject to...**

- maintaining subject to reduction (to be specified)
- renewal subject to reduction (to be specified)
- lifting of suspension subject to reduction (to be specified)

Negative opinion:

If during an initial (I) or extension (E) assessment, the CAB could not demonstrate to the audit team and the AC the conformity of its quality system to the applicable standards, its technical competences in the domain covered by accreditation, and its capacity and reactivity to raise quickly the non-conformities identified during the assessment, the AC proposes a **negative opinion for...**

- granting
- extension
- lifting of suspension

If during a surveillance (S), prolongation (P) or complementary (C) assessment, the CAB could not demonstrate to the audit team and the AC the conformity of its quality system to the applicable standards, its technical competences in the domain covered by accreditation, its capacity and reactivity to raise quickly the non-conformities identified during the assessment, the AC proposes a **negative opinion for...**

- maintaining and proposes...
 - ✓ a suspension
 - ✓ a withdrawal
- renewal and proposes...
 - ✓ a suspension
 - ✓ a withdrawal
- lifting of suspension and proposes...
 - ✓ a withdrawal

Synoptic table of the decisions based on the Accreditation AC opinions:

Types of assessment	Opinion	Formulation of the opinion	Decision applying to...
I / S / E / P / C	Positive opinion	Positive opinion for...	G / M / E / R / <u>L</u>
I / S / E / P		Positive opinion for... subject to a complementary assessment	G / M / E / R
S / P / C		Positive opinion for... subject to a partial suspension of the scope	M / R / <u>L</u>
		Positive opinion for...subject to a reduction of the scope	M / R / <u>L</u>
I / E / C	Negative opinion	Negative opinion for...	G / E / <u>L</u>
S / P / C		Negative opinion for...and proposes suspension of accreditation	M / R
		Negative opinion for...and proposes withdrawal of accreditation	M / R / <u>L</u>

Assessments: I = Initial ; E = Extension ; S = Surveillance ; P = Prolongation ; C = Complementary



Decisions: G = Granting ; M = Maintaining ; E = Extension ; R = Renewal; L = Lifting of suspension.

5. Decision-making process

According to the law of the 4th of July 2014 on the reorganisation of ILNAS, the head of OLAS or his deputy, takes the decision based on the opinion of the AC.

Decision making is recorded in the form “*F035 – Décisions relatives à l’accreditation*” which incorporates the opinion of the auditors and the AC, as well as any required motivation in case of a negative decision or if it diverges from the auditors or AC opinion. The accreditation decision comes into effect with the signature of the form “*F035 – Décisions relatives à l’accreditation*”. A letter of notification of the decision is sent to the CAB.

The form « *F025 – Feedback to the assessors* » is sent to the concerned assessors to inform them about the opinion delivered by the AC, and their feedback about the quality of the assessment and the report.

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6. Complementary rules

National Accreditation Register

For a granting, a renewal or a lifting of suspension the CAB is registered, respectively registered again, in the National accreditation register. In the case of an extension the Register is updated.

Suspension and withdrawal

In case of suspension or withdrawal, the CAB is withdrawn from the National accreditation register. When an accredited CAB is suspended for more than 18 months following the notification of suspension, its accreditation is considered as withdrawn.

The withdrawal and suspension lead to:

- A ban on using its status of accredited CAB,
- A ban on issuing reports or certificates covered by accreditation during an initial assessment,
- A ban on using the OLAS logo.

These decisions are effective at the date of reception of the notification by the CAB. The CAB is immediately withdrawn from the National accreditation register.

A suspension can only be lifted by a complementary assessment.

In case of a withdrawal the CAB must return the accreditation certificate to OLAS.

Complementary assessment

If the AC recommends a complementary assessment following a granting or an extension assessment it must take place within a period of 6 months following the notification of the decision by the head of OLAS's department. After this period, the application for granting or extension of accreditation is cancelled except if the CAB can prove valuable reasons to explain this delay.

If the AC recommends a complementary assessment following a surveillance or renewal assessment it must take place within a period of 6 months following the notification of the decision by the head of OLAS department, or his deputy. After this period, the accreditation is suspended completely or partially for a period of 18 months. If the CAB does not lift the suspension within this period, the accreditation is withdrawn completely or partially.



A complementary assessment can be performed based on documents or on a visit on site.

Reduction of the accreditation scope

The reduction of an accreditation scope is effective at the date of reception of the notification by the CAB. To restore the removed activities in its accreditation scope the CAB must address a new application for extension to OLAS.

Application for suspension, reduction or voluntary withdrawal of accreditation by a CAB

The CAB can, at any time, apply for a reduction, a suspension or a withdrawal of accreditation by simple letter signed by a person entitled to engage the CAB. The National accreditation register and the scope of accreditation will be updated and the modifications notified to the CAB.

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The withdrawal and suspension lead to:

- A ban on referring to its status as an accredited CAB,
- A ban on issuing reports or certificates covered by accreditation during an initial assessment,
- A ban on using the OLAS logo,
- The return of the certificate of accreditation to OLAS in the event of voluntary withdrawal.

Each voluntary suspension which is not lifted by the accredited CAB within 18 months after reception of the notification, leads to the withdrawal of accreditation.

In the case of withdrawal the CAB must return the original of its accreditation certificate to OLAS.

Major non-conformities

Before to grant, extend, maintain, renew or lift a suspension of accreditation, all major non-conformity must be closed and its application controlled according to the procedure P002.

7. Sanctions

Sanctions against the CABs may apply in certain situations. Before any sanction is announced, each situation will be analysed in detail by the head of OLAS department or his deputy.

7.1 Specific situations that could lead to sanctions covered by the law

In accordance to the article 18 of the law of the 4th July 2014 concerning the reorganization of ILNAS, punishment will apply from 251 EUR to 25,000 EUR, to imprisonment from 8 days to 6 months or only one of those penalties may apply to:

- any person who invokes an accreditation without having a valid accreditation;
- any person who has used or affixed the semi-figurative mark « OLAS », such as registered at the Benelux Office for intellectual property, without being accredited;
- any person who has used or affixed the semi-figurative mark « OLAS » such as registered at the Benelux Office for intellectual property, on certificates or reports for activities other than those for which he is accredited.



7.2 Other situations that may lead to sanctions not covered by the law

The situations here below are those referenced in the document *IAF MD 7 :2010 - Harmonization of Sanctions to be applied to Conformity Assessment Bodies*, and will apply to all accredited CABs:

- inability of a CAB closing non-conformities in a timely manner;
- unresolved complaints against a CAB;
- non-payment of annual fee, audit invoices or others,
- fraudulent behavior of the CAB;
- certification according to accreditation standards.

Possible sanctions for the first three situations are:

- complementary assessment ;
- reduction of accreditation scope ;

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- suspension or withdrawal of accreditation.

Possible sanctions for the last two situations are:

- withdrawal of accreditation for the first situation;
- suspension of accreditation for the last situation.

OLAS will inform the CAB and the AC of any sanction expressed without any delay and in specific cases (e.g. suspension or withdrawal of accreditation), also the IAF secretariat (cf. IAF MD 7 : 2010).

8. Appeal procedure

OLAS takes decisions based on the opinion of the AC in accordance with article 5 of the law of July 4, 2014, concerning the reorganisation of ILNAS.

In the case of disputed decisions with regard to accreditation or a sanction, the CAB may address an internal administrative appeal for reconsideration at OLAS.

For the administrative appeal, a delay of 15 working days is allowed to the CAB, starting from the notification of the decision by the head of OLAS department, or his deputy, to present its remarks to OLAS. They are transferred to the AC. The final decision is taken based on the opinion of the AC.

If, following the administrative appeal, a disagreement persists, the CAB may contact the public mediator « Ombudsman» for help. The Ombudsman is an appendage of the parliament, responsible for receiving complaints by physical or legal persons, about a decision or cases relating to the governmental administrations or municipal services, as well as public institutions depending of the Government (<http://www.ombudsman.lu>). In this case, the CABs must comply with the specific procedures established by the Ombudsman.

In case of a judicial remedy to the administrative tribunal, the appeal will be handled in accordance with the law of 21 June 1999 concerning the rules of procedure at the administrative courts (<http://www.jurad.etat.lu>).