QM
Quality manual
of the Luxembourg Office of Accreditation and Surveillance

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1. Purpose of the OLAS Quality manual

Purpose of the present document is to:

- state the remits set out by OLAS,
- describe its organization and its operation,
- visualize the quality system.

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

- to national and european legal arrangements,
- to requirements of the international standard ISO/IEC 17011 – General requirements for bodies providing assessment and accreditation, and to directives of the following organizations and to EA, IAF and ILAC guidelines.

The Quality manual and the associated procedures, appendixes 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 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.

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 that meet 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, fast, 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.

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 quality 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  
**EA:** European co-operation for Accreditation  
**IAF:** International Accreditation Forum  
**ILAC:** International Laboratory Accreditation Cooperation

4. Luxembourg Office of Accreditation and Surveillance

4.1 Legal personality of OLAS and its legal basis

OLAS is the sole accreditation body of CAB in Luxembourg. It is a department of ILNAS which is a governmental administration under the authority of the Minister of the Economy and Foreign Trade. The legal basis supporting the accreditation system is constituted by:

- The **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 Structure of OLAS

4.2.1 ILNAS organizational chart

4.2.2. Organizational chart of OLAS

OLAS

Administration

Committees

Auditors and experts

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The files and the job description of OLAS staff are described in appendix A018 – job descriptions. A nominative table makes the association between the table and the different jobs of OLAS. It is signed by all OLAS staff members.

To keep itself informed regarding accreditation, OLAS is participating to the EA, IAF and ILAC working groups.

4.2.3 OLAS administration remits

OLAS administration is in charge of the following remits:

- **CAB accreditation:**
  - OLAS day to day management and the management of accreditation files,
  - definition and updating of accreditation programmes,
  - relations with the accreditation committee and the ad hoc committees,
  - management of the national accreditation register and the national compendium of assessors,
  - external relations with the European and international accreditation bodies,
  - claims, complains and appeals,
  - management of the ISO/IEC 17011 quality management system.

- **Good Laboratory Practices (GLP):**
  - communication and coordination between the monitoring authorities as regards GLP,
  - organization of audits of GLP at national level,
  - representation of Luxemburg's interests in the competent international and European bodies concerned with the GLP.

- The evaluation and surveillance of notified CABs with respect to the Luxemburgish legislation transposing EU harmonization legislation.

4.2.4 The OLAS committees

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

- The Accreditation Committee, named hereafter « the AC »,
- The impartiality committee,
- The ad hoc committees.

4.2.4.1 The Accreditation Committee

The AC mission includes the following:

- 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 compendium 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.
4.2.4.2 Impartiality committee

The mission includes the following:

- 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 impartiality committee is made up of the following members in a balanced way and without predominance of interest:

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

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

4.2.4.3 Ad hoc committees

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

4.3 Impartiality

4.3.1 Objectivity

4.3.1.1 Accreditation programmes

The objectivity of accreditation programmes defined and updated by OLAS is preserved because they’re based on:

- national and European legislation,
- applicable European and international standards and other normative documents as regards accreditation, and
- any other document from European and international accreditation bodies.

4.3.1.2 OLAS staff

OLAS staffs\(^1\) with the statute of civil servant or public employee is not allowed, considering the Administrative code, to exercise any action or any activity that could jeopardize their independence and integrity.

The Administrative Code enforces the civil servant to respect the professional confidentiality concerning all the information that he could learn about within the limits of its functions\(^2\).

The remuneration of the staff is not depending on its grade and its step\(^3\).

4.3.1.3 Accreditation committee

The qualification of the AC members (see clause 6.3.5), and the guidelines to deliver an opinion defined within the procedure \textit{P003 – Decision making process}, allow to preserve the objectivity of the OLAS accreditation decisions.

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.

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1 General Statute of the civil servant, Art. 9 and following; Administrative code 2000
2 General statute of the civil servant, Art. 11 and following; Administrative code 2000
3 General statute of the civil servant, Art. 20 and following – treatment of the functionary; Administrative code 2000
4.3.1.4 Impartiality committee

The balanced representation without any predominance of interest within the impartiality committee (see clause 4.2.4.1), is likely to preserve the impartiality of principles and policies related to the functioning of the OLAS accreditation system.

4.3.1.5 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 appendix I in the mission statement reminds to the assessors the code of ethics. The appendix shall be signed by the assessors 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.

4.3.2 Representativeness of interested parties

The impartiality committee is the committee which represents all the interested parties in an equilibrated manner (see clause 4.2.4.2).

4.3.3 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.

4.3.4 OLAS Independence

As shown by the organizational chart of ILNAS (cf. clause 4.2.1), OLAS is a department operating independently from the other departments. It has its proper management system based on the standard ISO/IEC 17011, its own staff, its own logo and it supervises its own expenses and incomes.

Apart from the general information concerning accreditation, the criteria and procedures concerning the accreditation system, OLAS prohibits itself to give consultancy and to offer assessment conformity services.

4.3.5 Related bodies

In order to verify that the accreditation system of OLAS functions confidentially, objectively and impartially in relation to its related bodies, a review was carried out.

There are four types of related body to consider:

- Private related bodies;
- The accredited CABs represented in the AC and in the impartiality committee;
- Related bodies that are part of the government;
- Related bodies of ILNAS.

1/ The analysis shows there is no private related body that is linked by common ownership or contractual arrangements to OLAS.

2/ The participation of accredited CABs representatives to the accreditation committee was analysed to ensure they respect the principles of impartiality an confidentiality necessary to the decision making process.
The analysis shows, despite the signature of the ethical and deontological code, the participation of these representatives is a potential risk for confidentiality and impartiality in the decision making process for the following reasons:

- The presence to the AC of concurrent accredited CABs or managing contractual relationships, could affect the objectivity of their decisions, one to another;
- A CAB representative in the AC could block the accreditation of a competitor which is not represented in the AC;
- The dissemination of the accreditation reports to the CABs representatives is a risk for the confidentiality of sensitive information.

The analysis of these different situations shows that only the two last items need the implementation of a process to reinforce the confidentiality and impartiality aspects linked to the decision making process.

Before accreditation, every new candidate to an accreditation, OLAS will insure that:

- The CABs representatives in the AC have to be accepted by the candidates to an accreditation;
- The dissemination of their assessment reports to the CABs representatives has to be authorized by the candidates to an accreditation.

These two conditions have been verified and validated for all the customers already accredited and the candidates already identified.

To avoid problems in the future, as far as possible, OLAS will ask to professional associations representing relevant fields to ensure the legitimacy of the CAB representatives.

3/ Each CAB being part of the government is considered as related body. The related CAB don’t compromise the confidentiality, the objectivity and impartiality of the accreditation activities of OLAS, due to the fact that they have different directorates, different personnel, names, logos and symbols distinctively different and that they are under the guardianship of other ministries.

The impartiality committee, in which all the parties are represented, guarantees that the related CABs have no advantage comparing to the other organizations candidates to an accreditation.

The CAB related to ILNAS must be accredited by an accreditation body signatory to the mutual recognition agreements of EA.

4/ The other departments of ILNAS, as the department of standardization and digital trust and the department of market surveillance and legal metrology, are also considered as related bodies concerning the requirement 4.3.7 – note 2 of the standard ISO/IEC 17011.

However, according to the law of the 4th July 2014 on the reorganisation of ILNAS, the administration has clearly identified departments whose tasks are defined in the corresponding articles. In addition, each of the ILNAS’s departments is managed by different heads of departments.

With this new version of the law, OLAS is clearly identified as the national accreditation body of CAB. In this respect, OLAS is responsible for its own accreditation decisions and the intervention of the ILNAS director is no longer necessary.

Under these conditions, the activities carried out by other departments, such as legal metrology, regarded as CAB due to its regulatory inspection activities, can no longer compromise the impartiality and independence of accreditation decisions taken by OLAS.

OLAS also has its own staffs, which is not involved in the operation of another department of the administration. He supervises the budget articles that cover its activities, such as for the payment of auditors.

OLAS has its own management system based on ISO / IEC 17011 and it also has its own logo which uniquely identifies vis-à-vis the outside world.
4.3.6 Accreditation decision

In accordance to the paragraph 2, article 5 of the law of the 4th July 2014 OLAS takes its decisions concerning accreditation based on the opinion of the AC. The details of the decisional process are developed in the procedure P003 – Decision-making process.

The decision is formalized by filling up form F035 – Décisions relatives à l’accréditation.

4.4 Arrangements concerning confidentiality

4.4.1 OLAS staff

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

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

The auxiliary persons are bound by a contract to the State that contains dispositions concerning obligations and confidentiality.

The auxiliary staff signs a code of ethics F019 – Code of ethics and deontology for the auxiliary staff of OLAS.

4.4.2 Accreditation committee and the impartiality committee

The members of the AC the members of the impartiality committee, the experts and persons eventually consulted are obliged to the strictest confidentiality about the facts and documents that they have come to know about by the occasion of the instruction of the file. The members of the AC must sign a professional code F020 – Code of ethics and deontology for the members of the AC.

4.4.3 Assessors and experts

The quality and technical assessors, as well as the experts sign the Professional ethics associated to the forms F002A – and F002B – “Application for technical assessors”, that specify the rules in vigour concerning the respect of confidentiality.

The principles of impartiality and independence are reminded to the assessors in the appendix I of the mission statement that they must sign before each mission.

4.5 Legal responsibility and financing of accreditation

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.

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 draws up on an annually basis his budgetary proposals in order to the operation of the accreditation and forwards them to the Budget and Administration Department. 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.

4.6 Accreditation activity

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:
  - management systems according to the standards ISO/IEC 17021 and ISO/IEC 17021-1,
  - of products according to the standards ISO/IEC 17065,
  - of service providers for digitization and electronic archiving according to standards ISO/IEC 17021-1 and ISO 27006,

Due to a lack of internal competences, OLAS doesn’t provide accreditation to CABs working in the railway domain. Upon receipt if such application, OLAS will contact an European accreditation body signatory of the mutual recognition agreement.

All the applicable documents for the CAB accreditation are identified in the appendix A006 – Applicable standards and guides.

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

If no delay for the application of a standard (technical or other) is prescribed by OLAS, the delay is one year starting from the publication date.
The accreditation candidates shall conform to the legislation into force, especially concerning the right of establishment.

4.6.2 Guides concerning accreditation

OLAS publishes guides concerning accreditation called appendixes:

- A002 - Rights and Responsibilities of Accredited bodies,
- A003 – Guide for the use of the OLAS logo,
- 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,
- A019 – Legislation concerning notification of CABs,
- A022 - Medical laboratories – presentation of the national legislation

4.6.3 Extension of scope of OLAS activities

Increasing the scope of OLAS’ activities may not be accomplished by other than amendments to current laws and their corresponding Grand Ducal regulation orders.

4.6.4 Extension to new activities of accreditation

Each application leading to an extension to new activities of accreditation of OLAS is subject to a preliminary analysis and a preliminary information research. By “new activities”, OLAS refers to:

- A new standard;
- A new version of a standard;
- One or more new technical disciplines;
- One or more new sub-disciplines.

4.6.4.1 Documentation:

Before any extension to new activity of accreditation, the case manager makes sure to have all relevant documents (standards, guidelines EA, ILAC, IAF) or published from other accreditation bodies to cover as much as possible its needs.

OLAS adapts also its documentary system (Quality manual, procedures, appendices, instructions and formularies) to the new activity.

The AC must be informed of this expansion to a new activity.

4.6.4.2 Assessors and experts:

If OLAS isn’t disposing of the necessary assessors and experts for the extension to a new activity of accreditation, it has recourse to the quality and technical assessors or experts inscribed at other accreditation bodies signatories of the mutual recognition agreements.
To find a quality or technical assessor or an expert, the case manager sends to the accreditation bodies:

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

After reception of the name(s) of the assessors or experts replying to the research criteria, OLAS contacts them to ask their agreement in principle to participate to an accreditation assessment for OLAS.

In case of agreement, the assessor or expert receives all the necessary information concerning the registration to the National register of quality and technical assessors. This inscription is made in conformity with the procedure P004 – Assessors qualifications and monitoring assessor competence.

OLAS communicates also all the necessary information concerning the functioning of its accreditation process. All the documentation is available on the Internet site www.portail-qualite.lu

4.6.4.3 Records:

All the pertinent information exchanged with the organizations and assessors or experts (post, e-mail, phone calls) concerning each research is kept in the file of the concerned customer.

4.6.4.4 Trainings:

If the extension to new activities makes new requirements necessary (standards, applicable guides) OLAS organizes the training of its personnel and of the members of the AC.

4.6.4.5 Review of an application for extension to a new activity

Any accreditation to a new standard or extension to new disciplines or sub-techniques must be submitted via an application form F001A, F001B and F001C. Each application is reviewed by the case manager to verify that:

- the application form is complete;
- form F001D – Declaration for conformity assessment is signed;
- the CAB submitted to the OLAS the latest version of its quality manual;
- the CAB submitted to OLAS certificate(s) of accreditation and scope(s) of accreditation of any other accreditation body, if applicable;
- The CAB submitted to OLAS other additional documents authorization(s) to exercise, etc., if applicable;
- For any medical, testing or calibration laboratories, the form F023 – Interlaboratory comparison program was submitted to OLAS;
- the quality manual is consistent to the given referential;
- the initial assessment or the extension assessment can be achieved within the time requested by the applicant OEC.

The accreditation manager verifies that the draft of the scope of accreditation is properly completed, clearly defined and signed.

4.6.4.6 Organization of first evaluations:

In case of extension to a new standard or a new version of a standard, an observer of OLAS accompanies the first assessment to monitor its correct operation activity to convince himself of the correct development.
4.6.4.7 Verification of smooth functioning:

OLAS proceeds to a formal verification of the good functioning of extensions to new standards or new versions of a standard during a management review. If problems are discovered during the first evaluations, OLAS makes the necessary adjustments.

The F004A – Check-list: Review of an accreditation application enables to follow up the completeness of the information necessary to the extension of the accreditation activities of OLAS for a new activity of accreditation.

4.6.5 Extension to new sector schemes

OLAS can accredit new sector schemes for certification on demand of its clients as far as these schemes are conforming to the regulation.

Currently OLAS accredits certain of its certification bodies following the standards OHSAS 18001 for the management systems for health and security of work, ISO 14001 for certification of environmental management systems and ISO/IEC 13485 for the management systems for medical devices.

The extension to new schemes of certification is made following the same procedure as planned at the § 4.6.4 concerning the extension to new standards or new versions of a standard.
5. Management

5.1 General arrangements

In order to succeed its missions as defined in the law of the 4th July 2014, OLAS has built up a management system conforming to the standard ISO/IEC 17011:2004.

5.2 The quality system of OLAS

OLAS management system is composed by documents that allow to organize and to operate CAB’s accreditation. This « documentary system » is composed of a QM, of procedures, of appendixes and forms, designed to its needs.

1) Quality manual (QM) sets out the general arrangements for OLAS operation, the quality policy, legal and standards based foundations as well as the accreditation criteria.

2) Principle purpose of the procedures is to establish the operation of the accreditation process as well as the management of the assessors and experts.

3) Appendixes fix some general and technical arrangements.

4) Forms are used to record OLAS activities.

5) Internal instructions with practical information for the organisation of daily work.

6) Records are a result of the operations of OLAS and are detailed in Appendix A009 – Control of records.

Valid documents (French and English) of the quality management system 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”.

The updated version of this document is available on www.portail-qualite.lu.

The printed versions are not managed.
5.3 Document management

5.3.1 Purpose

The OLAS document management system achieves the following objectives:

- Make updated documents available to interested persons,
- Remove all outdated versions of documents from circulation.

The QMa is responsible for document management.

5.3.2 Identification

The quality system documents are identified as follows:

1) By document system category:
   - QM = Quality manual
   - P = Procedure
   - A = Appendix
   - F = Form
   - INT = Instruction

2) Three identification numbers (ex: P001, A006, F003A, INT001…), no identification number is marked upon the QM,
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).

5.3.3 Verification and approval of new documents

As the head of department is also the quality manager, the new documents are verified by another member of OLAS staff in order to have a second point of view on the document. The final approval of the new documents is done by the QMa.

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

5.3.4 Amendments to documents

Amended documents are verified and approved in the same manner as the 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 the procedures and appendices appear on the flyleaf 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.

5.3.5 Periodic revision of the quality management system

Each document of the quality management system is yearly reviewed. A proof of this review is kept by the QM. The results of the review are presented during the management review.
5.3.6 Distribution

Quality system documents aren’t distributed neither in internal, nor in external, in their printed version. Each staff member using working documents is responsible for checking updated versions.

The consultation of the quality system documents can be done by Internet. The update of the documents available on the Internet website is managed by the QMa. Documents limited to use by OLAS personnel are available on the server.

Any printed quality system document is not considered as updated document. On each document appears the sentence “Printed versions are not managed”.

5.3.7 Management of documents originating outside of OLAS

The main external documents are the following:

- 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 printed from the Internet site. Each person who uses a printed working document is responsible to control its validity.

OLAS does monitoring of the national legislation relating to accreditation by following publications in “Mémorial A”. The result of this monitoring is published on the OLAS Internet site in order to assist auditors 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 appendix A006 – Applicable standards and guides.

5.3.8 Reference language and management of translations

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

Only the QMa verifies documents translated into English.

5.3.9 Modifications of requirements concerning accreditation

Before modifying accreditation requirements, OLAS informs the laboratories and accredited organizations, the members of the AC, the quality and technical assessors as well as the experts, in order to take into account the expressed opinions.

The application delays of modifications are fixed case by case.

5.4 Control of records and archives

Records are treated according to the law dated August, 2nd 2002 concerning the protection of persons with regard to the processing of personal data.

With regards to the size of OLAS all the staff members have access to all the records to guarantee the permanence of the service.

The access to OLAS offices is restricted to the staff of the administration having a badge. Any person external to OLAS is accompanied while in the office. During the night the building is under the surveillance of a company specialized in security.

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

The updated version of this document is available on www.portail-qualite.lu.

The printed versions are not managed.
Documents concerning CABs are kept locked in 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 quality system documents are stored at least 5 years.
After the period of storage, documents are destroyed by a company specialized in the destruction of documents or by using a paper shredder.
The details concerning the control of records are available in the appendix A009 – Control of records.

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

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

5.7 Internal audits
OLAS organizes internal audits to verify the implementation and efficiency of the quality system and its continuous improvement.
All OLAS activities are audited at least once a year on the basis of standard ISO/IEC 17011.
Because of its size and because OLAS internal audits are performed on each point of the standard, an audit programme is not necessary. 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 – Improvement report.
Because OLAS is a small structure, internal audits are performed by external auditors.

5.8 Management review
Yearly, the entire OLAS staff meets to conduct a management review of the functioning and effectiveness of the quality 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 to this review and in which are at least examined:

- Follow-up actions of the previous assessment,
- Complaints, appeals, objections, non-conformities and derogations,
- Results of internal audits and trends revealed by non-conformities,
- Results of peer evaluations, if appropriate,
- Information coming from interested third parties,
- Periodical review of management quality system,
- Implementation of the accreditation process,
- Modifications which could affect the management system,
- Achievement status for policies and objectives,
- Achievement status for quality objectives,
- The achievement of the training plan,
- Trainings of OLAS and their evaluation,
• The follow-up of quality and technical auditors and experts skills,
• The evaluation of quality and technical auditors and experts,
• The needs in resources,
• Participation in international activities.

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

Minutes include the following:

• An action plan containing among others preventive and improvement actions of the management system and its processes to implement and the services and the processes of accreditation conforming to the appropriated standards and the expectation of interested third parties,
• A quality plan,
• Definition of needs in resources including auditors,
• Definition or redefinition of policies and measurable objectives,
• If appropriate, an action plan on training.

5.9 Objections and complaints

Management of objections and complaints is treated in the procedure P006 – Management of objections and complaints.

5.10 Derogations

Management of derogation is treated in the procedure P007 – Derogations.

6. Human resources

6.1 Staff working for the accreditation body

6.1.1 OLAS Staff management

OLAS staff qualification criteria as well as the description of tasks performed are detailed in the appendix A018 – job description.

6.1.2 Staff recruitment

Public staff recruitment is operated according to the procedure of the Recruitment Service of the Ministry of the Civil Service and of the Administrative Reform. It is based upon the volume 3 of the Administrative Code.

6.1.3 Assessors and experts management

OLAS selects assessors and experts to ensure the accreditation assessments of the CABs.

The inscription criteria of the assessors and experts to the “National Register of Quality and Technical Assessors” and the follow-up of their competences are detailed in the procedure P004 – Assessor and technical expert’s qualification and monitoring assessors and technical experts competence.

To proceed to the inscription of assessors and experts OLAS uses the following forms:

• F002A – Application for quality assessors
• F002B – Application for technical assessors
• F028 – List of audits realised during the last 3 years

These forms F002A and F002B contain professional ethics, signed by the assessors and experts that specify engagements to respect in the frame of accreditation activities.
The form F026 – *Qualification of assessors and experts application* allows to check that the information transmitted by the assessors and the experts is complete.

The “National Register of Quality and Technical Assessors” is published on the Internet site of OLAS.

### 6.2 Staff involved in the accreditation process

#### 6.2.1 OLAS Staff

The qualification, the initial education and ongoing training required for each OLAS staff member is specified in the appendix A018 – *job description*.

#### 6.2.2 The assessors and experts

OLAS qualifies its assessors and experts based on criteria like the initial education and ongoing training, the professional qualification, the experience in the practice of accreditation assessments, the knowledge of accreditation standard as well as knowledge and specialized experience in one of specific conformity assessment activities covered by accreditation.

To validate the initial education of its assessors and experts, OLAS calls in ad hoc committees to verify these criteria.

The detail of the selection, training, formal approval and the follow-up of the assessors and experts are defined in the procedure P004 – *assessor qualification and monitoring assessor competence*.

### 6.3 Follow-up of performances and competences

#### 6.3.1 Ongoing qualification of OLAS personnel

Each civil servant, prior to his employment, has to follow a traineeship and has to participate to trainings and succeed exams according to the law dated April, 16th 1979 fixing the General Statute of the State civil servants as modified as well as the implementing regulation.

To be promoted the civil servant and the public employee have to participate to a training cycle according to the law dated March, 28th 1986 harmonizing the conditions and procedures for promotion in the different careers of the State administrations and services and the implementing regulations.

Each year, the head of department define, in collaboration with the staff, a training plan to improve the ability of the staff to fulfill the OLAS missions. The training plan is put together with the plan of the other departments in the document: ILNAS training plan.

In case of a long absence (duration over 3 months) of an OLAS staff member, a training on the quality system is operated when he returns to update his knowledge.

#### 6.3.2 Training of the new OLAS staff to the accreditation system

The training of the new staff is done under the supervision of the head of department and is about at least:

- Introduction to the quality management system,
- Study of procedures, appendixes and forms,
- Study of the standard ISO/IEC 17011,
- Study of the different phases of an accreditation file,
- Quality assessor training on an accreditation standard (non applicable criteria for the person responsible for invoicing and the secretary),
- Participation to at least one AC.
6.3.3 Individual and annual discussion of the OLAS personnel

Once a year, an interview of each OLAS staff is organized. The ILNAS director is in charge of the interview of the head of department. The other OLAS staff is interviewed by the head of department. The objective of the interview of staff is to:

- Encourage the exchange between the staff and their immediate superior,
- Clarify the responsibilities,
- Motivate the staff to pursue their professional commitment,
- Lead a dialogue about needs pointed out concerning training and/or tools,
- Discuss about the expectations of the staff concerning the professional evolution,
- Evaluate the competences and the performances of the staff and to make a report about the work of the previous year.

To carry out this interview OLAS uses the questionnaire put at the disposal by the Ministry of the Civil Service and the Administrative Reform.

6.3.4 Follow-up of performances and competences of assessors and experts

The procedure P004 gives details about the monitoring performances of the assessors by the use of one of the following forms:

- F009 – Evaluating the assessment form
- F010 – Customer satisfaction with regard to the accreditation procedure
- F011A – Evaluating the services of a technical assessor or a junior quality assessor
- F011B – Evaluating the services of a quality assessor
- F011C – Evaluating the effectiveness of a quality and/or technical assessor
- F025 – Feedback to the assessors

Each year, OLAS communicates the result of his evaluations to each assessor and expert having participated to the assessments. In addition to that, the form “F025 – Feedback to the assessors” is sent to every participating assessor, in order to inform them about the CAs opinion and the appreciation of their reporting, so that they can take note of it and in order to improve

To follow up the competences concerning the functioning of its quality system, OLAS sends every year a 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 the assessors and experts.

In order to train its new assessors and experts to the operation of its quality 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.

6.3.5 Procedure of qualification, follow-up of qualification and evaluation of competences of the AC members

Evaluation of competences is based on a table showing competence criteria. A scoring grid takes into account the obsolescence of knowledge with number of cases a digressive rating. The table of competences is reviewed at least once a year by the members and the secretary.

6.3.5.1 Qualification of a new AC member:

To be considered as a member, the candidate must reply to the following qualification criteria:

- A diploma awarded by an establishment of higher education of at least 3 years and 5 years of professional experience in at least one of the areas covered by accreditation or a professional experience of at least 10 years in one of the areas covered by accreditation,
- General training on at least one accreditation standard,
Training on the OLAS quality system,
To be representative of one of the three groups represented in the AC,

The competences of the AC members are evaluated using the form F034 – Evaluation of the competences of candidate members at the Accreditation Committee. The AC is responsible of the validation of the qualification of its members.

If the candidate fits to all the qualification criteria enounced before then he can benefit of a right to vote starting with his first participation to the AC.

If the candidate doesn’t dispose of training to an accreditation standard and/or training to the OLAS quality system he disposes of a period of a maximum one year to acquire the necessary trainings. After the period of one year, the AC evaluates the file of the candidate to ensure that all the criteria are respected.

If the evaluation of the criteria is positive, the candidate is nominated definitively by OLAS with full rights.

If the criteria aren’t fulfilled by the candidate he isn’t retained. OLAS notifies his refusal concerning the nomination of a candidate.

6.3.5.2 Follow-up of the qualification of an AC member:

In order to ensure itself of the maintaining of the competences of the AC, the members must reply to the following qualification criteria:

- Follow, each year, at least a continuous training proposed by OLAS or a recognized training organization, about the accreditation standards and/or the evolution of the quality system,
- Participate to at least 50% of the annual Accreditation Committees (except acceptable justification),
- To send to OLAS the yearly update of the curriculum vitae and the external training certificates if necessary.

In case of non respect of these criteria the AC can organize a meeting of consultation in order to define on case by case about the action to be taken.

6.3.5.3 Evaluation of competences of Committee members:

The evaluation of competences of the AC members is dealt by the internal rules of the AC. A table and a rating scale allowing the monitoring of the competences of the AC members based on objective criteria.

6.4 Records concerning personnel

6.4.1 Files of the OLAS personnel

According to the grand-ducal regulation dated April, 13th 1984 defining the documents included in the personnel file it exists, for each civil servant and public employee, a personal file including all the documents for administrative use or from administrative origin and the staff and the documents related to the personal and professional situation as well as those concerning his career.

The file of OLAS 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 public employee a file is constituted at the Ministry of Civil Service and of Administrative Reform with all the necessary documents to the calculation and to the establishment of salary and pension of the civil servant.
OLAS is managing the job description of its staff describing the responsibilities, the authorities, the hierarchic links and the minimum criteria for training. The job description is put together with the other department sheets in the document: Job description.

A nominative chart links together the staff and the different jobs of OLAS. It is signed by all the OLAS staff.

**6.4.2 File of the assessors and experts**

OLAS updates its assessors and experts the files in printed version. Regularly information concerning the new assessments performed or a modification of professional activity is requested to the assessors and experts.

All this information is also available in software used as a tool for the selection of the assessment teams.

These data are safeguarded every day following the procedure documented in the clause 5.4 of this QM. The data are treated according to the law dated August, 2nd 2002 concerning the protection of persons with regard to the processing of personal data.

**7. Accreditation process**

**7.1 Criteria and information**

As explained in the chapter 4.6.1, accreditation of CABs is awarded in application of standards or other national, European or international standards concerning accreditation or each other document from international and European bodies and organizations active in the area of accreditation. These documents are indicated in the appendix A006 – Applicable standards and guides.

All the updated documents of the OLAS quality system can be accessed from the Internet site of OLAS under the heading “accreditation documents”.

**7.2 Processing applications for accreditation**

The processing of accreditation applications of CABs is documented in the procedure P001 – Processing Applications to grant, extend, renew, reduce, suspend and retire accreditation.

The necessary information for a CAB registration is available 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** – Obligation 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 appendix A004 – Scope of accreditation and traceability to international standards 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 the information given 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.
7.3 Review of resources

Before the registration of a CAB, OLAS reviews its resources to ensure that the policy, the procedures and the necessary competences to succeed its accreditation mission are available. The result of the review is reported in the form F004A – Check-list – Review of an accreditation application.

7.4 Subcontracting accreditation activities

OLAS doesn’t sub-contract any activities related to accreditation, except in the frame of international activities as detailed in the appendix A014 – cross frontier accreditation.

Using external assessors and experts is not considered as subcontracting.

7.5 Preparation of the accreditation assessment

In case of need OLAS can make preliminary visits to the initial granting assessment of an accreditation for example if comprehension problems remain concerning the definition of the assessment program or of the accreditation scope.

The detail of the preparation of the accreditation assessment is documented in the procedure P002 – Performing assessments.

7.6 Documents review and records

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 writing up by the lead assessor using the form F003N – Review of documents prior to the granting assessment.

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

7.7 Performing assessments

CABs assessments are performed as documented in the procedure P002.

7.8 Analysis of findings and assessment report

The assessment team realizes an analysis of findings revealed during the assessment of the CAB conforming to the procedure P002 – Performing assessments.

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

- F003A ISO17025-17020-17065 report
- F003B ISO15189 report
- F003C ISO17021-1 report
- F003D ISO17021-1-17065 report
- F003F ISO17025-ISO 15189 report
- Form F017 Summary sheet of all criteria verified during the assessment

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

The form F003M – Follow-up of accreditation assessments filled out by the lead assessor 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 him also to propose to OLAS the points of the standard or the technical areas to control in priority during the next assessments.

The form F003N – Document review before initial assessment, filled in by the lead assessor, help him to write a structured report in case of identification of major non-conformities during the documentary review, for an initial assessment.

Before its sending to the Accreditation Committee, the assessment report is checked in full by the case manager using the form F004B – Check-list : Review of the assessment report ISO 17025-17020-17065 ; F004C – Check-list : Review of the assessment report ISO 15189 ; F004D – Check-list : Review of the assessment report ISO 17021-1 ; F004E – Check-list : Review of the assessment report ISO 17021-1-17065.

7.9 Decisional process and granting of accreditation

The decision making process regarding the granting of CABs accreditation is documented in the procedure P003 – Decision making process.

7.10 Appeals and legal remedies

Request expressed by a CAB in order to reconsider any unfavourable decision taken by OLAS concerning an accreditation file or concerning a sanction taken against him.

The functioning of the process is described in detail in the P003 – Decision-making process.

7.11 Surveillance assessment and reassessment

7.11.1 CAB accreditation cycle

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.

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

The accreditation cycle is detailed in procedure P002 – Performing assessments.
7.11.2 Follow-up 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 areas) must be evaluated by an audit team at least one time. In order to guarantee the follow-up of the general areas of the evaluations OLAS uses the following form:

- *F021 – Follow-up of the accreditation scope.*

7.12 Extension assessments

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

7.13 Suspension, reduction or withdrawal of accreditation

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

7.14 Sanctions

The application of possible sanctions against the CAB is described in the procedure P003, in accordance with article 18 of the law of the 4th July 2014 concerning the reorganization of ILNAS and the IAF document MD 7: 2010.

7.15 Records concerning CABs

The details concerning the control of records are at the disposal in the appendix A009 – Control of documents.

7.15 Inter laboratory comparisons

OLAS has a policy of management of inter laboratory comparisons for the testing and calibration laboratories defined in the appendix A015 – Inter laboratory comparisons.

Form *F032 – Revue de la participation aux essais inter laboratoires*, is used to verify the effective participation of the laboratories, on the whole scope of accreditation and the complete cycle. It also allows giving & getting a feedback to the assessors with regard to OLAS, EA and ILAC requirements in this field of accreditation.

8. Relations between OLAS and the accredited CAB

8.1 Obligations of the CAB

The obligations of the CAB accredited by OLAS are formalized in the following document:

- *A002 – Rights and responsibilities of accredited laboratories and organizations.*

8.2 Obligations of OLAS

The obligations of OLAS are formalized in the following documents:

- *A002 – Rights and responsibilities of accredited laboratories and organizations.*

The updated version of this document is available on www.portail-qualite.lu.

The printed versions are not managed.
8.2.1 Publication of accredited bodies

The names, the addresses and the technical appendices of the accredited CAB are published on the Internet site of OLAS under the heading « National accreditation register ».

8.2.2 Cross frontier accreditation

EA, IAF and ILAC, define accreditation as a non-competitive activity between countries managing an accreditation system. Nevertheless OLAS can be obliged under certain conditions to accredit a CAB in a foreign country.

The appendix A014 – Cross frontier accreditation gives the requirements regarding the operation of cross frontier accreditation according to the guides IAF GD 3:2003 – IAF Guidance on Cross Frontier Accreditation et ILAC-G21:09/2012 – Cross Frontier Accreditation – Principles for Cooperation.

8.2.3 Use of EA, IAF and ILAC logos

OLAS is a signatory of the EA Multi-Lateral Agreement within the following areas:
- Testing, calibration and medical laboratories
- Inspection bodies
- Certification bodies for products and management systems

Through mutual recognition agreements between regions and international organizations, OLAS has also signed agreements on mutual recognition of ILAC and IAF for the same areas.

EA does not have a specific logo for its recognition.

If necessary, OLAS is authorized to use the IAF and ILAC logo in the domains it is signatory.

8.2.4 Notification of important modifications to EA, IAF and ILAC

In the case of modifications of its status or its scope of accreditation as well as changes of staff concerning key jobs, the quality manager of OLAS notifies this as soon as possible to EA, IAF and ILAC.

8.3 Use of OLAS logo

The use of the OLAS logo by the accredited CAB is defined in the appendix A003 – Guidelines for the use of the OLAS logo.