

Consolidated version of

The Swedish Board for Accreditation and Conformity Assessment (Swedac) Regulations (STAFS 2011:33) on Accreditation of Laboratories

The heading has this wording through (STAFS 2018:3)

Amendment introduced up to and including STAFS 2018:3

Scope

Section 1 These regulations apply to laboratories that are accredited or are applying for accreditation by Swedac.

The regulations are a supplement to Swedac's regulations and general guidance (STAFS 2015:8) on accreditation. For certain areas, regulatory authorities or Swedac have, in consultation with regulatory authorities, issued more detailed specific regulations that supplement these regulations. *(STAFS 2015:9).*

Definitions

Section 2 In these regulations, the applicable definitions are stated in

1. The standard SS-EN ISO/IEC 17025:2018 – *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017)* and
2. The standard SS-EN ISO 15189:2012 – *Medical laboratories – Requirements for quality and competence.* *(STAFS 2018:3).*

Requirements in standards and other documents

Section 3 An accredited laboratory must meet the requirements of the standard SS-EN ISO/IEC 17025:2018.

An accredited medical laboratory must meet the requirements in one of the following points

1. The standard SS-EN ISO/IEC 17025:2018,
2. The standard SS-EN ISO 15189:2012,
3. The standard SS-EN ISO 15189:2012 and SS-EN ISO 22870:2016,
4. The standard SS-EN ISO/IEC 17025:2018 and the standard SS-EN ISO 15189:2012
or
5. The standard SS-EN ISO/IEC 17025:2018 and the standard SS-EN ISO 15189:2012 and SS-EN ISO 22870:2016. *(STAFS 2018:3).*

The heading immediately before § 4 has been discontinued through (STAFS 2018:3).

Section 4 When laboratories perform tests in the field of measuring emissions from stationary sources, the laboratory shall also meet the requirements of SIS-CEN/TS 15675:2007.

When laboratories perform tests in the field of doping control with the approval of the World Anti-Doping Agency, the laboratory shall also meet the requirements of version 9.0 of The World Anti-Doping Code International Standard for Laboratories (ISL) dated 2 June 2016. (STAFS 2018:3).

Reference to accreditation

Section 5 Reference to accreditation shall be included on the front page of the report or calibration certificate. (STAFS 2018:3).

Section 6 *has been repealed through (STAFS 2015:9).*

Section 7 An accredited calibration laboratory should, when possible, tag calibrated objects with a label bearing the text "Calibrated".

A calibrated object that has only undergone a limited calibration should, when possible, be tagged with a label bearing the text "Limited Calibration".

Date of calibration, report number and accreditation number shall be shown on the label.

Section 8 *has been repealed through (2015:9).*

Content of reports and calibration certificates

Section 9 If only limited testing or calibration has been carried out, this shall be clearly shown in the report or calibration certificate.

Section 10 An accredited laboratory reporting results within the framework for its accreditation shall work to ensure that reports and calibration certificates are not used for misleading purposes.

Testing and calibration comparisons

Section 11 An accredited laboratory shall keep itself informed about testing and calibration comparisons as well as proficiency testing schemes available on the market. The laboratory shall participate in the comparisons and proficiency testing schemes that are necessary in order to confirm the competence of the laboratory.

Other provisions

Section 12 Swedac may, in individual cases and if there are special reasons, grant exemptions from the application of these regulations.

These regulations enter into force on 1 January 2012, on which date the Board's Regulations and General Guidelines (STAFS 2007:9) for the Accreditation of Laboratories are repealed.

STAFS 2013:19

1. These regulations enter into force on 1 January 2014.
 2. The provisions in §§ 2 and 3 may be applied in their previous wording until 30 November 2015.
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STAFS 2015:9

These regulations enter into force on 1 November 2015.

STAFS 2017:5

These regulations enter into force on 1 October 2017.

STAFS 2018:3

1. These regulations enter into force on 1 July 2018.
2. The provisions in §§ 2 and 3 may be applied in their previous wording until 30 September 2018.

Appendix

Has been repealed through (STAFS 2018:3).