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P004

Authorizing of assessors and technical experts and monitoring of their competences and performances

Modifications: p. 12

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1. Definitions

Quality Assessor / Team leader (TL)

A person who is competent and experienced in the evaluation of a CAB in accordance with the accreditation standards, and more particularly, in the evaluation of the general organization. The quality assessor has to be authorized and registered in the “National Register of Quality and Technical Assessors” before acting for OLAS. The function of team leader is always given to a quality assessor.

Missions of the team leader:

- assists OLAS, if necessary, in the selection of the assessment team,
- draws up the assessment program,
- does the document review in the context of an initial assessment,
- coordinates the work of the team on site,
- supervises the assessment team,
- represents OLAS and the assessment team during the assessment,
- carries out the evaluation of the quality management system,
- takes all the decisions on the execution of the assessment,
- writes an assessment report covering the requirements for which he is responsible and coordinates the redaction and validation of the final assessment report.

If more teams are necessary to assess a CAB, each team is supervised by a team leader. To assure the coordination of the assessment, OLAS appoints one of the quality assessors to assure the function of the team leader.

Junior Quality Assessor

A quality assessor who does not have the practice of 4 assessment.

The junior quality assessor may be asked by the team leader to do a part of the quality assessment. OLAS do not charge the missions performed by the junior quality assessor to the CAB.

The junior quality auditor has to be authorized and registered in the "National Code of Quality and Technical Auditors" before acting for OLAS.

Technical Assessor

A person who is competent and experienced in one or more technical domains and the evaluation of CABs following accreditation and technical standards related to the concerned domain. He is appointed to perform technical assessments, accompanied by a team leader. If for organizational reasons, it is necessary (for example witnessing assessments of inspection, testing or certification organisms), the technical assessor will realize an assessment without a team leader.



The technical assessor has to be authorized and registered in the “National Register of Quality and Technical Assessors” before acting for OLAS.

Each technical assessor is responsible for writing the part of the assessment report that applies to him. The final assessment report remains however under the responsibility of the team leader.

Technical Expert

Person having professional expertise or specific knowledge to contribute to the evaluation of the technical conformity of a CAB in a specific domain.

Technical experts do not assess independently as they are not qualified as assessor and always work under the responsibility of the team leader or a technical assessor.

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The technical expert has to be authorized and registered in the « National Register of Quality and Technical Assessors » before acting for OLAS.

Ad-Hoc Committee

See definition in the chapter 5.5.3 of the quality manual.

National Register of Quality and Technical Assessors (Register)

The National Register of Quality and Technical Assessors is the list of quality, technical and junior assessors or technical experts recognized as competent and registered by OLAS to realize the accreditation assessments of CABs.

2. Qualification of assessors and experts

2.1. Competence criteria applicable to assessors and experts

2.1.1. Définitions¹

The ratings of evaluation of the OLAS evaluation forms (F009; F010; F011A, F011B) are defined below. In the case of a "fair" evaluation, it is recommended to provide explanatory information on the concerned criteria. In case of an "poor" evaluation, an additional explanation is required.

2.1.1.1. Excellent

Who "... possesses the maximum number of qualities required to correspond, almost perfectly, to the ideal representation of his nature, his function or to manifest a very clear superiority over other things or persons of the same type."

2.1.1.2. Good

Who "... responds positively to what is expected of it, in terms of its nature, function, effectiveness, etc.».

2.1.1.3. Fair

Who "...can pass.....; which, without being good, is acceptable, admissible..."

2.1.1.4. Poor



Who "...does not achieve the desired or necessary quantity or quality. Otherwise, deficient.....".

2.1.2. Assessors and experts already qualified by other ABs

OLAS recognises the qualification of assessors/experts issued by another accreditation body signatory of the multilateral agreement of EA (European co-operation for accreditation).

These assessors/experts are considered as compliant with the competence criteria below to be registered in the OLAS National Register of Quality and Technical Assessors (hereinafter referred to as "National Register").

¹ cnrtl.fr : Centre National de Ressources Textuelles et Lexicales

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2.1.3. Assessors and experts qualified by OLAS

With the exception of duly motivated derogations, OLAS applies the following criteria to qualify its assessors and experts:

Education

Assessors and experts must hold a diploma awarded by a higher education institution.

Equivalencies to the minimum educational requirements may be granted depending on the applicant's professional experience and its current and past positions.

Professional experience

Quality assessors must have at least 5 years of professional experience, including 2 years of activities related to quality management within the last 4 years prior to the application. A professional experience in the domain for which he is applying is considered an asset.

Technical assessors and **experts** must have at least 5 years of professional experience, including 2 years of relevant experience in the technical area for which they apply during the last 4 years prior to the application. Guidelines for the definition of "relevant professional experience" of technical assessors and experts is provided as an appendix to this document.

Assessment experience

Quality assessors must have participated in at least 4 accreditation assessments as a junior quality assessor before being formally qualified as a quality assessor. Quality assessors who are already qualified for one accreditation standard, do not have to perform a juniorat in order to be qualified for an additional standard. However, they are monitored and evaluated by an OLAS observer during their first assessment. If a technical assessor wants to become a quality assessor, the juniorat is reduced to 1 accreditation assessment.

Technical assessors have to have participated in at least 1 accreditation assessment in presence of the team leader, before being formally qualified as a technical assessor.

There is no minimum assessment experience required from **technical experts**.

Language proficiency

Assessors and experts have to be able to perform an assessment in one of the three official national languages (Luxembourgish, French and German) or in English.

Qualification of assessors/experts



To be registered in the OLAS National Register of Quality and Technical Assessors, assessors (quality and technical ones) must have followed a training which is equivalent to a training described in chapter 3.1 of the present procedure.

In contrast to the assessors, experts do not need a training for a specific accreditation standard to be registered in the National Register. Experts are qualified by OLAS based on their technical competencies.

3. Assessor and expert training

OLAS recognises assessor training organised by any other accreditation body signatory of EA multilateral agreement.

If possible, all trainings are conducted or organized in compliance with the ILAC guide *G3:08/2012 Guide – Guidelines for Training Courses for Assessors Used by Accreditation Bodies*.

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3.1. Initial training of assessors

Following its needs, OLAS can organize trainings on accreditation standards in order to qualify assessors for an accreditation standard. These trainings may be organized in collaboration with a training organization.

These trainings shall cover the following topics:

- The requirements of the specific accreditation standard,
- Assessment techniques,
- The baseline of standard ISO 19011,
- A final exam to control the acquired knowledge of the candidates.

Competence for an additional accreditation standard may be acquired through the participation in a training module of at least 2 days covering that standard.

The initial training of the quality assessor includes a juniorat, during which he can carry out part of the quality system audit under the responsibility of the team leader.

3.2. Evolution of a new version of a standard

If an assessor is already qualified for a standard, he can acquire competence for a new version of a standard by:

- Participation in a training or assessor harmonization meeting (organised by OLAS or any other EA signatory) or
- The preparation and conduct of training or
- Professional experience (e.g. assessments) or
- By self-study followed by a written test organized by OLAS.

3.3. Initial training of technical experts

Before mandating an expert for an assessment and in order to formally authorizing him to participate, OLAS asks him to get a copy of the concerned standard and sends him:

- Training exercises with regard to the related standard (e.g. presentations),
- A questionnaire related to the presentation,
- A direct link to the OLAS training exercises on findings, available on the OLAS homepage.

OLAS controls the result of exercises and tests, which are added to the applicant's individual file.

3.4. Training to the accreditation system of OLAS

OLAS organises trainings on its accreditation system for assessors and technical experts.

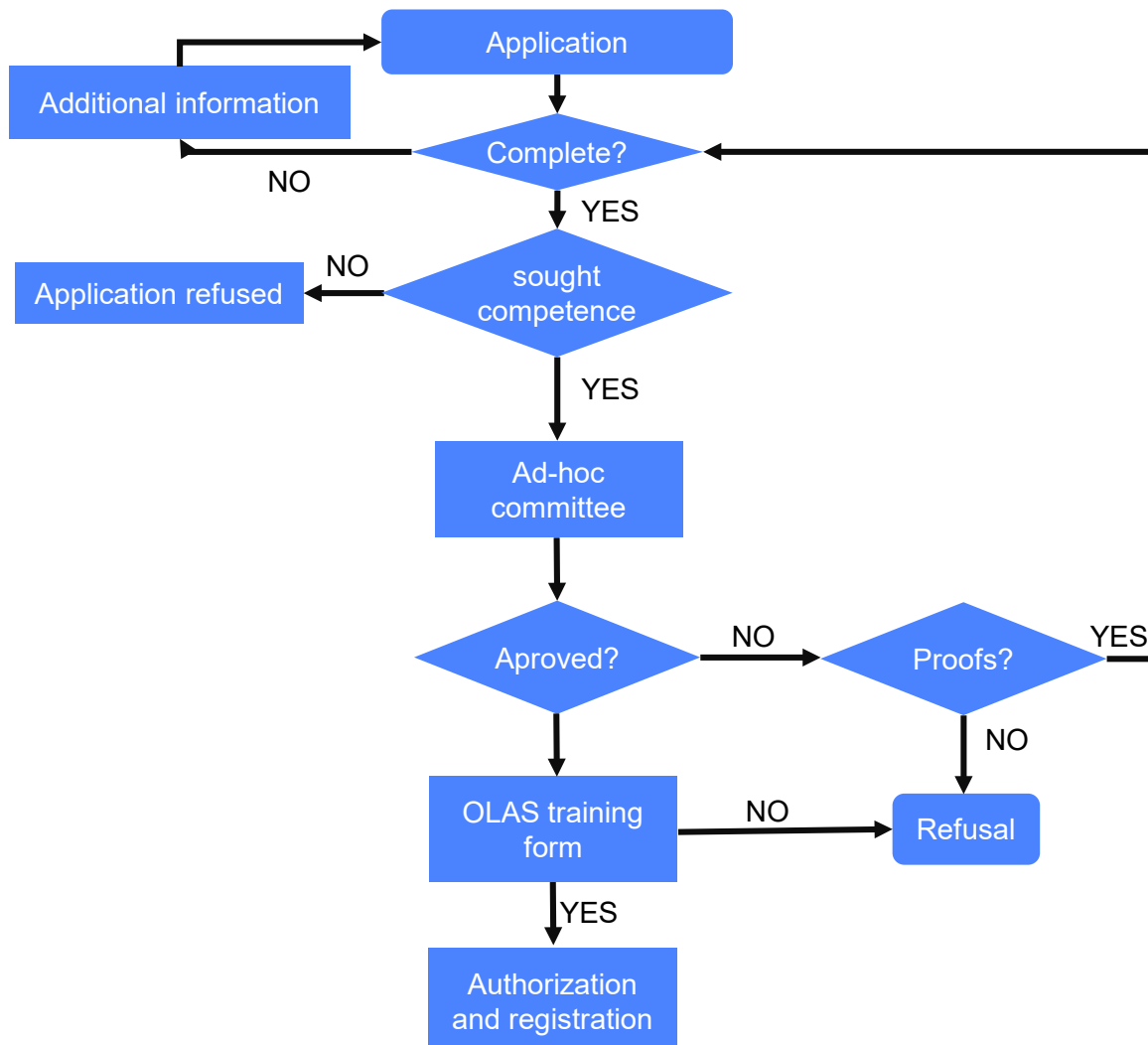
As part of the formal authorisation, each new assessor/expert is required to familiarize himself with the OLAS procedures and policies and to complete the OLAS form *F041 – Fragebogen für neue Begutachter und Sachverständige*. An individual correction, based on the form *F041A - Fragebogen für neue Begutachter und Sachverständige & Auswertung*, is transmitted to the assessor by OLAS before carrying out his first mission.



3.5. Continuous training

Ongoing training of assessors and experts is guaranteed through the following tools:

- Annual organization of a **Day of the Accreditation Community**, to ensure an update of the knowledge of the assessors and experts, among others. During this event, OLAS informs all participants of important changes to the OLAS accreditation system. OLAS publishes all documentation used during the event, to all persons who did not participate.
- **Systematic information** of assessors and experts in case of modification of accreditation requirements, in order to take into account their expressed opinions.
- **Information by the accreditation managers** during preparation of the assessments. Where relevant, the regulatory database and/or Annex A022 - *Medical Biology Laboratories - Presentation of National Legislation* are sent to the assessors as part of the preparation for their assessments.
- **Distribution of the newsletter “Auditor’s special” whenever necessary** containing information on modifications of the OLAS quality system, updates of forms, etc.
- **Distribution of annual questionnaires** on the OLAS system (*F043 - Questionnaire pour auditeurs et experts - formation continue*) and/or assessment situations. Every participant receives an individual result form based on the form *F043A – Fragebogen mit Antworten und Auswertung Fortbildung*.

4. Procedure for the authorization of assessors and experts



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Step 1. Verification of application for registration

OLAS verifies that the forms *F002A and/or B - Application for Quality and Technical Assessors* are correctly filled out.

If the application is incomplete, OLAS asks the applicant for additional information.

OLAS uses the forms *F026 – Qualification des auditeurs et des experts* and *F026A - Annexe pour la qualification des auditeurs et experts* to verify that the applicant fulfils the required competence criteria.

Step 2. qualification of assessors and experts

If the application is complete, it is transmitted to an ad hoc committee to get an opinion.

If the ad hoc committee gives a positive opinion on the file of an auditor/expert, in accordance with the competence criteria defined in chapter 2, OLAS continues the process of authorizing the auditor/expert for the identified domains.

If the ad hoc committee gives a negative opinion, OLAS may ask additional documents from the applicant to prove his competence, or refuses the application.

The ad hoc committee also validates correlation between qualifications by other accreditation bodies and the accreditation domains defined by OLAS (Annex A005).

Step 3. Authorization and registration in the National Register

Authorization also takes into account OLAS's needs for assessors in the respective domains.

The authorization of an auditor/expert is validated by successful completion of OLAS training form *F041 - Questionnaire for new auditors and experts*, on the functioning of OLAS.

When all criteria are met, OLAS updates the database of auditors and experts and sends a notification letter with the mention of their name: "quality auditor", "junior quality auditor", "technical auditor", "expert" or "trainer", the standard (s) and technical fields, if any, for which they are qualified.

As soon as they are registered in the National Register, the quality, technical auditors and expert qualified by another accreditation body member of EA are managed in the same way as auditors and experts qualified by OLAS.

5. Performance monitoring and evaluation of assessors and experts



The monitoring of assessor's and expert's performances is based on the following tools:

- Observation during the assessment,
- Review of assessment reports,
- Feedback from CABs,
- Feedback from personnel.

If an assessor or an expert is evaluated "insufficient" in one or several criteria of the evaluation forms (F009, F010, F011A, F011B, F011C), OLAS will consider that as a complaint against the assessor or the expert (cf. chapter 7 of the present procedure). If one or several criteria of the evaluation forms are evaluated "fair", OLAS will react according to the criticality of the concerned criteria.

5.1. Observation during the assessment

Technical assessors and experts, as well as junior quality assessors are observed during each assessment by the team leader. Thus they are observed on all accreditation schemes they assess.

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The results of each observation are recorded on the form *F011A - Evaluating the services of a technical assessor or junior quality assessor*.

If a technical assessor cannot be observed by a team leader as he systematically intervenes on his own, he is evaluated at least every three years by an OLAS observer.

Additionally, every newly registered assessor or expert is observed during one of his first assessments by an OLAS observer.

The results of the observation are recorded on the form *F011B - Fiche d'évaluation des prestations d'un auditeur ou expert par un observateur de l'OLAS*. Whenever possible, an "immediate" evaluation is communicated to the auditor at the end of the on-site observation (orally or by email within 5 working days of the concerned assessment).

Each team leader is observed by OLAS on-site at least once every three years. As the monitoring of assessors is performed, OLAS strives to cover all accreditation schemes for which the assessors carries out assessments. The results of each observation are recorded on the evaluating form of the assessor's performance by the OLAS observer *F011B – Fiche d'évaluation des prestations d'un auditeur ou expert par un observateur de l'OLAS*. On this occasion, the OLAS observer uses the opportunity to evaluate also the performances of technical assessors and experts, where possible.

When an assessor does not perform any assessment for a period of three years, it is not possible to evaluate the assessors performance on site. As soon as the assessor performs assessments for OLAS again, the monitoring program retakes.

5.2. Review of assessment reports

Assessments reports are evaluated using the following forms:

- *F004B – Check-list: Revue du rapport d'audit ISO 17025-17020-17065,*
- *F004C – Check-list: Revue du rapport d'audit ISO 15189,*
- *F004D – Check-list: Revue du rapport d'audit ISO 17021-1,*
- *F004E – Check-list: Revue du rapport d'audit ISO 17021-1-17065.*

In addition, the reports are evaluated by the accreditation committee using the form *F009 – Fiche d'appréciation du rapport d'audit par le CA*.

5.3. Feedback from CAB



After the decision with regard to accreditation, OLAS requests the form *F010 – Customer satisfaction with regard to the accreditation procedure* to be submitted by each CAB.

5.4. Feedback from personnel

If an on-site monitoring is not possible, OLAS evaluates the assessor's or expert's performance using the form *F011C – Fiche d'évaluation des performances d'un auditeur qualité et/ou technique*. This evaluation considers the participation in trainings, review of assessment reports and/or the results of the evaluation by CABs.

5.5. Notification of the evaluation results to the assessors and experts

Once a year, the results of their evaluations are sent to the assessors and experts having carried out assessments by OLAS.

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Nevertheless, in the case of a valid objection against an assessor or an expert following an assessment, OLAS applies the policy described in chapters 6 or 7 respectively.

6. Renewal of the registration in the Register

The registration of an assessor is valid for a period of 3 years. The registration process is described in chapter 3 of the present procedure. Only the initial validation of the qualification is ensured by an ad hoc committee. A registration is renewable.

The renewal of the registration of an assessor or an expert is managed by OLAS. OLAS contacts the assessor or the expert two months before the end of his registration to ensure to have all the documents proving the maintaining of the applicants competences. These documents include the form *F002A and/or B – application form*, an updated curriculum vitae, recent qualification or training certificates and a list of the assessments performed for another accreditation body signatory of the multilateral agreement of EA during the last 3 years (*F028 – List of assessments realised during the last 3 years*).

The competence criteria for a renewal are identical to the competence criteria. For an assessor or expert having realized assessments for OLAS during a period of 3 years, the case manager makes sure that, before his renewal, the result of the evaluation of his performances is positive. In general, absence of participation in ongoing trainings specified in chapter 2.2.2 can also justify a refusal of the renewal of the registration.

At the end of the registration period, OLAS alerts assessors and expert who have not submitted their documents. If no documents are sent to OLAS 2 months after the end of the validity, the head of OLAS department sends a notification of withdrawal and the quality manager withdraws the assessor or expert from the Register. The information recorded in the database is archived after the withdrawal of the assessor or the expert, by OLAS.

If, later on, the withdrawn/archived assessor or the expert wishes to register again in the Register, the registration is treated as an initial qualification.

7. Complaints against an assessor or an expert

In case of complaint against an assessor or an expert (a comment of a client on form *F010*, a letter of complaint or an insufficient evaluation on one of the OLAS forms), OLAS applies the procedure *P006 – Treatment of objections and complaints*.



The head of OLAS department can formulate a warning, remove the assessor or expert from the Register or decide to close the case.

8. Withdrawal of an assessor or an expert from the Register

OLAS can withdraw an assessor or an expert:

- following a complaint against the assessor or expert,
- if the assessor or expert does not wish to renew his registration in the Register or does not reply within 2 months following expiration of his registration.
- if the assessor or expert does not fulfil anymore the competence criteria defined in chapter 2,
- for not respecting the code of conduct.

The decision of withdrawal is taken by the head of OLAS department. The concerned assessor or expert is notified.



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The assessors or the experts can lodge an appeal against the decisions of OLAS to the accreditation committee or the administrative tribunal.

9. Internal auditor

OLAS has its internal audits carried out by external auditors. Contrary to the assessors used for the accreditation of CAB's, they may not be registered in the Register.

To perform an internal audit, they must prove their competence for the standard ISO/CEI 17011 either by having put it in place during the creation or the administration of other accreditation bodies, or because they are qualified as assessor in the framework of mutual recognition assessments for EA.

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Annexe – Guideline for the definition of « relevant professional experience »

For the definition of “relevant professional experience”, for the qualification of technical assessors and experts set out under chapter 2.1, OLAS uses the following non-exhaustive list.

1. Accreditation of laboratories

A relevant professional experience may be justified by experience in or knowledge acquired by:

- a laboratory or sectors of activity identical to those the technical assessor (or expert) will have to assess;
- general principles related to the management and techniques used in a laboratory;
- terminology as well as standards and regulations related to the domains concerned;
- general metrology principles, in particular those related to the domain to be assessed;
- more specific metrology knowledge, if a laboratory performs itself the calibration of its equipment.

For internal calibration (3rd route according to ILAC P10):

A relevant professional experience may be justified by:

- A proof of a training in metrology (certificate or program of the training) including the main units concerned by internal calibration in testing/medical laboratories (mass, volume, temperature, dimensional...);
- A proof of performing trainings in the domain of metrology;
- Knowledge of the principles of uncertainty calculation (GUM) and on International Vocabulary of Metrology (VIM);
- If applicable, personnel experience of management of metrological issues in a laboratory.

2. Accreditation of inspection bodies

A relevant professional experience may be justified by experience in or knowledge acquired by:



- inspection activities or in sectors of activity identical to those the technical assessor (or expert) will have to assess;
- technical characteristics of products, equipment, facilities or processes to be assessed;
- terminology as well as standards and regulations related to the domains concerned;
- general metrology principles, in particular those related to the domain to be assessed.

For internal calibration (3rd route according to ILAC P10):

The same competence requirements as for laboratories shall apply.

3. Accreditation of management system certification bodies

A certification assessor working for a management system certification body is not accepted as accreditation assessor / expert, except in some exceptional and motivated cases. In that situation, his activity as certification assessor will be mentioned in the notification to the organism that will be assessed.

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The qualification (registration, renewal of registration, etc.) of technical assessors with regard to their competences in technical domains SMQ1, SMQ4 and SMQ5 is performed according to the clusters defined in the documents IAF MD17:2015 (SMQ1 et SMQ4) and IAF MD22:2018 (SMQ5).

A technical assessor qualified for a critical domain of a cluster, may be qualified, after validation by the assessor himself, for all non-critical codes of the same cluster.

For the domain SMQ1 (Quality management systems):

Relevant professional experience, for the area of activity in question, is defined as experience and knowledge required dealing with:

- procedures, methods and technical characteristics of products;
- practices specific to the area of activity.

For the domain SMQ4 (Environmental management systems):

A relevant professional experience is defined as experience and knowledge required in the environmental sector (production, prevention, environmental manager, competent body) and dealing with:

- specific terminology;
- applicable environmental legislation;
- environmental aspects of products and their impact;
- critical environmental aspects related to processes and products;
- the most recent environmental technologies to prevent any pollution.

For the domain SMQ5 (Occupational health and safety management systems)

A relevant professional experience is defined as experience and knowledge required in the field of occupational health and safety and dealing with:

- the specific terminology;
- the applicable environmental legislation.



For the domain SMQ3 (Information security management systems (ISO 27001)):

According to document IAF MD13:2015, technical assessors and experts have to have the following knowledge and competencies:

- ISMS related terminology and principles including ISO/IEC 27000;
- understanding of assessment techniques included in ISO/IEC 27007 and ISO/IEC TR 27008;
- deeper level of knowledge of standard ISO/IEC 17021 and ISO/IEC 27006;
- deeper level of knowledge of standard ISO 27001;
- deeper level of knowledge of general legal and regulatory requirements related to ISMSs;
- generic ISMS related technology including:
 - information security technologies and practices,
 - information and communication technology,
 - risk assessment and risk management;
- CAB's client processes and operations associated with ISMS.

4. Accreditation of product and person certification bodies

A certification assessor working for a product or person certification body can be accepted as accreditation assessor / expert.

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Relevant professional experience is defined as experience and knowledge required to dealing with:

- procedures and technical characteristics of products;
- practices specific to the area of activity;
- standards applicable to the products and domains concerned;
- sampling, test and inspection methods within the context of product certifications;
- and/or issues related to the organisation of exams within the context of person certifications.