

Swedish Board for Accreditation and Conformity Assessment Regulations



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The Swedish Board for Accreditation and Conformity Assessment's (Swedac) Regulations and General Guidelines for Accreditation of Bodies that Certify Products;

ratified on 26 August 2013.

In accordance with 3 § of the Accreditation and Conformity Assessment Ordinance (2011:811), the Swedish Board for Accreditation and Conformity Assessment (Swedac) hereby decides on the following regulations and general guidelines.

Scope

1 § These regulations apply to bodies that are accredited or are applying for accreditation by Swedac, for the certification of products.

These regulations are complementary to Swedac's Regulations (STAFS 2010:10) and General Guidelines for Accreditation.

Definitions

2 § In these regulations the standard ISO/IEC 17065:2012 refers to SS-EN ISO/IEC 17065:2012 – *Conformity assessment – Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012)*.

3 § These regulations use the definitions given in the standard ISO/IEC 17065:2012.

In these regulations, products refer both to physical products as well as processes and services.

Conditions for accreditation

4 § A body applying for accreditation for product certification shall show that the requirements in the standard ISO/IEC 17065:2012 have been met.

Accredited product certification bodies shall conduct their operations in accordance with the standard ISO/IEC 17065:2012.

*General guidelines to 4 §
General requirements for staff (section 6.1, standard ISO/IEC 17065:2012)*

The requirements regarding competence and experience should be regarded as covering all functions within the certification body – for example the management, evaluation and certification functions.

The management function

At the management level, the certification body should have good knowledge of the certification process and the body's own routines, and have general knowledge regarding the different normative documents.

The certification function

The function that makes decisions on certification should have sufficient competence regarding the normative documents, the body's own routines, and the process of evaluation so as to be able to independently assess the evaluations performed.

Application for accreditation

5 § An application for accreditation shall contain information about the areas of accreditation in the form of products or product categories, and for each area of accreditation, information on

1. the normative documents against which certification will be performed;
2. a description of how the conformity assessment will be performed;
3. which certifications have respectively been performed and planned;
4. routines to ensure the body's own competence; and
5. the results of the certification body's evaluation of the available competence.

6 § A body applying for accreditation shall show that the normative documents against which the certification under accreditation is to be done, as well as the application documents and the documents for production control or the equivalents, are unambiguous and publicly available.

The interested parties concerned shall have been provided with the opportunity to participate in the work on producing the normative documents.

Auditing the certification process

7 § Prior to a decision on accreditation, a certification body shall provide Swedac with the opportunity to participate as an observer during certification in accordance with the certification body's procedures, and to review the documentation from such certifications.

8 § A certification body shall ensure that, prior to a decision on accreditation and during surveillance assessments, its clients permit Swedac to participate as an observer during examination and other parts of the certification process.

Use of the accreditation mark and other references to accreditation

9 § Under the condition that the certification includes monitoring of production, an accredited certification body may give a business for which a product has been certified the right to reproduce the accreditation mark together with the name or symbol of the certification body on reports, certificates or equivalent material.

10 § A certification body that gives a business the right to reproduce the accreditation mark in accordance with 9 § shall ensure that the mark is not used in such a way or in such a context that could lead to misunderstandings about the scope or content of the accreditation.

If the certification body is made aware of the fact that the accreditation mark is being used in violation of the first paragraph, the body shall demand immediate rectification and inform Swedac of what has occurred.

The certification body shall see to it that the accreditation mark is not used once a certification that forms the basis for a concession in accordance with 9 § has ceased to apply.

Miscellaneous

11 § A certification carried out before a decision on accreditation has been announced is valid as a certification under accreditation if, after a review, the certification body can verify that the conditions that apply to certification under accreditation have been met. Such a certification review shall be documented.

12 § If the normative document that is being used is ambiguously worded or is in some other way incomplete, the certification body shall make this known to those responsible for the document.

13 § If there are special reasons, Swedac may, in individual cases, grant an exemption from these regulations.

Transitional provisions

1. These regulations come into force on 1 October 2013, when Swedac's regulations and General Guidelines (STAFS 2007:12) for Accreditation of Bodies that Certify Products cease to apply.

2. Accredited certification bodies may apply the older wording of 3 § instead of 4 § of these regulations until 16 September 2015.

On behalf of Swedac

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