

Consolidated version of

The Swedish Board for Accreditation and Conformity Assessment's (Swedac) Regulations and General Guidelines (STAFS 2011:18) for accreditation of inspection bodies;

The translation includes the following amendment STAFS 2012:11

Scope

1 § These regulations apply to inspection bodies that are accredited or are applying for accreditation by Swedac.

The regulations are a supplement to Swedac's Regulations and General Guidelines for Accreditation (STAFS 2010:10). For some of the inspection fields, the regulatory authorities or Swedac in consultation with the regulatory authorities, have issued more detailed special regulations that supplement these regulations.

Definitions

2 § These regulations use the definitions given in the standards

1. SS-EN ISO/IEC 17000:2005 - *Conformity assessment - Vocabulary and general principles*
2. SS-EN ISO/IEC 17020:2012 - *Conformity assessment - Requirements for the operation of various types of bodies performing inspection.* (STAFS 2012:11)

Requirements in standards and other documents

3 § An accredited inspection body shall meet the requirements of standard SS-EN ISO/IEC 17020:2012.

When the results of testing or measurement are used as a basis for decision-making during inspection, the body conducting the testing or measurement shall

1. monitor, control and record the environmental conditions that affect the quality of the results,
2. assess the measurement uncertainty of the testing and measurement results based on all factors relevant to measurement uncertainty and undertake a measurement uncertainty assessment to guarantee the testing or measurement result,
3. use validated and appropriate methods in order to confirm that the testing or measurement methods are suitable for their purpose.

Validation of testing or measuring methods in accordance with the second paragraph 3, is not required when testing or measurement is performed using a method that meets established specifications. In such cases, however, the body must be able to show that the method has been used correctly. (STAFS 2012:11)

General guidelines on 3 §

The standard SS-EN ISO/IEC 17020 contains a number of comments on the standard text, which can be used to advantage as guidance by the control body.

Measurement uncertainty assessments as described in the second paragraph 2, should not be required for simpler measurements.

3 a § Swedac regulations and guidelines (STAFS 2011:33) for accreditation of laboratories state that if bodies intend to operate as accredited laboratories, they must meet all the requirements of the standard SS-EN ISO/IEC 17025:2005 - *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)*. (STAFS 2012:11)

Reference to accreditation

4 § Provisions that an accredited inspection body may use the accreditation mark or the text “body accredited by Swedac” on inspected items are set out in 29 § in STAFS 2010:10 concerning accreditation.

If the accreditation mark or the text “body accredited by Swedac” is used on the inspected item the inspection body shall, in addition to the requirements stated in 17-21 §§ in STAFS 2010:10 concerning accreditation, below the mark or in connection to the text indicate its accreditation number and the standard ISO/IEC 17020. In conjunction with the standard, depending of the type of inspection body, the letter A, B or C shall be indicated. The date of the inspection shall also be indicated in connection to the accreditation mark or the test.

The first and the second paragraph shall not be applied in those cases when marking of inspected item is stipulated in other regulations

Inspection procedures

5 § For a specific conformity assessment procedure concerning inspection bodies type C, following a decision by the regulatory authority, one and the same person may perform installation, service and maintenance and the subsequent inspection. In these cases

1. service and other actions shall have been completed before the inspection starts, and
2. personnel performing inspection shall sign an assurance where they agree not to let the responsibility for actions related to installation, service or maintenance implicate the implementation and the outcome of the inspection.

Miscellaneous

6 § An accredited inspection body shall, where appropriate, participate in meetings organized or directed by Swedac or the regulatory authorities for exchange of experiences. The costs of participation shall be borne by the inspection body.

7 § In individual cases, and if there are special reasons, Swedac may grant dispensation from these regulations.

STAFS 2011:18

These regulations come into force on 1 August 2011, on which date the Board's Regulations and General Guidelines (STAFS 2007:8) for the Accreditation of inspection bodies shall cease to apply.

STAFS 2012:11

These regulations come into force on 1 October 2012.

The following document apply to accredited inspection bodies

EA IAF/ILAC – A4:2004 – Guidance on the Application of ISO/IEC 17020.