Interpretation of Terminology used in clause 5.1 and Guidelines to Assessment Focus

PURPOSE

This supplement has been designed to interpret and give advice on how to assess conformance to the requirements set out in section 5.1 of EA-2/13.
Authorship

This document has been written by the EA HHC.

Official language

The publication may be translated into other languages as required. The English language version remains the definitive version.

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1. **Background**

The development of this supplement to EA-2/13 was initiated in order to clarify the meaning of the requirements stipulated in section 5.1. This section of EA-2/13 was formulated to closely follow the corresponding text in the document SOGS N595 EN revision 6. However, in this document certain expressions are used which were identified as requiring further interpretation in order to achieve a harmonized implementation. In addition a need was identified for advice on how the fulfillment of these requirements could be assessed. Thus, this supplement to EA-2/13 interprets, and gives advice on how to assess conformance to, the requirements stipulated in section 5.1 of the main document.

2. **Key concepts**

Below are listed definitions of key concepts used in clause 5.1. Also guidance is given on how to assess whether the specified requirements are fulfilled.

2.1 **Same organisation (5.1.8)**

**Definition:**
Group of legal entities, composed of head office and local sites connected with the head office on the basis of contractual or equivalent legal relationships, operating under the same commercial name and logo.

**Comments to definition:**
The names of the individual legal entities may be slightly different but shall include the commercial name of the organisation. The names of the individual legal entities may e.g. include letter codes defining type of organisation (e.g. “Ltd” or “GmbH”) or regional identifiers (e.g. “Svenska” or “Deutsche”). The commercial name may be translated, partially or in full, to accommodate the local market.

**Assessment focus:**
- Contractual agreements or documentation of other legal relationships between head office and local sites
- Registration of the commercial name and logo
- Marketing material
- Issued reports and/or certificates

2.2 **Same management (5.1.2)**

**Definition:**
Same set of persons or organisational entities of the **same organization** taking overall responsibility for the accredited activities.

**Assessment focus:**
- Organisation charts linked to named individuals
- Reporting lines from sites to the head office
- Descriptions of authorities and responsibilities of persons;
  - approving policies and instructions for conformity assessment activities,
  - approving authorities and responsibilities of personnel involved in conformity assessment activities, and
- authorising certificates and reports.
- Names of persons at the head office assigned authorities and responsibilities to control and monitor activities performed at local sites, including decisions concerning resource management etc.
- Evidence of monitoring from head office to the local site in every aspect (managerial, financial and operational). (Note that the sole performance of internal audits is not considered sufficient for taking responsibility for accredited activities.) Evidence of monitoring may be written instructions and records produced and maintained.
- Evidence of effective communication within the organisation. Special care should be taken where there is not a single language of communication within the organisation used by all members of the management in a position to influence the quality of the accredited services.
- Is transfer of overall managerial and operational responsibility for activities of the local site to personnel employed by a foreign company (Head Office) possible according to the company legislation in the country where the local site is established?

2.3 Same quality management system (5.1.2)

Definition:
Set of linked rules and procedures defined by same management to allow it to take responsibility for accredited activities.

Comments to definition:
The linkage is to be achieved through table of contents or by reference.

In order for the quality management system to be considered as the same it shall be designed to provide the same outcome of accredited activities regardless of where the activities are carried out or by whom. The policies governing conformity assessment activities shall be the same throughout the organisation. To provide consistency of results:
- The same management is to define in the same quality management system any sub-sets of alternative rules and procedures, used e.g. by different local sites or throughout different geographical regions.
- All activities defined by the same quality management system are covered by an internal audit program managed and approved by the same management, and the outcome of individual audits, including decisions on corrective actions, is channelled through affected management at all levels as the situation warrants.
- All activities of the same quality management system are subject to a management review by the same management. The outcome of the management review, including any decisions, is channelled through affected management at all levels as the situation warrants. The same management has the authority and legal means to enforce corrective and preventive actions.

Assessment focus:
- Management system structure.
- Rules for approval of policies and instructions.
- Implementation of policies.
- Application of requirements for competence, procedures for qualification and monitoring of personnel involved in conformity assessment activities.
- Internal audit program. Documentation of internal audits. Communication of corrective actions. Lack of same or similar non-conformances recurring throughout the organization.
- Procedure for management review. Documentation of management reviews. Communication and implementation of decisions. Lack of similar problems recurring throughout the organization.
2.4 Responsibility for accredited activities (5.1.1, 5.1.5 and 5.1.8)

Definition:
Responsibility for the performance and outcome of accredited activities.

Comments to definition:
In order to take responsibility for accredited activities the head office shall have full operational control over these activities. To this end, the head office shall have appropriate technical competence and the resources to assure control over the full scope of accreditation. To take responsibility for the outcome of accredited activities is to take responsibility for;
- the competence and resources used,
- the rules and procedures applied,
- the consistency obtained and quality achieved through the application of these rules and procedures,
- the impartiality displayed applying these rules and procedures, and
- the contents of issued reports and/or certificates.

The responsibility is to be upheld;
- towards the customer,
- towards authorities,
- towards the public, and
- in court.

Assessment focus:
- harmonising conformity assessment outcomes through;
  ➢ common or equivalent procedures
  ➢ common or equivalent competence, training, qualification and monitoring requirements
- supervising conformity assessment activities, e.g. by means of
  ➢ internal audits
  ➢ participation in proficiency testing schemes
  ➢ monitoring activities
  ➢ the checking of data, calculations, analyses and reports or certificates
- documentation of communication with authorities
- handling of complaints and appeals, both at the level of the head office and at the level of the local sites
- handling of impartiality issues, both at the level of the head office and at the level of the local sites
- handling of media coverage, both at the level of the head office and at the level of the local sites
- handling of legal cases, both at the level of the head office and at the level of the local sites

3. Common questions

How do we deal with a scenario where the local site is also an independently accredited local CAB?
Prior to establishing an agreement it shall be made clear which legal entity will take responsibility for the contract with the client and under which identity the accredited work will be performed. The entire process then has to be performed following the quality management system of the accredited body contracted for the work. Any reports or certificates issued shall identify the accreditation under which the work is performed.
Who takes responsibility for the contract review if it is done locally?
Answer: This is up to the CAB to decide. If the responsibility is put locally, the head office shall take appropriate measures to implement needed policies, harmonise the procedures and supervise the activities. See interpretation of “responsibility for accredited activities”.

Are local office personnel able to authorise contracts on behalf of the head office?
The contract signature is a fundamental indicator of responsibility. Two basic cases exist:
- Unique contracts are signed with individual customers. In this case the contracts shall be signed by head office personnel.
- A standardised contract is signed or otherwise agreed with individual customers. In this case the standardised contract, e.g. in the form of a template, specifying requirements, prices and contents of assessment shall be approved by head office personnel. The acceptance of assignments related to such a contract may be signed by local personnel.