

Consolidated version of

The Swedish Board for Accreditation and Conformity Assessment's (Swedac) Regulations and General Guidelines (STAFS 2011:5) for notified bodies;

The translation includes the following amendment STAFS 2012:10

Scope

1 § These regulations apply to bodies that are or are applying to be notified to the European Union in accordance with 7-9 §§ of the Act concerning Accreditation and Conformity Assessment (2011:791) for tasks associated with conformity assessment in accordance with Community harmonisation legislation.

The regulations do not apply to the extent otherwise is specifically provided in the relevant sector legislation relating to special requirements on the body in accordance with the Community harmonisation legislation to which the notification applies. (*STAFS 2011:28*)

Definitions

2 § The following definitions apply in these regulations:

notified body: a body that is or is applying to be notified to the European Union in accordance with 7-9 §§ of the Act concerning Accreditation and Conformity Assessment (2011:791) for tasks associated with conformity assessment in accordance with Community harmonisation legislation, such as notified body, approved body, recognised third party body, competent body.

conformity assessment: a process where it is shown whether specified requirements relating to a product, a process, a service, a system, a person or a body have been fulfilled.

certificate: a document certifying conformity produced by a notified body in accordance with Community harmonisation legislation, such as certificate, EC type certificate, report.

third party body: a body that fulfils such a degree of independence as follows from the harmonised standards referred to in article 2.9 and 2.10 of the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 on the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) NO 339/93¹. (*STAFS 2011:28*).

¹ EUT L 218, 13.8.2008, s. 30 (Celex 32008R0765)

Requirements on notified bodies

3 § Notified bodies shall have the competence that is needed and be suitable for the task the notification relates to.

In 7 § of the Act concerning Accreditation and Conformity Assessment (2011:791) is stated that assessment of bodies applying to be designated or notified for tasks related to conformity assessment according to Community harmonisation legislation (notified body) shall be performed by accreditation unless otherwise is prescribed.

Notified bodies which shall not be accredited in accordance with the second paragraph shall be assessed according to the following standard or standards which are applicable unless otherwise stated in the sectoral legislation.

- a) the standard SS-EN ISO/IEC 17020:2012 - Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection,
- b) the standard SS-EN ISO/IEC 17021:2011 – Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems,
- c) the standard SS-EN ISO/IEC 17024:2003 – Conformity Assessment - General Requirements for Bodies Operating Certification of Persons,
- d) the standard SS-EN ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories, or
- e) the standard SS-EN 45011 – General Requirements for Bodies Operating Product Certification Systems. (*STAFS 2012:10*)

General guidelines to 3 §

Has been repealed by (STAFS 2011:28).

4 § In addition to the requirements according to 3§, for notified bodies, the following also applies.

1. In order to be notified, the body shall fulfil the requirements in Items 2-11.
2. A notified body shall be organised in accordance with Swedish law and shall be a legal entity.
3. A notified body shall be a third party body independent of the organisation or product it assesses.

A notified body may be a body belonging to a business organisation or a sector organisation representing companies involved in construction, manufacturing, delivery, installation, use or maintenance of the products it assesses, provided the notified body can prove that it is independent and that there is no conflict of interests.

4. A notified body, its top management and the personnel responsible for ensuring conformity assessment is made may not consist of the entity constructing, manufactur-

ing, delivering, installing, buying, using or maintaining the products being assessed, or of an entity representing any of these parties. This shall not prevent the use of assessed products that are necessary for the activities within the notified body or personal use of the products.

A notified body, its top management and the personnel responsible for ensuring conformity assessment is made, may neither participate directly in the construction, manufacturing, marketing, installation, use or maintenance of these products, nor represent parties carrying out such activities. They may not participate in any activity that can affect their objectivity and integrity in conjunction with the conformity assessment for which the body has been notified. This shall apply in particular to consultancy services.

A notified body shall ensure that the activities of its subsidiaries or subcontractors do not affect the secrecy, objectivity or impartiality of its conformity assessment.

5. A notified body and its personnel shall carry out conformity assessment with the greatest possible professional integrity, have technical competence in the specific area and be free from all pressure and inducement, in particular financial incentives, that may affect their judgement or the results of their conformity assessment. This applies particularly for pressures and inducements from persons or groups of persons affected by the activities in question.

6. A notified body shall be able to carry out all the tasks relating to conformity assessment laid down in the Community harmonisation legislation to which the notification refers for such a body and for which it has been notified, irrespective of whether these tasks are carried out by the notified body or on its behalf and on its responsibility.

At all times, at each conformity assessment and for each type or category of products for which it has been notified, a notified body shall have at its disposal

- a) the requisite personnel with technical knowledge and sufficient experience to carry out conformity assessment,
- b) descriptions of procedures for carrying out conformity assessment; these procedures must allow openness and ensure the procedures can be repeated; the notified body shall have suitable routines and procedures for differentiating between the tasks it carries out in its capacity as a notified body and all other activities,
- c) procedures that make it possible for the notified body to carry out its activities with the requisite consideration paid to a company's size, sector and structure, the complexity of the product technology in question and the serial character of the production process.

A notified body shall have the requisite funds in order to carry out correctly the technical and administrative tasks in conjunction with conformity assessment and shall have access to the equipment and the aids that are necessary.

7. The personnel responsible for carrying out conformity assessment shall have

- a) satisfactory technical and professional training covering all types of conformity assessment within the area for which the body has been notified,
- b) satisfactory knowledge of the requirements for the assessments they make and authority to carry out these assessments,

- c) sufficient knowledge of and insight into the fundamental requirements, the applicable harmonised standards and the relevant provisions in Community harmonisation legislation and their instructions for implementation,
- d) the ability to draw up certificates, protocols and reports showing that the assessments have been made.

8. A notified body shall ensure that the body, its management and assessment personnel are impartial.

The remuneration to the management of and the assessment personnel at the body must not be dependent on the number of assessments made or the results of the assessments.

9. A notified body shall have professional indemnity insurance, unless the government assumes responsibility under Swedish law or the government itself takes direct responsibility for the conformity assessment.

General guidelines to 4 §, Item 9

In order to determine what risks a notified body runs, a risk analysis of the body should be carried out. The scope and amount of the indemnity insurance should be adjusted to suit the result of the risk analysis. The indemnity insurance should cover injury to persons and damage to property as well as financial loss caused without any connection to injury to person or damage to property.

10. Provisions governing secrecy for a notified body are contained in 22 § of the Act (2011:971) concerning Accreditation and Conformity Assessment.

11. A notified body shall participate in, or ensure its assessment personnel are aware of, the relevant standardisation work and the work carried out in the coordination group for notified bodies set up in accordance with the relevant Community harmonisation legislation. The body shall use the administrative decisions and documents that are the result of the group's work as general guidelines. (STAFS 2011:28)

Application for notification

5 § Application for notification shall according to 4 § of the ordinance (2011:811) concerning Accreditation and Conformity Assessment be submitted to Swedac. (STAFS 2011:28)

6 § The application shall be accompanied by a description of the conformity assessments or the module/s for conformity assessment and the product/s the body considers itself to be competent to assess, as well as an accreditation certificate, if such exists, issued by a national accreditation body within the EEA (European Economic Area), which confirms that the body fulfils the requirements in 4 §.

If the body cannot show any accreditation certificate, it shall submit to Swedac all supporting documentation required for control, recognition and regular surveillance to ensure the requirements of 4 § are fulfilled.

General guidelines to 6 §

The application should be done on a form provided by Swedac. An application to extend an existing notification may be made using the same form.

7 § For government authorities, special provisions governing applications for notification are included in 9 § of the Ordinance (2011:811) concerning Accreditation and Conformity. (*STAFS 2011:28*)

Subsidiaries and subcontractors of notified bodies

8 § If a notified body employs a subcontractor or a subsidiary for specific tasks connected to the conformity assessment, the body shall ensure the subcontractor or subsidiary fulfils the requirements in 4 §, pp. 2-11. The notified body shall inform Swedac of this.

The notified body shall assume full responsibility for the tasks carried out by the subcontractor or subsidiary, irrespective of where they are located.

An activity may be contracted to a subcontractor or carried out by a subsidiary only if the customer agrees to this.

At the request of Swedac, the notified body shall provide the relevant documents relating to the assessment of the subcontractor's or subsidiary's qualifications and the work carried out by these in accordance with the Community harmonisation legislation to which the notification applies.

Notified bodies' duty to inform

9 § A notified body shall inform Swedac of

1. any rejection, limitation and temporary or final recall of a certificate,
2. any circumstance that affects the scope of and conditions for the notification,
3. any request from an authorised sector authority for information on conformity assessment, and
4. any conformity assessment made within the framework for the notification and all other activities, including cross-border activities and activities as subcontractor, if Swedac should so request.

A notified body shall provide relevant information on issues relating to negative and, if requested, positive results of conformity assessments to other bodies notified in accordance with the Community harmonisation legislation to which the notification relates that carry out similar conformity assessments covering the same products.

Coordination of notified bodies

10 § A notified body shall participate in the European Commission's sector-specific or cross-sector coordination or cooperation groups that have been set up for these bodies, direct or through appointed representatives.

11 § At the request of Swedac, a notified body shall account for the way in which and to what extent it has participated in the European Commission's coordination and cooperation groups.

Withdrawal of notification and termination of activities as notified body

12 § Provisions governing that Swedac, in certain cases, may decide to limit or, temporary or in full withdraw the notification are contained in 10 § of the Act (2011:791) concerning Accreditation and Conformity Assessment. (STAFS 2011:28).

13 § In the event of limitation, temporary withdrawal or withdrawal of notification, or if the notified body has terminated its activities, the notified body shall ensure that its documentation is either handled by another notified body or, on request, is kept available for Swedac or an authorised sector authority.

Miscellaneous

14 § Provisions that a notified body shall provide access to premises and provide information to the extent requested by Swedac to enable it to assess the body and make a decision about notification or perform surveillance are included in 19 § of the Act (2011:791) concerning Accreditation and Conformity Assessment. (STAFS 2011:28).

General guidelines to 14 §

Normally, Swedac will carry out surveillance visits in consultation with the notified body. However, unannounced surveillance visits may occur if there is a need.

15 § According to 21 § of the Act (2011:791) concerning Accreditation and Conformity Assessment, a notified body assessed according to 7 § shall pay fees to Swedac for its assessment and surveillance. More detailed provisions about such fees are included in regulations issued by Swedac. (STAFS 2011:28).

16 § When a notified body markets services not covered by its task as a notified body, it must not give the impression that such services are carried out in this capacity.

17 § In individual cases, and if there are special reasons, Swedac may grant dispensation from the implementation of these regulations.

STAFS 2011:5

1. This regulation comes into force on 30 June 2011, when the Board's Regulations (STAFS 2002:6) for bodies notified to the European Union for tasks in conjunction with conformity assessment under EU legal regulations and general guidelines to these regulations shall cease to apply.
2. Bodies notified before 30 June 2011 may act as notified bodies if they fulfil the requirements in STAFS 2002:6. However, this shall apply at the most up to and including 31 December 2014, or any time prior to this when Swedac makes a renewed assessment of the body.

STAFS 2011:28

This regulation comes into force on 1 August 2011.

STAFS 2012:10

These regulations come into force on 1 October 2012.