



Unclassified

Surveillance of an accredited conformity assessment body (CAB)

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1 Aim and object

The present document rules the surveillances of accredited bodies, carried out by the Swiss Accreditation Service (SAS).

2 Basics

- The Ordinance on the Swiss Accreditation Systems and the Designation of Testing, Conformity Assessment, Registration and Approval Bodies (AccDO, SR 946.512)
- The Ordinance on the Fees charged by the State Secretariat for Economic Affairs in the Field of Accreditation (FeeO-Acc, SR 946.512.7)
- SAS Document No. 707 "Rights and obligations within the scope of accreditation"
- SAS Document No. 741 "Cooperation between SAS and applicant in the context of accreditation"
- SAS Document No. 738 "Accreditation of conformity assessment bodies with branch offices inland and abroad"
- Standards of the ISO/IEC 17000 and further standards in accordance with Annex 2 of the AccDo
- International Documents of the EA, ILAC and IAF¹

3 Definitions

3.1 Surveillances

Definition according to ISO/IEC 17011, clause 3.22:

Process, carried out by the accredited body for a defined accreditation scope, to determine the competences of a CAB, based on standards and further normative documents.

3.2 Documentation surveillance

"Documentation surveillance" is understood as the evaluation of the most significant documented rules and measures for the upholding of competence in accordance with the standards relevant to the accreditation, without necessitating a visit to the accredited CAB. Documentation surveillance may be performed as an additional measure to the regular on-site assessments in certain situations (e.g. changes within the CAB not requiring any surveillance visit), but do not replace regular surveillance activities (see Section 5.3).

3.3 Surveillance visit

A "surveillance visit" is understood as an assessment performed on the premises (respective at the locations) where the accredited CAB operates (on-site assessments).

3.4 Accompanied activities (so-called witness audits)

Standard ISO/IEC 17011 requires from the accreditation services to ensure, during the on-site assessment, that a representative number of accredited activities and staff involved in these activities, is observed and evaluated. This observation constitutes a part of the evaluation of the technical competence of an accredited CAB.

In the case of inspection and certification bodies as well as testing and calibration laboratories, which carry out accredited tasks at their client's premises, the assessment also in-

¹) For further informations see also: www.sas.admin.ch / www.european-accreditation.org / www.ilac.org / www.iaf.nu

cludes, in addition to the assessments at the CAB, the witnessing and observation of the activities of persons who carry out inspections, audits or tests/calibrations on their client's premises.

Usually, the SAS assessment team does not intervene before the observed activities have officially been declared completed by the CAB. Ideally, the witnessing is carried out in order that the planning, introduction, application, interpretation and statement of results can be assessed.

After the surveillance of the respective activity, the SAS assessment team deliberates, together with the assessed person(s), on the situation they found, and gives a respective opinion concerning the carrying out of the witnessed activity. In doing so, the self-awareness of the accompanied persons and the feedback provided by the SAS assessment team are compared in the form of an external perception. The result is taken into consideration in the assessment report in an adequate manner.

Besides witnessed activities, the SAS assessment team may also consider alternative ways for the CAB assessment during the implementation of the visits at their client's premises, if no witness audits are required according to normative or international prescriptions. The common reappraisal of already carried out or planned activities and the specific questioning of the clients of the CAB, concerning the impact and benefit of the activities which have been carried out at their premises, can also be involved in the CAB assessment.

4 General remarks

4.1 Obligation to provide information

According to article 17 of the Ordinance on the Swiss Accreditation System, all CABs are bound to communicate, without being asked, to the SAS any major change in their accreditation scope. These changes could consist in:

- organisation changes,
- responsible persons,
- premises,
- testing instruments and facilities.

The SAS document No. 741 contains detailed information on documents that are to be submitted to the SAS. The notification has to occur one month following any change at the latest.

4.2 Lead Assessor (LA)

Every incoming accreditation application is transmitted by the respective head of Unit to a lead assessor (LA) for handling. Normally, the same LA remains responsible for the corresponding accredited body after the accreditation has been granted and decides predominantly independently on the further procedure within the frame of the accreditation requirements and assessment planning. The LA takes the SAS prescriptions into consideration, manages the client's file and sees to it that any amendments communicated to him/her by the accredited CAB are added to the client database.

The SAS assessment team decides case-by-case on the upholding of the accreditation of the accredited CAB (see Section 8.1). If measures need to be taken (e.g. renewed assessments, the demand of additional proofs, scope modifications in the accreditation register), the LA initiates them him-/herself. The head of Unit and/or head of SAS make all decisions regarding the areas of accreditations (e.g. extension) and status changes (e.g. suspension), based on each situation.

The LA may arrange with the expert(s) and the head of Unit about possible obscurities and the need of harmonisation within the SAS.

The LA informs his/her unit periodically about the planned and already carried out surveillances and – when advisable – about the present situation in the accredited CABs.

4.3 Disagreements, complaints procedure

In case of personal disagreements between the LA and the persons in charge of the CAB and/or with technical experts, which cannot be solved bilaterally, the LA shall immediately inform the head of Unit, in order to find a common solution as quickly as possible.

If the disagreements occur during a surveillance, in a form that influences the accreditation procedure, the CAB has to be informed, a respective reservation has to be formulated and recorded with the further SAS statement in the corresponding surveillance report.

The rulings on the complaints procedure are stipulated in SAS Document No. 707.

5 Frequency of surveillances

5.1 Surveillances following the first accreditation

The validity of the granted accreditations is defined in the Ordinance on the Swiss Accreditation System and lasts for a maximum of five years. During that time, the SAS carries out regular surveillances. In accordance with the requirements of the international ISO/IEC 17011 standard and the SAS regulation, the first surveillance is to take place no later than 12 months after the date of first accreditation. The following surveillances in the first accreditation period are carried out 14 months (12 to 16 months) after the last on-site assessment. On the basis of the assessment result or complaints formulated by third parties, the SAS may carry out at any time additional assessment activities at the accredited CAB.

5.2 Surveillances following the renewal of accreditation

Once the accreditation has been renewed for the first time, surveillances are carried out 20 months (18 to 22 months) after the last on-site assessment.

Shorter surveillance intervals must be determined by the LA if the following conditions are met:

- Major changes in key personnel (primarily technical personnel) as well as organisational and technical infrastructure and related processes relating to the accreditation scope must be recorded.
- The accredited CAB does systematically and efficiently monitor all measures required as part of the accreditation:
 - internal audits,
 - management assessment,
 - assessment of the proficiency tests and Inter-Laboratory Comparisons,
 - assessment of customer feedback or feedback from previous assessments by the SAS.
- Major non-conformities have been found at the assessment.

5.3 Additional assessment activities

Assessments for the purpose of extending the accreditation not included in the regular on-site assessments, witness audits, on-site verification of correct rectification of non-conformities, document monitoring and other extraordinary assessment activities do not influence the regular surveillance visit intervals and therefore are carried out in addition to the surveillance visit as and when required.

6 Surveillance procedure

6.1 Planning

The planning of the surveillances is the responsibility of the LA. He/She contacts the accredited body at appropriate notice, and, if necessary, the corresponding responsible technical expert(s) as well, and arranges with them a date for the surveillance visits, if it has not already been fixed during the previous visit.

The accredited CAB submits an application for extension of the accreditation (Form No. 899f083) to the responsible LA at least 6 months in advance, if an extension of the scope of accreditation is requested during the next assessment. The application must be submitted as early as possible if the extension applied for goes beyond the professional competence of the present SAS assessment team and if an additional technical expert is therefore required.

Note: At the end of every surveillance visit, the dates, witness audits and technical fields regarding the next assessment should be fixed.

If important changes occur in the accredited CAB or extensions of the accreditation scope should be assessed outside regular surveillances, then additional surveillances may also be organised between the CAB and responsible LA.

6.2 Preparation

The basic information for the preparation of surveillances is to be found in the documentation of the accredited CAB and current SAS documents, reference documents as well as the results of previous accreditation assessments, renewed accreditations, extensions and surveillances.

Particular consideration is paid to:

- non-conformities of the previous assessment,
- changes in the field of activity,
- personnel transfers,
- changes in the conformity assessment procedure and in the facilities,
- modifications of the management / quality management system,
- the impact of the management system / quality management system, e.g. in form of results from internal audits and conclusions from management reviews,
- the use of the accreditation logo and other logos with a licensing contract, if applied (e.g. ILAC and/or IAF logos).

During each surveillance activity, several elements of the relevant international accreditation standard are always examined in detail. The emphasis of the assessment is to be placed – if possible – on the specific technical aspects. The selection of these system elements is to be such that all elements of the relevant accreditation standard(s) as well as the expert fields and branches are checked at least once within a period of **5 years** (5-year program, established by the SAS assessment team).

For a more efficient preparation of the assessment, the LA requires from the accredited CAB specific written indications concerning the changes occurred since the last visit. The CAB provides the assessment team with the documents to be submitted according to SAS document no. 741 and the information on the changes 2 months before the planned assessment. Based on the submitted documents and the regulations described above the LA establishes an assessment plan. For the specific technical elements and case-by-case, the LA brings in the expert(s). The assessment plan of the surveillance visit is submitted together with the time and cost estimate, to the accredited CAB, approx. 4 week prior to the assessment.

The LA leads the surveillance visit together with the entrusted expert(s) or alone in exceptional cases. With the assistance of the head of Unit and in compliance with the internal SAS

regulations, the responsible LA decides on the assignment and correct composition of the SAS assessment team, which is deployed for the surveillance.

If disagreements concerning the assignment of technical experts cannot be clarified with the accredited CAB, the department head and, as last resort, the head of the SAS, decide on the composition of the SAS assessment team.

SAS competence profiles concerning the assigned technical experts:

- The "Type A-Technical Experts", with an adequate assessment practice and/or having taken part in a recognised assessor course, may carry out surveillance visits or parts of them by themselves, if they have been mandated by the SAS. They are also allowed to carry out, assess and comment witness audits without being accompanied by the responsible LA. In such a case, the LA defines the fields to be assessed in advance and ensures that the mandated technical experts are also able to assess aspects, which are normally examined by the LA, by themselves. Technical experts only carry out surveillance visits on their own in exceptional cases.
- The "Type B-Technical Experts" with less assessment practice may not carry out surveillance visits alone. This means that the LA requires a periodic feedback from the "Type B-Technical Expert" and punctually accompanies the latter to the interviews during surveillance visits. The LA defines the fields to be assessed in advance and ensures that the "Type B-Technical Experts" are able to use the corresponding assessment techniques. A punctual accompaniment of the "Type B-Technical Expert" by the LA and the periodic assurance of his approach during the on-site assessment constitute a prerequisite.

6.3 Performance

The surveillance visit is usually subdivided as following:

- opening discussion,
- evaluation of the impact of measures taken by the accredited CAB, concerning quality management and quality assurance,
- evaluation of the implementation of the CAB management system in comparison with the current requirements of the pertinent standards,
- evaluation of the technical competence of the involved CAB employees,
- assessment of the CAB at work on its premises or – if called for – at a witness audit or field trials,
- interpretation of the observations and results in form of the resulting report and the certificates of the conformity assessment,
- closing discussion.

The LA and the technical expert review their observations made during the surveillance visit and summarise the results at the closing discussion. Together with the technical expert, the LA draws up, where necessary, non-conformities and arranges a date for their completion together with the accredited CAB, pursuant to the requirements in SAS Document No. 707.

For testing laboratories and inspection bodies, which have a corresponding share in the tests carried out during a conformity assessment, the periodic surveillance may also include the participation in Inter-Laboratory Comparisons / proficiency testing activities and the interpretation of the results which have been obtained.

For calibration laboratories, comparative measurements and the systematic establishment of measurement uncertainty estimations are evaluated and used for the periodic surveillance of the accredited CAB.

The surveillance visit may – after a previous information / feedback with the accredited CABs – also include the questioning and/or the surveillance of their clients and subcontractors.

Likewise, all the CAB sites which provide services for the purpose of conformity assessment are periodically assessed within the framework of the surveillance of the accredited CAB (see SAS Document No. 738).

6.4 Documentation

The result of the surveillance visit is compiled in a report and transmitted to the accredited CAB.

The SAS informs the Accreditation Commission, respective in the legally regulated field also the responsible federal office according to an individual agreement with the latter, on the surveillances performed and on the corresponding results.

7 Documentation surveillances

The LA of the SAS may specify a document surveillance as an additional assessment activity such as the verification of the continuing stability of a CAB, the checking of changes within a CAB not requiring an on-site assessment, etc. A document surveillance may comprise the following:

- The assessment of the modifications in the management system, including the organigram, which lists the names of the key personnel.
- *Note:* This can also include the assessment of the most important procedural instructions.
- The assessment of the audits from the past year respective their summary, in which the CAB's responsible management confirms, that the internal audits were performed in keeping with the last planning.
- The assessment of the summary of the annual management review.
- The measures implemented during the previous period as well as those concerning the human resources development in order to maintain the necessary level of knowledge of the responsible personnel in the accredited field of the organisation.
- The assessment of additional relevant documents. These are to be determined by the LA specifically for the organisation.

8 Decisions

8.1 Confirmation of the accreditation

If no serious weaknesses are found and all previous non-conformities have been solved, the accredited CAB receives, after a successful surveillance, a surveillance report, which contains the conclusions concerning the assessed elements and – if pertinent – the non-conformities. If the non-conformities have been solved in a timely and correct manner, the maintenance of the accreditation is confirmed. In the case of a documentation review, the report may be reduced to a confirmation.

8.2 Suspension or withdrawal of the accreditation

If the surveillance results show that the relevant requirements are no longer fulfilled respective the non-conformities have not been solved within the agreed deadline, and this without a plausible explanation, the LA may request a reduction, the suspension or withdrawal of the accreditation, in accordance with Article 21 of the AccDO, from the head of the SAS.

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