



Schweizerische Eidgenossenschaft
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Federal Department of Economic Affairs,
Education and Research EAER
State Secretariat for Economic Affairs SECO
Swiss Accreditation Service SAS



Accreditation in Switzerland & Challenges

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Outline

- ❖ **Swiss Accreditation Service SAS**
- ❖ **Accreditation activities**
- ❖ **International network and goal**
- ❖ **Collection of challenges**
- ❖ **Conclusion – Summary**



Swiss Accreditation Service SAS (1/3)

- **Service active since 1991**
- **Office in Bern.**
- **726 accredited conformity assessment bodies (CABs).**
- **Personnel: 40 permanent (36 FTE, 21 Lead Assessors / File Managers).**
- **About 500 external technical experts regularly used in assessments managed by permanent staff of SAS.**
- **Operates on a not-for-profit basis.**



Swiss Accreditation Service SAS (2/3)

- **Operating budget 9.5 million CHF / year (+/- 80% covered by accredited CABs).**
- **Acts as independent governmental service underpinned by law on accreditation and designation and given fee structure.**
- **Linked to State Secretariat for Economic Affairs SECO (providing basic services to SAS; until 2006 linked to METAS).**



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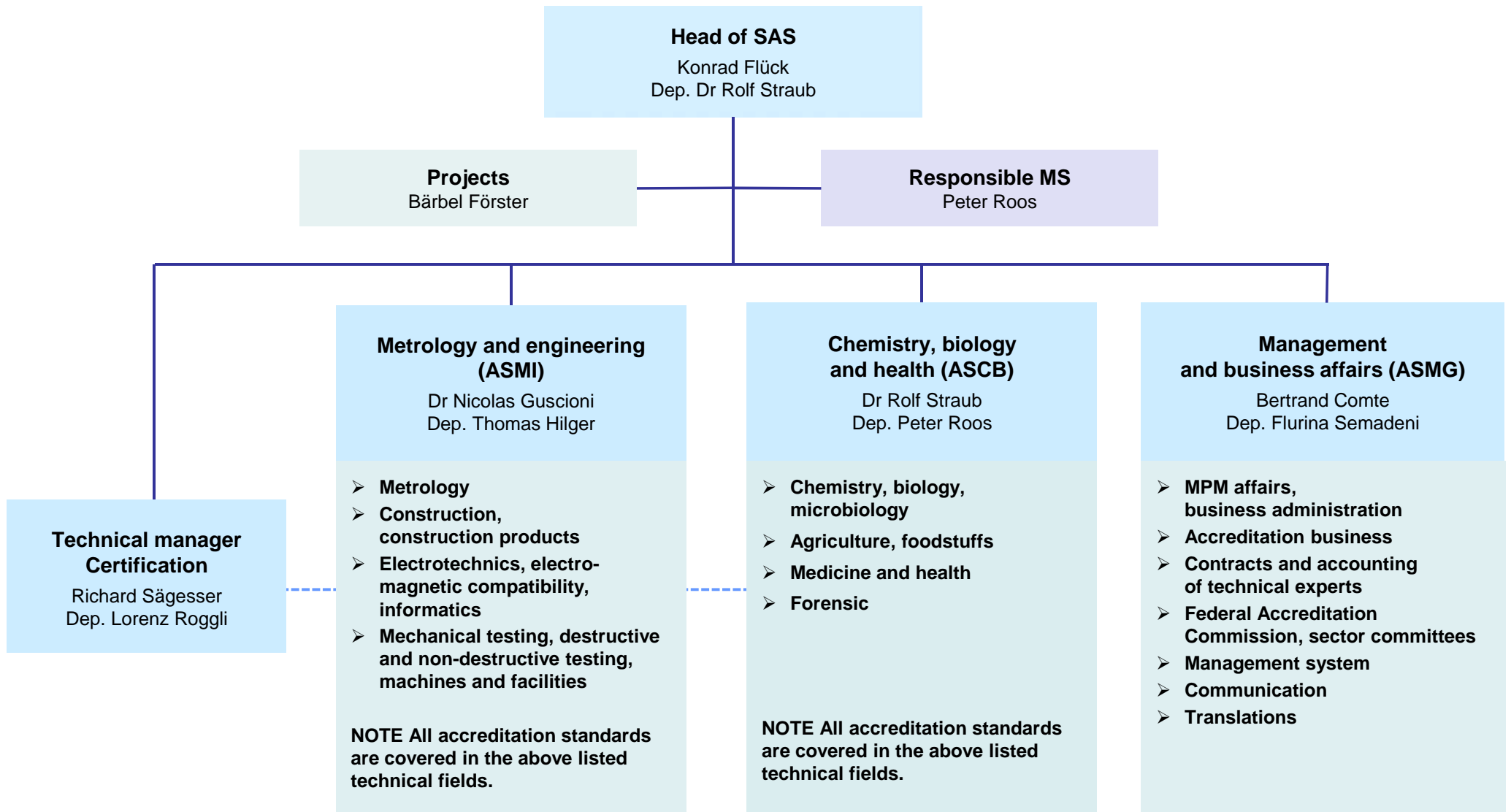
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Swiss Accreditation Service SAS (2/3)





SAS – Accreditation activities (1/2)

Laboratories	Testing and Calibration Laboratories	ISO/IEC 17025
	Medical Laboratories	ISO 15189
Inspection Bodies		ISO/IEC 17020
Certification Bodies	for Management Systems	ISO/IEC 17021
	for Persons	ISO/IEC 17024
	for Products	ISO/IEC 17065
Providers of Proficiency Tests		ISO/IEC 17043
Producers of Reference Materials		ISO Guide 34



SAS – Accreditation activities (2/2)

Accredited bodies in accreditation fields in %:

- 58 - Testing (Med. Labs ca. 20)
 - 18 - Inspection
 - 13 - Calibration
 - 4 - Certification - Product
 - 3 - Certification - Management System
 - 2 - Certification - Person
 - 1 - Reference material
 - 1 - Proficiency testing
- 89 %
- ...the challenge in dealing with ...



International Accreditation Networks

... in which SAS acts as a member:



Main objectives

- Mutual recognition of accreditations among the member states in the EU & EFTA.
- Mutual recognition of accreditation bodies (ABs) and certificates issued by accredited CABs on a global (worldwide) context.
- Prevention of barriers to trade and multiple accreditations.



... as such SAS underlies the EA-rules

- Peer Evaluation by EA in 2015.
- **SAS' competence was again formally stated by EA in spring 2016 in the fields of ...**
 - calibration, testing, medical examination (according to ISO 15189), inspection, certification of management systems, persons and products.
- **Supporting international recognition of certificates & reports issued by SAS-accredited CABs.**



... acting as a central pillar supporting

❖ Quality assurance

(...e.g. increasing structure in the CAB's organisation...)

❖ Consumer protection

(...e.g. by assessing CAB acting as notified bodies...)

❖ Economic competitiveness

(...e.g. test/inspect it once, accept it everywhere...)

➤ Accreditation as a means to establish confidence





Challenge – home made (1/2)

- **Economy generally demands required service with a fast and reliable delivery and appropriate quality for the cost involved. This is also valid for the execution of accreditation services (...as it is close to market needs).**
- **For a governmental body like the SAS, adequate timely response to a demand is subject to far more organisational restrictions than for private economy.**
Furthermore, restrictions in the public procurement process limits in some cases awarding multiple mandates to experts.
- **Various requests of accreditation (for routine work as well as for new fields & schemes) reach SAS almost weekly.**
- **Training activities and maintaining of recent knowledge of assessors to cover all fields needs a lot of resources.**



Challenge – home made (2/2)

- **Despite the fact that the amount of accredited CABs is only slightly increasing there were since years considerable mergers of accredited laboratories into multisite bodies.**
(...results in only one CAB for the yearly statistics but with several sites and more complex structure).
- **SAS assesses in all technical fields in three languages (G, F, I; as well as in English in some cases). Therefore, it is often very difficult to get all necessary competences including advanced language skills into the assessment teams.**
- **SAS assesses in Switzerland as well as abroad (Europe and the whole world) and this causes additional burden to staff.**
- **SAS is constantly acting with the aim to ameliorate the respective situation taking also into account an increasingly changing environment.**



Challenge – Revision of standards

- Standards in all sectors are periodically revised.
- CABs applying such revised – **and often abundantly extended standards** – let us, the ABs, know, that our accreditation service is getting more and more intensive and expensive as well ...
- Nevertheless, changes in the respective standards were mainly decided by the national standardisation organisations (... and not the ABs)!
(... e.g. ISO 15189 contains the term “shall” 322 times and ISO/IEC 17025 263 times in the respective standards!)
- **ABs have in consequence only little choice and degrees of freedom in applying the new standard(s). It is expected that the AB acts accordingly under the relevant rules, in view to assess the conformity/competence of the applicant CAB in an impartial and independent manner.**



Challenge – ISO/IEC 17011:2011j (1/2)

- **Despite the fact, that the entry into force of the new standard for accreditation bodies is not yet defined, the future content is more or less known.**
- **Perhaps delicate issue: Criteria of competence regarding the personnel of accreditation bodies including experts were enlarged & specified. This may lead to a more difficult and expensive procurement of personnel & experts and higher costs of such personnel.**

(... one more example of higher requirements in a standard leading to corresponding costs for the ABs and subsequent for the accredited CABs).



Challenge – ISO/IEC 17011:2011j (2/2)

- **In the discussion regarding the revision of this standard also many of directly concerned ABs were very active.**
- **This is valid for the SAS as for other European ABs.**
- **Thus, even worse alterations of the standard could be prevented (... e.g. a standard accreditation validity of less than 5 years).**
- **At large, the overall result is quite good as long as ILAC and IAF will not later add restricting requirements to ABs assessing in particular fields.**
(... e.g. see the amount of mandatory documents issued in these two international organisations!)



Challenge – Revision of ISO/IEC 17025 (1/3)

- **As cited before, 58 % of the CAB accredited by SAS are laboratories;**
- **... out of the total number of 424 laboratories, 406 are accredited under ISO/IEC 17025:2005 (including 95 calibration laboratories).**
- **The relative high number of laboratories means that SAS will especially be challenged to assess with existing resources such a number of applicants in due time based on to the future version of the standard ISO/IEC 17025!**



Challenge – Revision of ISO/IEC 17025 (2/3)

The new standard

- **will get a format that is more in line with new ISO formatting guidelines;**
- **contains a basic format that is similar to other new standards such as ISO/IEC 17020 and ISO/IEC 17065;**

(... option A and option B for the management system. ⇒ How to treat option B is already a controversial issue for ABs around the world identified in assessments of inspection bodies).

CD2 ISO/IEC 17025; 8.1.3 Option B

A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of [clauses 4 to 7 of ISO/IEC 17025](#) also fulfils at least the intent of the management system section requirements (8.2 - 8.9).

ISO/IEC 17020; 8.1.3 Option B

An inspection body that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of [this International Standard](#), fulfils the management system clause requirements (see 8.2 to 8.8).

- **will be aligned to ISO 9001:2015 principles on resources and process.**

(... following the philosophy requires less documented procedures and policies.

⇒ It focuses more on the outcomes of a process, but it can be more difficult to prove sustainability and harmonized approach with less written proves).



Challenge – Revision of ISO/IEC 17025 (3/3)

The new standard

- **will put additional rigor to assure the quality of results.**

(... in many parts of the standard, risk analysis will be required in some form [*identify risks to its impartiality in new clause 4.1.4, 7.17a), 8.1.2 a), 8.5 /.1, .2 and .3, 8.9.4 a)-k)*] ⇒ very likely becomes a matter of opinion (applicant laboratory versus assessment team, as the base is unclear how risk assessment should be performed, presented, judged and evaluated).

ISO/TS 22367:2010, Medical laboratories. Reduction of error through risk management and continual improvement

ISO 31000:2009, Risk management – Principles and guidelines, provides principles, framework and a process for managing risk

ISO 14971:2007, Medical devices – Application of risk management to medical devices

...



To conclude...

SAS is the national accreditation body and a part of the Swiss Federal Administration.

Base for accreditation in Switzerland is a law on accreditation and designation (... compatible to Regulation (EC) 765/2008).

SAS accredits mainly laboratories and inspection bodies from all sizes (from a “one-man” organisation to companies up to several hundred employees) located at a single to multiple sites.

Challenges are mainly identified:

- **in the internal structure of the Service as a Governmental Body,**
- **in the particularities of Switzerland as a multilingual society,**
- **in the increasing amount of assessment tasks triggered by new & revised normative requirements of all kind in all technical fields (leading to proliferation of standards and considerable work).**
- **Proper transfer from old to new requirements in due time not always knowing all particularities when applying it in assessment for the first time (... ultimate challenge for both parties!).**



End



**Thank you for
your attention!**

Any questions?

**THANKS
YAY!**