



Unclassified

Guide for Technical Experts

Document no. 704.ew

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All of the functions stated in the masculine form are to be equally understood for men and women.

All modifications of the present document form an integral part of the contract and are to be communicated in writing to the technical experts.

1 Audit team

In order to perform the assessment, the Swiss Accreditation Service (SAS) appoints the following personnel:

Lead assessors (LA): They bear responsibility towards the SAS for the performance of assigned assessment procedures, for the purpose of the granting, surveillance, renewal and extension of accreditation of a **Conformity assessment body (CAB)**.

They have a technological-scientific education and normally work experience in the fields, in which they conduct assessments. A LA can also act as Technical Expert (TE) in an assessment procedure; in such a case, these rules apply for him by analogy.

Technical experts (TE): Technical experts are mandated to carry out important parts of the technical assessment in the accreditation procedure of a CAB, mostly under the direct guidance of the LA, and are specialists in their technical field.

The SAS nominates, depending on the accreditation scope and in consultation with the applicant, one or several technical experts for the duration of the accreditation procedure.

The selection of the TE takes place through the LA and is based on different possibilities, e.g.

- on recommendation of another LA,
- the person is already known by the SAS after having attended a technical expert course,
- at the suggestion of the applicant and after an internal examination carried out by the SAS,
- based on name lists of professional and trade associations.

TE can be recruited from following organisations: federal offices, canton and municipal offices, institutes, vocational and trade schools, colleges, universities and private companies in Switzerland and abroad.

The SAS issues a frame contract to the TE for the corresponding assessment activity in the accreditation procedure. The TE is mandated individually for each work assignment in favour of the SAS. He can be mandated as a private person or as employee of his organisation.

2 Qualification of the technical expert

The TE has a deep, established knowledge and experience concerning the individual sections or the whole field of activity of the CAB to be assessed.

The SAS differentiates between:

- **“A-Expert”** (previous knowledge and experience in accreditation issues; repeatedly employed)

TE, who have attended the SAS TE course or equal courses and have sufficient assessment experience. The “A-expert” has previously participated in at least **three (3)** assessments for the granting or renewal of accreditation as a “B-expert” or shows alternatively a total of **six (6) days** assessment practice. Without participating in a TE course, the TE should be able to show at least (8) days assessment practice.

If TE have already acted on behalf of other national accreditation services from EA, ILAC and IAF MLA, in the same technical field, the assessment days can be taken into account upon production of evidence of these activities.

The evidence has to be recorded electronically and filed in the technical expert file. In order to give the technical expert the possibility to perform an assignment autonomously, he has to be accompanied and evaluated positively by the LA (using the corresponding form), before being given the grade of “A-expert”. For this, an individual introduction of the TE by an SAS LA is always a prerequisite.

TE can be recommended by a LA as “A-expert” to the head of Unit (HU) of the corresponding assessment department, if they meet the requirements of an “A-expert”. The recommendation is always made with a current evaluation of the TE.

An “A-expert” can carry out assessments for the surveillance on-site or witness audits (accompaniment of activities, conducted by the CAB to be assessed) autonomously. For these assessments, he is mandated by the LA and acts in the name of the SAS. The SAS requirements as well as the type of reporting have always to be observed.

Contrary to a “B-expert”, an “A-expert” doesn’t normally need a direct accompaniment and support by the LA on-site.

The LA bears the responsibility, in the name of the SAS, for the proper conduct of the assessment activity towards the assessed body. In any case, he has the power to issue instructions for the TE.

- **“B-expert”**

A “B-expert” has either not yet participated in the SAS technical expert course resp. doesn’t have enough know-how yet as a member of an SAS audit team. A new TE, who hasn’t participated yet in the SAS technical expert course, is introduced individually into the accreditation procedure by the LA. “B-experts” are secured by the LA during the on-site activity.

Regular expert meetings, conducted by the LA, are firmly included in the assessment programme. They are always part of an assessment.

3 Records concerning technical experts

The following data concerning technical experts are registered and safeguarded in the SAS database:

(The data labelled with *) are treated confidentially towards SAS external persons. However, information can be handed over in agreement with the TE)

- name and address;
- phone and fax numbers / E-mail addresses (private)*);
- employer’s address, if relevant, including phone and fax numbers / E-Mail addresses (business);
- social security number*);
- framework contract*);
- all the assignments of the technical expert;
- individual introduction to the activity or confirmation of participation in courses, conventions, SAS seminars or training courses of other national accreditation services (if available);
- possible additional training in the assessment field and management system*);

- education and further training^{*)} and professional experience^{*)} as well as other technical qualifications^{*)};
- information concerning the grading of experts as “A-Expert” or “B-Expert” as well as periodic evaluations during the conduct of activities within the framework of assessments for the SAS^{*)}.

Questionnaire for technical experts: The necessary information concerning the TE is mostly gathered from the “Questionnaire for Technical Experts”. The document is regularly brought up to date, but this at the latest after 5 years. The TE informs the LA about any important changes concerning his training and further training or professional situation, in a proactive manner. The LA who mandates the TE makes sure, that possibly lacking information is handed in later, and the corresponding adjustments can be made to the SAS database.

4 Assessment procedure

The assessment procedure is defined in the corresponding guides. All assessments are carried out with the aid of guides and checklists. The guides, and especially the checklists, are considered to be a support for the audit team, as long as the results obtained during the assessment can be found adequately in the audit report. The SAS differentiates between:

- **Standard checklists:** These checklists serve to examine, whether the requirements of the underlying accreditation standards are met. They can be downloaded under www.sas.admin.ch.
- **Special checklists:** Where necessary and useful, additional SAS checklists for assessments in specific technical fields exist. They can be downloaded under www.sas.admin.ch.
- **Individual checklists:** Individual checklists can also be established and used as assessment preparation by the TE. These checklists should, if possible, be arranged with the SAS before the assessment.

5 Contract with the technical experts

The TE receives a general frame contract, signed by the LA and one of the SAS heads of unit. The TE can be mandated either as (1) private person or (2) ad personam as employee of his employer. In the first case, the TE is recommended, where appropriate, to seek the agreement of the employer.

In the second case, the employer co signs the frame contract. The TE as well as his employer acknowledge the obligations, which go along with the activity within the framework of an accreditation procedure, notably, the employer doesn't impact on the accreditation procedure and acknowledges, that the TE is also bound by official secrecy towards him.

Based on the frame contract, the LA arranges the assignment of the TE in writing and informs the body to be assessed accordingly. In doing that, he clarifies, if the body to be assessed accepts the TE assignment resp. which reasons would speak against his assignment.

6 Tasks of the technical expert

The regulations of the Ordinance on the Swiss Accreditation System SR 946.512 and the requirements of the international Standard ISO/IEC 17011 apply.

The exact assessment procedure and the role of the technical expert are described in the corresponding current SAS guides, which are available on a topic basis and can be downloaded under www.sas.admin.ch.

To perform an assessment, the TE is granted access to all relevant documents, fields and premises of a CAB. He accompanies and assesses employees of a CAB, and this also for activities conducted outside the actual locations of the CAB (e.g. during field sampling or during audits or inspections performed at their clients place).

The TE informs the LA, in case that he has not the documents of importance to him at his disposal, four (4) weeks (resp. twenty (20) working days) before the assessment date.

The core tasks of the TE are:

- the evaluation concerning the technical competence of the personnel and maintenance of the necessary knowledge in the technical field, the suitability of procedures and proceedings, the infrastructure and equipments and the available localities of the CAB.

The TE are under the obligation to:

- perform technical assessments in accordance with the SAS requirements, under the guidance of the LA;
- make a contribution to the preparation and programme of the assessment, as agreed with the LA;
- establish, if necessary and in consultation with the SAS, a specialist checklist;
- work according to the defined programme;
- inform the LA immediately about their findings;
- co-sign the application;
- deliver an assessment report within 5 working days resp. in consultation with the LA;
- give an opinion concerning the completed audit report (if necessary and agreed with the LA);
- participate in courses and continuous training of the SAS, which serve as information exchange for technical experts;
- invoice expenses within one month after the completion of SAS' work.
- protect all the received documents from the body to be evaluated from foreign access and to keep them safe;
- hand over the documents to the SAS in case of a contract dissolution;
- keep the official secrecy;
- inform the LA early on about possible absences or events, which could prevent him from the timely execution of the tasks;
- inform the LA, before accepting the mandate, about circumstances, which could call his independence, impartiality and integrity in connection with his activity as TE into question (see also point 7).

7 Independence, impartiality

The technical expert ensures that he is free from any interests, which could lead to his acting differently than always in a trustworthy, independent and impartial way as well as in a non discriminating manner towards the CAB to be assessed.

Possible business or private connections (e.g. consulting activity, mutual collaboration within the framework of bigger projects, family ties, close friendships, common university or university of applied sciences attendance) have to be disclosed by the technical expert before the assessment. The TE also informs the LA of possible, current or over the last five (5) years existing connections of his employer with the CAB to be assessed and possible collaborations and partnerships, as far as he is aware of them.

8 Billing

Assessment - Accreditation

The necessary amount of hours for the preliminary discussion and assessment, deducting breaks (meals) is to be invoiced at cost at the hourly rate stated in the contract.

It involves in essence the

- planning, preparation and conduct of the preliminary discussion;
- planning, preparation and conduct of the assessment for the granting, maintaining, extension or renewal of accreditation;
- issue and correction of the audit report and the accreditation register;
- control of the proofs of correction submitted by the CAB, concerning the removal of corrective actions, either with a document assessment or a renewed visit on-site;
- additional correspondence within the framework of the accreditation procedure with the SAS and the CAB, if appropriate.

Travel times and travel costs

The effective travel costs of the TE can only be brought into account upon production of the original receipt.

- For the bus, train and ship:
 - Refund of a full-price first class ticket, provided that the expense can be proven;
 - Refund of a half-price first class ticket without receipt or when using a SBB General Abonnement;
 - Federal employees, who have a Federal General Abonnement, are not entitled to an indemnification of trips, when using public transportations.
- For public transportations in cities and suburbs: the price of the ticket:
- For the plane: the plane ticket "Economy Class" (or in case of long trips outside Europe, according to an agreement with the SAS);
- For the private car and motorcycle: max. CHF 0.70/km (usually the shortest distance).

The TE can charge the SAS for **half** of the plain travel time (the shortest possible) within Europe, which isn't used for work concerning the preparation or the follow-up of the assessment activity, at the hourly rate stated in the contract. Waiting time, delays or detours are at the charge of the traveller. For longer trips, within and beyond Europe (with a total of more than ten (10) hours), the accounting of the travel time takes place after a special agreement.

If work concerning the preparation or the follow-up of the assessment activity is done during the outward or return journey, it can be charged at the hourly rate agreed in the frame contract.

The duration shown as plain (shortest possible) travel time, reduces itself correspondingly, and **half of it** can be charged afterwards.

Meals and expenses for the overnight stay

A flat fee of CHF 27.50 is paid for lunch and dinner. If lunch exceeds this amount, a maximum of double the flat fee is reimbursed upon submission of the original receipt together with the technical expert invoice. In accordance with the applicable SECO regulations, a maximum of CHF 180.00 is paid for hotel accommodation per night upon submission of original receipt.

Criteria for TE concerning the time needed for the preparation and the reporting

- For an assessment day (for the granting, extension or renewal of accreditation): between approximately 4 to maximum 6 hours;
- For two assessment days (for the granting, extension or renewal of accreditation): between approximately 6 to maximum 9 hours;
- For an assessment day (for the surveillance of accreditation), the above mentioned lower time statements apply as criteria.

Information / cost estimate

The technical expert is to inform the LA, without being asked and early on, about an expense to be invoiced, which would exceed the cost estimate developed by the LA for the technical assessment of the CAB.

Billing

The invoice template (Form 899f103n), which the lead assessor makes available to the technical expert in the course of issuing mandates, is used for the creation of the invoice for expenses and must be completed in full. The order number, which is already entered in the invoice template, must not be changed.

When issuing mandates and invoices via the employer (on company stationery), form 899f103n must be completed and enclosed with the invoice. The original documents (e.g. train tickets, airline tickets, hotel invoices, taxi receipts) must be enclosed with the invoice. However, lunch receipts for less than CHF 27.50 do not need to be submitted.

It is compulsory for all experts of pension age to state the period during which the services were rendered when invoicing their fees as this ensures that the social security contributions and income subject to contributions is calculated and entered correctly. The period during which the work is performed, in other words the period from the start of preparations of the assessment activities to the check of the rectification of non-conformities must be entered.

Following points cannot be invoiced:

- General training periods relating to the accreditation system, and the participation in general events concerning further training in connection with the accreditation;
- Meal breaks;
- The time needed for the personal training and introduction "to the object", as far as they are not absolutely necessary for the assessment of activities within the framework of accreditation.

Additional information

The SAS reserves the right to make a reduction of the request, in case of non-verifiable or excessive refund requests concerning the expenses or in case of groundless or late communication of the fixed / estimated costs for the activity as TE.

The responsible LA furnishes particulars concerning the cost estimate, billing and compensation practice.

Note: Chapter 8 as well as form 899f103n apply for all TE, except for the technical experts coming from the Federal Administration, who participate in the assessment in the name of their employer. Normally, the regulations of the Federal Finance Administration (FFA) concerning accounting for services (in consideration of the materiality limit) apply for employees of the Federal Administration.

The TE from the Federal Administration notifies the responsible SAS LA about the number of hours spent, who passes this information and the corresponding costs on to the CAB, if no contrary agreements between the federal offices have been made. Agreements between the SAS and the federal offices are concluded by the heads of department and the head of the SAS.

The credit for the beneficiary will take effect 30 days after the filing of the bill and its formal approval by the SAS.

As of January 1st, 2016, the furnishers and service providers of the federal administration are required to submit electronic bills if the total amount exceeds CHF 5'000.00 during the contract period.

By means of this so-called e-billing all necessary billing-data can be transmitted from the invoicing party to the invoice recipient electronically.

This obligation applies to the invoicing of the technical experts who have a foreign domicile and for those whose invoicing is done by their employers. All the other technical experts are still excluded from the duty of submitting electronic bills.

9 Annexes

- Annex 01: Withdrawn (see form 899f103n)
- Annex 02: Sample of a technical expert's report (available only in German and French)

10 References

- SR 946.512, Ordinance on the Swiss Accreditation System and the Notification of Testing, Conformity Assessment, Registration and Matriculation Bodies (Accreditation and Notification Ordinance, AkkBV)
- ISO/IEC 17011: General requirements for accreditation bodies accrediting conformity assessment bodies
- Regulations of the Federal Finance Administration (FFA) concerning accounting for services

11 Amendments in the Edition of Mai 2016, Rev. 16

- Addendum to Section 8 (Invoicing): Use of form 899f103n and compulsory stating of period during which the services were rendered for experts in pension age
- Withdrawal of Annex 01

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Beilage 02

Schweizerische Akkreditierungsstelle SAS
(Name des Leitenden Begutachters/der Leitenden Begutachterin)
Holzikofenweg 36
3003 Bern

Bericht des Fachexperten/der Fachexpertin für die Akkreditierung (oder Überwachung oder erneute Akkreditierung)

Begutachtung vom dd.mm.yyyy
(oder Überwachung oder Begutachtung zur Erneuerung der Akkreditierung vom dd.mm.yyyy)

Anwesenheit Fachexperte / Fachexpertin: Datum

A Antragsteller

Name der begutachteten Stelle

Anmerkung: Sämtliche hier gewählten Beispiele beziehen sich auf Prüflaboratorien.

B Dokumente

Von der SAS übergebene Dokumente:

Falls von der SAS Dokumente abgegeben wurden, die für die Begutachtung des Prüflaboratoriums wichtig sind, bitte hier aufführen.

Vom Antragsteller übergebene Dokumente:

Eine vollständige Liste ist nicht notwendig. Bitte nur Dokumenttypen angeben oder die Liste der vom Antragsteller gelieferten Dokumente benutzen.

Beispiele (kursiv gedruckt):

CD mit sämtlichen Dokumenten aus dem Qualitätshandbuch

Für die Prüfungen (z.B. Lebensmittelmikrobiologie, Hämatologie, analytische Chemie) wurden folgende Fachdokumente geliefert:

- *neues Verfahren: Nr. 01-123*
- *neue Dokumente: Nr. 01-345, 02-456*

Anmerkung: Andere allgemeine Dokumente gemäss Liste des Prüflaboratoriums.

C Liste der Labormitarbeitenden, mit denen der Fachexperte gesprochen hat

Das Organigramm oder die Personalliste benutzen, wenn mehrere Personen befragt wurden:

Beispiel:

Frau X. Y., Biologin, Laborleiterin

Frau Y. Y., Laborantin, Bereich Chemie

Herr R. F., Physiker, Verantwortlicher Qualitätsmanagement

oder

Anmerkung: Kontaktpersonen auf dem beigefügten Organigramm aufgeführt.

D Liste der vom Fachexperten begutachteten Verfahren

Die Verfahrensnummern benutzen, um die begutachteten Analysenmethoden aufzulisten. Die Liste des Prüflaboratoriums benutzen, wenn die Anzahl der begutachteten Methoden zu gross ist.

Beispiel:

Nr. der begutachteten Methoden, gemäss Liste des Prüflaboratoriums:

- 01-123, genaue Bezeichnung
- 01-345, Abkürzung des Verfahrens
- SOP 112-14, Bestimmung des Fettgehalts in Milch mittels HPLC
- PA-Z123, Zugfestigkeitsprüfung an Hohlkörpern

oder

Anmerkung: Begutachtete Methoden sind auf der beigefügten Liste aufgeführt.

E Liste der vom Fachexperten begutachteten Einrichtungen

Die Referenznummern / Codierung des Prüflaboratoriums benutzen bei der Auflistung der begutachteten Einrichtungen.

Anmerkung: Eine Kopie der Einrichtungsliste des Prüflaboratoriums direkt benutzen, falls die Anzahl der begutachteten Einrichtungen zu gross ist.

Beispiel:

Nr. der begutachteten Einrichtungen, gemäss Liste der Einrichtungen

GC/MS-1, Typ

HPLC-3, Typ

Waagen, Typ

Zentrifuge-2, Typ

Analysenautomat, Typ

F Überprüfung der Nichtkonformitäten aus der vorhergehenden Begutachtung

(Nur gültig für Überwachung oder Erneuerung der Akkreditierung)

Die Nummern der anlässlich der Begutachtung vor Ort überprüften Nichtkonformitäten angeben, wertender Kommentar und Schlussfolgerungen abgeben. Erledigungskontrolle mit einem kurzen Kommentar versehen, indem festgehalten wird, ob der getroffene Entscheid oder die Umsetzung der Korrekturmassnahmen angemessen sind.

Anmerkung: Kommentare und Schlussfolgerungen zu denjenigen Nichtkonformitäten abgeben, die bis zu dieser Überwachungsvisite erledigt werden mussten oder zu denjenigen, von denen der Fachexperte glaubt, dass ihre Umsetzung vor Ort genauer überprüft werden sollte.

Beispiel:

Die Nichtkonformitäten 2 und 4 aus der letzten Überwachung wurden vor Ort kontrolliert und sind in Ordnung.

Nichtkonformität 2: Für den Fall, dass der Auftrag nicht durchgeführt werden kann, ist der Ablauf in der Vorschrift xyz nun klar beschrieben und wird korrekt umgesetzt.

Nichtkonformität 4: Die Reagenzien werden jetzt zu Anfang der Analyse auf dem Formular XY aufgezeichnet. Die Rückverfolgbarkeit der verwendeten Lose ist nun gewährleistet.

Zusammenfassend kann festgehalten werden, dass die vom Laboratorium erbrachten Korrekturmassnahmen für diese beiden Nichtkonformitäten gut sind. Die beiden Nichtkonformitäten sind erledigt.

G Überwachte Normpunkte

Für jeden Punkt, der vom Fachexperten begutachtet wurde, erfolgt eine beurteilende Zusammenfassung (positive und/oder negative Aspekte).

Anmerkung: Nicht alle nachfolgend aufgelisteten Systemelemente müssen vom Fachexperten zwingendermassen behandelt worden sein.

Die Nummern der bei der Begutachtung ausgesprochenen Nichtkonformitäten werden den hier erfolgten Kommentaren zugeordnet. Die Empfehlungen werden eindeutig als solche gekennzeichnet.

Anmerkung: Bei der Überwachung werden die Punkte behandelt, die im Überwachungsprogramm erwähnt werden oder anlässlich der Visite mit dem Leitenden Begutachter der SAS abgesprochen wurden.

- **Organisation**
- **Managementsystem**
- **Externe Zusammenarbeit**
- **Pflege des Managementsystems**
- **Personal**

Beispiel:

Seit dem letzten Überwachungsbesuch hat es zwei Austritte und zwei Eintritte beim Laborpersonal gegeben. Infolge der Austritte gab es in zwei Sektionen (Chemie und Mikrobiologie) Wechsel beim Führungspersonal. Frau Chem (neue Mitarbeiterin) hat die Leitung der Sektion Chemie übernommen, Frau Mikro (interner Wechsel) hat die Leitung der Sektion Mikrobiologie übernommen. Diese beiden Personen sind für ihre neuen Funktionen bestens qualifiziert, indem sie folgende Ausbildungs- bzw. Erfahrungsnachweise vorlegten:

- **Räumlichkeiten**

Beispiel:

Die Räume im Bereich Werkstoffprüfung wurden seit dem letzten Überwachungsbesuch renoviert und vergrössert. Dadurch können nach Ansicht des Labors die Prüftätigkeiten fließender ineinander übergehen.

- **Einrichtungen**

Beispiel:

Sämtliche Einrichtungen sind gemäss Vorschrift eindeutig gekennzeichnet und inventarisiert. Die Wartungen und Kalibrierungen werden gemäss den Wartungsanweisungen durchgeführt und korrekt dokumentiert.

Das Anbruchsdatum der Reagenzien wird nicht aufgezeichnet. Diese Information ist im Zusammenhang mit der Gebrauchsdauer der Reagenzien wesentlich und wird deshalb künftig aufgezeichnet:

- **Probennahme**

Beispiel:

Die Blutentnahme erfolgt in einem separaten, dafür vorgesehenen und adäquat eingerichteten Raum. Für die Blutentnahme bestehen Entnahmevorschriften, die von den Laborantinnen eingehalten werden.

Die Patienten werden korrekt identifiziert und die anlässlich der Blutentnahme durchzuführenden Aufzeichnungen erfolgen korrekt auf den dafür vorgesehenen Formularen.

- **Handhabung von Prüfgegenständen**

Beispiel:

Die Proben sind klar identifiziert und die Daten, die zur Identifikation verwendet werden, elektronisch abgespeichert. Die Proben können von der Entnahme bis zur Entsorgung zurückverfolgt werden.

- **Prüfverfahren**

(Abhängig vom Typ A, B oder C: Entwicklung, Validierung, Modifikationen, Einführung/Freigabe, Handhabung, Auswertung, Anweisungen, Aufzeichnungen).

Beispiel:

Für das neue Prüfverfahren xyz, welches in den Geltungsbereich der Akkreditierung eingebracht werden soll, wurde ein vollständiges Validierungsdossier erstellt, aus dem die Lenkung des Verfahrens hervorgeht bzw. dessen Leistungsgrenzen ersichtlich sind. Das Prüfverfahren xyz wird vom Laborpersonal gut beherrscht und kann somit in den Geltungsbereich der Akkreditierung aufgenommen werden.

Andere begutachtete Prüfverfahren (siehe Liste unter Punkt D): Die internen Kontrollen dieser Verfahren werden aufgezeichnet und liegen in den Vorgaben der Regelkarten.

- **Sicherung der Qualität von Prüfergebnissen**

(Inklusive Teilnahme an Vergleichs- und Eignungsprüfungen und deren Ergebnisse, interne Kontrollen/ externe Kontrollen).

Beispiel:

Das Prüflaboratorium hat in allen relevanten Bereichen an Vergleichs- und Eignungsprüfungen teilgenommen. Daraus konnten die folgenden Massnahmen abgeleitet werden;

Überprüft wurden folgende Ringversuche/Externe Qualitätskontrollen: Code, Bezeichnung, Veranstalter, Parameter/Analyst, Datum der Teilnahme.

- **Prüfberichte**

H Schlussbemerkungen

Die Begutachter erhalten auf Grund der Begutachtung insgesamt einen sehr positiven Eindruck. Die Kompetenz des Personals sowie die qualitätssichernden und vertrauensbildenden Massnahmen überzeugen.

Datum:

Der Fachexperte/die Fachexpertin:

Beilagen:

Kopie an: