1. Application

1.1 This accreditation regulation contains requirements for companies (laboratories, certification and inspection bodies) where a DANAK accreditation is the basis for being appointed as notified body or Recognised Third Parti Organisation in accordance with EU legislation.

1.2 It is stated in Regulation (EC) No 765/2008, article 5 *Operation of accreditation* and decision 768/2008, article R 22 *Application for notification*, that an accreditation certificate (decision on accreditation) can be used as documentation for meeting requirements in relevant EU legislation (directives, regulations etc.)

1.3 It is stated in executive orders whether there in Denmark are requirements for accreditation as basis for being notified and which requirements in directives and regulations are to be assessed during accreditation.

1.4 European Accreditation (EA) has published EA-2/17 M:2020 - *EA Document on accreditation for notification purposes*. The requirements in this document shall be complied with when accreditation is used as basis for appointment as notified body.

2. Application on accreditation and extension

2.1 When applying for accreditation or extension of accreditation for notification it shall be stated which EU-directive or regulation the accreditation shall declare conformity with.

2.2 Annex A in EA-2/17 contains lists of preferred accreditation standards for the different types of conformity. In section 4.2 in EA-2/17 it further appears that the preferred standard shall be used unless the national authorities have published requirements to use another standard.

2.3 In annex B to EA-2/17 it is stated that in addition to the preferred standard (for instance ISO/IEC 17065), additional requirements may apply from other standards (e.g. ISO/IEC 17021-1) when the activities as mentioned relate to these standards. Fulfilment of these additional requirements in other accreditation standards shall be stated in the accredited company's management system. Related MD documents from IAF should be considered for assessment of modules based on quality management systems (e.g. module D and E). For module H it is required to comply with relevant MD documents.

For accreditation as basis for notification to the construction products regulation AVCP system 3 it though appears that there are no additional requirements to the preferred standard ISO/IEC 17025 in other accreditation standards.

2.4 Fulfilment of all requirements to the notified body in the EU directive or regulation shall be documented in the management system. The requirements stated in the EU directives which are to be fulfilled through accreditation will often appear in a Danish executive order on implementation. If there are requirements to the notified body in the directive which are not stated in the executive order, and which are requested not to be assessed by accreditation this shall clearly appear from the application and it will be stated in the accreditation documentation (decision and accreditation certificate) that these requirements are not assessed.

2.5 The application shall specify the extent of accreditation by indication of e.g. directives, regulations, harmonised standards, product areas, modules. The specification shall follow the layout of the EU Commission database of notified bodies, NANDO or a database relevant for the area.

2.6 It shall be clearly stated in the application if the accreditation is to be used as basis for notification of an area not yet specified in the NANDO database.

2.7 The company shall keep updated with interpretations from the sector groups for notified bodies mentioned in EU documents relevant for the applied accreditation scope and it shall be stated in the management system of the company how interpretations are being implemented.

3. Maintaining accreditation

Implementation of the preferred standard

3.1 Annex A in EA-2/17 contains lists of preferred accreditation standards for the different types of conformity. In section 4.2 in EA-2/17 it further appears that the preferred standard shall be used unless the national authorities have published requirements to use another standard.

Accreditations that are not using the preferred standard for the area and where the national authorities have not published requirements on the use another standard therefore shall change to the preferred accreditation standard to maintain accreditation.

Application shall be forwarded on accreditation to the preferred standard accompanied by documentation for compliance with the requirements in the standard and in other related documents with requirements.

3.2 In annex B to EA-2/17 it is stated that in addition to the preferred standard (for instance ISO/IEC 17065), additional requirements may apply from other standards when the activities relate to these standards (e.g. ISO/IEC 17021-1). Fulfilment of these additional requirements in other accreditation standards shall be stated in the accredited company's management system. Related MD documents from IAF should be considered for assessment of modules based on quality management systems (e.g. module D and E). For module H it is required to comply with relevant MD documents.

3.3 It is in EA-2/17 stated that the requirements shall be implemented 14 April 2023. For DANAK to be able to process the implementation of the requirements at the regular visits, above mentioned requirements shall be implemented before the 1 April 2022.

Implementing new additional requirements

3.4 The additional requirements in annex B to EA-2/17 have been updated. For the accreditations that are not required to change to another accreditation standard DANAK will assess the implementation of changed requirements at the regular visits.

3.5 Accredited companies using accreditation as basis for a notification shall continuously ensure that no notified work is carried out according to standards or specifications, not enlisted as the harmonised basis in Nando or a database for the relevant area.

3.6 In case new normative documents specifying the scope of accreditation c.f. item 2.5 above are published the accredited company shall apply for extension or change of their accreditation accordingly, before accredited or notified work is carried out.

3.7 Accredited companies shall continuously ensure compliance with the requirements in clause 2.2, 2.3, 2.4 and 2.7 above.

4. References

Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products.

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.

EA-2/17 M:2020: *EA Document on Accreditation for Notification Purposes*.

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 Danish version should be consulted.

DANAK, 28 August 2024