An unofficial translation, in case of any discrepancies between the English version and the original Swedish version the latter will prevail.

SWEDAC

Consolidated version of

The Swedish Board for Accreditation and Conformity Assessment's (Swedac) Regulations and General Guidelines (STAFS 2010:10) on Accreditation;

The translation includes the following amendment STAFS 2012:9

Introduction

Scope

1 § These regulations apply to bodies that are accredited or to those applying to be accredited by Swedac. Additional provisions are contained in special regulations for accreditation within each area. *(STAFS 2011:29)*

Definitions

2 § These regulations reference is made to

CIPM MRA agreement	An international agreement on mutual recognition of measurement results (The International Committee on Weights and Measures Mutual Recognition Arrangement)
EA	The European accreditation co-operation organisation (European co-operation for Accreditation)
EMAS	The EU Eco Management and Audit Scheme
GEP	Practice that is based on EU directives and assumes that surveys, such as field trials, should be planned, conducted and reported in a well-documented manner (Good Efficacy Practice)
IAF	The international forum for the accreditation of Certification bodies (The International Accreditation Forum)
IAF MLA Mark	A mark which shows that the accreditation has been granted within the framework of the International Accreditation Forum Multilateral Recognition Arrangement
ILAC	The international forum for the accreditation of laboratories and inspection bodies (The International Laboratory Accreditation Cooperation)
ILAC MRA mark	A mark that shows that the accreditation has been granted within the framework of the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement
ISO 14065	The SS-EN ISO 14065:2012 standard - Greenhouse gases - Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition (ISO 14065:2007)
ISO 15189	The SS-EN ISO 15189:2007 standard - Clinical laborato-

	ries - Particular requirements for quality and competence
ISO/IEC 17020	The SS-EN ISO/IEC 17020:2012 standard - Conformity assessment - Requirements for the operation of various types of bodies performing inspection
ISO/IEC 17021	The SS-EN ISO/IEC 17021:2006 standard – Conformity assessment - Requirements for bodies providing audit and certification of management systems
ISO/IEC 17024	The SS-EN ISO/IEC 17024:2003 standard - Conformity assessment - General requirements for bodies providing certification of persons (ISO/IEC 17024:2003)
ISO/IEC 17025	The SS-EN ISO/IEC 17025:2005 standard - General requirements for testing and calibration laboratories (ISO/IEC 17025:2005)
ISO/IEC 17043	The SS-EN ISO/IEC 17043:2010 standard - Conformity assessment - General requirements for proficiency testing (of laboratories)
ISO/IEC 27006	The ISO/IEC 27006:2007 standard – Information technology Security techniques - Requirements for bodies providing audit and Certification of information security management systems
ISO/TS 22003	The ISO/TS 22003:2007 technical specification - Food safety management systems - Requirements for bodies providing audit and certification of food safety management systems
ISO Guide 34	ISO Guide 34:2009 - General requirements for the competence of reference material producers
EN 45011	The SS-EN 45011:1998 standard - Certification bodies - General requirements for bodies providing product certification of products (ISO/IEC Guide 65:1996)
Instruments	Testing/calibration, certification of products, management systems and persons, etc.
Conformity mark (for verification)	A mark used or issued under the rules of a conformity assessment procedure, indicating that an identified product, process or service is in conformity with a specific standard or other regulations.
Bodies	Organisers of proficiency testing programs, certification bodies for certification of products, management systems and persons; inspection bodies, laboratories, environmental verifiers, producers of reference material, verification bodies and bodies that plan, perform and report on efficacy studies according to Good Efficacy Practice (GEP)
SI units	The units in the internationally accepted SI system of units
Subcontractor	A company engaged by an accredited body to perform a service that is part of its accreditation

(STAFS 2012:9)

Accreditation

Applications for and decisions on accreditation

3 § An application for accreditation or amendment of the scope of accreditation must be submitted to Swedac.

General Guidelines on 3 §
Applications for accreditation can be submitted on forms provided by Swedac. The form specifies the information that the application must contain. This is also available for each respective area at <www.swedac.se>, the Swedac website.

Applications for extended accreditation should be submitted at least three months before a planned surveillance visit in order to allow assessment in conjunction with such surveillance.

Applications for accreditation from overseas bodies are administered in accordance with the provisions of EA, ILAC and the IAF guidelines available at <www.swedac.se>, the Swedac website.

4 § Provisions on the accreditation of government authorities are contained in 8 § of the Accreditation and Conformity Assessment Ordinance (2011:811). *(STAFS 2011:29)*

5 § Decisions on accreditation are reached by Swedac after an evaluation of the body.

The decision is communicated within one month of receipt by Swedac of the documentation necessary for the evaluation of the body. Necessary documentation refers to a complete application in accordance with the Act (2009:1079) on Services on the internal market, which means that applicants shall have submitted to Swedac all the documents necessary for determining whether accreditation can be granted or not, that the assessment report has been completed and that an account of corrective actions has been submitted to Swedac that does not require supplementary information.

If the investigation of the issue of accreditation requires this, the processing time can be extended by up to a month on no more than one occasion. The applicant is notified of the reasons for this extension prior to the expiry of the original closing date.

In accordance with 8 § of the Act (2009:1079) on Services on the internal market, the applicant is sent a note of confirmation that Swedac has received the necessary documentation.

Assessment before a decision on accreditation and surveillance

6 § Provisions relating to the effect that a body governed by these regulations shall at Swedac's request grant access to premises, information and documents to the extent required for its surveillance as described in 19 § of the Accreditation and Conformity Assessment Act (2011:791). *(STAFS 2012:9)*

General guidelines on 6 §
Swedac usually makes surveillance visits after consultations with the accredited body, but unannounced visits may occur should the need arise.

7 § During the first four years after notification of an accreditation decision, an accredited body shall undergo surveillance in the form of
1. supplementary assessment six months after notification of the decision,
2. surveillance visits that normally take place every twelve months after notification of the decision, and
3. reassessment four years after notification of the decision.

Subsequently, surveillance shall normally take place every sixteen months and reassessment every four years.

In addition, surveillance can be undertaken whenever necessary for any particular reason. *(STAFS 2012:9)*

Requirements for accreditation

8 § A body may be accredited for only such tasks that it is itself competent to perform.

9 § An accredited body shall possess a financial stability that does not jeopardize its ability to meet the requirements for accreditation.

> *General guidelines on 9 §*
> Accreditation is withdrawn when an accredited body is declared bankrupt, unless the administrator can demonstrate that its operations can be continued without any loss of quality.

10 § An accredited body shall ensure that adequate resources within the appropriate area of expertise are assigned for the task to be performed. The accredited body shall also ensure that sufficient time for the assignments is scheduled and that other aspects of these operations are performed under conditions that provide the quality essential to the assignments.

11 § An accredited body shall promptly inform Swedac of changes that could affect its ability to meet the requirements for its accreditation or the conditions under which it conducts its operations.

> *General guidelines on 11 §*
> Essential changes that may affect the body's ability to fulfil the requirements for the accreditation are e.g.
>
> 1. change of key personnel or key functions
> 2. coming or ongoing organizational changes
> 3. physical movement of the entire or parts of the activities to new premises
> 4. loss of essential equipment
> 5. change of ownership
> 6. change of legal person
> 7. bankruptcy
> 8. financial instability or
> 9. essential increase of the number of persons with functions within the accredited activities *(STAFS 2011:29)*

12 § Measurement results from an accredited operation shall, whenever possible, be traceable to SI units. Traceability to SI units is to be achieved either by engaging a calibration laboratory accredited by a signatory to international agreements in accordance with 32 § or a body that is a signatory to the CIPM MRA agreement.

Where traceability to SI units is not possible, the accredited body shall use another accepted procedure in order to demonstrate the reliability of its measurements.

> *General guidelines on 12 §*
> A procedure that shows the reliability of the measurements may, for example, comprise the use of certified reference materials.

13 § When a subcontractor is used, the provisions of 14 § and 25-28 §§ shall apply, unless otherwise specified in other statutes.

14 § An accredited body shall inform the client in writing that it intends to engage a subcontractor and, where appropriate, obtain the former's approval, preferably in writing.

15 § An accredited body shall have procedures for withdrawal and cancellation of reports, certificates, testimonials and conformity marks.

Accreditation of notified bodies

15 a § The Accreditation and Conformity Assessment Act (2011:791) states that assessment of bodies that apply for designation or notification for tasks in connection with conformity assessment or according to harmonized EU legislation (notified body) will be achieved through accreditation, unless otherwise prescribed. *(STAFS 2011:29)*

Limitation and withdrawal of accreditation

16 § In accordance with 6 §, first paragraph of the Accreditation and Conformity Assessment Act, Swedac may decide on restriction or withdrawal of an accreditation certificate under Article 5.4 of Regulation (EC) No 765/2008.

If an accredited body wishes for its accreditation to be withdrawn, a written request for withdrawal shall be submitted to Swedac. *(STAFS 2012:9)*

Reference to accreditation

General Provisions

17 § Reference to accreditation employs either the legend "a body accredited by Swedac" or an accreditation mark, which denotes the following symbol.

18 § The accreditation mark and the legend "a body accredited by Swedac" may be used only in accordance with the provisions of these regulations.

Within certain accreditation areas there are specific provisions on the accreditation mark, in regulations issued by other regulatory authorities.

19 § The accreditation mark or the legend "a body accredited by Swedac" may be used only together with the accredited body's name, mark or logo. The accreditation mark may not have a dominant position or size relative to the name, mark or logo.

20 § With reference to its accreditation, an accredited body shall ensure that misunderstandings do not arise as to the extent or significance of accreditation.

Reference to accreditation shall not be made in such a way that it gives the impression that Swedac is responsible for the contents of the document or for the operation in question.

21 § Has been repealed by *(STAFS 2012:9).*

Reference to accreditation in reports, certificates or testimonials

22 § When an accredited body reports results from its accredited operations, it shall state in its reports, certificates or testimonials that such work has been performed in its capacity as an accredited body.

When an accredited body reports results from the accredited operation together with results from non-accredited operations, the report, certificate or testimonial shall clearly indicate the results that pertain to the accredited operation.

Reports, certificates or testimonials from an operation not included in the accredited operation may not contain any reference to accreditation.

23 § In individual cases, and if there are special reasons, an accredited body does not need to refer to the accreditation provided that the customer and the accredited body have agreed in writing at the customer's request that the work was not performed by the body in its capacity as an accredited body.

24 § When an accredited body refers to its accreditation by means of the accreditation mark, the body shall state its accreditation number and the standard that forms the basis for its accreditation below that mark, in accordance with the *Appendix* to these regulations.

When an accredited body refers to the accreditation by means of the legend "a body accredited by Swedac", the body shall state its accreditation number and the standard that forms the basis for its accreditation in conjunction with the legend.

With reference to accreditation only the standard that forms the basis for accreditation shall be stated. Two standards shall be stated in cases where
1. laboratories are accredited to both the ISO/IEC 17025 and ISO 15189 standards
2. certification bodies are accredited to both the ISO/IEC 17021 and ISO/IEC 27006 standards
3. certification bodies and environmental verifiers are accredited to both the ISO/IEC 17021 and EMAS standards, and also
4. certification bodies are accredited to both the ISO/IEC 17021 standard and the ISO/TS 22003 technical specification.

A body which is accredited to the ISO/IEC 17020 standard shall also include the letter A, B or C in conjunction with the standard.

Bodies that are accredited with respect to the requirements of GEP shall indicate their accreditation number and GEP below the accreditation mark or in connection with the legend "a body accredited by Swedac".

General guidelines on 24 §
Swedac provides the accreditation mark with an indication of the accredited number of the accredited body and the relevant standard or equivalent.

Reference to accreditation in the use of subcontractors within the same conformity assessment procedure

25 § If an accredited body uses a subcontractor for tasks within the conformity assessment procedure to which the accreditation relates, the body may refer in reports, certificates or testimonials to its accreditation only if the subcontractor is accredited for the task in question.

However, an accredited calibration laboratory may not refer to its accreditation in calibration certificates if calibration has been performed by a subcontractor.

26 § If an accredited body uses a subcontractor for tasks within the conformity assessment procedure and to an extent to which the accreditation relates and the subcontractor is not accredited for the task at hand, the accredited body, however, may refer in reports, certificates or testimonials to its own accreditation, provided that the subcontractor meets the requirements of a relevant ISO/IEC standard and also that the accredited body
1. has notified Swedac that it intends to use a subcontractor,
2. has undertaken a supplier assessment of the subcontractor,
3. assumes responsibility for the subcontractor's work, and
4. shall give Swedac an opportunity to examine its assessment of the subcontractor.

Reference to accreditation in the use of subcontractors within different conformity assessment procedures

27 § If an accredited body uses a subcontractor for tasks within a conformity assessment procedure for which that body is not accredited, the subcontractor shall be accredited for the task at hand in order that the accredited body shall be able to refer to its accreditation in reports, certificates or testimonials.

28 § If an accredited inspection or certification body uses a subcontractor for tasks within a conformity assessment procedure for which that body is not accredited and the subcontractor is not accredited for the task at hand, the accredited body may refer, however, in reports, certificates or testimonials to its accreditation, provided that the subcontractor meets the requirements of a relevant ISO/IEC standard and also the accredited body
1. has notified Swedac that it intends to use a subcontractor,
2. has undertaken a supplier assessment of the subcontractor,
3. assumes responsibility for the subcontractor's work, and
4. shall give Swedac an opportunity to examine its assessment of the subcontractor.

General guidelines on 27-28 §§
For example, it may prove necessary for an accredited inspection body to use laboratories for tasks that support the inspection assignment. Similarly, it may prove necessary for an accredited body that certifies products to engage inspection bodies or laboratories for tasks that support the certification assignment.

The provisions of 28 § may apply to the operating of an examination facility for candidates for certification of persons.

Examination by Swedac of the ability of the accredited body to assess contractors may include a review of documentation or its participation as an on-site observer during such an assessment of subcontractors.

Reference to accreditation of tested, calibrated or inspected/verified objects

29 § The accreditation mark or the legend "a body accredited by Swedac" may be used on the tested, calibrated or inspected/verified objects in accordance with the provisions of Swedac regulations for each respective accreditation area or other regulatory authorities' regulations.

Reference to accreditation on letterheads and on or in the advertising and marketing materials

30 § An accredited body may use the accreditation mark or text "a body accredited by Swedac" on letterheads and on, or in, advertising and marketing materials, but not on business cards or the like.

On letterheads and on, or in, advertising and marketing materials, the accredited body may state all standards for which it is accredited below the accreditation mark or in conjunction with the legend "a body accredited by Swedac".

31 § If an accredited body uses the accreditation mark or the legend "a body accredited by Swedac" on letterheads in connection with quotations, where the quoted service is not included in the accreditation, the body shall clarify that the quotation includes services not covered by the accreditation.

Reference to international agreements on mutual recognition

32 § An accredited body may refer to international agreements on mutual recognition through the use of the ILAC MRA mark or the IAF MLA mark or by using a caption that refers to the EA, ILAC or IAF. Such a reference may be made only in combination with the use of the Swedac accreditation mark and in accordance with the provisions of these regulations.

The accredited body may use the ILAC MRA mark or the IAF MLA mark provided that the body has concluded an agreement with Swedac, to whom an application for such use must be submitted.

General guidelines on 32 §
Within the EA, ILAC and IAF, international agreements on mutual recognition of accreditation and accredited services have been concluded among the various accreditation bodies. Information on the extent of these agreements is available on the EA, ILAC and the IAF websites <www.european-accreditation.org>, <www.ilac.org> and <www.iaf.nu>, respectively.

When an accredited body in conjunction with the accreditation mark refers to one of the above agreements, this should be done using the following wording.

1. "Accredited by a signatory to the IAF MLA agreement for _ _ _", or
2. "Accredited by a member of the IAF MLA for _ _ _ "

References to the ILAC and EA agreements are made in the same way.

The ILAC MRA mark has the following appearance:

The IAF MLA mark has the following appearance:

33 § The accredited body may not refer to international agreements on mutual recognition on letterheads nor on, or in, advertising and marketing materials.

Other provisions

34 § An accredited body which as a result of its accredited activities may be liable for damages, shall ensure that such compensation can be paid by means of an insurance policy or in some other manner.

General guidelines on 34 §
In order to determine the risks that the accredited body runs, a risk analysis should be undertaken. The insurance cover and insured amounts should be tailored to the risk analysis.

35 § Provisions that an accredited body shall pay a fee to Swedac are contained in 21 § of the Accreditation and Conformity Assessment Act (2011:791). Provisions on such fees are contained in Swedac's regulations for fees. *(STAFS 2011:29)*

36 § Swedac may, in individual cases and if there are special reasons, grant an exemption from these regulations.

Transitional provisions

1.These regulations come into force on 1 January 2011, on which date the Board's regulations and general guidelines (STAFS 2007:7) on accreditation will cease to apply.
2. In the case of the accredited bodies that have been granted a two-year surveillance interval, the provisions of 7 § will not start to apply until after re-assessment of these accredited bodies.
3. If another statute cites provisions in Swedac regulations and general guidelines (STAFS 2007:7) on accreditation, which have been replaced by the provisions of these regulations, the new provisions shall apply instead.

STAFS 2011:29

These regulations come into force on 1 August 2011.

STAFS 2012:9

These regulations come info force on 1 October 2012.

Appendix

Examples of combinations of the accreditation mark, accreditation number and the relevant standard or equivalent in reports, certificates or testimonials

0000
ISO/IEC 17025

0000
EN 45011

0000
ISO/IEC 17020 (A)

0000
GEP

0000
EMAS

0000
ISO/IEC 17025
ISO 15189

0000
ISO/IEC 17021
ISO/IEC 27006

0000
ISO/IEC 17021
EMAS

0000
ISO/IEC 17024

Examples of combinations of the accreditation mark, accreditation number and the relevant standard or equivalent that may be used on letterheads and also on or in advertising and marketing materials

0000
ISO/IEC 17020 (A)
ISO/IEC 17025
ISO/IES 17021