

## Swedac's policy for cross-frontier accreditation

### Framework to control how Swedac can operate accreditation abroad

This policy complies with the provisions in

- Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

This policy also complies with the recommendations given and the requirements in

- EA-2/13 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members  
ILAC-G21 Cross-Frontier Accreditation – Principles for Cooperation

### Accreditation of organizations headquartered abroad that perform *key activities*<sup>1</sup> abroad

Swedac undertakes accreditation according to the heading above only when all the following criteria are met:

- i. There is an explicit request from the customer, the customer's customer or regulatory authority that cannot be met otherwise.
- ii. The activities take place in markets that are important to the Swedish export industry or for Swedish companies.
- iii. Accreditation and assessment (within the EA region) can be performed under the provisions of the EU Regulation 765/2008 and EA-2/13.
- iv. Swedac has access to the competence needed for the assignment.
- v. Accreditation and surveillance can be performed safely and with the maintenance of confidence in the accreditation.
- vi. The assessment can be performed with acceptable safety for the personnel.
- vii. The customer accepts that Swedac cooperates with the local accreditation body (if applicable).

The wording of (iii) implies that accreditation abroad only can be considered if any of the following conditions are met.

- a) The country, in which the applicant organization has its head office, has decided not to establish a national accreditation body and has not agreed with another accreditation body to manage accreditation in the country.
- b) The national accreditation body of the country where the applicant organization has its head office is not a signatory to the EA MLA for activities within the area applied for.
- c) The national accreditation body of the country in which the applicant organization has its head office considers that they do not have the sufficient competence or resources within the area applied for.

The wording of (iv) implies that accreditation for a purely national conformity assessment scheme normally cannot be accepted.

## **Accreditation of organizations headquartered in Sweden that perform *key activities*<sup>1</sup> abroad**

Swedac undertakes accreditation according to the heading above only when all the following criteria are met:

- i. Accreditation and assessment (within the EA region) can be performed under the provisions of the EU Regulation 765/2008 and EA-2/13.
- ii. Swedac has access to the competence needed for the assignment.
- iii. Accreditation and surveillance can be performed safely and with the maintenance of confidence in the accreditation.
- iv. The assessment can be performed with acceptable safety for the personnel.
- v. The customer accepts that Swedac cooperates with the local accreditation body.

The provisions of (i) implies that Swedac shall ask the national accreditation body in the country where the *key activities* are performed if it is willing to perform the assessment on behalf of Swedac, unless any of the following circumstances exist:

- a) The country, in which the applicant organization has its head office, has decided not to establish a national accreditation body and has not agreed with another accreditation body to manage accreditation in the country.
- b) The national accreditation body of the country where the applicant organization has its head office is not a signatory to the EA MLA for activities within the area applied for.

The wording of (ii) implies that accreditation for a purely national conformity assessment scheme normally cannot be accepted.

The assessment takes into account the limitations and guidelines set out in EA-2/13.

When Swedac uses another accreditation body for assessment assignments it acts as a subcontractor to Swedac. When subcontractors are use agreements, based on the instruction in doc no 1311, shall be established. Swedac requires subcontractors to be signatories to ILAC's MRA, to IAF's MLA or to the relevant regional MLA when the regional organisation is a signatory to the ILAC' MRA or IAF's MLA. Consequently, the accreditation bodies listed as signatories to the ILAC MRA on [ilac.org](http://ilac.org), the IAF MLA on [IAF.nu](http://iaf.nu) and to the EA MLA on [european-accreditation.org](http://european-accreditation.org) are approved by Swedac as subcontractors of assessment services.

## **Assessment of organizations headquartered abroad that perform *key activities*<sup>1</sup> in Sweden**

When Swedac receives a request from another accreditation body to perform an assessment on its behalf of an organization performing *key activities* in Sweden Swedac undertakes this assignment, unless one of the following circumstances exists:

- i. The request comes from an accreditation body that is not a signatory to the ILAC or IAF MLA on conformity assessment or is not a signatory to the corresponding agreement within a regional cooperation organization for accreditation bodies that is a signatory to the ILAC or IAF MLA on conformity assessment.
- ii. Accreditation and assessment (within the EA region) cannot be performed under the provisions of the EU Regulation 765/2008 and EA-2/13.
- iii. Swedac does not have access to the technical competence needed for the assignment.
- iv. Swedac does not have sufficient knowledge of the framework that govern the accreditation.

Case (iv) often applies in the case of foreign conformity assessment schemes, e.g. schemes based on national regulations. Swedac may accept to perform such assessments, but only when the following circumstances apply:

- a) The applicant body is not able to apply to the national accreditation body for the requested scope or it is not currently accredited by the national accreditation body.
- b) The national accreditation body for the particular conformity assessment scheme is prepared to provide assessors or experts to perform or participate in the assessment.

In exceptional cases Swedac may refuse to perform the mission if the current work load is too high. Such exceptions should be avoided in cases where the assessment is to be carried out against Swedish regulations. To facilitate this, it is Swedac's policy to annually, preferably in September, give notice to accreditation bodies concerned that Swedac intends to carry out such assessments but would like to be informed about planned assessment activities for the coming year before the 1<sup>st</sup> October.

- 1) What is meant by "key activities" is defined in doc no 1274.