



Unclassified

Cooperation between SAS and applicant in the context of accreditation

Document No. 741.ew

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1. Introduction

Accreditation is an internationally recognised tool for building trust in the work of conformity assessment bodies (CABs). An accreditation formally confirms that a CAB meets the specified requirements for the activities it has been accredited for and that it has the necessary professional, managerial and organisational competences. Accredited CABs maintain a management system to ensure the quality of their work. Reports and certificates issued by accredited CABs therefore enjoy a high degree of trust and respect in Switzerland and abroad.

In Switzerland, CABs are accredited formally in accordance with the Accreditation and Designation Ordinance (AkkBV, SR 946.512) and contentual on the basis of the international standards listed in the annex to the Accreditation and Designation Ordinance. In accordance with the Accreditation and Designation Ordinance and the underlying Federal Act on Technical Barriers to Trade (THG, SR 946.51), the Swiss Accreditation Service (SAS) is responsible for accrediting CABs. It evaluates the CAB to be accredited, assesses compliance with the relevant accreditation requirements and issues the accreditation if the requirements have been met.

Obligation of regulations: The obligation of specified regulations are defined by the following terms in this document:

- must – obligation
- shall – recommendation
- can – option

2. Object

This document regulates the cooperation between the SAS and the applicant. The relevant rights and obligations when cooperating with the SAS are specified in SAS Document 707 "Rights and obligations in the context with the accreditation".

The general accreditation process is based on:

- the Ordinance on the Swiss Accreditation System and the Designation of Testing, Conformity Certification, Registration and Approval Bodies of 17 June 1996 (Accreditation and Designation Ordinance; AkkBV),
- standard ISO/IEC 17011 "General requirements for accreditation bodies accrediting conformity assessment bodies",
- the documents of the EA, ILAC and IAF as well as the SAS and
- the international standards relevant to the accreditation in accordance with Annex 2 of the Accreditation and Designation Ordinance.

3. Definitions and abbreviations

The definitions in accordance with clause 3.1 in SAS document 707 apply.

Abbreviations	Meaning (URL)
AccDO	Ordinance on the Swiss Accreditation Systems and the Designation of Testing, Conformity Certification, Registration and Approval Bodies (AccDO)
EA	European co-operation for Accreditation (www.european-accreditation.org)
IAF	International Accreditation Forum (www.iaf.nu)
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation (www.ilac.org)
ISO	International Organisation for Standardisation
CAB	Conformity assessment body
LA	Lead Assessor
MLA	Multilateral Agreement (EA) Multilateral Recognition Agreement (IAF)
MRA	Mutual Recognition Arrangement (ILAC)
MS	Management system
NC	Non-conformity
SAS	Swiss Accreditation Service SAS (www.sas.admin.ch)
SCESe	Swiss Certification Service, "e" for Persons - Experts
SCESm	Swiss Certification Service, "m" for management systems
SCESp	Swiss Certification Service, "p" for products, processes and services
SCS	Swiss Calibration Service
SIS	Swiss Inspection Service
SPTS	Swiss Proficiency Testing Service
SRMS	Swiss Reference Material Service
STS	Swiss Testing Service
TE	Technical Expert

4. Accreditation criteria

4.1. Management system (MS) of the applicant

The applicant shall maintain a management system that meets the requirements of the relevant international accreditation standard in accordance with Annex 2 of the Accreditation and Designation Ordinance. The SAS verifies this management system comprehensively during the assessment. The management system, including all relevant documents and records, may be kept in paper or electronic form. If the electronic form is selected, special attention

must be paid to the regulations concerning access as well as those regarding access rights and data protections.

4.2. Technical fields

In agreement with the applicant, the SAS selects for the assessment impartial TE from public offices, the education sector (colleges and universities) or the private industry, who have an in-depth knowledge of the technical fields to be accredited.

4.3. In situ conformity assessments

If a CAB is asked to execute conformity assessments or parts thereof on site, clear guidelines have to be established in order to reduce risks linked to non-controllable external conditions. The SAS includes "in situ conformity assessments" in its assessment and lists them separately within the accreditation scope.

4.4. Accreditation scope

The accreditation scope comprises all activities of a CAB for which it is accredited. The accreditation scope is listed in detail in a table. Examples of accreditation scopes can be downloaded from the SAS website (www.sas.admin.ch).

5. Accreditation process

5.1. Application for accreditation

The SAS informs the interested CAB on its website (www.sas.admin.ch) or verbally on the accreditation options, their prerequisites and the accreditation process. Key documents (forms, specific regulations, reference documents, etc.) can be downloaded from the SAS website. CABs interested in obtaining an accreditation must submit the completed form 899f070 "Application for the accreditation of a conformity assessment body (CAB)" plus all relevant attachments to the SAS.

5.2. Information meeting

The objectives of the information meeting are:

- the further procedure is to be roughly defined,
- the applicant gives the SAS general information on its activities, equipment and organisation,
- any branches and their activities relevant to the accreditation are identified,
- the applicant provides the SAS with all available documents as stated under Section 5.6,
- the preliminary accreditation scope is defined,
- questions regarding evaluations of in situ conformity assessments (e.g. tests, calibrations, certifications of persons or products) are discussed,
- suggestions for the appointment of possible TE are discussed,
- the SAS provides the applicant with a reference document self-assessment and, if available, specific technical papers or documents for the interpretation of the requirements of the accreditation standards as well as, if relevant, additional requirements in legally applicable areas; alternatively, these documents can also be accessed on the SAS website,
- the SAS informs the applicant about the accreditation process and fixes an approximate date for the assessment,
- the SAS provides the applicant with an estimate of the costs; more accurate information can be provided after the preliminary visit.

5.3. Specification of the accreditation scope and appointment of TE

The applicant must submit the scope to be accredited to the SAS with the assistance of the lists that have been made available to it. The SAS provides the applicant with suitable sample lists of previously accredited CABs upon request. The applicant may consult the scopes of previously accredited CABs that have been published on the SAS website.

The SAS appoints the TE after discussion with the applicant and after the applicant has provided the SAS with a detailed draft of the applied scope. The SAS informs the TE about the international and Swiss accreditation system and, if necessary, instructs them in the assessment technics to be used.

5.4. Preliminary visit

The preliminary visit serves to prepare for the assessment and comprises the following:

- A preliminary on-site assessment by the assessment team (LA and TEs): Assessment of the premises, equipment, personnel, practical application of methods and other aspects relevant to the type of accreditation on the basis of the documents submitted by the CAB and the self-assessment (reference document) of the applicant; only verbal feedback from this assessment is provided,
- the determination of a detailed working schedule up to accreditation, including the specification of a timetable and a possible assessment date,
- if necessary, the determination of specific tests (proficiency tests, in situ conformity assessments, etc.),
- the designation of all other locations of the CAB from where key activities are executed and which have to be included in the accreditation scope,
- the discussion on the compliance of the documents submitted in accordance with Section 5.6 with the relevant accreditation standard,
- the determination of the accreditation scope to be taken into consideration for the assessment,
- the gathering of additional knowledge regarding the facts relevant to the assessment from the CAB and the appointment of the TE as a basis for an updated cost estimate and the preparation of the detailed assessment plan.

5.5. Assessment plan and cost estimate

The LA prepares an assessment plan for the planned on-site assessment based on the knowledge obtained during the preliminary meeting. He also prepares an updated cost estimate reflecting both the costs expected to be incurred by the LA and TEs involved (see Annex 02 to this document for details on the budget). The CAB is provided with the cost estimate and assessment plan prior to the on-site assessment.

5.6. Assessment of the documentation

The SAS reference document completed by the applicant (self-analysis) plus references to the regulations stipulated in the applicant's management system and, where necessary, additional information by the applicant form the basis for the assessment. The documents and comments listed are checked for non-conformities, plausibility and the correct practical implementation during the assessment.

The applicant must provide the SAS with the following documents at least two months before the assessment without further prompting:

- name, address, legal and organisational status of the CAB (organigram and current excerpt from the commercial register or legal basis in the case of public institutions, if not already submitted to the SAS),
- description of tasks and responsibilities,
- list of the personnel employed in the field for which accreditation is sought, including description and proof of training, professional experience and function,
- appointment of persons responsible for the management system, with indication of training and function,
- management system manual as well as other valid quality requirements and procedures within the field to be accredited,
- samples of reports, certificates, etc. planned for the period following accreditation,
- list of subcontractors, including their accreditation status, and current subcontracted activities,
- other documents for the technical assessment by the expert; these documents can be demanded directly by the expert,
- completed reference document (self-assessment),
- other documents as required by the specific regulations by the SAS regarding the relevant accreditation standard (see Section 6 et seq. of this document) and/or the responsible authorities in the regulated areas.

The SAS assessment team reviews the applicant's documentation. Deviations are discussed during the on-site assessment.

5.7. Assessment at the CABs premises and at all other sites from where key activities are executed

5.7.1 Opening meeting

The assessment team starts the assessment with an opening meeting to clearly define the purpose of the assessment and the requirements of an accreditation and to confirm the assessment schedule as well as the scope to be assessed.

5.7.2 Assessment by the assessment team

Based on the assessment plan the SAS assessment team checks if:

- the applicant meets all requirements of the international standard applicable to the selected type of accreditation in accordance with Annex 2 of the Accreditation and Designation Ordinance,
- the management system of the applicant meets the requirements of the relevant accreditation standard,
- the provided documentation is used in practice by the applicant,
- the relevant regulations are respected in practice,
- the requested procedures are applied in a correct manner,
- the applicant can provide evidence of its competence for the scope applied for,
- the relevant legal bases are upheld within the regulated area (see Document 729 " SAS Rules for Accreditation Purposes in the context of Notification - Designation of Conformity Assessment Bodies (CAB)", where relevant).

The applicant must ensure that sufficient personnel is available during the assessment to provide the SAS assessment team with competent information on the entire scope applied for.

5.7.3 Witnessing of CAB activities on site by the SAS:

The SAS accompanies the CAB to be accredited or already accredited in the performance of their activities specified in the scope of the applied for or granted accreditation on site at their customers' premises. The SAS specifies the activities to be accompanied. The applicant must provide the SAS assessment team with suitable opportunities for accompanying the selected activities and inform the clients in question.

This type of assessment enables the SAS to evaluate employee competences and the purposefulness of processes and work instructions for their application within the accreditation scope. The activities observed by the SAS must represent the relevant accreditation scope.

5.7.4 Assessment result

The assessment team informs the applicant of the result at the end of the assessment as part of a final discussion. During this discussion the assessment team reports the findings made during the assessment and the non-conformities are handed over to the applicant in writing. On this discussion, the CAB gets the opportunity to ask questions regarding the findings, the non-conformities, should they exist, as well as questions in regard to their basis. The applicant is informed by the assessment team, as well, if and under which conditions or obligations to which requirements and for which scopes it supports an application for accreditation. If the applicant does not meet the requirements for accreditation, it may be necessary to re-assess parts of or all of the scope.

5.7.5 Assessment report

The assessment team prepares a report on the results of the assessment, which is provided to the applicant, which is expected to respond with a statement.

The report contains the following points:

- the applicant,
- the assessed CAB,
- the assessed part of the scope,
- the scope applied for,
- the participants of the SAS (LA, TEs, observers) and applicant,
- judgment and comments issued by the SAS assessment team with regard to the assessed points,
- non-conformities identified by the assessment team,
- possible improvements.

5.8. Decisions made by the SAS

The Head of SAS decides whether to grant or decline an accreditation based on the applications received and the statements made by the responsible head of Unit of the SAS and the Federal Accreditation Commission.

6. Additional regulations for certification bodies

The additional regulations for certification bodies for management systems, persons and products, processes and services applicable for the accreditation are listed in the SAS Document 509 "Additional regulations for the accreditation of certification bodies".

7. Additional regulations for inspection bodies

7.1. Scope

The degree of independence of the inspection body as defined in the requirements specified in Annex A of the standard SN EN ISO/IEC 17020 is entered in the SIS register as type A, B or C. The inspection body may provide the SAS with its own expectation regarding which one of the three types it will be allocated, but the final decision in this regard rests with the assessment team.

7.2. Additional documentation regarding Section 5.5 that must be provided to the SAS by inspection bodies

- Description of the allocation of the inspection body to the legal entity it is part of
- Description of the administrative structure of the organisation
- Relationship with other companies (e.g. group) and other organisations (associations, authorities, etc.)
- Description of the activities, apart from inspections, that the legal entity also engages in
- Proposal regarding the inspection body's degree of independence (type A, B or C)
- Name of the technical manager
- List of equipment and devices

Documents required for witness audits

The following documents and information must be submitted to the SAS no later than one month prior to the witness audit:

- audit schedule or legal basis (identification, if already submitted),
- information on the objective of the audit, address, route planner, if available, or contact details,
- requirements regarding the qualifications of the inspectors who perform the inspection witnessed by the SAS.

8. Additional regulations for calibration laboratories

8.1. Calibration process

All calibration processes within the scope of an accreditation must either be defined by international, national or company-internal calibration instructions (calibration regulations, standards). The requirements of SAS Document 702 "Ensuring the traceability of measuring results to the International System of Units SI" must be complied with.

The calibration laboratories must also refer to the calibration instructions that have been followed when issuing certificates to their clients.

8.2. Additional documentation regarding Section 5.5 that must be provided to the SAS by calibration bodies

- List of valid calibration processes (calibration instructions) for the scope to be accredited, including a calculation of uncertainties based on document EA-4/02 and receipts for traceability,
- list of calibration equipment and devices,
- list of special calibration equipment "on-site",

- information on the calibration rooms' characteristics,
- list of reference standards or materials used,
- results of participation in interlaboratory comparisons (ILC).

8.3. Points assessed in addition to Section 5.7.2

- Results of the interlaboratory comparisons, expressed using the EN factor,
- Results of participations in ILCs.

8.4. Interlaboratory comparisons

Interlaboratory comparisons are suitable tools for measuring the quality and competence of a calibration laboratory. The accredited calibration laboratory must participate in such interlaboratory comparisons. The SAS may request such participation as part of the accreditation.

9. Additional regulations for testing laboratories

9.1. Scope

Depending on the type of activities carried out by a testing laboratory and in accordance with the mandatory documents ILAC G 18, EA-2/15 M and EA-4/17 M, the scope is determined with a varying degree of flexibility. The SAS distinguishes between three types of flexibility, which, however, are identical with regard to the laboratory's professional competence relating to the test methods specified. The assessment focuses on different aspects, depending on which one of these three types of flexibility is applied to the accreditation scope.

The requirements of SAS Document 702 "Ensuring the traceability of measuring results to the International System of Units SI" must be complied with.

9.1.1 Type A: Accreditation based on defined test methods

With this type of accreditation, the definition of the accreditation scope is based on the products or material groups, on the technologies, types of tests and measuring principles applied as well as the clearly defined standardised or self-developed methods. All methods are listed individually in the STS register showing the revision date. The correct application of these methods is checked in detail during the assessment.

The testing laboratory must apply to the SAS for the inclusion of modifications to these methods as well as new methods in the accreditation scope. These methods must be assessed before being included in the accreditation scope.

9.1.2 Type B: Accreditation based on defined test methods which can be modified

As in the case of type A, the definition of the accreditation scope for this type of accreditation is based on the products or material groups, the technologies, types of tests and measuring principles applied as well as standardised or self-developed methods whose correct application is thoroughly examined during the accreditation assessment.

Testing laboratories may adapt these methods to specific (e.g. clients') requirements at short notice, depending on the situation, without prior consultation with the SAS. Such adjustments shall be minor modifications only; in no case shall they lead to the introduction of new measuring principles or a basic change of the test method.

Precondition for this type of accreditation is the existing and controlled competence to evaluate the risks linked to the modifications made. Corresponding workflows and responsibilities for the characterisation and validation of modified test methods must also be defined.

All methods are listed in the STS register, however without stating the revision date. Within the framework of their documentation control, type B testing laboratories keep a list, showing

all test methods introduced within the accredited scope. This list also states the current revision date of the methods. Regular surveillance visits to the accredited type B testing laboratories focus on the assessment of revised test methods.

The testing laboratory must apply to the SAS for the introduction of a new test method. The new test methods must be assessed before being included in the accreditation scope.

9.1.3 Type C: Accreditation based on defined types of tests and measuring principles

For this type of accreditation, the definition of the scope is based on types of tests and measuring principles whose application the testing laboratories have proved their competence for. These types of tests and measuring principles are defined in the STS register (middle column). In contrast, the test methods are listed in summarised form only within the different technologies.

Precondition for this type of accreditation is the existing and controlled competence to introduce or develop new test methods, including the assessment of the corresponding risks and the validation of the methods. Such assessment assumes that the characteristic quality features of a test method are known. Consequently, the accredited testing laboratory is also expected to understand the client's problems as well as to be able to execute the tests using the appropriate test methods.

Type C testing laboratories have relevant and specified workflows and responsibilities for the introduction and characterisation of new test methods and their validation for the adequate use, at their disposal.

Within the framework of their document control, type C testing laboratories keep a list of all introduced test methods. This list also shows the actual revision date of the methods. Regular surveillance visits to the accredited type C testing laboratories focus on the assessment of revised test methods.

The test method list must contain the following:

- product or group of substances (matrix, material, test item),
- type of test, measuring principles,
- characteristic/group of substance/measurand,
- type of procedure (commercial, standardized, own procedure),
- specification of internal instruction (method),
- referencing of commercial procedures (name, manufacturer), literature sources of procedures from literature and standards in the case of standardised procedures,
- version information of instruction,
- date of release of procedure.

Furthermore internal and external quality controls about procedures shall be specified.

In specialized fields where further information is required, the SAS provides templates in Excel including the required information for the specialized field.

In the STS register, a reference to the test method list has to be made and it must be provided for all interested parties. The following formulation is added at the end of the detailed tabular presentation:

"The testing laboratory maintains a list with detailed information on the activities within the scope of accreditation. It is available upon request at the testing laboratory."

The testing laboratory must apply to the SAS for the introduction of new types of tests and measuring principles within the accredited scope. These new types of tests and measuring principles must be assessed before being included in the accreditation scope.

9.1.4 Additional documentation regarding Section 5.6 that must be provided to the SAS by testing laboratories

- List of valid test methods for the scope to be accredited, including – where applicable – details of the limits of their abilities,
- list of test equipment and devices,
- list of special in situ test equipment,
- information on the test rooms' special characteristics (if required),
- list of reference standards or materials used,
- results of participation in interlaboratory comparisons and proficiency testing.

10. Additional regulations for proficiency test providers

10.1. Scope:

The SAS distinguishes between two accreditation types for providers of proficiency tests: the so-called fixed scope, type A, and the flexible scope, type B. Both accreditations are identical with regard to the professional competences relating to the proficiency tests listed in the accreditation scope, but differ in their degree of flexibility when introducing modified or new proficiency tests. Both types are assessed according to different aspects.

10.1.1 Type A (fixed scope): The accreditation is based on clearly defined, non-modified proficiency test schedules

In this type of accreditation, the accreditation scope is defined by the technical area, products, parameters and designation of the proficiency test. All individual products and parameters must be listed in the SPTS register.

The proficiency test provider must apply to the SAS for the inclusion of modifications to these proficiency tests as well as the introduction of new proficiency tests in the accreditation scope. Modified or new proficiency tests must be assessed by the SAS before being included in the scope.

10.1.2 Type B (flexible scope): The accreditation is based on defined and modifiable ring tests

The proficiency tests are described in the register by stating the technical areas, product groups and group parameters. The individual products or parameters are stated wherever relevant. The names of the proficiency tests, as offered to the participants, must also be listed.

In this type of accreditation, the proficiency test provider is authorised to modify the proficiency test schedules to meet specific requirements (e.g. client requirements) without first informing the SAS. Such modifications may be made to the products used or the parameters to be determined, but not to the technical areas. The approved modifications are small changes.

The inclusion of new proficiency tests or substantial modifications to existing proficiency tests within the accreditation scope must be applied for with the SAS. These proficiency tests must be assessed by the SAS before being included in the accreditation scope.

The prerequisite for obtaining this type of accreditation is the proven professional competence for assessing the scope of the modifications performed and related risks with regard to the results and validity of the proficiency tests offered. Methods for modifying and approving these modifications must be established. The responsible persons with the relevant decision-making power must be specified.

All proficiency tests must be listed in the SPTS register. However, there is no obligation to state the individual products or parameters as well. All providers must keep a list of all proficiency tests that clearly identify the corresponding modifications among their documentation. This list must show the technical areas, individual products and individual parameters of all proficiency tests offered within the accreditation. The regular surveillances of type B proficiency test providers carried out by the SAS focus on the modification of the proficiency tests.

11. Additional regulations for producers of reference materials

11.1. Additional documentation regarding Section 5.6 that must be provided to the SAS by the producers of reference materials

- List of valid test methods used for characterising the reference materials,
- list of test equipment and devices,
- information on the test and production rooms' special characteristics,
- list of calibration equipment and reference standards used,
- results of participation in interlaboratory comparisons and proficiency testing.

12. Annexes

Annex 01: Time schedule for initial accreditation

Annex 02: Cost estimate of the accreditation of a CAB

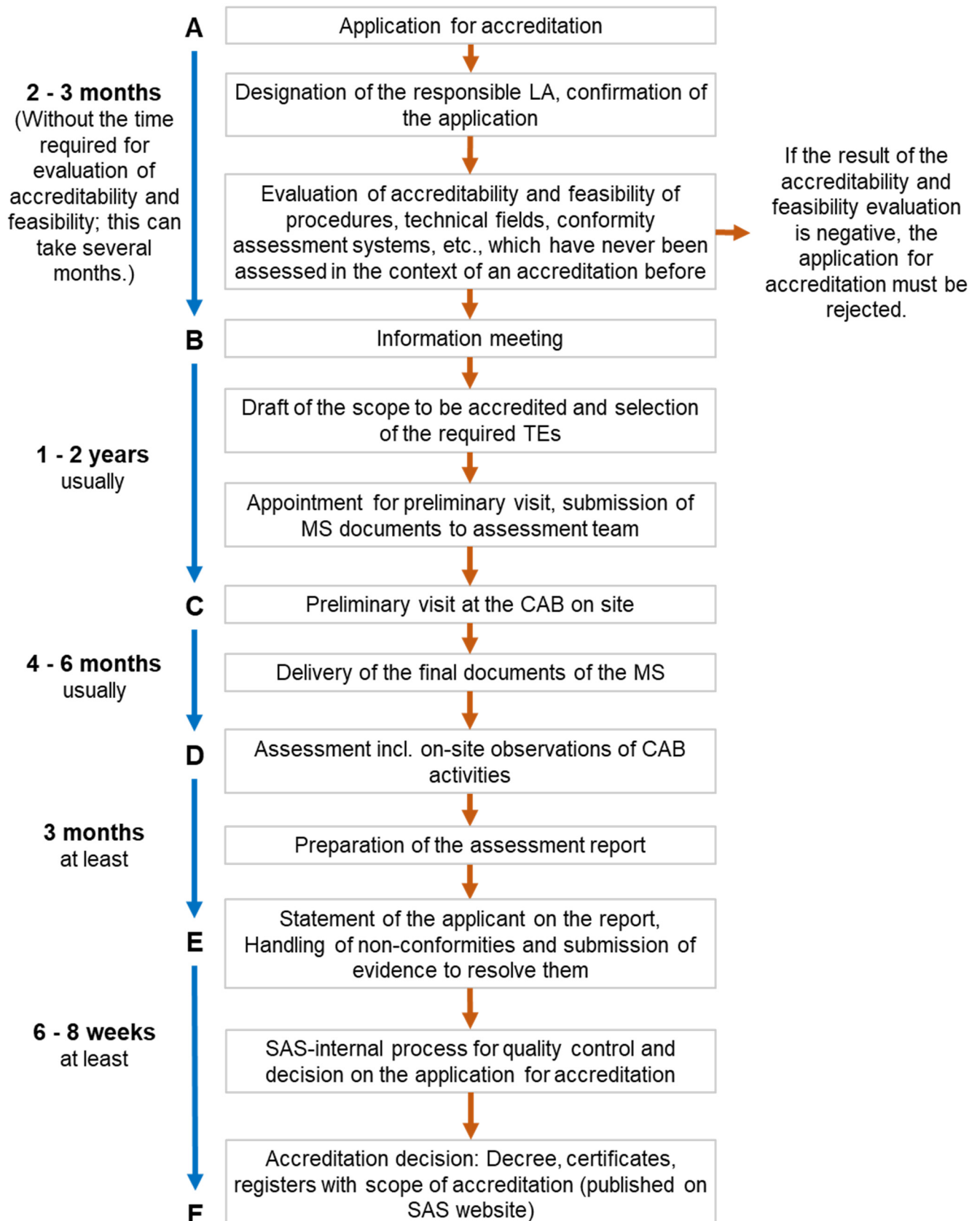
13. Changes of this version

- Consequent use of terms: CAB, testing laboratory, calibration laboratory, assessment plan, LA, experts
- Section 3 Reference to SAS document 707 regarding the normative basis of terms
- Section 4 Explanation of obligation of regulations
- Section 5.7 Insert 5.7.1 Opening meeting and specify 5.7.4 Assessment result
- Section 5.7.5 Term "recommendations" replaced with "possible improvements"
- Section 9.1.3 Definition of content of the list of accredited procedures

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Time schedule for initial accreditation (without representation of potentially occurring process loops)





Annex 02

Cost estimate of the accreditation of a CAB

Registration fee

Type of CAB	Amount in CHF
The same for all CABs	1'500

Fees for granting the accreditation

Activity	Amount in CHF
SAS assessment, depending on CAB, volume, number of departments, etc., of: <ul style="list-style-type: none"> Information meeting Search for experts Evaluation of documents submitted Preliminary visit Document assessment, assessment of management system (management manual) Coordination of experts Assessment schedule Assessment Determination of the register for the scope applied for Specification of the non-conformities Assessment report Checking the implementation of the corrective actions Administration, correspondence, database, updating the scope register Certificates Travel costs Expenses 	Approximately 14'000 to 24'000
Per expert and depending on size of the scope, incl. travel costs	Approximately 6'000 to 10'000

Annual fee

Type of CAB	Amount in CHF
Inspection body	3'850
Certification body for products, processes and services	
Producer of reference materials	
Validation and verification body	
Type A testing laboratory	2'000
Calibration body	
Type B testing laboratory	2'450
Type C testing laboratory	3'100
Proficiency test provider (Type A/B)	
Certification body for persons	
Certification body for management systems	2'000 + 25 / certificate
Additional branch offices	+ 500 / branch office

Fees for the surveillance of the accreditation

Activity	Amount in CHF
Surveillance by the SAS depending on size (extension, where applicable) of scope <ul style="list-style-type: none"> • Document assessment • Coordination of experts • Surveillance schedule • Surveillance • Checking the register • Specification of the non-conformities • Surveillance report • Checking the implementation of the corrective actions • Administration, correspondence • Travel costs • Expenses 	Approximately 4'500 to 8'000
Per expert and depending on size of the scope, incl. travel costs	Approximately 3'500 to 6'000

Fees for witness audits carried out at the premises of the CAB's clients

Activity	Amount in CHF
SAS witness audit (per auditor/expert for a 1-day visit) <ul style="list-style-type: none"> • Document assessment • Coordination of experts • Witnessing and assessing the CAB's activities • Specification of the non-conformities • Witness audit report • Checking the implementation of the corrective actions • Administration, correspondence • Travel costs • Expenses 	Approximately 4'000 to 7'000
Per expert (1-day visit), incl. travel costs	Approximately 3'000 to 5'000
Comment: The assessment for accreditation or the surveillance of an accreditation may require witnessing activities performed at the premises of the CAB's clients on one or more occasions.	

Note: The Ordinance on the Fees charged by the State Secretariat for Economic Affairs in the Field of Accreditation (GebV-Akk) applies. A more detailed estimate will be provided with the respective assessment schedule. The timely submission of complete documents and the targeted implementation of accreditation criteria help to prevent unnecessary time loss and additional costs.