



Swiss Confederation

**No classification**

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## **Rights and obligations in the context of accreditation**

Document No. 707.ew

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## 1 Purpose

The regulations of this document are based on and complete the legal bases provided in section 2. They determine the relations between the Swiss Accreditation Service SAS, the conformity assessment bodies (CAB) accredited by SAS and organisations applying for an accreditation.

These rights and obligations apply mutatis mutandis for all other services provided by the SAS.

## 2 Legal basis

The following laws form the basis for accreditation and its relevant processes:

- The Federal Act on Technical Barriers to Trade (TBA), particularly Article 3 Terminology, Article 10 Accreditation and Chapter 5 Penalties;
- Ordinance on the Swiss Accreditation Systems and the Designation of Testing, Conformity Assessment, Registration and Approval Bodies (AccDO);
- Ordinance on the Fees charged by the State Secretariat for Economic Affairs in the Field of Accreditation (FeeO-Acc);
- General Fees Ordinance (GFeeO);
- Federal Act on Administrative Procedure (APA);
- Federal Act on the Liability of the Federal Government, the Members of its Authorities and its Public Officials (GLA) and
- Federal Act on the Law on Transparency in Administration (BGÖ)

Based on Article 5 and Appendix 1 AccDO, the requirements of the international standard SN EN ISO/IEC 17011 are also mandatory for the activities of the SAS.

The mandatory international standards for the accreditation of CAB's are listed in AccDO, Appendix 2. In this document, they are referred to as "accreditation standards".

Based on Article 22 AccDO, the SAS is a member of the following international organisations in the accreditation and conformity assessment sector whereby it represents Switzerland's interests:

- European co-operation for Accreditation (EA)
- International Accreditation Forum (IAF)
- International Laboratory Accreditation Cooperation (ILAC)

Based on the membership in these organisations, the mandatory regulations of these organisations are also a mandatory part of the SAS regulations.

## 3 Definitions, abbreviations and references

### 3.1 Definitions

The definitions of the ISO Guide 2, the standards SN EN ISO/IEC 17000, SN EN ISO 9000 as well as the international accreditation standards according to AccDO Appendix 2 apply.

### 3.2 Abbreviations and references

Abbreviation	Meaning (URL)
AccDO	Ordinance on the Swiss Accreditation System and the Designation of Testing, Conformity Assessment, Registration and Approval Bodies (Accreditation and Designation Ordinance; SR 946.512)
APA	Federal Act on Administrative Procedure (Administrative Procedure Act; SR 172.021)
BGÖ	Federal Act on the Law on Transparency in Administration
CAB	Conformity assessment bodies (laboratories, inspection bodies, certification bodies, reference material producers and proficiency testing providers)
EA	European co-operation for Accreditation ( <a href="http://www.european-accreditation.org">www.european-accreditation.org</a> )
EA-2/13 M	EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members
EN	European standard
EXTE	SAS technical expert
FeeO-Acc	Fees Ordinance for Accreditation Services of the State Secretariat for Economic Affairs (available in German, French and Italian)
GFeeO	General Fees Ordinance (SR 172.041.1)
GLA	Federal Act on the Liability of the Federal Government, the Members of its Authorities and its Public Officials (Government Liability Act; SR 170.32)
IAF	International Accreditation Forum ( <a href="http://www.iaf.nu">www.iaf.nu</a> )
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation ( <a href="http://www.ilac.org">www.ilac.org</a> )
ISO	International Organization for Standardization
ISO Guide 2	Standardization and related activities – General vocabulary
LA	SAS Lead Assessor
MLA	Multilateral Agreement (EA) Multilateral Recognition Agreement (IAF)
MRA	Mutual Recognition Arrangement (ILAC)
NC	Non-conformity
SAS	Swiss Accreditation Service SAS ( <a href="http://www.sas.admin.ch">www.sas.admin.ch</a> )

Abbreviation	Meaning (URL)
SAS Document 709.ew	Guideline for the surveillance of accredited bodies
SAS Document 738.ew	Accreditation of conformity assessment bodies with branch of-fices inland and abroad
SAS Document 739.ew	SAS rules for references made to accreditation
SAS Form 899f070	Application for the accreditation of a CAB (available in Ger-man, French and Italian)
SC	Subcontractor
SECO	State Secretariat for Economic Affairs ( <a href="http://www.seco.admin.ch">www.seco.admin.ch</a> )
SN	Swiss standard
SN EN ISO 9000	Quality management systems – basic information and termi-nology
SN EN ISO/IEC 17000	Conformity assessment – terminology and general information
SN EN ISO/IEC 17011	Conformity assessment – general requirements for accredita-tion services which accredit conformity assessment bodies
SPC	Swiss Penal Code (SR 311.0)
TBA	Federal Act on Technical Barriers to Trade (SR 946.51)

## 4 Independence and impartiality of the SAS

From an administrative viewpoint, the SAS is subordinate to the State Secretariat for Economic Affairs (SECO). This means that SECO is responsible for the preparation of the annual service agreement with SAS in accordance with the new Management Model for the State (NMS). This also means that, unless specified otherwise in individual cases, SAS can use the services of the SECO service areas of organisation, law and accreditation (OA) for horizontal and resource issues (Human Resources, IT, Logistics, Finance, Business Management, Law) and that the SECO instructions and specifications within these areas also apply to SAS.

With regard to finances, SAS represents a separate accounting area that is independent of SECO. The responsibility for this accounting area lies with the SAS Director.

From a technical perspective, i.e. in all questions relating to accreditation, SAS is independent of SECO. The Head of SAS makes independent, instruction-bound and impartial decisions based exclusively on accreditation-relevant standards when granting or withdrawing an accreditation and when extending or reducing the scope of the accreditation based on AccDO and, in particular, the international standard SN EN ISO/IEC 17011.

The SAS conducts all accreditation activities on an impartial basis and thus ensures the objectivity of the evaluations and decisions. Any conflicts of interests are continuously identified and eliminated. The SAS accredits CAB's to carry out specific conformity assessment tasks pursuant to international standards that suit their competences. An assessment of a CAB's competence is made regardless of the CAB being a private or public body and regardless of the superior goals pursued by the CAB through such accreditation. In other words, the SAS

assesses the competence of a CAB exclusively on the basis of the compliance with all relevant requirements for the accreditation applied for.

The SAS does not provide any services that could have a negative impact on its impartiality and credibility. In particular, it does not provide any consulting services nor any support for the preparation and maintenance of accreditations. In cases in which the SAS offers public courses or seminars (e.g. for technical experts), it cannot be assumed that accreditation will be easier, quicker or less expensive after completion of this training.

An application for accreditation according to a standard listed in the AccDO, Appendix 2 may be submitted to the SAS by any interested CAB according to Article 4 AccDO. The impartial treatment of all applications is based on the relevant legal basis (AccDO, FeeO-Acc) and the additional publically accessible accreditation regulations.

The SAS provides its services to all applicants whose application for accreditation is within the scope of their accreditation activities with regard to SAS rules or the Ordinance on the Swiss Accreditation System. Access is not conditional upon the size of the applicant CAB or membership of any association or group, nor is conditional upon the number of CAB's already accredited. The principles, processes and procedures of the SAS are not discriminatory and are used in a non-discriminatory manner.

## 5 Prioritisation

The accreditation activities are carried out according to the following priorities:

- Priority 1: Work on existing accreditations. The following prioritisation applies within this group:
  - a) Renewal of existing accreditations;
  - b) Monitoring of existing accreditations.
  
- Priority 2: Applications for accreditation or applications for an extension of the scope of existing accreditations within the regulated sector. The following prioritisation applies within this group:
  - a) CABs to be and already accredited pursuant to Chapter 3 AccDO;
  - b) CABs for which accreditation is required by law;
  - c) CABs that may more easily obtain legal authorisation through an accreditation.
  
- Priority 3: Applications for accreditation or applications for an extension of the scope of existing accreditations outside the regulated sector. The following prioritisation applies within this group:
  - a) CABs that apply harmonised standards;
  - b) CABs that apply non-harmonised standards of national or international organisations;
  - c) CABs that apply their own processes and/or company-specific methods.

## 6 Application for accreditation

Organisations interested in obtaining accreditation may apply to the SAS. Form 899f070 "Application for the accreditation of a conformity assessment body (CAB)" should be used for this purpose and is considered to be a legally enforceable arrangement with the SAS.<sup>1</sup>

The application for accreditation of an organisation is deemed to have been submitted once it has been fully completed, signed and received by the SAS, including all relevant documents.

An application for accreditation expires after five years of non-activity if an accreditation cannot be granted within this period. A new application for accreditation must be submitted if there is still an interest in obtaining an accreditation.

## 7 General obligations of the accredited CAB

Upon accreditation, accredited CABs commit to comply with the regulations in AccDO, the standards relevant to the accreditation, the binding regulations of EA, ILAC and IAF and the supplementary regulations of the SAS and to provide evidence of this compliance. This includes the agreement to implement any changes to the accreditation requirements (see section 16). Accredited CABs must download the relevant current regulations of EA, ILAC, IAF and SAS from their websites, implement them and comply with them.

The accredited CAB must not publish any documents or advertisements that may cause uncertainty about the accredited area or damage the reputation of the accreditation.<sup>2</sup>

The accredited CAB has to provide SAS employees and technical experts (EXTE) appointed by the SAS unrestricted access to all facilities, installations and information and to provide any documentation relevant to the accreditation upon request. The SAS decides which personnel is interviewed or witnessed.

Outside parties-persons may only be brought in after consultation with and the agreement of the accreditation body. These persons have a strict observer status and must not disrupt the assessment. If requested by the SAS, the CAB must enable the assessment team to accompany the conformity assessment activities. If applicable, the CAB must oblige its customers to grant access to the SAS assessment team so that the performance of the CAB can be assessed during the implementation of conformity assessment activities at the customer's premises.

The CAB is also obliged to communicate any relevant changes in the CAB to the SAS 4 calendar weeks before assessment using the form "Informationen zur Vorbereitung der Begutachtung vom ..." (available in German, French and Italian). This form must not be used for the application for extensions to accreditation. Changes that result in an extension of the scope of accreditation (e.g. new conformity assessment processes, revised standards, additional locations at which conformity assessments are carried out etc.) must be communicated to the SAS with an application for the extension of the accreditation (see detailed regulations under section 10.6).

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<sup>1</sup> See SAS website

<sup>2</sup> See SN EN ISO/IEC 17011 no. 8.1.1.g



The accredited CAB takes note that the SAS can undertake assessments under the supervision of third parties, based on international agreements. The CAB has to provide such observers with the same unrestricted access to all facilities, installations, information and documentation relevant for the assessment as for the assessment team of the SAS. Furthermore, the CAB must accommodate to the needs of the SAS related to the due dates for assessments within the frame of the periodic Evaluation of the SAS.

The CAB is obliged to assist in the investigation and resolution of any accreditation-related complaints about the CAB referred to it by the SAS.

If the accredited CAB does not comply with these obligations, the SAS may suspend or withdraw parts or the entire accreditation. If there is evidence of fraudulent behaviour, if the CAB intentionally provides false information or if the CAB conceals information, the SAS shall reject the application or terminate the assessment process.

## **8 Appointment of the assessment team**

The SAS appoints the Lead Assessor (LA) responsible for an applicant or accredited CAB and informs the applicant about the appointment. The SAS also appoints the external technical experts (EXTE) relevant to the area of application applied for and informs the applicant of the intended EXTE using form 899f120. By signing this form, the applicant confirms acceptance of the selected EXTE and confirms that no risks to impartial expertise have been identified.

In justified cases, the applicant may request to the SAS to change the LA or EXTE. The SAS must receive a written request to this matter no later than 10 working days following the announcement of the assessment team. The Head of SAS shall decide in cases of conflict.<sup>3</sup>

## **9 Non-conformities and recommendations**

### **9.1 General**

Deviations from the accreditation requirements are reported to the CAB in writing as non-conformities (NC). An accreditation is granted respectively received under the condition<sup>4</sup> that the CAB resolves the stated NC's. An NC is considered to be resolved if the SAS receives an analysis of the extent and cause (e.g. root cause analysis) of the NC and a specific description of the resolution in good time and the assessment team considers this to be a sufficient corrective action.

### **9.2 Major non-conformities**

Before issuing a first accreditation or an extension of the scope of an existing accreditation, proof of the rectification of all major NCs must be submitted by the CAB and the assessment team must deem them to be sufficient corrective measures.

Any major NC uncovered during the period of validity of an accreditation must be rectified within 25 working days and proof thereof submitted to the SAS. The NC's are deemed to have been rectified once the corrective measures have been assessed as being sufficient by the assessment team.

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<sup>3</sup> See Article 10 AccDO

<sup>4</sup> See Article 14 Paragraph 3 AccDO

### **9.3 Minor non-conformities**

Before issuing an accreditation and extension of the scope of an existing accreditation, proof of the rectification of all minor NCs must be submitted by the CAB and the assessment team must deem them to be sufficient corrective measures.

Any minor NC uncovered during the period of validity of an accreditation must be rectified within three months and proof thereof submitted to the SAS. The NC's are deemed to have been rectified once the corrective measures have been assessed as being sufficient by the assessment team.

In rare cases, where it is impossible to rectify a minor NC within three months, the assessment team may determine a maximum period of nine months. Any such exception must be justified in writing. The CAB must give the SAS regular feedback on the status of the rectification of the NC. The relevant periods and proof to be submitted are arranged and placed in writing.

### **9.4 Delays in the rectification of non-conformities**

If delays in rectifying the NC become apparent, the CAB must inform the SAS of this fact and provide a reason before the end of the agreed period. In justified cases, the SAS may grant a one-off extension of no more than 10 working days for major NC and no more than three months for minor NC.

### **9.5 Non-conformities that have not been rectified or not rectified on time**

If a NC has not been rectified (e.g. no proof or insufficient proof submitted) or not rectified on time or in full (even after subsequent processing of the NC as required by the SAS), the SAS may suspend or revoke the affected parts or all of the accreditation.

NC's relating to an extension of the area of application of the accreditation, which has been applied for, must also be rectified within three months. If the SAS does not receive sufficient proof of the rectification of the NC within a maximum period of six months, taking into consideration the maximum extension period as stated in section 9.4, the process is closed and the CAB has to re-apply for an extension of the scope.

### **9.6 Recommendations**

The team's observations on areas for possible improvement may also be presented to the CAB, but shall not recommend specific solutions. Feedback on recommendations is not required.

## **10 Decisions made by the SAS**

### **10.1 General information**

The LA submits an application to the Head of SAS, based on the assessment made of the applicant.

Once the relevant Head of Unit and the Federal Accreditation Commission have issued a statement, the Head of SAS makes a decision regarding the application for accreditation. This decision is formally communicated to the applicant.

If the assessment of the applicant CAB is more than 9 months prior to the submission of the application for the accreditation decision – particularly in the case of first accreditation, the

Head of the SAS may request additional assessment activities. This is so that the current situation in the CAB can be taken into account in the decision to grant accreditation. The applicant CAB has to pay any additional costs.

If the accreditation or extension requirements have not been met, a re-assessment may be arranged with the applicant CAB and carried out before the application to the Head of SAS. The applicant CAB has to pay additional costs of such re-assessment.

## **10.2 Granting of an accreditation**

An accreditation is granted for a maximum period of five years. The period of validity of the accreditation is specified in the formal certification.

The formal decision issued by the SAS, the scopes of accreditation (see Section 11) in all language versions and the certificates are official documents. The scopes of accreditation are published on the SAS website ([www.admin.sas.ch](http://www.admin.sas.ch)). These official documents must not be amended.

## **10.3 Refusal of an accreditation**

If the requirements for the issuance of an accreditation have not been met, the assessment team applies for the accreditation to be declined by the Head of SAS.

The decision to decline the accreditation is formally communicated to the applicant.

## **10.4 Suspension of accreditation**

### **10.4.1 General information**

Suspension means a temporary suspension of accreditation.. A suspension may be issued for parts of the scope of the accreditation or for the entire accreditation. In its formal decision, the SAS specifies factors such as the duration and conditions for the removal of the suspension.

A suspension may be issued for a period between six and 18 months, but the suspension must not exceed the period of validity of the current accreditation. The SAS determines the assessment activities required for revoking the suspension. These have to be concluded no later than four months before the suspension expires.

The listing on the SAS website is amended for the period of suspension of parts of the scope of the accreditation. During the period of suspension for the entire accreditation, the references to the accreditation of the CAB and related listings are removed and the CAB is listed under "Suspended accreditations" instead.

During the period from the decreed suspension until the completed cancellation of the suspension, neither the activity under accreditation nor reference to the accreditation for the areas in question are permitted (cf. TBA Chapter 5). The CAB shall inform its affected clients of the suspension of its accreditation and the associated consequences without undue delay.

If the requirements for the revocation of the suspension have not been met by the end of the suspension period, the withdrawal of the accreditation or of parts of the scope of the accreditation is decreed.

### **10.4.2 Suspension initiated by the SAS**

The SAS decrees a suspension, if during the current accreditation period the requirements for the maintenance of the accreditation or of parts of the scope of the accreditation are no longer met.

### **10.4.3 Suspension initiated by the accredited CAB**

An accredited CAB may apply in writing for a suspension of the accreditation or parts of the scope of the accreditation at any time. Such application may be made if circumstances arise that would create a situation in which the accreditation requirements are no longer met, such as changes of management, technical areas, premises and fittings.

## **10.5 Withdrawal of an accreditation**

### **10.5.1 General information**

A withdrawal may be decreed for parts of scope of the accreditation or for the entire accreditation.

The listing on the SAS website is amended after the withdrawal of parts of the scope of the accreditation. After the withdrawal of the entire accreditation, the references to the accreditation of the CAB and related listings are removed from the SAS website.

After withdrawal, it is not permitted to reference the accreditation for the areas in question (cf. TBA Chapter 5). The CAB shall inform its affected clients of the withdrawal of its accreditation or parts of its accreditation and the associated consequences without undue delay. This also applies in the event of voluntary reduction of the scope or voluntary cancellation of the accreditation.

For new accreditation of the parts of the accreditation scope affected by the withdrawal, the CAB shall submit an application for extension of the accreditation to the SAS as per Section 10.6.

After withdrawal of the full accreditation, new accreditation requires an application for accreditation as per Section 6 – as for a first accreditation.

### **10.5.2 Withdrawal initiated by the SAS**

The SAS may decree a withdrawal if the requirements for the maintenance of the accreditation or parts of the scope of the accreditation are no longer met during the current accreditation period.

### **10.5.3 Withdrawal initiated by the accredited CAB**

An accredited CAB may at any time apply in writing for a withdrawal of the accreditation or parts of the scope of the accreditation.

## **10.6 Extension of the scope of the accreditation**

An accreditation is issued for a specific scope. An accredited CAB may apply for an extension of the scope of its accreditation at any time. The body submits a completed application for extension to the SAS together with all applicable technical documents (e.g. new processes, bases, validations etc.).

The SAS classifies the extension applied as a minor or a major extension of the scope and based on this decision, determines the assessment activities required for processing the application. As a rule, extensions of the scope of the accreditation are implemented in addition to a regular surveillance or assessment for the renewal of the accreditation (see prioritisation in section 5). The planned assessment duration is increased according to the extension applied for.

For completely new procedures, for new standards and for private or proprietary programmes or schemata, the SAS must first carry out a feasibility analysis. This is done as the

basis for determining whether the bases are sufficient for the relevant requirements for accreditation and which prerequisites are required in order for the accreditation process to be implemented correctly (“accreditability”). The required prerequisites include, amongst others, the provision of necessary SAS-internal personnel resources, the availability of suitable LAs and the preparation of additional internal or external guidance. The applicant CAB has to pay any additional costs.

The Head of Unit decides about minor extensions of the scope of the accreditation and the Head of SAS about all other extensions after first consulting with the Federal Accreditation Commission.

## 11 Scope of an accreditation

The SAS prepares a listing for each accredited CAB containing its activities covered by the accreditation and publishes it on the SAS website. The accredited CAB must provide the SAS with the bases and records for preparing the listing in the form specified by the SAS. This also applies to all language versions of the scope of accreditation requested by the CAB (German, French, Italian, English).

The activities included in the scope of the accreditation must be clearly stated.

The conformity assessment procedures and the normative bases are usually listed with a version number or the output date. Special rules apply for the accreditation areas in which flexible validity areas are possible.

- Laboratories (STS) and proficiency testing providers (SPTS)

For the laboratories who carry out tests or examinations (STS) and the proficiency testing providers (SPTS), the special regulations in SAS document 741.dw (Sect. 9 or 10) apply for the presentation of the listings. Other exceptions must be checked in individual cases and are only possible if agreed with the SAS.

- Certification bodies for management systems (SCESm)

For certification bodies for management systems (SCESm), a version number or output date of the certification standard / programme must be given.

Any requests for changes to a new version for conformity assessment processes or normative bases must be submitted to the SAS with the form “Application for extension of accreditation” (cf. notification obligation as per section 7). If currently valid versions of conformity assessment processes or normative bases are replaced and thus lose their validity, the related changes must be reported to the SAS before the expiration of the validity of the current versions. This is also the case if the CAB waives the extension of the validity area with the new versions.

If conformity assessment processes or normative bases are included in the listings after agreement from the SAS without specification of the version number or the output date, the CAB must use document control to ensure that they always use the up-to-date valid standards.

If the CAB carries out in the regulated area only parts of the activities specified in the legal bases or normative bases, these must be specified in detail.

If a CAB has several subsidiaries from which accredited activities are carried out, the listings must clearly show which activity is carried out in which subsidiary. Other locations that are not subsidiaries but which carry out at least one activity shown in the directory can be listed (cf. SAS document 738.dw).

The respective activities within the scope of the accreditation may only be stated to third parties once the scope of accreditation contains these activities and has been approved and officially published by the SAS.

## 12 Accreditation certificates

Accreditation certificates provide the accredited CABs with a means of communicating their valid accreditations to third parties in the form of proof of their performance. Accreditation certificates are official certificates in the sense of article 110 par. 5 of the Swiss Penal Code (SPC, SR 311.0) but do not form an essential part of the formal decision.

Accreditation certificates are issued optionally by the SAS upon request from the accredited CAB and incur a fee.

If an accredited CAB has several subsidiaries at which accredited activities are carried out, the certificate also gives the location of the additional subsidiaries included in the validity area of the accreditation as well as the full address of the head office (cf. SAS document 738.dw). Premises that are not valid as "branch offices" as per SAS document 738.dw are not listed on the certificates.

## 13 References to accreditations

According to Article 16 AccDO, accredited CABs may refer to their valid accreditations during the daily business. An accreditation mark specific to the CAB as described in Article 4 AccDO may be used for this purpose or reference to accreditation may alternatively be given in written form, but the accreditation number must also be mentioned.

Reports, confirmations and certificates may only be recognised under the accreditation if these documents correctly mention the accreditation mark, i.e. in accordance with the binding regulations of the SAS document 739.ew "SAS rules for references made to accreditation".

In addition to the use of the SAS accreditation mark, CABs can also request to use the international IAF or ILAC accreditation mark (see SAS document 739.dw Section 6).

With regard to false references to the accreditation in legal correspondence, the penalty clauses of the Swiss Federal Law on Technical Barriers to Trade (TBTL) are applicable.

- Certification bodies for management systems

For certification bodies for management systems, it is prohibited to grant certificates outside of the accreditation for standards and technical areas that form part of the accreditation (decision of the IAF as per resolution 2015-14 from November 06, 2015).<sup>5</sup>

- Certification bodies for persons

For certification bodies for persons, it is prohibited to grant certificates outside of the accreditation for standards and technical areas that form part of the accreditation (decision of the IAF as per resolution 2017-19 from October 30, 2017).

- Certification bodies for products, processes and services

For certification bodies for products, processes and services, it is prohibited to grant certificates outside of the accreditation for standards and technical areas that form part of the accreditation (decision of the IAF as per resolution 2018-13 from October 31, 2018).

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<sup>5</sup> Cf. <http://www.iaf.nu/upFiles/MilanGAResolutionsFinal.pdf>

## **14 Surveillance assessments and repeated issues of accreditations**

### **14.1 Surveillance**

During the validity period of an accreditation, the SAS periodically monitors the activities of the accredited CABs on the basis of Article 19 AccDO, article 7.9 of SN EN ISO/IEC 17011 and of the relevant EA, IAF and ILAC documents.

If during these surveillance activities, the assessment team notices that part or all of the accreditation requirements are no longer met, it considers to apply for a suspension or withdrawal of parts or all of the accreditation.

The binding regulations of SAS document 709.ew "Guideline for monitoring accredited bodies" apply.

If the SAS obtains information that an accredited CAB may no longer meet the accreditation requirements, the SAS may assess the situation at any time by carrying out unscheduled monitoring.

### **14.2 Assessment after re-issue of accreditation**

12-15 months before the expiration of the validity of the accreditation, the CAB is sent the form "Application for renewal of accreditation" so that it can communicate the application or waiver of renewed accreditation to the SAS in good time. If the CAB is interested in a renewed accreditation, it shall return the completed and signed form to SAS 12 months before the expiration of the valid accreditation.

The assessment for the repeated accreditation is scheduled 120 – 180 days before expiration of the validity of the current accreditation.

On the termination of any due non-conformities, it must be taken into account that the decision process for awarding accreditation, which lasts at least 5 weeks, can only be started after the documentary evidence on the rectification of the NC has been submitted and checked and after confirmation of correct rectification of the NC in the assessment report. Delays to the accreditation process may mean that the repeated accreditation can only be ordered after expiration of the validity of the previous accreditation and that the CAB has no accreditation for a certain period of time.

## **15 Changes within the accredited CAB**

Important changes within an accredited CAB (such as legal status, legal structure, affiliation to an organisation, ownership changes, internal structure, resources and locations, scope of accreditation, business policies, directors, executives and expert staff whose knowledge and function is essential to the competence of the CAB), that may have an impact on the capacity, competence, quality and other criteria linked to the accreditation must be reported to the SAS immediately, and in any case within 30 days at the latest.<sup>6</sup>

The SAS decides on any resulting assessment activities or further actions.

When changing the legal owner (change in company identification number CIN) of a CAB, the accreditation relating to a previous owner usually becomes void. The new legal owner must subsequently reapply to SAS for accreditation.

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<sup>6</sup> See Article 17 AccDO

If, in the view of the CAB, the change in legal owner results in no relevant changes within the CAB (no influence on capacity, competence, quality, infrastructure or other criteria associated with the accreditation), the CAB may submit a justified application to the SAS to retain the previous accreditation. To ensure seamless accreditation, a corresponding application must be submitted in writing at least 3 months before the change in legal owner. After examination of the application by the assessment team, the Head of the SAS can amend the accreditation documents as per AccDO article 20.

## 16 Changes to accreditation requirements

Changes of the relevant bases for the accreditation must be implemented by the accredited CAB within the period specified by the EA, IAF, ILAC, the ISO, the standard owner, relevant authorities or the SAS respectively. If the changes to bases are not implemented within the specified periods, the areas of the accreditation affected by them or the entire accreditation will become invalid.

In the legally regulated area, a withdrawal or suspension of accreditation or of relevant parts of accreditation as well as a voluntary reduction of the scope of accreditation are reported to the responsible Federal Office.

The SAS informs accredited CABs timely about any upcoming changes. It may obtain the opinion of interested groups on planned changes.

If an accredited CAB is unable or unwilling to implement the changed bases within the specified period, it has to inform the SAS that it wishes to waive the relevant part of the scope of the accreditation or the entire accreditation before the end of the period.

If the CAB does not implement the adjustments required to comply with the changed bases and does not inform the SAS on time about its waiver of the affected part of the scope of the accreditation or the entire accreditation, the SAS carries out an assessment before the end of the specified period. This assessment incurs a fee. If non-conformities are found during this assessment and these are not rectified before the end of the specified period, the SAS decrees the withdrawal of the relevant part of the scope of the accreditation or the entire accreditation.

The SAS does not issue a formal decision for the reduction of the scope of accreditation if standards for the accreditation and proprietary systems within the scope of the accreditation become invalid after a specified transitional period. The relevant areas are removed from the scope without information on the accredited CABs.

## 17 Subcontractors of the accredited CABs

CABs may appoint subcontractors (SC) to carry out work covered by the accreditation. The basic principles of the appointment of SC are contained in Article 18 AccDO, which states that SC must be accredited in Switzerland or hold an equivalent qualification for the respective area of activities. In other words, only CABs with an accreditation issued under a MLA or MRA of the EA, IAF or ILAC may be appointed.

The CABs must ensure that their SC do not appoint another SC to carry out the work appointed to them.

Work may only be outsourced to non-accredited CABs in exceptional circumstances. Prior to outsourcing work in such circumstances, the CAB outsourcing the work must check, assess and clearly document the competence of the SC. Any outsourcing of parts of a conformity assessment process to non-accredited SC whose contributions to the process are stated under the accreditation must first be presented to the SAS for assessment.



The CAB must state services rendered by non-accredited SC as such in all documentation provided to customers for the assessment of conformity if the same documents also contain accredited conformity assessment processes, regardless if parts of or entire conformity assessment processes are outsourced.

If an SAS accredited CAB commences a collaboration with a new SC whose services are included in the accredited conformity assessment documentation, this is classed as a major change within the meaning of section 15 within the accredited CAB and must be reported to the SAS immediately. Such changes may impact the assessment activities scheduled by the SAS.

## **18 Subcontractors of the SAS**

The SAS usually carries out its own activities. In certain cases, such as the assessment of activities of foreign SAS accredited bodies, it may appoint a SC. It may also use the accreditation reports issued by foreign accreditation services. The SAS avails itself of accreditation services that are members of a multilateral regional or international agreement in the accreditation sector.

To strengthen the international accreditation system with national accreditation services, the SAS recommends that Swiss CABs obtain local accreditations for their international business activities.

## **19 Recognition of accredited services**

Accredited CABs undertake to place equal importance on test reports as well as calibration and conformity certificates issued by other accredited CABs than their own documentation, if these CABs have been accredited by a member of the multilateral agreements of the EA, IAF or ILAC.<sup>7</sup>

## **20 Multiple locations in Switzerland and abroad**

If a CAB operates locations or subsidiaries at home and abroad under the accreditation of the SAS, it is obliged to comply with the rules in SAS document 738.dw "Accreditation of conformity assessment bodies with branches in Switzerland and abroad".<sup>8</sup>

Such CABs must also comply with the legal compliance sanctions imposed by the Swiss Confederation in its ordinance on the Embargo Act. Detailed information on the applicable sanctions can be found on the SECO website under the keywords "Export Controls" and/or "Sanctions".

## **21 Language versions in SAS documents**

Within the scope of accreditation, the SAS provides relevant documents in the languages German, French and Italian. Documents with international relevance are, as an exception, also provided in English, however this may be subject to an additional cost.

SAS documents in the above languages are provided based on the demand.

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<sup>7</sup> The listings of the countries signed up to the agreements of the EA, IAF and ILAC can be accessed on the websites of these organisations.

<sup>8</sup> See document EA-2/13 and Article 4 AccDO.

## 22 Costs

According to Article 37 AccDO, the applicant assumes the actual costs incurred during accreditation processes. The rates are specified in the FeeO-Acc and the Gen. FeeO-Acc.

The cost estimate made by the SAS and provided to the CAB is based on the assumption of a proper accreditation process. The costs listed in the cost estimate may be exceeded if any unexpected activities come up.

The SAS decrees the suspension or withdrawal of the accreditation if expenses and fees are not paid. Ongoing accreditation processes are interrupted and the remaining fees have to be paid.

During the period of a suspension of the accreditation, the annual fees will be fully charged. In the case of withdrawal or termination of the accreditation, the annual fees will be billed on a pro rata temporis basis up to the date of withdrawal or termination of the accreditation.

## 23 Confidentiality

The SAS and the persons involved in the SAS accreditation processes (members of the Federal Accreditation Commission, EXTE etc.) treat all information obtained through the accreditation process as confidential, unless the law requires for such information to be disclosed. Unless forbidden in law, the CAB will be informed about the above disclosure.

The BGÖ [Federal Act on the Law on Transparency in Administration] determines that third parties can submit an application to view the files of an administration process. The SAS shall inform the affected bodies about such applications. The disclosure takes place with consideration of valid data protection provisions.

## 24 Storage of customer data and documents

The SAS stores customer data and documents for a minimum period of 10 years. The customer data and documents are destroyed after the expiration of the storage period without notifying the customer and under compliance with the legal requirements.

## 25 Objections and complaints

There is a difference between:

- Objections to the SAS<sup>9</sup> and
- Complaints against formal decisions made by the SAS for the attention of the Federal Administrative Court<sup>10</sup>.

### 25.1 Objections to the SAS

An affected party may object the behaviour of an SAS-accredited CAB within the scope of their accreditation or the behaviour and working methods of the LA and EXTE as well as about other actions taken by the SAS. All objections to the SAS must be made in writing and contain a relevant justification.

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<sup>9</sup> In the sense of ISO/IEC 17011, No. 5.9

<sup>10</sup> Pursuant to Article 44 et seqq. APA

The SAS systematically records objections and processes them at the relevant level. A written statement will be issued to the complainant.

## **25.2 Appeals against formal decisions made by the SAS**

Appeals against formal decisions made by the SAS are regulated by Article 44 et seqq. of the Federal Act on Administrative Procedure (APA).

An appeal against formal decisions made by the SAS may be addressed to the Federal Administrative Court, PO Box 9023, St. Gallen, Switzerland within 30 days after their issuance. Appeals must contain the claim and justification, including a list of evidence to be provided, and the signature of the complainant or his/her representative. The relevant formal decision made by the SAS and the certificates stated as evidence must be attached if the complainant has access to them.

The CAB carries all costs according to Article 63 APA.

## **26 Liability**

According to the Federal Act on the Liability of the Federal Government, the Members of its Authorities and its Public Officials (GLA), the Swiss Confederation assumes liability for damages caused to third parties by employees of the SAS during the execution of their official activities.

## **27 Changes of the accreditation areas provided by the SAS**

The SAS may extend, not extend or reduce its range of services as it sees fit. It will consider the opinions of interested parties, if appropriate.

The SAS carries out feasibility studies and, if required, a check of accreditation suitability ("accreditability"), based on detailed information provided by applicants, for applications for accreditation in areas that the SAS does not yet cover. Based on the results, the SAS decides if it wishes to become active in the area applied for – and under which conditions – or if it wishes to refrain from doing so. Such applications are processed based on the provisions of the FeeO-Acc.

If the SAS arrives at the opinion that its provision of certain accreditation services is no longer viable, it may reduce its range of services.

If applicable, the SAS can permit accreditation by third-party accreditation bodies that are members of the MLA or MRA of the EA, IAF or ILAC in the corresponding area.

For accreditations in the regulated sector, the options for SAS must be discussed with the responsible authorities in good time.

## **28 Implementation and transitional regulations**

The present version of document 707.ew, rev. 15 enters into force on 01.01.2019 with the following transitional regulations.

Transitional regulations:

- Re. section 13 Reference to accreditation:  
The regulation in section "Certification bodies for persons" must be applied from 30.10.2020.

- Re. section 13 Reference to accreditation:  
The regulation in section “Certification bodies for products, processes and services” must be applied from 31.10.2021.

## 29 Changes in this version

The following amendments have been made since the previous version 707.ew, 2016-10, rev. 14 of this document:

- Body has been replaced by CAB throughout the document
- Section 4: various additions on impartiality based on the new requirements of standard ISO/IEC 17011:2017
- Section 6: specification that form 899f070 “Application for the accreditation of a conformity assessment body (CAB)” is a valid legally enforceable arrangement with the SAS and that the original must be sent to the SAS by mail.
- Section 7: additional obligations for accredited CABs have been included based on the new requirements of standard ISO/IEC 17011:2017 and in the 3<sup>rd</sup> paragraph: “or to provide any documentation relevant to the accreditation upon request” replaced by “and to provide any documentation relevant to the accreditation upon request”.
- Section 9.1: documentation on resolution of the NC submitted to the SAS has been specified based on the new requirements of standard ISO/IEC 17011:2017.
- Section 9.6: add the possibility to present recommendations to the CAB
- Section 10.1 3<sup>rd</sup> paragraph: inclusion of opportunity for Head of SAS to require additional assessment activities for the decision on accreditation if the assessment on which the application is based on is more than 9 months in the past.
- Section 10.4.1 4<sup>th</sup> paragraph: expansion to obligation of CAB to keep their customers informed about a suspension.
- Section 10.5.1 3<sup>rd</sup> paragraph: supplemented with obligation of CAB to inform their customers about any withdrawal.
- Section 11 1<sup>st</sup> paragraph: “official languages” replaced by “German, French, Italian”.
- Section 11 9<sup>th</sup> paragraph: specification of prerequisite for the inclusion in the scope of premises that are not valid as “branch offices”.
- Section 12 3<sup>rd</sup> paragraph: exclusion of the inclusion on certificates of premises that are not valid as “branch offices”; minor specification on the handling of NC.
- Section 13 6<sup>th</sup> paragraph: addition of IAF resolutions 2017-19 and 2018-13
- Section 15 1<sup>st</sup> paragraph: addition of “and in any case within 30 days at the latest”.
- Section 15 3<sup>rd</sup> paragraph: specification of the regulation for change in legal owner.
- Section 16 2<sup>nd</sup> paragraph: supplemented with information to the competent Federal Office in the regulated area.
- Section 21: addition of regulation on languages versions of SAS documents.
- Section 23: addition of opportunity to view accreditation documents on the basis of Transparency in Administration legislation and information on the affected CAB.
- Section 24: Precision with the consideration of all regulatory requirement, in relation to the destruction of documents.

- Section 27: addition of possible check of accreditation suitability (“accreditability”).
- Section 28: update of section on implementation and transitional regulations.

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