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1. Application

This accreditation regulation applies for DANAK accreditation according to:

- DS/EN ISO/IEC 17065 Conformity Assessment Requirements for bodies certifying products, processes and services (DS/EN 45011 General requirements for bodies operating product certification systems can be used until 15 September 2015).
- 2) DS/EN ISO/IEC 17024 Conformity assessment General requirements for bodies operating certification of persons.
- DS/EN ISO/IEC 17021 Conformity assessment Requirements for bodies providing audit and certification of management systems, in combination with additional requirements in other standards or technical specifications. The term 'technical specifications' should be understood as documents issued by ISO in the same way as standards named 'Technical Specifications'

2. Scope of accreditation

- 2.1. An accredited certification body may only declare that it has been accredited for the activities covered by the scope of the accreditation.
- **2.2.** A scope of accreditation is defined individually and is clearly delimited by statement of:
- 1) For certification of <u>products</u>, <u>processes and services</u>:
 - a) the products, processes and services that can be certified
 - b) the standards or possibly other normative documents according to which the products, processes or services can be certified, and
 - c) the certification system, i.e. the functions covered by the certification with regard to type testing, inspection, evaluation and surveillance of manufacturing and quality control as well as surveillance and testing of manufactured products.
- 2) For certification of persons:
 - a) the activities which shall be covered by the qualifications of the persons, and
 - b) the standards or possibly other normative documents stipulating the requirements for the qualifications of the persons.
- 3) For certification of <u>management systems</u> of companies':
 - a) the standards or possibly other normative documents stipulating the requirements for the management system, and
 - b) the business sectors or areas etc. with regard to the Commission's regulation (EF) No. 1893/2006 of 20 December 2006 about establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains. When special conditions cause that the NACE codes do not lead to relevant delimitation of the accreditation area another relevant delimitation can be used.

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- 4) For certification of management systems within the food area:
 - a) the standards or possibly other normative documents stipulating the requirements for the management system
 - b) included categories and sectors with regard to ISO/TC 22003.
- 5) For certification of management systems within information technology:
 - a) the standards or possibly other normative documents stipulating the requirements for the management system.
- **2.3** In connection with stipulating the scope of accreditation all localities, in Denmark or abroad, where key activities are conducted under the accreditation, shall be identified.
- **2.4** Key activities in item 2.3 are for certification of <u>management systems</u> understood as:
 - a. formulation of politics
 - b. development of processes and procedures
 - c. initial approval of audit personnel and control of their training
 - d. monitoring of audit personnel
 - e. application review
 - f. designation of audit personnel
 - g. management of audit by surveillance and renewal, and
 - h. final review of report or decision on certification
- **2.5** Key activities in item 2.3 are for certification of <u>products</u>, <u>processes and services</u> understood as:
 - a. formulation and approval of politics
 - b. development and approval of processes and procedures
 - c. assessment of competence and approval of technical personnel and subcontractors
 - d. management of monitoring the competence of personnel and subcontractors and the results
 - contract review including technical review of applications and determination of the technical requirements for certification activities within new technical fields or fields with a limited sporadic activity
 - f. decision on certification including thorough technical review of evaluation activities
- **2.6** Key activities in item2.3 are for certification of persons understood as:
 - a. formulation and approval of politics
 - development and approval of processes and procedures, necessary for running the system for certification of persons, including requirements for selection and approval of the persons performing the assessments
 - c. review of application and contractual arrangements relating to assessment and certification of persons

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d. development, evaluation and maintenance of the scheme for certification and re-certification

- e. decision on certification of persons, including signature or authorisation of certificates
- f. development and approval of politics, processes and procedures regarding decision on appeals and complaints received from applicants, candidates, certified persons and their employers as well as from other parties regarding certification process or -criteria
- g. final decision regarding appeals or complaints.
- **2.7** Applicants and accredited certification bodies shall document how activities on all locations are controlled and managed.
- **2.8** In order for DANAK to relate to the activities carried out abroad by the certification body under DANAK accreditation, the following information shall be provided for each accreditation:
 - a. number of certificates issued for each scheme in every country

 Examples of schemes within management systems is ISO 14001, within product certification

 GLOBAL G.A.P. and within certification of persons fusion welding
 - b. number of local offices from where the certification body carries out certification activities according to the information mentioned in item a
 - c. whether the certification body uses local staff to carry out certification activities according to the mentioned information in item a
 - d. which local offices that are responsible for carrying out/or managing key activities as defined in item 2.4 2.6 or from where local personnel carrying out key activities are being managed.
 - e. the certification body's measures and procedures for managing all activities being carried out from a local office or by local personnel.
- **2.9** The information mentioned in item 2.8 shall be provided annually (usually in November) at request from DANAK. DANAK can however, request an update of the information at other times as e.g. at planning of a visit.

3. Performance of certification

- **3.1** Performance of an accredited service within one of the business sectors of the scope of accreditation determines special technical, professional competence within the sector and the specific service.
- **3.2** The management of the certification body shall be competent to and in practice perform assessment of whether the available technical, professional competence is sufficient to perform certification within the delimited scope of accreditation.
- **3.3** If compliance with specifications is being verified by measurement, the measurement equipment must be calibrated. Documentation on traceability for the measurement equipment's calibration shall be available. This calibration shall be carried out by an accredited laboratory covered by EA's multilateral agreement (EA's MLA), ILAC's arrangement on mutual recognition (ILAC's MRA) or by a metrology institute included in the mutual recognition arrangement of national metrology institutes (CIPM's MRA) within calibration, where this is possible for field. Furthermore, measurement uncertainty must be determined.

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4. References

Section 2.1: DS/EN ISO/IEC 17011, 8.1.1 f

Section 2.2: DS/EN ISO/IEC 17011, 7.9.5

Section 2.3: DS/EN ISO/IEC 17011, 7.9.4 c

Section 2.4: IAF/ILAC-A5, M.7.5.7.3

Section 2.5: IAF/ILAC-A5, M.7.5.7.2

Section 2.6: IAF/ILAC-A5, M.7.5.7.4

Section 2.7: DS/EN ISO/IEC 17011, 8.1.1

Section 2.8 and 2.9: IAF MD 12, 3.1

Section 3.1 and 3.2: DS/EN ISO/IEC 17011, 8.1

Section 3.3: DS/EN ISO/IEC 17011, 8.2.2

This accreditation regulation comes into force 1 November 2014. 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.

DANAK, 6 October 2014	
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