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QM

Quality manual of the Luxembourg Office of Accreditation and Surveillance (OLAS)



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4.6.2. Guides concerning accreditation 5.1. ILNAS organization chart 6.1.2.2. Assessors et experts	19.09.2023
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1. Purpose of the OLAS Quality manual

Purpose of the present quality manual (QM) is to:

- define the OLAS' missions,
- describe its organization and its operation,
- present its management system.

OLAS management system, as shown in this manual, conforms:

- to national and European legal arrangements,
- to requirements of the international standard ISO/IEC 17011:2017 –Requirements for accreditation bodies accrediting conformity assessment bodies.

The Quality manual and the associated procedures, annexes and forms are the basis for the conclusion of multilateral recognition agreements with international and European accreditation bodies.

This QM is only covering the activities of CAB accreditation.

2. Statement and commitment of the head of OLAS department

As head of OLAS department, I commit myself to implement with all the resources at my disposal the conformity of the Luxembourg accreditation system to the national and European legislation, to European and international standards and normative documents as regards accreditation and any other document from European and international accreditation bodies in order to maintain signature of the EA, IAF and ILAC mutual recognition agreement by OLAS.



I commit myself to implement policies and procedures defined in the management system in a non-discriminatory and impartial way to give the necessary confidence to guarantee the recognition of accreditation certificates issued by OLAS.

Being aware of the importance of impartiality in its accreditation mission, I commit myself to implement the necessary means to avoid any conflict of interest, commercial or financial pressure, in order to guarantee that OLAS' accreditation decisions are taken in a strictly objective manner.

Furthermore I commit myself to maintain the highest level of competence of the OLAS staff, the assessors and experts and the accreditation committee members, in order to guarantee the quality of the services meeting the requirement of all the interested parties, with transparency, meeting costs and deadlines.

As head of OLAS department my main objectives are:

- to provide to our customers a quality of service adapted to their needs meeting their requirements,
- to respect and enforce laws, regulations and all other applicable reference in the accreditation domain,
- to sign and maintain mutual recognition agreements with European and international accreditation bodies,
- to maintain the operation of a transparent, efficient and non-discriminatory accreditation system,
- to guarantee the impartiality of the OLAS operation and of its decision making process,
- to guarantee the competence of the OLAS staff, the accreditation committee members, the assessors and experts, with trainings and development of their competences,
- to implement strict controls in order to ensure a high level quality of services.

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To meet these objectives the OLAS staff, the accreditation committee members as well as the assessors and experts shall collaborate to the continuous improvement of their level of performance.

The results of internal audits and EA evaluations, the complaints, the objections, the non-conformities, the derogations, as well as the information resulting from the careful monitoring of the assessors and experts are the basis of the efficiency review and operation of the management system.

Dominique FERRAND
Head of department

3. Terms and definitions

OLAS: Luxembourg Office of Accreditation and Surveillance

ILNAS: Luxembourg Institute for standardization, accreditation, safety and quality of product and services.

CAB: Conformity assessment body.

Accreditation of a CAB: attestation delivered by a third party, regarding a CAB, representing a formal recognition of its competence to perform the specific activities of evaluating conformity.

QMa: Quality manager

QM: Quality manual



AC: Accreditation Committee

IC : Impartiality Committee

EA : European co-operation for Accreditation

IAF : International Accreditation Forum

ILAC : International Laboratory Accreditation Cooperation

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4. Luxembourg Office of Accreditation and Surveillance

4.1. Legal personality of OLAS and its legal basis

OLAS is the sole accreditation body of CABs in Luxembourg. It is a department of ILNAS, which is a public administration under the authority of the Minister of the Economy and Foreign Trade.

The European legal basis supporting the accreditation system consists of:

- the regulation (EC) n°765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products

The national legal basis supporting the accreditation system consists of:

- the modified law of the 4th July 2014 concerning the reorganisation of ILNAS.
- the grand-ducal regulation dated 12th April 2016 concerning implementation of articles 3, 5 and 7 of the amended law of 4 July 2014 on the reorganization of the ILNAS.

4.2. Accreditation agreement

The obligations of the CABs accredited by OLAS are described in the form *F001D – Statement for conformity assessment bodies*.

4.3. Use of accreditation symbols and other references to accreditation

The use of the OLAS' logo, accreditation symbol and references to the international recognition of accreditation by OLAS is defined in the annex *A003 – Guidelines for the use of the OLAS logo and accreditation symbol*.

4.4. Impartiality requirements

4.4.1. Independence of OLAS

ILNAS organization chart (see chapter 5) identifies OLAS as one of the six departments of the administration. OLAS operates its own management system (Standard ISO/IEC 17011), has its own personnel to perform legal attributions, and takes its own decisions independently from the other departments. With regard to financial resources to perform its missions, OLAS is supervising its incomes and expenditure. OLAS has its own logo and accreditation mark different from the other departments of the administration.

Apart from general information on accreditation and on its accreditation system, OLAS does not give any consultancy or conformity assessment activities.

4.4.2. Objectivity of OLAS' personnel



4.4.2.1. OLAS staff

OLAS staff has the status of a civil servant or a state employee.

In accordance with the *amended law of 16 April 1979 laying down the general status of State officials*, it is forbidden for OLAS staff to have, directly or through another person, interests likely to compromise its independence in a company subject to the control of its administration or service, or in connection with its administration or service.

OLAS personnel who, in the performance of their duties, have to decide on a case in which they may have a personal interest that could compromise their independence must inform their hierarchical superior.

It is forbidden for OLAS personnel to disclose the facts of which they have got knowledge by reason of their duties and which are of a secret nature by their nature or by the instructions of

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the superiors, unless exempted from them by the minister of the jurisdiction. These provisions also apply to staff that have ceased their duties.

Any misappropriation, any communication contrary to the laws and regulations of parts or service documents to third parties is prohibited.

Staff salary only depends on grade and step (General statute of the civil servant, Art. 20 and following)

4.4.2.2. Accreditation committee

The qualification of the AC members (see clause 6.1.1.3), and the guidelines to deliver an opinion defined within the procedure *P003 – Decision making process*, allow to preserve the objectivity of the OLAS accreditation decisions.

The impartiality rules applicable to AC members are published in the annex *A023 - Accreditation committee – Rules of procedures*. To demonstrate their engagement in terms of impartiality and confidentiality, the AC members shall sign the form *F020 – Code of ethics and professional deontology for OLAS' committee members*.

The composition and the operation of the AC allow avoiding any commercial or financial pressures that could jeopardize the impartiality of the opinions it gives.

4.4.2.3. Impartiality committee

The balanced representation without any predominance of interest within the impartiality committee (see clause 4.4.3), is likely to preserve the impartiality of principles and policies related to the functioning of the OLAS accreditation system. To demonstrate their engagement in terms of impartiality and confidentiality, the AC members shall sign the form *F020 – Code of ethics and professional deontology for OLAS' committee members*.

4.4.2.4. Assessors and experts

The assessors' objectivity is defined in the code of ethics annexed to the forms *F002A – Application for quality assessors* and *F002B – Application for technical assessors*. The code of ethics shall be signed by the assessors.

The annex I in the mission statement reminds to the assessors the code of ethics. The assessors and experts shall sign the annex by before each mission.

The assessors are not submitted to commercial or financial pressures because they shall be independent of the bodies they assess and because their fees are paid by OLAS and not by the assessed body.



4.4.3. Impartiality committee

To enable the effective participation of interested parties in preserving its impartiality, in a balanced manner and without predominance of interests, OLAS has set up an IC.

The members of IC represent:

- the authorities ;
- the economic partners ;
- the accredited clients,
- the consumers.

The missions as well as the operation of the IC are detailed in the chapter 5.5.2 of the QM.

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4.4.4. Risk management process link to impartiality

The criteria, the identification, the analysis, the evaluation and the treatment of risks related to impartiality are documented by the OLAS in the form *F052 - Risks to impartiality*. This document is validated by the impartiality committee. The sources of risks analysed include OLAS' activities, its relationships, as well as its staff relationships.

An FMECA (Failure Modes, Effects and Criticality Analysis) is carried out to analyse the risks related to OLAS' activities and relationships, as well as to the relationships of its staff. Form *F049 - Risk Analysis Form* is used whenever it is necessary to analyse a particular risk case. This analysis must be carried out by a person not involved in the identified situation.

The form F052 is reviewed at least once a year, as well as any change or any new situation deemed potentially at risk. Staff members, committees, assessors and experts must declare any potential conflict of interest whenever relevant.

The residual risks, resulting from the process of processing the risks identified by the analysis of each activity or situation, are traced on form F052.

The OLAS Head of Department reviews all residual risks. If, despite the means of control implemented by the OLAS, one of them cannot be reduced to an acceptable level, accreditation is not granted.

4.4.5. Non-discrimination of the accreditation process

OLAS puts its services at the disposal of all bodies which application meets the activities and the limits defined in the policy and in the national and European legislation.

The access to accreditation is not influenced by the size of the CAB or by the link to an association or a group. Accreditation doesn't depend on the number of laboratories or organizations already accredited by OLAS.

The objectivity of the accreditation programs developed and updated by OLAS is preserved since they are based on:

- national and European legislation,
- European or international standards or other normative documents applicable to accreditation,
- any other documents from European and international accreditation bodies.

4.4.6. Notification of important modifications to EA, IAF and ILAC



In the case of modifications of its status or its accreditation program as well as changes of staff covering key positions, the quality manager of OLAS notifies them as soon as possible to EA, IAF and ILAC.

4.5. Financing and liability

4.5.1. Legal responsibility of accreditation

OLAS legal responsibility is State responsibility. The State and the other legal persons governed by public law are liable, each one within the frame of his missions of public service, of all damage caused by the malfunctioning of both administrative and legal services, subject to "a matter already judged" (res judicata) according to the law dated September, 1st 1988 regarding the civil liability of the State and of public institutions.

To cover the risks related to the assessors' activities during their missions, OLAS has taken out professional liability insurance.

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4.5.2. Financial operation of accreditation

The incomes and expenses regarding the operation of OLAS are governed by the national public budget according to the article 104 of the Constitution and the article 2 of the amended law dated June, 8th 1999 on the budget, the accounting and the public treasury.

The national public budget is the annual law foreseeing and authorizing all public incomes and expenses to be done during the business year voted for.

OLAS head of department is in charge of the budget. OLAS budget is included in the global budget of the administration. The budgetary proposals are then transmitted to the Ministry of Finance, respectively the General Inspection of Finance (IGF) by April, 30th at the latest each year. After examination of the budgetary proposals by the IGF in May/June the draft budget is finalized for the beginning of September/October to be introduced at the Chamber of Deputies in October. The budget is voted at the latest on Thursday of the third complete week in December to enter in force as by January, 1st of the forthcoming year.

The estimates of expenses regarding OLAS are signed by the head of department. The incurring and order to pay are signed by the ILNAS director. Approval of invoices before payment is made by the administrative assistant of OLAS.

The financial controller is in charge of the control of the incurring and of the order to pay of all the expenses and the control of the payment of all the non-fiscal incomes regarding accreditation.

The payment of expenses and recovery of the incomes regarding accreditation are managed by the public accountants of the public treasury and the Administration of Direct Contributions.

The Court of auditors inspects the legality of the incomes and expenses and the good financial management of the public funds.

Application fees paid by the bodies candidate to an initial or a prolongation of their accreditation, respectively the annual accreditation fee (GDR of 12th of April 2016), are the only OLAS income. The payment of the assessors and experts represents the major part of the expenses.

According to the clause 4.2.5 of the ISO/IEC 17011 standard, the OLAS head of department is responsible for the supervision of the OLAS finances.

Invoicing handling is described in detail in procedure P010 and in instruction INT002.



4.6. Establishing accreditation schemes

4.6.1. Standards and guides applicable to accreditation activities

The CAB accreditation is performed regarding European and international standards, other normative documents as regards accreditation and any other documents from European and international accreditation bodies.

OLAS issues accreditation to:

- testing laboratories according to the standard ISO/IEC 17025,
- calibration laboratories according to the standard ISO/IEC 17025,
- medical laboratories according to the standard ISO 15189,
- inspection bodies according to the standard ISO/IEC 17020,
- certification bodies of:
 - products, processes and services according to the standards ISO/IEC 17065,

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- management systems according to the standards ISO/IEC 17021-1, ISO/IEC/TS 17021-2, ISO/IEC/TS 17021-3 and ISO/IEC/TS 17021-10
- information security management system, service providers for digitization and electronic archiving according to the standards ISO/IEC 17021-1 and ISO/IEC 27006,

All applicable documents for the accreditation of CABs are identified in the annex A006 – *Applicable standards and guides*.

All documents defined in A006 and the appropriate accreditation standard constitute the accreditation programs that OLAS offers accreditation for.

~~If OLAS doesn't fix delay for the application of a standard (technical or other), the delay is one year starting from the publication date.~~

OLAS doesn't define any additional requirements apart from those already applicable in the standards and guides.

Due to a lack of customers or internal competences, OLAS doesn't provide accreditation to CABs in the following domains:



- Personnel certification according to the standard ISO/IEC 17024,
- Validation / verification of greenhouse gas emissions according to the standard ISO 14065,
- Proficiency testing according to the standard ISO/IEC 17043,
- Reference material producers according to the standard ISO 17034,
- Notified CABs according to the directive 2008/57/EC on the interoperability of the rail system within the Community.

Unless a specific interest is identified at national level for one of these domains, OLAS will forward applications to a European accreditation body signatory to the mutual recognition agreements for the areas concerned.

4.6.2. Guides concerning accreditation

OLAS publishes guides concerning accreditation called annexes:

- A002 – *OLAS' obligations,*
- A003 – *Guide for the use of the OLAS logo and accreditation symbol,*
- A004 – *Scope of accreditation,*
- A005 – *Accreditation domains covered by OLAS,*
- A006 – *Normes et guides applicables,*
- A007 – *Barème tarifaire des frais relatifs aux audits d'accréditation,*
- A008 – *Invoicing auditing services. Accreditation costs,*
- A009 – *Control of records,*
- ~~A010 – *Accreditation fees,*~~
- A011 – *Guidelines for checking and validating test and calibration methods according to ISO/IEC 17025,*
- A012 – *Management of fixed and flexible accreditation scopes*
- A013 – *Accreditation of multi-site organizations,*
- A014 – *Cross frontier accreditation,*
- A015 – *Proficiency testing by inter laboratory comparisons,*
- A016 – *Traceability of measurements results compared to national and international measurement standards,*
- A018 – *Job descriptions*
- A019 – *Legislation concerning notification of CABs,*

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- *A020 – Analyse des compétences requises pour l'accréditation des OEC procédant à la certification selon la norme ISO 27001*
- *A022 – Medical laboratories – presentation of the national legislation*
- *A023 – Comité d'accréditation – Règlement intérieur*
- *A024 – Analysis of accreditation domains*
- *A025 – Audit report writing guide*
- *A026 – Comité d'impartialité – Règlement intérieur*
- *A027 – Comité d'Accréditation – Analyse d'impartialité*
- *A029 – Approbation de personnels réalisant des assemblages permanents dans le cadre de la loi du 27 juin 2016 – Equipements sous pression*

Where applicable, guides developed by OLAS to meet normative requirements or EA, ILAC or IAF guidelines, have been developed with the participation of experts and interested parties.

For critical updates of these guides (challenging OLAS' policies and operations), experts and stakeholders are also involved in their drafting.

In order to keep informed on accreditation issues, OLAS participates in the EA, IAF and ILAC working groups.

4.6.3. Adequacy of accreditation programs

If OLAS decides to develop a new accreditation program, it verifies its compliance with conformity assessment standards based on its experience or other accreditation bodies signatories of the same mutual recognition agreements. It may also rely on the opinion of its experts or its accreditation members committee, or on the recommendations of the EA, ILAC or IAF guidelines.

This verification is done during the review of the suitability of a CAB's accreditation using form *F004G - Development / extension of an accreditation scheme or conformity assessment domain*.

If an accreditation program is developed in response to a request from the Minister or in accordance with a regulation, OLAS uses the accreditation standard imposed. If the implementation of the programme requires additional resources, OLAS applies to the Commission d'Economies et de Rationalisation (CER) for additional staff.

4.6.4. Developing/extending accreditation schemes



The development of a new accreditation program corresponds to accreditation to a new standard or a new version of an accreditation standard (level 3 or 4 standard).

The extension of an accreditation programme corresponds to the extension to a new general or technical field not yet covered by an accreditation.

4.6.4.1. Feasibility of developing/extending an accreditation scheme

Each application that is out of the accreditation schemes or general and technical domains already accredited by OLAS is subject to a preliminary analysis using form *F004G - Development / extension of an accreditation scheme or conformity assessment domain* and a preliminary information research in order to evaluate its feasibility.

Where OLAS is not able to respond to the extension to new accreditation schemes or new conformity assessment domains, OLAS will not proceed with an application that does not fall within the currently accredited accreditation schemes or conformity assessment domains, unless explicitly requested or agreed by the Minister of Economy.

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If OLAS cannot offer accreditation for new accreditation schemes or new accreditation domains, the concerned CAB is informed and may send its application for accreditation to another European accreditation body which is a signatory to the same mutual recognition agreements.

4.6.4.2. Development or extension of an accreditation scheme

4.6.4.2.1. Contact to assessors and experts

If OLAS has not the necessary numbers/type of assessors and experts for a new accreditation scheme or for the extension to a new accreditation scheme, the responsible accreditation manager has contacts other accreditation bodies signatories of the mutual recognition agreements which are active in this domain in order to get the following information:

- Reference to the accreditation standards (and/or associated guides);
- Points of the technical appendix for which he seeks specific competences;
- Period planned for the assessment;
- Language used (if different from French).

After identification of the required assessors or experts replying to the research criteria, OLAS contacts them in order to verify their competences and their interest in participating at accreditation assessment for OLAS.

If the assessor/expert accepts the OLAS proposal, he is informed about the procedure to be followed to register for the National register of assessors and experts. This registration is realised in accordance with procedure *P004 - Authorizing of assessors and technical experts and monitoring of their competences and performances*.

OLAS also provides all necessary information regarding the functioning of its accreditation process. All documentation is available on the website www.portail-qualite.lu

4.6.4.2.2. Application documents

When launching a new accreditation scheme (or extending an existing scheme), the accreditation manager in charge of the file ensures that he has access to all relevant documents (standards, EA guides, ILAC, IAF documents) or published by other accreditation bodies, to best meet his information needs.

If necessary, OLAS drafts its own application or guidance documents.

4.6.4.2.3. Point of view of interested parties



The accreditation comity (AC) is informed of each request for development or extension to new accreditation activities.

OLAS also carries out an analysis of the regulatory context of the concerned activity and, if necessary, contacts the competent authorities likely to be involved in the field.

When necessary, the OLAS also adapts its documentation system (QM, procedures, annexes, instructions and forms) to conform to the new activity.

4.6.4.2.4. Trainings

If for the launch of a new accreditation scheme (or extension of an existing programme) new requirements are necessary (standards, applicable guides), OLAS may be responsible for organising training for its staff, members of the AC, or assessors, or if necessary make a request for additional staff to the Commission for Economies and Rationalisation (CER) to cover its needs

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4.6.4.2.5. Records

The development or extension of accreditation programmes is recorded using form *F004G - Development / extension of an accreditation scheme or conformity assessment domain*.

For each research, all relevant information exchanged with organisations, assessors and experts (letters, e-mails, telephone interviews) is kept in the file of the assessor and/or concerned client.

4.6.4.2.6. Method of implementation or transition

Any launch of a new accreditation scheme (or extension of an existing program) is subject to a request from the relevant CAB via forms F001A, F001B or F001C. Each request is reviewed by the accreditation manager in charge of the file using the form *F004A – Check-list*.

The accrediting manager verifies that the draft technical annex is correctly completed, clearly defined and signed.

4.6.4.2.7. Organization of first evaluations

When a new accreditation scheme is launched, an OLAS observer follows the first assessment to ensure that it is running smoothly.

4.6.4.2.8. Verification of smooth functioning

OLAS verifies the proper functioning of extensions to new standards or new versions of standards during the management review. If problems are identified during the first assessments, OLAS makes the necessary adjustments.

4.6.5. Discontinuance or reduction of an accreditation scheme

In the event that OLAS ceases all or part of an accreditation scheme, it contacts all interested parties to ensure that this does not conflict with a development project of one of the parties related to the field of activity concerned. The following points will also be taken into account:

- Contractual obligations,
- Transitional provisions,
- External communication of the discontinuation/reduction of an accreditation scheme,
- Information on the stopped/reduced accreditation scheme.

4.6.6. Cross-border accreditation

EA, IAF and ILAC define accreditation as a non-competitive activity between countries with an accreditation system.

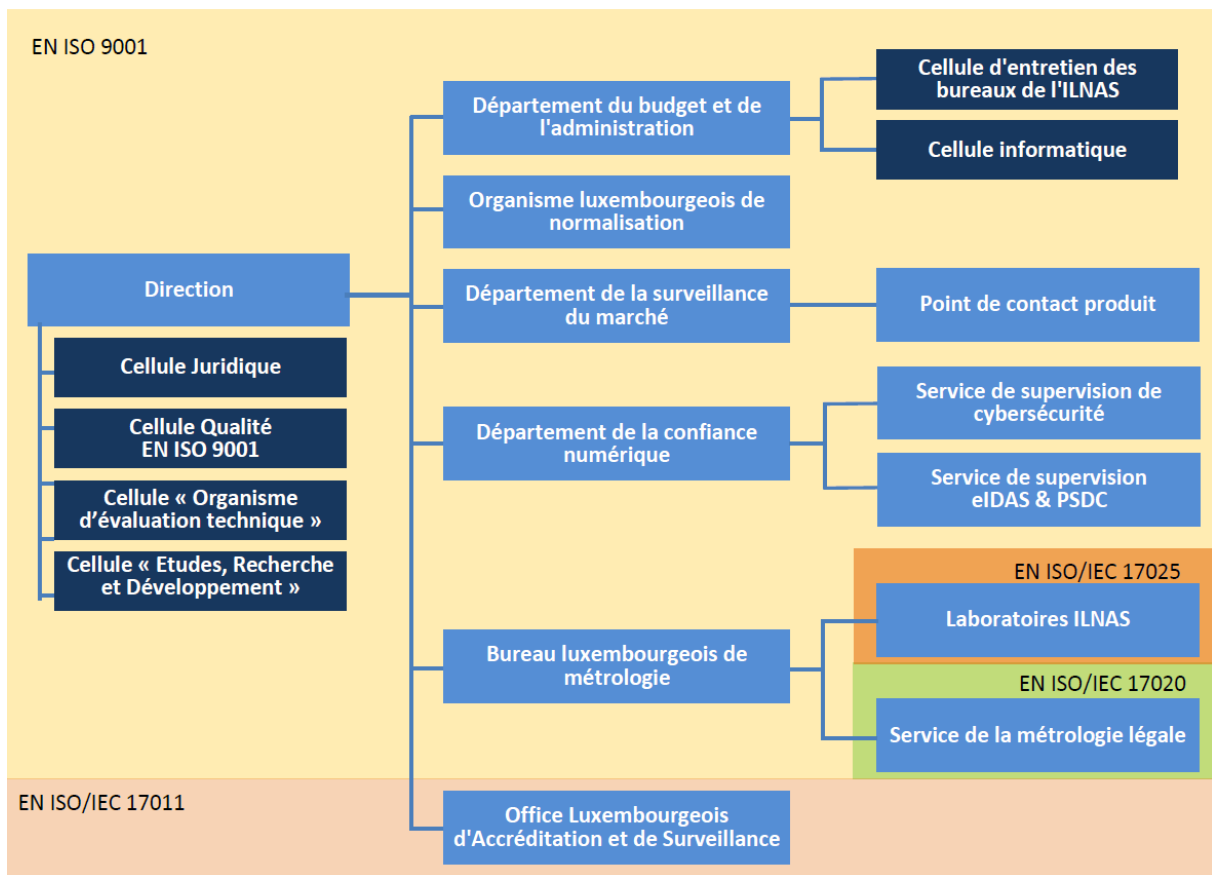
However, OLAS may, under certain conditions, be required to accredit a CAB in a foreign country.

Annex A014 provides requirements for the operation of cross-border accreditation in accordance with the recommendations of ILAC Guide G21:09/2012 Cross Frontier Accreditation - Principles for Cooperation

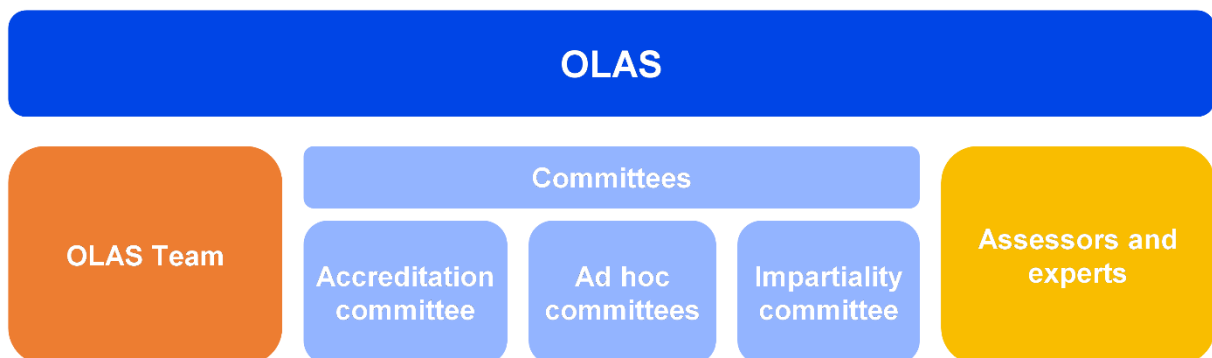
5. Structural requirements

The impartiality of OLAS is guaranteed by the means implemented in Chapter 4.4 of the MQ, as well as by the organisational structures of ILNAS and OLAS presented in Chapters 5.1 and 5.2 of the MQ. The legal personality of OLAS and its membership of ILNAS are described in Chapter 4.1 of the MQ.

5.1. ILNAS organization chart



5.2. Organization chart of OLAS





The files and the job description of OLAS staff are described in annex A018. A nominative table, *F018 – Matrice de compétences du personnel de l'OLAS*, is the link between staff and the various OLAS positions. It is signed by the OLAS permanent staff.

5.3. Missions of the OLAS permanent staff

OLAS permanent staff is in charge of the following missions:

- CAB accreditation:
 - OLAS day-to-day management and the management of accreditation files,
 - definition and updating of accreditation programmes,

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- relations with the accreditation committee and the ad hoc committees,
- management of the national accreditation register and assessors national register,
- external relations with the European and international accreditation bodies,
- complains and appeals,
- management of the ISO/IEC 17011 quality management system.
- The evaluation and surveillance of notified CABs with respect to the Luxemburgish legislation transposing EU harmonization legislation.

5.4. OLAS' decision-making responsibility

Article 5(2) of the amended law of 4th July 2014 reorganising ILNAS gives OLAS the power to take accreditation decisions on the basis of the opinion of its accreditation committee. For all accreditation domains covered by OLAS, as described in annex A005, the accreditation decision is never subcontracted.

Annex A018 describes the functions performed by OLAS permanent staff and assigns them the corresponding powers and responsibilities.

5.5. Missions of the OLAS permanent staff

To ensure its good functioning, OLAS disposes of three types of committees.

- The Accreditation Committee (AC),
- The impartiality committee (IC),
- The ad hoc committees.

5.5.1. The Accreditation Committee (AC)

The AC missions are:

- To make proposals concerning general orientation about the accreditation of CABs,
- To assist OLAS in the decision-making process by stating an opinion about each granting, extension, maintaining, renewal, complementary, refusal of granting or extension, suspension or raising of suspension, reduction and partial or complete withdrawal of an accreditation,
- To propose the eventual removal of a quality assessor, a technical assessor or an expert from the « National register of quality and technical assessors ».

The AC members are appointed by OLAS for their competence in the domains covered by accreditation.

Upon decision of the AC, the experts may be asked to assist to meetings, with consulting voice, on order to increase the technical expertise of the AC.



AC members have a three-year term that may be renewed.

The management of the AC is detailed in work instruction INT001.

5.5.2. Impartiality committee (IC)

The impartiality committee mission is to make proposals concerning the functioning of OLAS or all other question with regard to accreditation, especially questions concerning impartiality and development of rules and politics, which concern the functioning of the accreditation process.

The recommendations of the IC are followed up via improvement or preventive action sheets opened by the QM following the IC meeting.

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The impartiality committee meets at least once a year, invited by OLAS, to review the functioning of the OLAS in terms of impartiality. ILNAS management is invited to participate as an observer in the IC meetings.

Impartiality members are appointed by OLAS and have a three-year term that may be renewed.

5.5.3. Ad hoc committees

The ad hoc committees treat general and technical questions and analyse the qualification of assessors and experts. The ad hoc committee members are chosen for their technical competences considering the matters to be analysed. OLAS organizes the ad hoc committees whenever necessary.

An ad hoc committee is composed of one or more members chosen for their knowledge of the field. Members may be chosen among the members of the AC, OLAS staff or experts external to OLAS. They have to:

- Sign the code of ethics and professional conduct *F019 - Code of ethics and professional conduct for employees outside the OLAS (external experts)* or *F020 - Code of ethics and professional conduct for members of the OLAS committees (members of the accreditation and impartiality committee)*;
- Have training or professional experience related to an accreditation standard (for the qualification of quality assessors);
- Have training or professional experience related to the field concerned (for the qualification of technical experts or assessors).

6. Resource requirements

6.1. Competence of personnel

For the standard ISO/IEC 17011:2017, the term "personnel" is defined as the "personnel of the accreditation body" as defined in point 3.29 of the paragraph "Terms and definitions": Internal or external persons carrying out activities (by extension: "accreditation") on behalf of the accreditation body.

6.1.1. Determination of competence criteria

6.1.1.1. OLAS permanent staff

The competence criteria for OLAS staff are detailed in procedure *P009 - Authorisation of OLAS personnel and monitoring of their competences*. The description of the missions and duties they carry out are detailed in *annex A018*.



6.1.1.2. Assessors and experts

The detail of the selection, training, formal approval and the follow-up of the assessors and experts are defined in the procedure P004.

6.1.1.3. AC members

To be considered a member, the candidate must meet the following competence criteria:

- Higher education diploma of at least 3 years and 5 years' professional experience in at least one of the fields covered by the accreditation or at least 10 years' professional experience in one of the fields covered by the accreditation,
- General training to at least one accreditation standard,
- Training in the OLAS quality management system,
- Initial training through questionnaire *F041 - Questionnaire for new assessors and experts* and evaluation of the result,

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- Be representative of one of the three groups represented in the AC.

The competencies of AC members are assessed using form *F034 - Assessment of a Board Candidate's Competencies*. The AC is responsible for validating the qualification of its members.

If the candidate meets all the above qualification criteria, then he/she can benefit from a voting right from the first time he/she participates in a Board of Directors.

If the candidate does not have training in an accreditation standard and/or in the OLAS quality management system, he/she has a maximum period of one year to acquire the necessary training(s). After this one-year period, the Board assesses the candidate's file to ensure that all criteria are met.

When the evaluation of the criteria is positive, the candidate is definitively appointed as a full member by the OLAS.

If the criteria are not met, the candidate is not selected. The OLAS notifies its refusal to appoint the candidate.

6.1.2. Competence management

6.1.2.1. OLAS permanent staff

The « Centre de gestion du personnel et de l'organisation de l'Etat (CGPO) » organises the recruitment of civil servants by examination and competition and centralises the recruitment of civil servants.

The conditions for access to the public service are defined in volumes 1 and 2 of the Administrative Code for the Public Service.

All civil servants are subject to an “internship”- period before being hired, must undergo trainings and pass examinations in accordance with the law of 16th April 1979 establishing the general status of civil servants of the State as amended and its implementing regulations.

To advance to the next higher grade of their career, civil servants and public servants are subject to a training cycle in accordance with the law of 28th March 1986 harmonising the conditions and procedures for advancement in the various careers of public administrations and services and its implementing regulations.



The initial evaluation and monitoring of the skills of OLAS staff is detailed in procedure *P009 - Authorisation of OLAS personnel and monitoring of their competences*.

For a new staff member, the initial assessment follows the initial training programme defined to fulfil his or her function. The different steps of the initial training are described in form *F053 - Initial Training Program for OLAS staff*.

Every year, the head of the department, in consultation with the staff, draws up a training plan to improve the staff's ability to carry out OLAS missions. The training plan is grouped with those of the other departments in the document: ILNAS training plan.

In the event of a long absence (duration of more than 3 months) of one of the OLAS staff members, training on the management system is carried out on his return to update his knowledge.

The authorization of OLAS personnel, for each accreditation scheme and each of the functions identified in annex A018, is validated using form *F054 - Initial Authorization of OLAS Personnel*.

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6.1.2.2. Assessors et experts

To register assessors and experts, OLAS uses the following forms:

- *F002A - Application for quality assessor*
- *F002B - Application for technical assessors or expert*
- *F028 - List of assessments realised during the last 3 years.*

The initial evaluation of assessors and experts is detailed in procedure P004. It is tracked using form *F026 - Qualification of assessors and Experts*.

Procedure P004 provides details of assessors performances monitoring using the following forms:

- *F009 - assessors report appraisal sheet,*
- *F010 - Customer satisfaction with regard to the accreditation procedure,*
- *F011A - Evaluating the services of a technical assessors or junior quality assessor,*
- *F011B - Evaluation sheet of the performance of an assessor or expert by an OLAS observer,*
- *F011C - Documentary evaluation sheet of the performance of a quality / technical assessor,*
- *F025 - Feedback to assessors.*

Once a year, OLAS communicates the results of its evaluations to each assessor and expert who has participated in assessments, so that they can take them into account and, if necessary, improve. In addition, the form *F025 - Feedback to assessors* is sent to the concerned assessors in order to inform them of the opinion given by the Accreditation Committee in the event of a dissenting opinion, and/or in the event of a negative evaluation of their report, so that they are informed and can improve.

To monitor the skills related to the functioning of its quality system, OLAS sends an annual questionnaire to its assessors and experts. The questionnaires (*F043 - Questionnaire for assessors and experts - continuous training*) are collected by OLAS and the results taken into account for the qualification of its assessors and experts. A correction of the questionnaire is sent to assessors and experts.

To train its new assessors and experts in the functioning of its quality management system, OLAS sends them a questionnaire (*F041 - Questionnaire for new assessors and experts*). The questionnaires are collected by OLAS and the results taken into account for the qualification of new assessors and experts. A correction of the questionnaire is sent to them.



OLAS maintains a regulatory database listing the national regulations applicable to the domains covered by accreditation. This database is published on the OLAS homepage and sent to the assessors concerned for the preparation of their assessments. The procedure for updating this national regulatory database is described in detail in instruction INT005.

For the field of medical biology, annex A022 has been published in order to facilitate understanding of the regulatory environment.

The initial authorization of assessors and experts is based on the positive opinion of the ad hoc committee on the complete file and the reply to form F041. The meetings of the ad hoc committees for the qualification of assessors are recorded via an attendance list based on form *F024A - Attendance list Ad hoc committee for the validation of new assessors*.

6.1.2.3. Members of AC

The AC members are appointed by OLAS for their competence in the domains covered by accreditation.

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The evaluation of their skills is treated in their internal regulations A023 establishing the AC. A table and a rating grid make it possible to monitor the skills of the AC members on an objective criteria basis.

The competence chart is reviewed at least once a year by the members and the AC secretary.

The following competence criteria are considered when evaluating the competences of the AC members:

- Training and practice of accreditation standards and conformity assessment including training and/or assessment activities;
- Participation in accreditation AC meetings (at least 50%);
- Different types of continuous training;
- Participation in quality events that enrich competence.

Annually the AC members inform OLAS about updates with regard to their CV, if necessary.

If non-compliances with these criteria appear, the AC may decide to take appropriate measures on a case-by-case basis.

6.2. Staff involved in the accreditation process

6.2.1. OLAS Staff

OLAS has the necessary and sufficient staff to cover the tasks assigned to it by the amended law of 4th July 2014 reorganising ILNAS and in order to perform the functions defined in annex A018.

When becoming civil servants or state employees, OLAS staff have to accept the rules described in the Civil Service Administrative Code, which defines, inter alia, their duties in terms of confidentiality, impartiality, neutrality and integrity.

6.2.2. The assessors and experts



To carry out its accreditation assessments, OLAS has a sufficient number of assessors and experts registered in the National assessors register (OLAS software) to cover all the accreditation domains listed in annex A005. When OLAS identifies a need for additional assessors or experts to cover a new domain, OLAS contacts other MLA accreditation bodies.

OLAS is responsible for the initial training of his accreditation system of all its assessors and experts (form F041), as well as for the national regulations applicable to the domains covered by accreditation. If necessary, it also publishes internal policy documents to assist assessors and experts in carrying out assessment in the national context (annex A022).

Registration forms F002A and F002B contain a code of ethics, signed by assessors and experts, which specifies the commitments to be respected in the context of accreditation activities. Among other things, they undertake to inform OLAS, before accepting an assesment, of any existing, past or foreseeable relationship with the CAB to be assessed that could question their impartiality.

To assist its assessors and experts in carrying out their accreditation assessments, OLAS provides them with all the documents of its accreditation system (procedures, annexes and forms). These documents are available for download on the homepage "[portail qualité](#)". OLAS also provides them with all the information they need to prepare and carry out their missions (documents referenced in procedure P002).

The documents of the accreditation system are available in French and English. Some documents are also available in German in order to adapt to the linguistic particularities of some clients.

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6.2.3. The AC members

To assist it in its decision-making process, OLAS cooperates with the AC whose members have been chosen for their particular competences. Representatives shall make it possible to cover all the domains of accreditation listed in annex A005.

The functioning of the AC is described in annex A023. It defines the rules to be respected by members with regard to impartiality and confidentiality.

To demonstrate their commitment to these two principles, AC members have to sign form F020 – Code of ethics and deontology of committee members.

6.3. Personnel records

6.3.1. Records of OLAS staff

According to the grand-ducal regulation of 13th April 1984 defining the documents to be included in the personnel records, it exists, for each civil servant and state employee, a personal record including all the documents for administrative use or from administrative origin as well as documents related to the personal and professional situation and with regard to his professional career.

The file of OLAS permanent staffs is managed by the budget and administration department of ILNAS, and includes:

- a CV,
- a copy of initial education diploma,
- a copy of supplementary and continuous trainings certificates,
- for the external staff, the contracts with the State as well as the code of deontology signed.

Apart from the personal file of the civil servant and the state employee, another file is constituted at the Ministry of Civil Service and of Administrative Reform with all the necessary documents for the calculation and to the establishment of salary and pension of the civil servant.



OLAS is managing the job description of its permanent staff, describing the responsibilities, the rights, the hierarchic links and the minimum criteria for training. OLAS collects training certificates from its staff that are related to accreditation.

6.3.2. Assessors and experts records

OLAS manages its assessors' and experts' files in printed and electronic version. assessors and experts are regularly requested to provide information on qualifications, assessments carried out, training, the results of their supervision or changes in professional activity in order to keep their files up to date.

All this information is also centralized in software program which helps choosing appropriate assessment teams.

These data are backed up daily according to the procedure described in § 9.4 of this QM. The processing of such data is in accordance with Regulation No 2016/679 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free circulation of such data.

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6.3.3. Records of the AC members

The OLAS manages the files of its AC members in paper format. On a regular basis, information relating to new training or changes in professional activity is requested from AC members in order to keep them up to date.

All computer data collected by OLAS on AC members is centralized on the administration server. They are backed up daily according to the procedure described in § 9.4 of this QM. The processing of such data is in accordance with Regulation No 2016/679 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free circulation of such data.

6.4. Outsourcing of accreditation activities

OLAS doesn't sub-contract any activities related to accreditation, except in the frame of international activities as detailed in the appendix annex A014.

Using external assessors and experts is not considered as subcontracting.

7. Process requirements

7.1. Accreditation requirements

OLAS accredits CABs on the basis of national, European and international standards or other normative documents applicable to accreditation and any other documents from European and international bodies and organisations active in the field of accreditation (see chapter 4.6.1).

These documents are grouped in annex A006. All documents of the valid OLAS management system for CABs and assessors/experts are at their disposal on the OLAS homepage under the heading "documents d'accréditation".

7.2. Application for accreditation

The processing of accreditation applications of CABs is documented in the procedure P001 – Processing of applications regarding accreditation.

The necessary information for a CAB registration is grouped in the following forms:



- *F001A – Application to grant, extend or renew an accreditation of inspection organizations,*
- *F001B – Application to grant, extend or renew an accreditation of a testing or calibration laboratory,*
- *F001C – Application to grant, extend or renew an accreditation for an organization certifying products, systems, or personnel.*

To grant or renew an accreditation, the form *F001D – Statement for conformity assessment bodies* has to be duly completed and signed by the CAB and sent to OLAS together with the application form F001A, B or C.

The annex A004 gives complementary information about the definition of the accreditation scopes depending on domains (testing, calibration or medical laboratory, inspection or certification bodies).

Before the registration, OLAS reviews in detail the transmitted information by the CAB in the application forms. The result of the review is reported in the form *F004A – Check-list – Review of an accreditation application.*

The OLAS does not carry out any preliminary visits before the initial assessment.

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7.3. Resource review

The result of the review of the application is reported in form F004A. The ability to carry out the initial assessment in a timely manner is also taken into account.

If a new general or technical domain is to be accredited, OLAS reviews its resources to ensure that policies, procedures and the necessary competences to succeed its accreditation mission are available. The result of the review is recorded in the form F004G.

In case of a switch to a flexible scope, OLAS evaluates the application taking into account the requirements of document EA-2/15 - Requirements for the Accreditation of Flexible Scopes. The result of this review is recorded in form *F004E - Checklist: Review of an Application for Flexible Scope of Accreditation*.

7.4. Preparation for assessment

In order to have all the information relevant for the organisation of assessments, information on the main changes and the volume of activity of CABs is collected via the following forms:

- *F030 - Indicators,*
- *F030A - Monitoring Performance Indicators of Certification Bodies*
- *F045 – Assessment preparation - laboratories,*
- *F047 - Assessment preparation - inspection bodies.*

For testing and calibration laboratories, OLAS has a policy for the management of inter-laboratory comparisons as defined in annex A015.

Form F023 - inter laboratories comparison program, sent to OLAS before each assessment, verifies the effective participation of laboratories over the entire scope of accreditation.

The programme of the areas to be assessed is established using forms *F021A - Monitoring of the assessed technical areas over an accreditation cycle* and *F021B - Monitoring of the assessed technical areas by accreditation cycle of CABs active in the field of systems certification*. The choice of activities to be evaluated considers the risk factors identified in forms F021A and F021B. The final planning of the assessment is summarised in form *F003S - Assessment Plan*, which contains the information needed to organise the assessment, as well as the final assessment programme drawn up by the team leader.

Details of the preparation of the accreditation assessment are documented in procedure *P002 – Performing assessments and definitions* and *INT004 - Assessment time and sampling of assessed domains*. The organisation and follow-up of assessments is detailed in Instruction INT006.

7.5. Review of documented information



OLAS proceeds to a review of relevant documents furnished by the CAB before the accreditation assessment.

In case of a severe problem detected during this review the head of department can decide not to proceed to the initial assessment. A preliminary report is established by the quality assessor using the form *F003N – Document review before granting assessment*.

The detail of the review is documented in the procedure P002.

7.6. Assessment

The realisation of the assessment is described in procedure P002.

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The assessment team carries out an assessment of the CAB's competences in accordance with the requirements of the procedure P002.

This analysis is documented in the assessment report written on the base of the following documents:

- *F003A – ISO/IEC 17025-17020-17065 report,*
- *F003B - ISO15189 report,*
- *F003C – ISO/IEC 17021-1 report,*
- *F003D – ISO/IEC 17021-1-17065 report,*
- *F003F – ISO/IEC 17025-ISO 15189 report,*
- *F003H – ISO/IEC 17025 report,*
- *F003K – ISO/IEC 17020 report.*
- *F003L – ISO/IEC 17025-ISO 17020 report.*

OLAS requirements for the content of the assessment report are specified in annex A025.

Form *F003P – Short assessment report* is completed by the assessment team on site and preferably delivered to the assessed CAB before leaving or sent within 24 hours after the assessment. This form must also be sent to OLAS not later than 24 hours after the assessment.

In case of a witness assessment of a management systems certification body, the assessor 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 sent to the OLAS.

The form *F003M – Follow-up of accreditation assessments* filled out by the team leader permits OLAS to know his point of view about the duration of the assessment and about the number of technical assessors and experts implicated in the mission. This form permits also to identify the points of the standard or the technical domains to control in priority during the next assessment.

The form *F003N – Documentary review before granting*, filled in by the team leader and/or by the concerned technical assessors, helps to write a structured report in case of identification of major non-conformities during the documentary review, for an initial assessment.

7.7. Accreditation decision-making

Article 5.2 of the amended law of 4th July 2014 reorganising ILNAS, stipulates "OLAS shall decide on accreditation after having asked the opinion of the Accreditation Committee".

Before being transmitted to the CA, the accreditation manager in charge of the file, checks that the assessment report is complete. The result of this review is recorded in the following forms:

- *F004B - Checklist: Review of the ISO/IEC 17025-17020-17065 assessment report;*
- *F004C - Checklist: Review of the ISO 15189 assessment report;*
- *F004D - Checklist: Review of the ISO/IEC 17021-1 assessment report;*
- *F004E - Checklist: Review of the ISO/IEC 17021-1-17065 assessment report.*

The decision-making process for granting, maintaining, extending, suspending and withdrawing CAB accreditation is described in procedure P003. These decisions are formalized using form *F035 - Accreditation Decisions*. For each AC meeting, an attendance list is drafted on the basis of form *F024B – Liste de présence CA* and meeting minutes are written on the basis of form *F046B – Compte-rendu de la réunion du CA*.

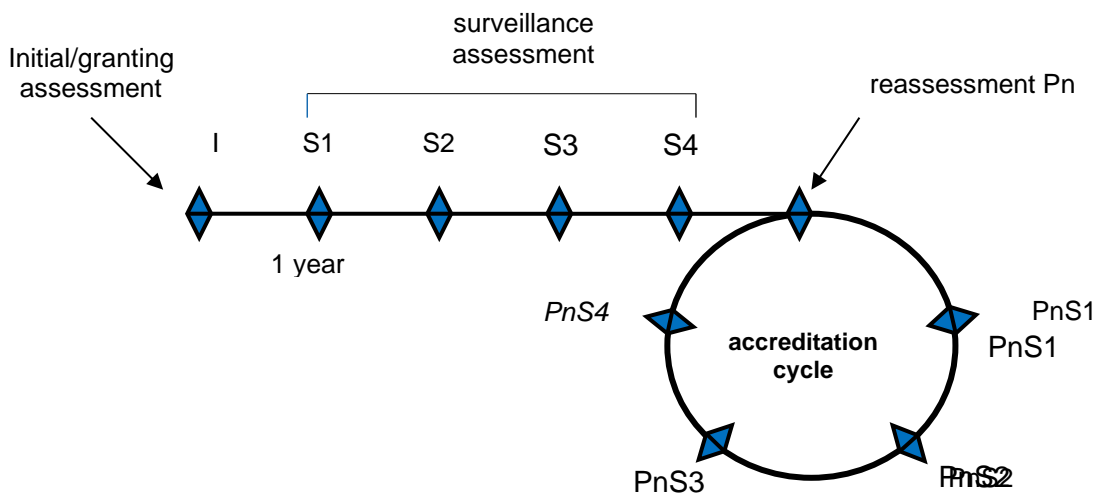
If the reduction, suspension or cancellation is requested by the CAB, the decision shall be taken by the head of OLAS department or his deputy and formalised by means of notification letter of the decision to the CAB. The process is described in procedure P001.

7.8. Accreditation information

The content of the accreditation certificate and its technical appendix, as well as the information published on the website, are described in annex A002 – OLAS responsibilities.

7.9. Accreditation cycle

7.9.1. Accreditation cycle of CABs





Accreditation is granted for a 5 years period and can be renewed. The accreditation date is the date when the head of department signed the document. The date of accreditation is the date of signature of the decision by the head of department. At the end of an accreditation cycle a renewal assessment is organised.

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 renewal decision.

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

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

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.

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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.

~~The accreditation cycle is detailed in procedure P002.~~

An additional assessment is organised when OLAS deems it necessary or on the basis of an opinion from the AC as provided for in procedure P003.

7.9.2. Monitoring of assessments

The main steps of the organization of the assessments of the CABs are registered in the OLAS management software.

During an accreditation cycle the whole accreditation scope (general domains) must be evaluated by an assessment team at least one time. In order to guarantee the follow-up of the general domains of the evaluations, OLAS uses the following forms:

- *F021A - Follow-up of the technical domains assessed during an accreditation cycle*
- *F021B – Follow-up of the technical domains assessed during an accreditation cycle of CABs active in the field of system certification.*

7.10. Extending accreditation

The procedure concerning extension assessments is documented in the procedure P002.

7.11. Suspending, withdrawing or reducing accreditation

The procedures concerning suspension, reduction or withdrawal of accreditation are documented on the procedure P003.

7.12. Complaints

Complaint management is handled in accordance with procedure *P006 – Complaint and appeal processing*.

7.13. Appeals

Appeal management is handled in accordance with procedure P006.

7.14. Records on conformity assessment bodies

The details concerning the control of records are detailed in the annex A009.

8. Information requirements



8.1. Confidential information

8.1.1. OLAS staff

The Civil servants and State employees are bound to the obligations and rules of confidentiality set out in:

- The amended law of the 27th of January 1972 laying down the arrangement for the State employees,
- The amended law of the 16th of April 1979 laying down the general stature of the State functionaries as modified.

External personnel is bound by contract, containing dispositions concerning obligations and confidentiality, to the State.

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External personnel signs a code of ethics *F019 - Code d'éthique et de déontologie pour les collaborateurs externes à l'OLAS*.

8.1.2. Accreditation committee and the impartiality committee

The members of the AC and the impartiality committee and experts are bound by the utmost confidentiality regarding the information and documents that they have become aware of during the investigation of the case in question. The members of the AC must sign the code of ethics *F020 – Code of ethics and deontology for the members of the AC*.

8.1.3. Assessors and experts

The quality and technical assessors, as well as the experts sign the code of ethics included in the forms *F002A – Application for quality assessors and F002B – Application for technical assessors* that specify the rules regarding the respect of confidentiality.

The independence and impartiality requirements are recalled to the assessors in the annex I of the mission order that they must sign before each assessment.

8.2. Publicly available information

The obligations of OLAS are described in the annex *A002 – OLAS's obligations*.

Publication of accredited bodies

The names, the addresses and the scopes of accredited CABs are published on the website of OLAS under the section « National accreditation register ».

Changes to the accreditation requirements

Before OLAS undertakes changes to the accreditation requirements, it informs all accredited CABs, the AC, assessors and experts in order to collect their opinion.

The implementing deadlines are fixed on a case-by-case basis.

The implementation of the changes is assessed by the team during the assessment. The verification is contained in the assessment report.

9. Management system requirements

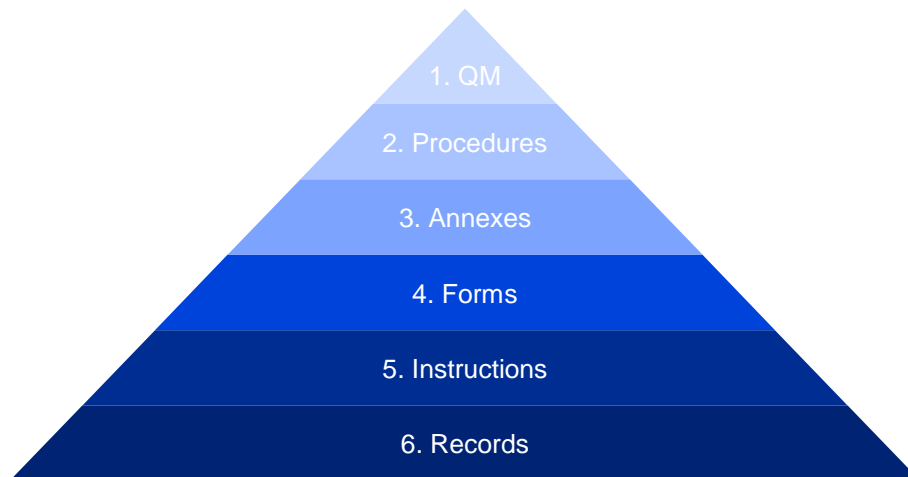
9.1. General

OLAS has established a management system according to ISO/IEC 17011:2017 in order to comply with the missions set out in the amended law of the 4 July 2014. The management system conforms to the option A of said standard.

The head of department appoints a quality manager as well as a deputy quality manager who are responsible for the monitoring and the update of the management system (including corrective actions, complaints, etc).

9.2. Management system

OLAS management system is composed of documents that allow to organize and to operate CAB's accreditation. The management system is composed of a QM, procedures, annexes, forms, instructions and records.



- 1) The Quality manual (QM) sets out the general dispositions for OLAS operation, the quality policy, legal and standards based foundations as well as the accreditation criteria.
- 2) The procedures is establish the operation of the accreditation process as well as the management of the assessors and experts.
- 3) The annexes establish some general and technical dispositions.
- 4) The forms are used to record OLAS's activities.
- 5) The internal instructions contain practical information for the organisation of daily work.
- 6) The records are the result of the operations of OLAS and are detailed in annex A009 – *Control of records*

All documentation is accessible to OLAS staff on the its network. The latest version of the QM is available on the website of OLAS.

Documents, in French, English and German if needed, of the management system, that are in force, are saved on the server in directory "en vigueur". Outdated versions are kept in the directory "périmé".

Documents currently being amended are saved in the directory "projet" until final validation and then moved to the directory "en vigueur".



9.3. Document control

9.3.1. Purpose

The OLAS management system has the following objectives:

- Make updated documents available to interested parties,
- Remove all outdated versions of documents.

The quality manager is responsible for document control.

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9.3.2. Identification

The management system documents are labelled as follows:

- 1) By category:
 - QM = Quality manual
 - P = Procedure
 - A = Annex
 - F = Form
 - INT = Instruction
- 2) Three identification numbers (ex: P001, A006, F003A, INT001...), the QM is not marked with a number,
- 3) Date of application and signature of the document (ex: 16.12.2007),
- 4) Version (ex: Version 01),
- 5) Number of pages (ex: Page 12/28).

9.3.3. Verification and approval of new documents

Every staff member of OLAS may introduce modifications to any documents of the management system or introduce new documents. The quality manager is in charge of the final validation of every document and the updating of the documents. This assures the revision by a second person before publication of documents.

The proof of the verification and the approval is done by affixing of the signatures on the *F029 – Approbation des documents avant leur diffusion* form.

9.3.4. Amendments to documents

Amended documents are verified and approved in the same way as prior versions.

Obsolete documents are stored on the server in the directory “PERIME”.

Amendments made in the Quality manual are identified by adding document history sheet on the second page of the manual. The most recent changes to the manual are outlined, respectively crossed out.

The latest amendments in procedures and annexes appear on the first page of these documents and are underlined, respectively crossed out, in the documents themselves.

For reasons of readability modifications are not identified when a document is completely updated.

Modifications in forms are not identified.



9.3.5. Periodic revision of the quality management system

Each document of the quality management system is yearly reviewed (before the yearly internal audit). Document review is registered in appendix *A000 - Listing of OLAS management system documents*. This list includes all OLAS QMS documents, including *responsible persons for the periodic revision*, their latest versions and the date they were updated. The results of the review are presented during the management review.

9.3.6. Distribution

Management system documents are not distributed in their printed version. Each staff member using printed documents is responsible for using the current versions.

Documents are accessible via the OLAS website. Documents limited to internal use by OLAS personnel are available on the network.

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Any printed management system document is not considered as a current version of the document. On each document appears the phrase "Printed versions are not managed", or similar.

9.3.7. Management of documents originating outside of OLAS

The main external documents are:

- national and European legislation,
- international and European standards relating to accreditation,
- documents issued by EA, IAF and ILAC.

When a standard or an external document is mentioned in OLAS documentation it is assumed that the document is the current version.

The documents concerning international organizations are directly accessed on or printed from on the respective website. Someone who uses a printed document is responsible to check its validity.

OLAS monitors the national legislation related to accreditation by following publications in "Mémorial A". The result of this monitoring is published on the OLAS Internet site in order to assist assessors in identifying and downloading national legislation applicable to organisms they assess.

All the applicable documents, including the external documents (except national and European legislation), are recorded in the annex *A006 – Applicable standards and guides*.

9.3.8. Reference language and management of translations

OLAS drafts its documents in French and has the most important among them translated into English and German. Only documents drafted in French are binding.

9.4. Records control

Records are treated according to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

Given the size of OLAS all staff members have access to all records to guarantee the service continuity.

The access to OLAS offices is restricted to the staff of the administration having an entrance badge. Any person external to OLAS is accompanied while in the office. During nights the building is under the surveillance of a security service.

Only OLAS staff has access to the documents on the file server.



Documents related to CABs are kept in locked filing cabinets in OLAS office.

All the electronic files are transferred every day to the "Centre des Technologies de l'Information de l'État" which is responsible for the data backup.

The documents relating to CABs are stored for at least 10 years. The records concerning the management system documents are stored at least 5 years.

After the period of storage, documents may be destroyed by a company specialized in the destruction of documents or by using a paper shredder.

The details concerning the records control are available in the annex *A009 – Control of records*.

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9.4.1. IT infrastructure of OLAS

OLAS relies on an IT infrastructure which is managed by the CTIE (“Centre de technologie et d’informations de l’Etat”) which is the central IT management department of the government of Luxembourg. Most of the software, allowed to be run by state servants and state employees, is managed centrally by the CTIE.

On the premise, ILNAS has designated a civil servant responsible for the local distribution of hardware to all ILNAS collaborators. For special software needs, the same person is responsible at ILNAS. With this arrangement, OLAS has a guaranteed supply of all hardware that it needs for its daily business (computers, monitors, peripherals, ...), as well as all needed software.

The CTIE ensures that all records which OLAS produces are stored on central servers which are backed up regularly (scheduled twice daily, weekly and monthly). OLAS has access to all these backups via usual operating system tools (Windows 10 network volumes).

Every computer issued to an OLAS collaborator is fitted with an encrypted hard disk and can only be decrypted using a passphrase that is only known by the collaborator. When OLAS collaborators work from outside the office, they can only access documents stored on the central server via a VPN tunnel.

All file servers to which OLAS has access and uses for its daily work, are included in the general user and group policies enforced the administrator at ILNAS level. This ensures that only personnel with the correct access rights may read and write to the OLAS folders. As per general IT administration practice, administrators have access to some parts of the file servers, which they need to be able to fulfil their duties. As all personnel with such privileges are also civil servants, either from ILNAS or CTIE, OLAS does not identify any confidentiality risk regarding its administrators.

In order to educate the civil servants about IT security, the CTIE has published a Charta which everyone has to adhere to. This includes everything from the rights of the user to his duties when using material which was made available to him by the CTIE. This reduces the risk of errors and manipulations during the daily work of OLAS.

9.5. Nonconformities and corrective actions

The management of non-conformities and corrective actions is treated in the procedure *P005 – Continuous improvement*.

9.6. Improvement and derogations

The management of preventive actions and improvement are treated in the procedure *P005 - Continuous improvement*.

Management of derogations is treated in the procedure *P007 – Derogations*.

9.7. Internal audits



OLAS organizes internal audits to verify the implementation and efficiency of the management system and its continuous improvement.

All OLAS activities are audited at least once a year on the basis of standard ISO/IEC 17011.

The audit shall take into account the results of previous audits. After the audit, the internal auditor writes a report including his comments and all the finding identified during the audit.

The findings identified by the auditor are recorded on the form *F007 – Fiche MLP*.

Because OLAS is a small structure, internal audits are performed by external auditors.

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9.8. Management reviews

Yearly, the entire OLAS staff meets to conduct a management review of the operation and effectiveness of the management system. The chair and the vice-chair of the AC are invited to the management review.

The QMa draws up a preparatory document for this meeting distributed before the meeting to all the participants, that serves as support and in which are at least examined:

- Follow-up of actions of the previous management review,
- Results of internal audits and trends revealed by non-conformities,
- Complaints, appeals, objections, non-conformities and derogations,
- Implementation of the accreditation process,
- Results of peer evaluations, if appropriate,
- Information coming from interested third parties,
- Information on the development of accreditation activities,
- Periodical review of management system,
- Accreditation of notified bodies,
- Good laboratory practice,
- The national legislation,
- Impartiality analysis,
- Modifications which could affect the management system,
- Achievement of the training plan,
- Trainings of OLAS and their evaluation,
- The monitoring assessors and experts skills and their evaluation,
- Participation in international activities,
- The need in resources,
- Definition of a training plan,
- Definition of new objectives.

Minutes of the management review are drafted by the QMa and distributed to all staff.

The minutes include all enumerated topics in the preparatory document and all discussions and decisions during the management review.