

Constitution of Swedish Board for Accreditation and Conformity Assessment

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Regulations amending the Swedish Board for Accreditation and Conformity Assessment's regulations (2020:1) and general advice on accreditation

STAFS 202X:XX

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Decided xxxx 20xx.

The Swedish Board for Accreditation and Conformity Assessment (Swedac) provides, on the basis of Section 3 of the Ordinance (2011:811) on Accreditation and Conformity Assessment regarding the Board's regulations and general advice (STAFS 2020:1) on Accreditation and Conformity Assessment

that 19, 27-30 §§ and 32 § shall be repealed,

that the headings closest to 24 and 25 §§ are deleted,

that 1-3, 9-11, 12-13, 16, 18, 20 §§ and 23-25 §§ should read as follows,

that Annex 1-2 is amended to read as follows,

that three new paragraphs, Paragraphs 9a and 35-36 §§, should be inserted, with the following wording.

Introduction

Scope of application

§ 1¹ These regulations apply to bodies that apply for or have been granted accreditation by Swedac.

Definitions and abbreviations

§ 2² For the purposes of this Regulation

1. *accredited report/accredited certificate, certificate, calibration certificate or statement*: a document containing the results of a conformity assessment activity included in the scope of accreditation of the accredited body and containing a reference to accreditation with the accreditation symbol or text;

2. *accreditation symbol* the representation in the following order of:

(a) Swedac's accreditation mark,

(b) accreditation number preceded by 'SE-V-' for bodies accredited for tasks in order to EMAS³,

(c) Conformity Assessment Procedure;

¹ Last version STAFS 2020:1.

² Last version STAFS 2020:1.

³ Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC.

(d) Conformity Assessment Procedure, accompanied by the relevant designated label (A), (B) or (C) for accredited inspection bodies, or ‘EMAS’ for bodies accredited for EMAS tasks,

3. *flexible scope accreditation*: accreditation the scope of which is defined in such a way as to allow the accredited body to make certain types of changes to the services offered under accreditation,

4. *witnessing*: observation of bodies when carrying out activities within the scope of their accreditation sought or granted,

5. *EA*: the European Co-operation for Accreditation,

6. *IAF*: the International Accreditation Forum,

7. *ILAC*: the International Laboratory Accreditation Cooperation,

8. *Conformity Assessment Procedure*: the conformity assessment activity of a body which is or may be accredited for that task. Examples of different conformity assessments are management system certification, testing and inspection,

9. *Standard for Conformity Assessment*: the standard for bodies carrying out a conformity assessment activity,

10. *conformity assessment/certification scheme*: a set of rules and procedures describing the objects, requirements and methodology of a given conformity assessment,

11. *body*: means company, operation, establishment or organisation possessing legal capacity,

12. *same management*: any person or group of persons within the same organisation who takes overall responsibility for the accredited activity,

13. *same management system*: a set of interconnected rules and processes established by the same management to enable that management to take responsibility for the accredited activity,

14. *same organisation*: group consisting of several bodies, spread over one or several locations, linked to the accredited body by a contract or an equivalent legal relationship operating under the same name and logo

15. *sub-scope*: specification of the scope of accreditation according to the principles applied in the IAF’s MLA contract,

16. *subcontractor*: person contracted by an accredited body to carry out a conformity assessment related activity, such as inspection or testing.

Requirements related to conformity assessment order and conformity assessment procedure

§ 3⁴ Swedac accredits conformity assessment bodies in accordance with the requirements of harmonised standards and any additional requirements referred to in Article 2.10 of the Regulation of the European Parliament and Council (EC) No 765/2008 of 9 July 2008 setting out the requirements for accreditation and repealing of Regulation (EEC) No 339/93. These requirements can be found on Swedac’s website www.swedac.se.⁵

Requirements for demonstrating that the conditions for accreditation are met

§ 9⁶ A body applying for accreditation shall demonstrate that it meets the requirements for accreditation.

⁴ Last version STAFS 2020:1

⁵ Last version STAFS 2020:1.

⁶ Last version STAFS 2020:1.

A body to which accreditation has been granted shall at all times comply with the relevant requirements for accreditation and be able to demonstrate that it does so.

The body shall provide Swedac with access to personnel, premises, equipment, information and documentation in the respects and with the advance planning necessary for Swedac to be able to assess whether the requirements for accreditation are met.

§ 9a A body applying for accreditation or is an accredited body shall organise and participate in witnessing to the extent that Swedac deems necessary to ensure that the requirements for accreditation are met and in such a way that it is possible for Swedac, or another accreditation body appointed by Swedac in its place, to participate.

A body that lacks a customer base may, after Swedac's consent, instead organise and participate in reality-simulated witnessing.

§ 10⁷ A body applying for accreditation or is accredited shall have arrangements with:

1. their customers by whom they undertake to allow Swedac assessors' teams to witness the work of the organisation at the customer's premises, and

2. their subcontractors by which they undertake to allow assessment teams from Swedac to witness the subcontractor's work with the customer or the accredited body's assessment of the subcontractor.

Swedac may grant exemptions from this provision if it is judged, in view of the activities of the accredited body, that such agreements are not necessary, or if the body's ability to conclude such agreements is restricted by other provisions.

§ 11⁸ A body applying for accreditation or an accredited body shall allow observers appointed by Swedac, EA, IAF or ILAC to attend Swedac's assessments. The same applies to the person taking part in the assessment in order to interpret.

Requirements related to the reference to accreditation

§ 12⁹ An accredited body shall always issue an accredited report, certificate, attestation, calibration certificate or statement for the tasks covered by its accreditation, unless otherwise provided for by law or regulation or specifically agreed between the body and its client. If such a contract is concluded, the accredited body must inform its customer that Swedac will then not be able to certify the reliability of the results of the service performed. Such a contract may not be concluded where the requirement for accreditation is prescribed, laid down in a Conformity Assessment Procedure, or where the document is to be used in relation to third party.

§ 13¹⁰ When a body refers to its accreditation, it shall use the appropriate accreditation symbol in Annexe 1 to these Regulations or refer to the accreditation in text. Where the body refers to the accreditation in text, the information in the text shall correspond to that resulting from the accreditation symbol.

⁷ Last version STAFS 2020:1.

⁸ Last version STAFS 2020:1.

⁹ Last version STAFS 2020:1.

¹⁰ Last version STAFS 2020:1.

Where a body refers to its accreditation in a report, certificate, attestation, calibration certificate or statement, it shall indicate its name, mark or logo in connection with such reference.

General advice to § 13

For example, when the body refers to the accreditation in text, the text could take the following form. <Accredited body name> with accreditation number <X> is accredited by Swedac for <conformity assessment> according to <conformity assessment procedure>.

§ 16¹¹ Before performing a service, an accredited body shall inform its customers and other stakeholders about the extent to which services offered will be performed under accreditation. After a service has been performed, the accredited body shall clarify in a report, certificate, attestation, calibration certificate or statement the extent to which the respective service has been performed under accreditation.

Requirements when referring to international mutual recognition agreements

18 §¹² A body accredited by Swedac may refer to international mutual recognition agreements by using the IAF MLA mark and the ILAC MRA mark provided that:

(a) the IAF MLA mark and the ILAC MRA mark may only be used in a context related to accredited activities and in combination with the Swedac accreditation mark.

(b) when referring to the IAF MLA, Swedac shall be a sub-scope signatory,

(c) when referring to the ILAC MRA mark, Swedac shall be a signatory at level three according to the ILAC guidelines,

(d) the accredited body must have procedures in place to ensure that they and their customers do not use the IAF MLA in a misleading manner. Information on which MLA/MRA agreements Swedac is a signatory can be found at www.swedac.se.

The ILAC MRA mark has the following appearance and should be rendered without changing the proportions or the font, and with the text in readable size. The mark shall be reproduced in blue or black on a background which does not make it difficult to read. When blue is used, the colours shall be CMYK C100 M56 Y0 K0, or Pantone Matching System 293C, or RGB R0 G0 B229.



¹¹Last version STAFS 2020:1.

¹²Last version STAFS 2020:1.

The IAF MLA mark has the following appearance and should be rendered without changing the aspect ratio or the font, and with the text in readable size. The mark shall be reproduced in black and white or in the colours pantone 2747 (dark blue) and pantone 299 (light blue) and on a background which does not make it difficult to read the mark. The width of the mark shall not be less than 20 millimetres in print or 75 pixels when using digital media.



Disclosure requirements in the event of changes

20 §¹³ An accredited body shall inform Swedac without delay of the following:

1. change of name of the body,
2. the decision to declare the body bankrupt,
3. change of the registration number,
4. change of ownership of the body or any other company to which the accredited body is affiliated which may affect its independence,
5. the transfer or termination of the body's activities, or
6. loss of competence or equipment necessary for the accredited activity.

An accredited body shall also, without delay, inform Swedac of other changes that may affect its ability to fulfil the requirements for accreditation or the conditions for the operation of the accredited body.

Requirements of list of services offered under accreditation and list of changes

§ 23¹⁴ An accredited body shall compile a list of the services it offers under flexible scope. The list shall be kept up to date and contain the information specified in Annexe 2 to this Regulation and shall be publicly available, unless there are reasons why such publication is inappropriate.

The body shall also maintain a list of the changes made within the flexible scope during the accreditation cycle. The list shall be updated each time an amendment is made and shall contain the following information:

- date of the change,
- scope of the amendment,
- if it affects the list referred to in the first subparagraph, and
- any reference to validation or verification.

§ 24¹⁵ A certification carried out before the notification of the accreditation decision shall be considered as a certification under accreditation if, following an audit, the certification body finds that the requirements for the

¹³ Last version STAFS 2020:1.

¹⁴ Last version STAFS 2020:1.

¹⁵ Last version STAFS 2020:1.

certification under accreditation have been met and an accredited certificate has subsequently been issued.

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§ 25¹⁶ Where an accredited certification body consents to a customer who has obtained certification of its management system or of a product to reproduce the certification body logo or certification mark in combination with the accreditation symbol, the certification body shall have a policy and procedures in place for such use.

A certification body which has given its consent under the first subparagraph shall ensure that the accreditation symbol is not used in a context or manner that could lead to confusion as to the scope or meaning of the accreditation.

If the certification body becomes aware that the accreditation symbol is being used in the context or manner referred to in the second subparagraph, it shall request correction and inform Swedac of the occurrence.

§ 36¹⁷ The requirements for activities, processes and documentation included in the chapter on management systems in the harmonised standard relevant for accreditation pursuant to § 3 also apply to requirements laid down in these regulations and in any additional requirements referred to in § 3.

§ 37¹⁸ An accredited body shall not offer conformity assessment services in the form of certification or verification/validation against any of the standards referred to in § 3.

1. This Constitution shall enter into force on XX 2025.

For Swedac

ULF HAMMARSTRÖM















Stina Benderix

¹⁶ Last version STAFS 2020:1.

¹⁷ Last version STAFS 2020:1.

¹⁸ Last version STAFS 2020:1.




Accreditation symbols to refer to accreditation in reports, certificates, attestations or calibration certificates.

 Ackred. nr. 0000 Certification of management systems ISO/IEC 17021-1	 SE-V-0000 Environmental verifier EMAS	 Ackred. nr. 0000 Personnel certification ISO/IEC 17024	 Ackred. nr. 0000 Product certification ISO/IEC 17065
 Ackred. nr. 0000 Verification ISO/IEC 17029	 Ackred. nr. 0000 Validation ISO/IEC 17029	 Ackred. nr. 0000 Proficiency test ISO/IEC 17043	 Ackred. nr. 0000 Calibration ISO/IEC 17025
 Ackred. nr. 0000 Test ISO/IEC 17025	 Ackred. nr. 0000 Test ISO 15189	 Ackred. nr. 0000 Production of reference materials ISO 17034	 Ackred. nr. 0000 Control ISO/IEC 17020 (A)
 Ackred. nr. 0000 Control ISO/IEC 17020 (B)	 Ackred. nr. 0000 Control ISO/IEC 17020 (C)		

The digits 0000 refer to the accreditation number and the EMAS accreditation number assigned by Swedac.

¹⁹ Last version STAFS 2020:1.

Examples of combined accreditation symbols that may be used to refer to accreditation on stationery, in marketing material or other communication media.

 Ackred. nr. 0000 Calibration Test ISO/IEC 17025	 Ackred. nr. 0000 Test ISO/IEC 17025 ISO 15189	 Ackred. nr. 0000 Control ISO/IEC 17020 (B, C)
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Information such as the body's list under § 23 on accreditation with flexible scope shall include**1. Certification bodies**

- type of certification (e.g. management system, product, process, service or person),
- certification scheme,
- requirements against which certification is carried out (often a standard and/or regulation),
- industrial sector (to be specified only when relevant), and
- category of product, process, service or person (to be specified only where relevant).

2. Inspection bodies

- type of inspection body (according to EN ISO/IEC 17020),
- conformity assessment procedure (to be specified only when relevant),
- the nature and extent of the inspection carried out,
- conformity assessment procedure against which the inspection is carried out (often a standard and/or regulation).

3. Calibration laboratories

- the best measuring power (CMC), expressed by:
 1. quantity or normal measurement,
 2. calibration or measurement method,
 3. instruments or materials to be calibrated or measured,
 4. measuring range and, where relevant, other parameters (e.g. applied voltage), and
 5. measurement uncertainty.

4. Testing laboratories including medical laboratories

- the material or product to be tested,
- the component, parameter or characteristics/study to be tested, and
- test, or type of test, and, where appropriate, test technique/measurement principle, test method or equipment used.

5. Organiser of test or calibration comparison

- comparison programmes,
- type of object, and
- quantity or characteristics or, where appropriate, the type of quantity or characteristics to be identified, measured or tested.

6. Producers of reference materials

- type of reference material (certified or not),
- object or material matrix,
- the characteristics or properties, and
- the methodology used to determine the property value.

7. Validation and verification bodies

- type of activity (validation or verification),
- the conformity assessment procedure to which the statement to be verified/validated relates (often a standard and/or regulation),
- verification or validation scheme (to be specified only when relevant),
- and
- industrial sector (to be specified only when relevant).

8. Other conformity assessment bodies

- the specific task for which the body is accredited,
- the requirements against which conformity is assessed,
- conformity assessment procedure (to be specified only when relevant),
- and
- industrial sector (to be specified only when relevant).

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