



Unclassified

Accreditation of conformity assessment bodies with branch offices inland and abroad

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Terms and abbreviations used in this document

Abbreviation, term	Definitions
AkkBV	Accreditation and Designation Ordinance (SR 946 512)
AB	Accreditation Body
CAB	Conformity Assessment Body
EA	European co-operation for Accreditation
EA-2/13 M:2012	EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members
EA-2/17 INF:2016	EA Document on Accreditation for Notification Purposes
GebV-Akk	Ordinance on the fees of the State Secretariat for Economic Affairs applied to accreditation (SR 946 513.7)
IAF	International Accreditation Forum
IAF MD 12:2016	Assessment of Certification Activities for Cross Frontier Accreditation
ILAC	International Laboratory Accreditation Cooperation
ILAC- G21:09/2012	Cross Frontier Accreditation - Principles for Avoiding Duplication
MLA / MRA	Multilateral Agreement / Mutual Recognition Agreement
OR	Federal Legislation in the field of administration of civil justice and enforcement
SAS	Swiss Accreditation Service
SAS Document 529dw	Collection of data to provide indicators of management system certification bodies' performance in accordance with Document IAF MD15:2014

This is a translation of the German document. In the event of ambiguities, please consult SAS Document 738.dw.

1 Objective and purpose

This document regulates the accreditation of conformity assessment bodies (CAB), like calibration, testing, inspection and certification bodies as well as reference material producers and proficiency testing providers (providers of interlaboratory comparisons, providers of external quality controls), with several branch offices in- and outside of Switzerland.

It defines when a branch office can be labelled as such, according to Article 14, paragraph 3 of the Swiss Ordinance on the Accreditation System and Notification (AkkBV, SR 946.512), and the Article 8, paragraph 2^{bis} of the Swiss Ordinance on the Charges for Accreditation (GebV-Akk, SR 946.513.7). The document further regulates the assessment within the framework of the accreditation, surveillance and renewal of accreditation of the CAB, including its national and international branch offices operating under the accreditation of the head office (so called “multi-sites”).

Sites not covered by the definition pursuant to Section 2.2 “Branch office”, but organisationally managed under the same identification as the head office, are considered to be part of the head office and integrated in the latter’s assessment.

2 Regulation for the head office and the branch office

2.1 Head office

The term “main or “head office” stands for the organizational unit which is declared the “main” or “head office” by the management of the CAB. The Accreditation number covers just one “main” or “head office”, however; several “branch offices” are possible.

2.2 Branch office

The term “branch office” stands for an organisational unit under the same identification as the “head office”, but with a site-specific identification or naming in the correspondence, in advertising etc., has its own organizational structure on “another site”¹⁾, where one or several of the key activities (see 3.1 below) are carried out by the local personnel under the accreditation of the “head office”.

The responsible head of the unit takes the initial decision about the status of sites based on the information given by the Lead Assessor (including the application of the CAB); whereby “risk-based assessment principles” are taken into account. The head of the unit also makes decisions for local activities and temporary facilities.

A regulated reference to the “head office” has to be established and be always visible for the duration of the validity of accreditation. As a result, it has to be clear that the “head office” exercises its leadership and competence as well as its responsibility in every respect concerning the activities of the “branch office”. Bodies with no such reference are not considered as being a “branch office” and cannot fulfil their tasks under the accreditation of the “head office”. If there is a need, they can, in meeting the normative criteria for accreditation in force, carry out an activity as subcontractor and seek their own accreditation in the respective country.

¹⁾ All buildings and premises inside of a clear geographically defined campus (e.g. in geographical boundaries of a company, of a hospital or collage round) are normally not considered as “another site” in the sense of this document (see also Section 1, last paragraph). On the other hand buildings and premises in the same locality but on sites outside the defined campus are rooted as “another sites” / “offices”, in the case they would fulfil the appropriate criteria for applied conformity assessment activities.

The head office and all of the branch offices to be included under the accreditation shall operate under the same management and the same global quality management system.

A “branch office” can have its own entry into the trade register. For “branch offices” in Switzerland - as well as in other countries - this entry is mandatory according to article 935 OR. However, a majority participation of the head office at the branch office has to be demonstrated to the SAS. The body accredited by SAS and declared as head office stays legally liable.

The responsibility of the head office is demonstrated based on contractual or equivalent legal relationships between the head office and the local branch offices, as well as internal regulations in the organisations specifying these relationships with regard to the management and responsibilities in more detail.

Moreover, all persons in the branch offices responsible for and taking conformity decisions shall be submitted for this activity directly to the person of the head office responsible for the accredited body.

The branch office(s) shall not offer accredited services under the multisite accreditation (accreditation of the head office) to the local market under their own name and logo or signet.

If these conditions are not met in all aspects, multisite accreditation cannot be granted.

3 Obligations of the CAB

3.1 Obligation to announce branch offices

The “head office” of the CAB has the obligation, without being asked and according to chapter 2, to state to SAS all its “branch offices” inland and abroad, in which tasks covered by accreditation of the “head office” are fulfilled.

This information shall include the legal connection with the “head office”, the conditions of ownership as well as the local organization and composition of the personnel of the “branch offices”. It also has to provide information concerning the implementation of pertinent requirements for accreditation (“key activities”) on site, particularly:

- the hiring of local personnel, the definition of assigned tasks and the needed technical competence to fulfil them;
- the records of local personnel, particularly its initial qualification and ongoing training (basic training and ongoing education) and their periodical surveillance);
- the contract review;
- the order-related assignment of the teams which carry out conformity assessments;
- the determination and release of local regulations and working procedures (particularly the validation and release of conformity assessment procedures);
- the determination of the local infrastructure;
- the approval of calibration, testing, inspection and certification reports and reports from suitability tests or reports on the characterisation of reference material, as well as certificates and applications (with decision of the corresponding conformity, when clearance / approval are included or without decision when it isn't included).

All changes have to be identified continually to SAS according to the SAS document no. 707. In general, whether the aforementioned “key activities” are actually performed at a given site is always decisive. Even if these “key activities” are only performed in part or temporarily within an accreditation period, the site qualifies as a “branch office”. If the “key activities” are

discontinued altogether, the CAB may submit a corresponding application for change of classification to SAS.

With regard to inspection, it must be noted that the inspectors may make a decision directly on-site without any other involved offices within their organisation. In such event, this is not considered a key activity and the location of each inspectors is not classified as a branch office. However, if the findings of the inspection is otherwise independently assessed, this assessment may be classified as a key activity and the site at which this takes place as a branch office. The actual situation at hand which is assessed by SAS is decisive.

3.2 Obligation to announce activities abroad carried out under the Swiss accreditation

The accredited CAB has the obligation to inform SAS about all its activities inland and abroad. This also includes information such as:

- in which countries,
- on which normative bases,
- in which technical fields,
- under inclusion of which bodies (e.g. as subcontractors),

it carries out conformity assessments as accredited CAB according to Section 1 “Objective and purpose”. This reporting occurs regardless of whether these activities are carried out

- directly from the “head office” of the CAB in Switzerland or
- from a “branch office” of the CAB inland or abroad.

Specifically for certification bodies, the SAS Document 529dw (Collection of data to provide indicators of management system certification bodies' performance in accordance with Document IAF MD15) must also be observed.

4 Accreditation, assessment and surveillance of branch offices

4.1 Provide of evidence of the requirements for accreditation

The CAB proves to the SAS that the requirements for accreditation are met in full at both, the “head office” and each “branch office”.

The sites of the included “branch offices” are listed separately in the corresponding scope of accreditation.

Conformity assessments carried out by involved “branch offices” under the Swiss accreditation which are not previously assessed and stated in the SAS accreditation directory, are illegitimate. The penal provisions of the Federal Law on Technical Barriers to Trade (TBTL) apply for incorrect notifications.

The branch offices may offer conformity assessment activities under the multisite accreditation to the local market only on behalf of the accredited head office. The certificates and reports issued under the multisite accreditation shall contain the name and address of the accredited head office without the logo of the branch office. However, these certificates may refer to the contact details of the branch office issuing the certificate or report in question. The certificates issued shall not create any confusion as to the CAB that holds the accreditation.

4.2 Planning of assessments

In regard to the current assessments in the framework of accreditation, SAS establishes an assessment plan, which, in addition to the “head office”, covers all the “branch offices” inland and abroad and includes a presumable accreditation period. Based on the assessment results and other knowledge or also in case of amendments concerning the scope of accreditation, the assessment plan is constantly reviewed.

Each “branch office” is assessed on site for the initial evaluation of the fulfilment of the accreditation requirements and for scope extensions (if relevant).

Assessments of “branch offices” for the purpose of surveillance of accreditation are carried out based on the sampling regulations defined in the SAS.

5 Cross-border activities

5.1 International requirements

The following requirements concerning cross-border activities are based particularly on the EA regulations in accordance with Document EA-2/13 (see Section 6).

In all cases where the SAS instructs the local accreditation body for the performance of the assessments at branch offices abroad, the SAS contact person for cross-border accreditations shall send a corresponding notification to the affected accreditation body no later than by the end of September of the year before [A1]. The SAS shall conclude a corresponding framework agreement with the mandated accreditation bodies.

5.2 Assessment for granting or renewal of accreditation for the Head Office

For assessments of “branch offices” abroad, carried out in the frame of granting or renewal of accreditation for the “head office” in Switzerland, SAS will usually involve the local or national AB, which will also permanently be informed about all activities of SAS. The local or national AB chosen as subcontractor by SAS will be periodically informed concerning the common activities.

In case of subcontracting or concerning the implication of local assessors, the SAS always considers the technical competence available and proven at the local or national AB for the assessments to be carried out on site. If there are no appropriately qualified assessors locally available, SAS will cover the needed technical expertise with own assessors.

5.3 Assessment for the surveillance of accreditation

For assessments concerning the surveillance of accreditation of “branch offices” abroad of CABs accredited in Switzerland, the SAS is based, as far as possible, on the services provided by the local or national AB. Therefore, SAS arranges cooperation through formal subcontracting or through joint assessment activity between SAS and the foreign accreditation body.

The following principles and rules are applied:

- the assessment activities of the SAS abroad are carried out after consultation and in agreement with the national/local AB;
- usually, assessments for the granting or renewal of accreditation are carried out by the SAS, in cooperation with the local or national AB;

- usually, assessments concerning the extension of the scope of accreditation, are handled the same way as assessments concerning the granting or renewal of accreditation;
- usually, assessments concerning the surveillance of the accreditation of a “branch office” abroad are carried out by the local or national AB. To this end, SAS subcontracts the work to the corresponding local or national AB and charges the coordination costs, as well as the operating expenses to the “head office” of the accredited CAB in Switzerland. In case of problems, the SAS can also carry out an assessment for the surveillance of the accreditation itself or take an active part in it;
- if the local or national AB is not a member of the multilateral agreement for the mutual recognition of EA, ILAC or IAF for the respective accreditation, the collaboration with the local accreditation body is ruled, according to the case, with the involvement of the SAS management;
- in principle, the language used is the one of the three official languages in Switzerland (German, French and Italian) respectively that of the “head office” in Switzerland or, if agreed and additional costs are covered, in English (there is no general entitlement to assessments in English or other languages);
- the correspondence and the bill for all assessment activities and expenses is addressed to the “head office” of the CAB in Switzerland.
- With a larger CAB operating “branch offices” inland and abroad it is possible that these “branch offices” also locally operate “branch offices” under their responsibility and thus are further linked on a lower level. These local “branch offices” on the second level are treated like “branch offices” of the first level of the organisational structure of the CAB. The SAS will accordingly assess and administer them, and will state them in the accreditation register of the CAB.
- A previous assessment followed by periodic surveillances are the basis for further activities of these secondary “branch offices” as well as all superior “branch offices” under the accreditation of the “head office” of the CAB in Switzerland.

6 Documentation

6.1 Documentation of branch offices and assessment reports

The documentation of the “branch offices” is written in the official languages (German, French, and Italian) of the “head office” of the CAB or, if there is an agreement, in English.

The SAS assessment reports are written in the official languages (German, French, and Italian) of the “head office” of the CAB and give at least the following information about each “branch office”:

- the onsite carried out conformity assessment procedures;
- the technical and organizational competence of the personnel;
- the structure and the management system;
- the equipment and accommodations, if necessary.

After agreement (and acceptance of the incoming additional costs) the report and the correspondence with the CAB can be done in English.

6.2 Recordings of the subcontractors

For assessments concerning the surveillance of accreditation abroad, which have been integrally delegated to a local or national AB, the SAS normally assumes the assessment

reports of these AB where possible. However, this only applies if relevant correspondence and the report are written in German, French, Italian or English.

Else, SAS can order a translation of the documents to the expenses of the accredited CAB.

In case a joint assessment has taken place, the SAS integrates the contributions of the substitutes of the foreign AB in its own assessment report.

6.3 Accreditation directories

Accreditation directories / registers feature the addresses of the “head office” that is responsible for the accreditation and individual “branch offices” as well as, under the respective address but the name of the head office, the conformity assessment procedures offered under the accreditation of the “head office”.

6.4 Accreditation certificate

The accreditation certificate contains in addition to the full address of the “head office”, the sites of the “branch offices” contained in the scope of accreditation.

6.5 Management of dossiers and data

SAS maintains for the “head office” and for each “branch office” of the CAB a separate dossier. Therein the individual correspondence with the head office and with each included “branch offices” are filed. If needed also records of the mandated foreign AB as well as all other pertinent records is filed. The “head office” and the “branch offices” are handled as their own group of data in the SAS database.

7 References

- AkkBV SR 946 512
- GebV-Akk SR 946 513.7
- EA-2/13 M:2012: EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members
- EA-2/17 INF:2016: EA Document on Accreditation for Notification Purposes
- IAF MD 12 2016: Assessment of Certification Activities for Cross Frontier Accreditation
- ILAC-G21:09/2012: Cross Frontier Accreditation - Principles for Avoiding Duplication
- SAS Dokument 529.dw: Erhebung von Leistungskennzahlen bei den Zertifizierungsstellen für Managementsysteme gemäss Dokument IAF MD15:2014

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