

Consolidated version of

**Swedish Board for Accreditation and Conformity Assessment  
(Swedac) Regulations and General Guidelines on Accreditation  
(STAFS 2020:1)**

Amended up to and including STAFS 2026:3

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*Scope*

**Section 1** These regulations apply to bodies that are applying for or have been granted accreditation by Swedac.

*Definitions and abbreviations*

**Section 2** In these regulations, the following definitions apply

1. *accredited report/accredited certificate, certificate, calibration certificate or certificate of conformity*: document containing results from an activity related to conformity assessment that falls within the accredited body's scope of accreditation, and which bears the accreditation symbol or includes a reference to accreditation in text,

2. *accreditation symbol*: presented in the order specified below

a) Swedacs accreditation mark

b) accreditation number, shall be preceded by "SE-V-" for bodies accredited for tasks under EMAS<sup>1</sup>,

c) conformity assessment procedure,

d) conformity assessment standard or "EMAS" for bodies accredited for tasks under Emas.

3. *accreditation with flexible scope*: scope of accreditation formulated in a manner that allows the accredited body to make certain types of changes to the service offered under the accreditation,

4. *witnessing*: observation of body while it performs activities within its applied-for or granted scope of accreditation,

5. *EA*: the European Cooperation for Accreditation,

6. *IAF*: the international cooperation organisation for the accreditation of certification, verification and validation bodies (the International Accreditation Forum),

7. *ILAC*: the international cooperation organisation for the accreditation of bio-banks, inspection bodies, laboratories, providers of proficiency testing schemes and reference material producers (International Laboratory Accreditation Cooperation),

8. *conformity assessment procedure*: activity related to conformity assessment carried out by a body that is, or can become, accredited for the task,

9. *conformity assessment standard*: standard for body performing conformity assessment activity,

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<sup>1</sup> Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the 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.

10. *conformity assessment scheme/certification scheme*: set of rules and procedures describing object, requirements and methodology for a specific conformity assessment,

11. *body*: company, enterprise or organisation that possesses legal capacity,

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

13. *same management system*: set of interrelated rules and procedures established by the same management to enable responsibility for accredited activities,

14. *same organisation*: group consisting of several bodies, located at one or more sites, linked to the accredited body through an agreement or equivalent legal arrangement, operating under the same name and logotype,

15. *sub scope*: specification of scope of accreditation according to the principles applied in the IAF Multilateral Recognition Arrangement (MLA),

16. *subcontractor*: party engaged by an accredited body to perform a conformity assessment activity, for instance assessment or testing.

### **Requirements related to conformity assessment scheme and conformity assessment procedure**

**Section 3** Swedac accredits conformity assessment bodies in accordance with such requirements in harmonised standards and any additional requirements referred to in Article 2(10) of Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93. These requirements are listed for each accreditation area on Swedac's website [www.swedac.se](http://www.swedac.se).

### **Requirements related to the accreditation service**

#### ***General requirements***

##### *Requirements for the application*

**Section 4** An application for accreditation shall be submitted to Swedac.

An application is required for:

- 1) new accreditation,
- 2) change of the scope of the accreditation,
- 3) extension of accreditation with new branches or sites, or
- 4) accreditation with flexible scope.

##### *General guidelines for Section 4*

An application for a change in the scope of the accreditation should be submitted no later than three months prior to a scheduled inspection in order to facilitate assessment in connection with such inspection.

**Section 5** If an application relates to a conformity assessment scheme, the conformity assessment scheme shall be suitable for accreditation in terms of its management, design and purpose. In its assessment, Swedac applies *Swedac's policy for assessing the appropriateness of the conformity assessment scheme with regard to accreditation*. The policy is published on Swedac's website [www.swedac.se](http://www.swedac.se).

**Section 6** In order for an application for accreditation to be granted, the activity must be conducted within or managed from an area in which Swedac has a mandate to decide on accreditation and is, in accordance with international agreements entered into, empowered to offer accreditation. Swedac processes applications for accreditation for activities outside Sweden's borders in accordance with *Swedac's policy for cross-border accreditation*. The policy is published on Swedac's website [www.swedac.se](http://www.swedac.se).

**Section 7** Accreditation may be granted to a body for activities that are managed by the same management through the same management system. In a case where accreditation is sought for activities involving more than one body, accreditation may be granted if the bodies belong to the same organisation. If the activities are of a cross-border nature, the following prerequisites also apply for the accreditation:

1. that the body allows an accreditation body in the country in which the activities are carried out to assess conformity assessment activities conducted there; and
2. that the body accepts that Swedac and an accreditation body in the country in which the activities are carried out can exchange information about the body, even if the foreign accreditation body has not conducted any assessment.

**Section 8** A decision on accreditation shall be issued within two months of Swedac having received the necessary documentation for the evaluation of the body. The term necessary documentation refers to an application made in full in accordance with the Internal Market Act (2009:1079), which requires that the applicant has submitted all the necessary documents to Swedac in order for it to assess whether or not accreditation can be granted, that the assessment report is completed, and that a certificate of corrective actions not requiring supplementary information has been received by Swedac.

If necessary due to the investigation of the accreditation case, the processing time may be extended on one occasion only, by no more than one month. The applicant is informed of the reasons for extending the processing time prior to the expiry of the original deadline date.

In accordance with Section 8 of the Internal Market Act (2009:1079), an acknowledgement of receipt is sent to the applicant when the necessary documentation has been received by Swedac.

*Requirements for showing compliance with the conditions for accreditation*

**Section 9** A body applying for accreditation shall demonstrate it meets the requirements for accreditation.

A body that has been granted accreditation shall at all times comply with applicable requirements and be able to demonstrate such compliance.

The body shall provide Swedac with access to personnel, premises, equipment, information and documentation to the extent and within the time frame necessary for Swedac to assess whether the requirements for accreditation are fulfilled.

**Section 9a** A body applying for accreditation or holding accreditation shall arrange and participate in witnessed assessments to the extent deemed necessary by Swedac to ensure requirements for accreditation are fulfilled, and in such manner that Swedac, or another accreditation body appointed by Swedac, can take part.

A body without client assignments may, subject to Swedac's approval, arrange and participate in simulated witnessed assessments.

**Section 10** A body that is applying for accreditation or that is accredited must have agreements with:

- 1) its customers, through which the latter undertake to allow the assessment team from Swedac to witness the body's work on-site at the customer's premises, and
- 2) its subcontractors, through which the latter undertake to allow the assessment team from Swedac to witness the subcontractor's work on-site at the customer's premises, or the accredited body's assessment of the subcontractor.

Swedac may grant exception from this provision if, in view of the activities of the accredited body, it is deemed that such agreements are not necessary, or if the body's ability to enter into such agreement is restricted by other legislation.

**Section 11** A body applying for accreditation or holding accreditation shall permit observers appointed by EA, IAF and ILAC to attend Swedac's assessments, unless there are reasons making such attendance inappropriate. The same applies to any person participating in the assessment such as an interpreter.

*Requirements related to references to accreditation*

**Section 12** An accredited body shall always issue an accredited report, certificate, declaration of conformity, calibration certificate or declaration for assignment covered by its scope of accreditation, unless otherwise provided by law of regulation, or specifically agreed between the body and its client. If such an agreement is made, the accredited body must inform its client that Swedac will not be able to attest reliability of the results of the service performed. Such an agreement may not be entered where accreditation is a prescribed requirement, is stipulated within the conformity scheme or where the document is intended to be used in relation to a third party.

**Section 13** When a body refers to its accreditation, it shall use the appropriate accreditation symbol in Appendix 1 to these regulations, or use text to refer to the accreditation. If the body uses text to refer to the accreditation, the information in the text must correspond to that in the accreditation symbol.

When a body refers to accreditation in a report, certificate, calibration certificate or declaration, the body must display its name, brand or logotype in the proximity of the reference to accreditation.

*General guidelines for Section 13*

When the body refers to the accreditation in text, the text can be formulated as follows, for example. <The name of the accredited body> with accreditation number <X > is accredited by Swedac for <conformity assessment activity> according to the < conformity assessment standard>

**Section 14** Swedac's accreditation mark has the following appearance and must be reproduced in blue with the colour CMYK 100.44.0.0, PMS 300, RGB 0.120.193 or HEX #0078c1, and in yellow with the colour CMYK 0.30.100.0, PMS 7409, RGB 253.185.19 or HEX #fdb913, or in black or white, against a background providing good contrast.



**Section 15** An accredited body may only refer to its accreditation if it does so in such a context and manner that there can be no doubt that the accreditation was granted by Swedac, no doubt which body has been accredited, and no doubt over the scope of the accreditation or its meaning.

**Section 16** Before a service is performed, an accredited body shall inform its customers and other stakeholders to what extent the offered services will be carried out under accreditation. After a service has been performed the accredited body shall, in the report, certificate, calibration certificate or declaration, clearly indicate to what extent each respective service has been carried out under accreditation.

**Section 17** When making reference to accreditation in a language other than Swedish, accepted terminology must be used, equivalent to the corresponding Swedish terms. The text in Swedac's accreditation mark may not be translated.

*Requirements when making reference to international agreements on mutual recognition*

**Section 18** A body that has been accredited by Swedac may refer to international agreements on mutual recognition after applying for this with Swedac. The use of the IAF MLA mark and the ILAC MRA mark is permitted under the following conditions:

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

b) when referring to the IAF MLA mark, Swedac must be signatory at the sub-scope level.

c) when referring to the ILAC MRA mark, Swedac must be signatory at level three according to ILAC's guidelines.

d) the accredited body must have procedures in place to ensure they and their customers do not use the IAF MLA mark in a misleading manner.

Information about which MLA/MRA agreements Swedac is signatory to can be found at [www.swedac.se](http://www.swedac.se).

The ILAC MRA mark has the following appearance and shall be reproduced without altering its proportions or font, with the text in a readable size. The mark shall be reproduced in blue or black, on a background that does not hinder readability. When blue is used, the colors shall be CMYK C100 M56 Y0 K0 or Pantone Matching System 293C or RGB R0 G0 B229.



The IAF MLA mark has the following appearance and shall be reproduced without altering its proportions or font, with the text in a readable size. The mark shall be reproduced in black and white or in the colors Pantone 2747 (dark blue) and Pantone 299 (light blue), and on a background that does not hinder readability. The width of the mark shall not be less than 20 millimeters in print or 75 pixels when used in digital media.



**Section 19** repealed by STAFS 2025:2

*Requirements for information in the event of amendments*

**Section 20** An accredited body shall, without delay, inform Swedac of the following:

1. any change in the body's name,
2. any decision to place the body in bankruptcy,
3. any change in the company registration number,
4. any change of ownership of the body or other company to which the accredited body is affiliated that may affect the body's independence,
5. any relocation or closure of the body's operations, or
6. any loss of competence or equipment necessary for the accredited activities.

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

*Requirements for information in the event of withdrawal of accreditation*

**Section 21** An accredited body must have procedures established to ensure that its customers receive information about the full or partial withdrawal of its accreditation, or limitation of its accreditation, when such information can be presumed to be of importance for the customers. The procedures shall also ensure that the customers receive information about the consequences of the withdrawal or limitation of the accreditation.

The information must be provided in such a way and to an extent that is appropriate in the individual case.

**Special requirements for accreditation with flexible scope**

*Requirements for the process used for the development and implementation of new services under accreditation*

**Section 22** A body that has been granted accreditation with flexible scope must apply a documented process for the development and implementation that includes and ensures the following:

1. how the body determines requirements for execution and results;
2. how the body develops and validates the process in relation to the set requirements;
3. how the body verifies that the requirements have been met;
4. that there is an allocation of responsibilities for managing the accreditation with flexible scope and for carrying out the activities included therein,
5. that the customer is informed in the contract review whether or not the assignment can be included in the accreditation with flexible scope, and
6. that the information about what is included in the accreditation is transparent and accurate.

**Section 23** The accredited body shall keep a list of the services that the body offers under flexible scope. The list must be kept up to date and contain the information specified in Annex 2 to this regulation, and be made available to anyone who requests it, unless there are reasons that make such disclosure inappropriate.

The body shall continuously maintain record of the changes made within the framework of the flexible scope. The record must include the following information:

- all changes made during the past five years
- date of the change
- what the change concerns

- whether it affects the list referred to in the first paragraph, and
- any reference to validation and verification.

**Section 24** A certification carried out before the decision on accreditation was issued is valid as a certification under accreditation if the certification body, following a review, is able to establish that the applicable prerequisites for certification under accreditation have been met and an accredited certificate has subsequently been issued.

**Section 25** In cases where an accredited certification body authorises a customer, that has been certified for its management system or product, to use the certification body's logotype or certification mark in together with the accreditation symbol, the certification body must establish and implement a documented policy and procedures governing such use.

A certification body given authorisation under the first subparagraph must ensure that the accreditation symbol is not used in such a context or manner that may lead to a misunderstanding over the scope or meaning of the accreditation.

If the certification body is made aware that the accreditation symbol is being used in such a context or manner as indicated in the second subparagraph, the body shall require correction and inform Swedac of the situation.

#### *Requirements for the use of information and communication technology in auditing*

**Section 26** When a certification body uses information and communication technology to facilitate an audit or to conduct the audit without on-site presence, measures must be taken to ensure adequate effectiveness in the audit process. These measures must include:

1. that the certification body has reached an agreement on the arrangement with the customer;
2. that a risk analysis of the effectiveness of the audit process has been carried out and documented, and that the necessary steps have been taken to ensure effectiveness in the audit process; and
3. that the audit report describes the extent and manner in which the audit process has been conducted based on the information and communication technology used to facilitate the audit or to conduct the audit without being on site.

**Section 27** repealed by STAFS 2025:2

**Section 28** repealed by STAFS 2025:2

**Section 29** repealed by STAFS 2025:2

**Section 30** repealed by STAFS 2025:2

**Section 32** repealed by STAFS 2025:2

### **Special requirements for accreditation of notified bodies**

#### *Requirements for reference to accreditation*

**Section 33** An accredited body that is also a notified body and is required to state the identification number assigned by the European Commission must, at the same time, refer to accreditation in accordance with these regulations.

This also applies to a body that is notified as a recognised third-party body to the European Commission.

## Other provisions

**Section 34** Provisions regarding the obligation of an accredited body to pay fees to Swedac are set out in Section 21 of the Act (2011:791) on Accreditation and Conformity Assessment. Provisions concerning such fees can be found in Swedac's regulations on fees.

**Section 35** Swedac may, in individual cases and where there are special reasons, grant exemptions from the application of these regulations.

**Section 36** The requirements regarding activities, processes and documentation included in the management system chapter of the harmonised standard relevant to the accreditation, as referred to in section 3, must also apply to the requirements set out in these regulations and to any additional requirements referred to in section 3.

**Section 37** An accredited body shall not offer services involving conformity assessment in the form of certification or verification/validation against any of the standards referred to in section 3.

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## STAFS 2020:1

1. These regulations enter into force on 1 August 2020.
2. These regulations repeal the following of the Board's regulations and general guidelines:
  - Special Regulations (STAFS 2003:12) for Accredited Laboratories Working in the Field of Non-destructive Testing,
  - Regulations and General Guidelines (STAFS 2007:10) for the Accreditation of Bodies that Plan, Carry Out and Report Efficacy Evaluations according to GEP,
  - Regulations and General Guidelines (STAFS 2007:13) for Accredited Bodies that Certify Management Systems,
  - Regulations and General Guidelines (STAFS 2010:11) for Accredited Environmental Verifiers according to EMAS,
  - Regulations and General Guidelines (STAFS 2011:18) for Accreditation of Inspection Bodies,
  - Regulations and General Guidelines (STAFS 2011:33) for Accreditation of Laboratories,
  - Regulations (STAFS 2011:34) for Accreditation of Providers of Proficiency Testing Schemes,
  - Regulations and General Guidelines (STAFS 2011:35) for Accreditation of Reference Material Producers,
  - Regulations (STAFS 2012:6) on the Accreditation of Bodies for Validation and Verification of Greenhouse Gases,
  - Regulations and General Guidelines (STAFS 2013:5) for Accreditation of Bodies that Certify Products,
  - Regulations and General Guidelines (STAFS 2013:6) for Accreditation of Bodies that Certify Persons, and
  - Regulations and General Guidelines (STAFS 2015:8) on Accreditation.
3. Bodies granted accreditation prior to 1 August 2020 must meet the requirements of Section 10, second paragraph, regarding subcontractors no later than 31 December 2020.
4. The repealed regulations of the Board's Regulations and General Guidelines (STAFS 2015:8) on Accreditation shall be applied until 31 December 2021 with regard to what is prescribed in Section 29 on the labelling of inspected items.

5. The repealed regulations of the Board's Regulations and General Guidelines (STAFS 2011:18) for Accreditation of Inspection Bodies shall apply up to and including 31 December 2021 with regard to:
  - a) what is prescribed in Section 5 on inspection procedures for accredited inspection bodies of Type C, and
  - b) what is prescribed in Section 6 on requirements for participation in meetings.

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STAFS 2025:2

1. This regulation enters into force 1 January 2026.

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STAFS 2026:3

1. This regulation enters into force 1 October 2026.
2. The provisions in Section 2, point 2 d), Annex 1 and Annex 1a shall apply by 30 September 2029 at the latest

On behalf of Swedac

HÅKAN PETTERSSON

Stina Benderix

### Accreditation symbols for reference to accreditation in reports or certificates, declaration or calibration certificates

The letters XXXX refer, respectively, to the accreditation number and the EMAS accreditation number assigned by Swedac.



Accred. No. XXXX  
Testing  
ISO 15189



Accred. No. XXXX  
Inspection  
ISO/IEC 17020



Accred. No. XXXX  
Certification of  
Management systems  
ISO/IEC 17021-1



Accred. No. XXXX  
Certification of  
Persons  
ISO/IEC 17024



Accred. No. XXXX  
Calibration  
ISO/IEC 17025



Accred. No. XXXX  
Testing  
ISO/IEC 17025



Accred. No. XXXX  
Validation and  
Verification  
ISO/IEC 17029



Accred. No. XXXX  
Production of  
Reference materials  
ISO 17034



Accred. No. XXXX  
Proficiency testing  
ISO/IEC 17043



Accred. No. XXXX  
Product certification  
ISO/IEC 17065



Accred. No. XXXX  
Biobanking  
ISO 20387



SE-V-XXXX  
Environmental  
Verifier  
EMAS

<sup>2</sup> Latest version of regulation STAFS 2020:1

**Information that the body's list in accordance with Section 23 on accreditation with flexible scope must contain:**

**1. Certification body**

- type of certification (e. g. management system, product, process, service or person),
- certification scheme,
- specification of requirements to which the certification refers (often a standard and/or regulations),
- industrial sector (only indicated when relevant), and
- category of product, process, service or person (only indicated when relevant).

**2. Inspection body**

- type of inspection body (according to EN ISO/IEC 17020),
- conformity assessment scheme (only indicated when relevant),
- type and extent of inspection, and
- specification of requirements to which the certification refers (often a standard and/or regulations).

**3. Calibration laboratories**

- Calibration measurement capability (CMC), expressed by stating:
  1. measurand and reference material,
  2. calibration or measurement method,
  3. instruments or materials to be calibrated or measured,
  4. measurement range and, additional parameters where applicable (e.g. applied voltage), and
  5. measurement uncertainty.

**4. Testing laboratories including medical laboratories**

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

**5. Proficiency testing providers**

- proficiency testing programme,
- type of object, and
- measurand or property or, where appropriate, the type or measurand or property to be identified, measured or tested.

**6. Reference material producers**

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

**7. Validation and verification bodies**

- type of activity (validation or verification),
- the specification of requirements to which the statement to be verified/validated relates (often a standard and/or regulations),
- verification or validation scheme (only indicated when relevant), and
- industrial sector (only indicated when relevant).

**8. Other bodies that conduct conformity assessment**

- the specific task for which the body is accredited,
- the requirements specification against which conformity is assessed,
- conformity assessment scheme (only indicated when relevant), and
- industrial sector (only indicated when relevant).