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A013 Accreditation of multi-site organizations

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South Lane Tower I 1, avenue du Swing L-4367 Belvaux Tel.: (+352) 247 743-60

Fax: (+352) 247 943-60 olas@ilnas.etat.lu www.portail-qualite.lu



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1. Introduction

This document describes OLAS's policies regarding the accreditation of conformity assessment bodies (CAB) which conduct conformity assessment activities on multiple locations.

The policies are applicable to all multi-site organisations which:

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- 1. Have their headquarters in the Grand-Duchy of Luxembourg,
- 2. Have their headquarters in the Grand-Duchy of Luxembourg and locations in an economy different from that of the Grand-Duchy of Luxembourg,
- 3. Have their headquarters in another country and locations in the Grand-Duchy of Luxembourg and/or in another economy.

In the last 2 cases, the annex A014 is applicable.

These policies concern already accredited CABs as well as applicants to an accreditation.

For medical biology laboratories, only technical platforms are considered as "sites" in the context of this document. The provisions relating to the assessment of sampling sites and sites carrying out point of care testing (POCT) are specified in annex *A022*.

2. Definitions

2.1. Multi-site organisation (=same organisation)

Legal entity or group of legal entities composed of headquarters and one or more locations legally linked to one another and operating under the same commercial name and logo.

Note: the names of the different legal entities might derive slightly, but they always have to include the commercial name of the organisation in one way or another (cf. EA-2/13 Annex §2.1).

2.2. Registered legal entity (= primary site)

Location of the multi-site organisation where the management (cf 2.4) of the conformity assessment body is located. This location is usually identical with the location of the headquarters.

2.3. Site (= location)

Location, legally linked to the registered legal entity where conformity assessment activities or support activities to the conformity assessment activities are conducted.

2.4. Same management (= management)

Person or group of people taking overall responsibility for all conformity assessment activities of the muti-site organisation.

2.5. Same management system

Set of linked rules and policies defined by the management to allow it to take responsibility for accredited activities.

2.6. Conformity assessment activities

Any accredited activity or activity applied for accreditation which leads to a statement of conformity with respect to a given reference document by establishing a report or certificate.

2.7. Supporting activity

Any support activity for a conformity assessment body activity according to IAF MD1.



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2.8. Alternative document

Document of a sub-set of documents of the same management system used by a CAB as an alternative to the higher-level document (e.g. translations of documents, ...).

3. Policies for the accreditation of a multi-site CAB

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3.1. Basic requirements

Every conformity assessment body conducting its conformity assessment activities or support activities in more than one location is considered as a multi-site CAB.

The following conditions need to be fulfilled to be eligible for an OLAS accreditation:

- 1. The management system of the CAB is managed centrally. It is defined, implemented and continuously monitored by the same management.
- 2. The same management is responsible for all issued reports and certificates.
- 3. The different sites do not offer conformity assessment activities under their own name.

OLAS will assess the fulfilment of these conditions based on the criteria given in Annex I.

The fulfilment of the conditions by the CAB is assessed by OLAS throughout the accreditation process, from the application to assessments.

3.2. Application for accreditation

When reviewing applications, OLAS checks if the body and all its sites covered by the scope of accreditation the CAB applied for are fulfilling the definitions and criteria given in this document. Therefore, the CAB needs to fill in the form F001E – Annex to an accreditation application of a multi-site organisation and enclose the following documents:

- Nominal organigram of the complete organisation
- Description of hierarchical links and reporting lines between all the sites
- Proof of legal links between the sites and the primary site
- Draft of the scope of accreditation where conformity assessment activities conducted by every site are indicated
- For initial assessments: reports of internal audits and management review covering all sites.

All activities by the different sites have to be clearly indicated in the form F001E and the scope of accreditation.

An accredited CAB may at all times apply for an extension of his accredited scope by another site. In this case, OLAS applies the policies from this document and of procedure P002 for the planification of the extension assessment.

3.3. Assessments of multi-site organisations

The following policies apply to multi-site CABs in addition to those in the procedure P002:

- For initial or renewal assessments, all sites included in the accreditation application will be assessed.
- For the extension by an additional site, the site in question is assessed mandatorily. An assessment of the primary site is done when necessary.
- During a complete assessment cycle, all sites are assessed at least once, when no other policy of P002 is applicable.
- The primary site is assessed at least every 2 years.
- The sampling of sites depends on:
 - The type of the site,
 - The previous assessment results,
 - The complexity of the accredited scope,



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- The geographical situation of the sites,
- The risk associated with the sites.

OLAS will include all sites being assessed in the cost estimate send to the CAB prior to the planned assessment.

This rule does not apply when the CAB performs activities in facilities made available by an external entity, under the cover of an agreement or a legally enforceable contract. Under these conditions, the following modalities shall be defined:

- Roles and responsibilities of each contracting part;
- Provision of equipment or facilities, their using conditions and their maintenance (including calibration);

The performed conformity assessment activities shall be mandatorily the same as the ones covered by the accreditation scope of the corresponding CAB.

4. Accreditation documents issued by OLAS

OLAS issues an accreditation certificate to the primary site including its name and address.

The scope of accreditation linked to the accreditation certificate lists all sites on the cover page or on a dedicated page.

The activities conducted on every site are clearly indicated in the scope of accreditation.



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Annex

Annex I Applicable criteria for multi-site CABs

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The following criteria are applicable to all multi-site CABs and are verified as needed when applying for accreditation (initial, renewal or extension) and during surveillance assessment.

I.1. Concerning the organisation of a multi-site CAB

The following criteria are verified:

- Existence of legal bindings between the primary site and all sites
- Registration of logos and marks for the economies included in the accreditation scope
- Marketing material
- Reports and certificates issued.

I.2. Concerning the same management

The following criteria are verified:

- Nominal organigrams of the organisation
- Hierarchical lines and links between sites
- Description of the responsibilities for the persons for:
 - Approbation of policies and instructions related to the conformity assessment activities,
 - o Approbation of personnel conducting conformity assessment activities,
 - Authorising certificates and reports,
 - Managing ressources,
- Evidence of monitoring all aspects of operation by the primary site of all other sites (internal audits are not sufficient evidence for taking responsibility for all activities)
- Evidence for efficient communication between sites

I.3. Concerning the same management system

The same management system needs to guarantee that all conformity assessment activities reach the identic results irrespective of the site. Therefore, all policies regarding the conformity assessment activities need to be the same throughout the body.

To provide consistency of the results:

- The management shall define alternative documents which may be used by the sites
- The management shall conduct internal audits covering all sites
- The management shall follow up on corrective actions
- During management review, the management system shall be reviewed completely.

The following criteria are verified:

- Description of the management system structure
- Approval rules for alternative documents
- The implementation of the policies on the different sites
- The management of the competence of personnel conducting conformity evaluation activities
- Reports, plans and follow-up of internal audits of the complete management system and all sites
- Reports, planification and follow up of management reviews covering the complete management system and all sites.

I.4. Concerning responsibility for accredited activities

The primary site, respectively the management, assumes responsibility of all activities of the CAB. To prove that the management assumes this responsibility for accredited activities, the



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CAB shall prove that the management has access to the technical competence and resources necessary to assure monitoring of the activities.

The management shall assume responsibility for:

- The used resources
- The implicated personnel
- The documents used
- The quality and consistency of results
- The preservation of impartiality and independence
- The contents of reports and certificates.

The CAB shall prove that management assumes responsibility for its activities:

- Towards customers
- Towards authorities
- Towards the public
- In court.

The following criteria are verified:

- Harmonisation of the conformity assessment activities through:
 - Use of equivalent documents
 - o Equivalent management of the personnel's competence
- Supervision of conformity assessment activities through:
 - Internal audits
 - Participation in proficiency testing schemes (where relevant)
 - Monitoring of accredited activities
 - Checking of reports and certificates
- Communication with authorities
- Management of complaints and appeals
- Management of impartiality
- Communication of media coverage (where relevant)
- Handling of legal cases.