

**Flexible accreditation scope for certification, inspection, validation and verification bodies**

No. : AB 20  
Date : 2024.07.30  
Page : 1/3

## 1. Purpose

The purpose is to simplify the handling of minor changes of the accreditation scope in order to implement changes in a faster and more flexible way. This accreditation regulation is based on the requirements in DS/EN ISO/IEC 17011:2017 and EA-2/15: 2023.

## 2. Application

This accreditation regulation applies for DANAK's accreditation of certification, inspection, validation and verification bodies.

## 3. Flexible accreditation scope

**3.1** Flexible accreditation scope means that it will be possible to make changes within the accreditation scope without DANAK first assessing the change and taking a decision on implementation of the change. DANAK will assess the implemented changes at the regular visits.

**3.2** Changes that might be comprised by the flexible accreditation scope are limited to changes in versions of the normative document accredited to. Normative documents are standards, national regulations (as e.g. national executive orders) or other documents with requirements. Special rules apply for the accreditation scope for 'Vejere og målere' as agreed upon.

**3.3** A flexible scope cannot be granted to standards for management systems such as e.g. ISO 9001, but a flexible scope is possible for e.g. executive orders used together with management system standards.

**3.4** A flexible scope is not possible for EU for EU directives and regulations. It is though possible to obtain flexibility for sub directives/regulations and standards as e.g. regarding interoperability in the railway system or for product standards applying to the construction product regulation.

**3.5** An amended normative document can only be used as a basis for accreditation when DANAK has announced that the document has been evaluated with a positive result with regard to being able to be used under accreditation. However, no evaluation of amendments to harmonised standards and executive orders is carried out.

## 4. Application and decision on flexible accreditation scope

**4.1** An accredited company shall apply DANAK if requiring a flexible accreditation scope.

**4.2** The conditions for obtaining flexible accreditation scope are as follows:

1. The company has been accredited for a specific scope for minimum 1 accreditation period (4 years).
2. The company has demonstrated ability to ensure efficient implementation of changes of new versions of normative documents within the accreditation scope, including:
  - Preparation of GAP analyses of changes and action plan for implementation of these.
  - Implementation of changes in management system including listing relevant competence criteria and assessment that the competence criteria have been met.
3. The company has implemented the requirements listed in item 5.

**Flexible accreditation scope for certification, inspection, validation and verification bodies**

No. : AB 20  
Date : 2024.07.30  
Page : 2/3

## 5. Requirements to bodies with flexible accreditation scope

**5.1** The company's management system shall include procedures describing how flexible scope is handled with regard to:

- Review and evaluation of changes including compliance with clause 3.5 above
- Efficient implementation of changes in the management system, including revising checklists, reports, certificates etc.
- Listing relevant competence criteria and assessment of whether competence criteria for assessment according to new or revised regulatory documents have been met
- Updating list of normative documents when activities regarding changes are completed and sending a copy to DANAK
- how to make a list of normative documents with version indication covered by the flexible accreditation area publicly available (possibly on request);
- Registration of performed actions.

The company's procedure shall also include:

- that customers are informed that a report/certificate cannot be issued under accreditation before activities relating to flexible areas have been completed, and that there may be changed conditions such as changed process and price
- that there are sufficient resources, including qualified personnel and other means to carry out the activities, as well as to ensure (by validation or verification) that the new or amended requirements document can be implemented effectively.

When a company has a flexible scope of accreditation and the above process has been completed for a desired change, the change can be introduced. In connection with the planning of the regular surveillance visits, DANAK shall be informed about introduced changes since the last visit. However, for accreditation for notification in the area of construction products, DANAK shall be informed before the application of new harmonised standards with regard to. updating the EU register NANDO.

**5.2** If the company finds that the new or amended requirements document has not been effectively implemented, the company shall ensure that a cause analysis is carried out as well as appropriate corrective actions. These include:

- That customers are informed that the validation did not give a satisfactory result and that accredited reports/certificates cannot be issued until approval has been obtained.
- Revision of relevant procedures and methodologies if the cause is specific technical problems.
- Redefinition of the delimitation of the flexible area. If necessary, DANAK must be informed with regard to changing the area of accreditation for flexibility.

**5.3** The company shall have employees appointed by the management to be responsible for handling changes within the flexible scope. The employee's competence shall be assessed and approved according to a specific professional field. The employees shall:

- evaluate changes and consequences relating to certification, inspection, validation and verification
- Ensure implementation of changes in the management system

**5.4** It shall be ensured that declarations, reports and certificates issued to customers always include exact reference to the normative documents (such as version number, date etc.)

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No.	:	AB 20
Date	:	2024.07.30
Page	:	3/3

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Any differences between the Danish and the English version of this document are not intended, but in case of doubt with respect to the correctness the version in Danish should be consulted.