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The full text

Technical Regulation No. 14 concerning provisions for certification and inspection bodies and CO_2-verifiers (TF14)

Pursuant to Section 14 (1) of the Danish Act No. 602 of 24 June 2005 regarding promotion of trade and industry, and further to Statutory Order on accreditation of companies to certification of persons, products and systems plus to inspection and to environmental verification (EMAS) the following provisions shall apply:

Part 1

Delimitation and general notes on accreditation

Scope

§ 1. This regulation concerns companies (certification bodies, inspection bodies and CO_2-verifiers) that apply for accreditation, or that have been accredited by DANAK, the Danish Accreditation and Metrology Fund (in the following DANAK) to undertake:

1) certification,
2) inspection, or
3) verification of greenhouse gas emissions (CO_2 -verification).

Scope of accreditation

§ 2. An accredited body may only declare that it has been accredited for activities that are covered by the scope of accreditation.

(2) The scope of accreditation must be defined individually and be clearly delimited.

(3) When defining the scope of accreditation the following information shall be given:

1) For certification of products, processes and services:
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 functions that are 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 the products manufactured.

2) For the certification of the companies' management systems:
a) the standards or possibly other normative documents stipulating the requirements for the management system, and
b) the business sectors or areas, etc. within which the individual management systems can be certified.

3) For certification of persons:
a) the activities which shall be covered by personal qualifications, and

b) the standards or possibly other normative documents stipulating the requirements for the personal qualifications.

4) For inspection:
a) the scope of inspection expressed in terms of products, equipment, materials, installations, systems, processes, services, etc. that may be inspected,
b) the nature and scope of inspection, e.g. inspection of new products, inspection of products in use or in operation,
c) the standards, regulations, methods, procedures, etc. according to which the inspection is performed, and
d) the type of inspection body with regard to independence.

5) For verification of CO_2-balances:
a) the normative documents stipulating the requirements, and
b) the delimitation of production units after activity, combustion or process emission, type of fuel, etc.

§ 3. In connection with stipulating the scope of accreditation all localities, in Denmark or abroad, where key activities are carried out in connection with the accreditation, shall be identified. By key activities is understood:
1) qualification, training and monitoring of assessment staff,
2) evaluation of applications and appointment of an assessment team,
3) decision on certification, and
4) review of reports.

(2) Applicants and accredited bodies shall document how the activities at all localities are managed and controlled.

§ 4. All services covered by the scope of accreditation must be carried out on a quality level equal to that required for the accredited services

Information to DANAK

§ 5. The accredited body shall inform DANAK about all changes in the circumstances on which the accreditation is based and which may have an impact on the preservation of the accreditation.
(2) The accredited body shall continuously forward material for the updating of the quality manual held by DANAK or information about changes of the quality manual available to DANAK.
(3) In the event of changes to the quality manual of the type referred to in (1) above, or in other documents received by DANAK, the accredited body shall draw DANAK's attention to such changes when forwarding the updated material.
(4) If an electronic quality system is used DANAK shall have access to it in a version that has a functionality similar to that used by the accredited body.
(5) The forwarding of material, cf. (2), (3) and (4) may take place electronically.

§ 6. Accredited bodies shall on request from DANAK provide all information necessary for the surveillance of the accreditation, including information about the prices and hourly rates applied by the accredited body as well as details about the relevant calculation basis.
(2) Accredited bodies shall receive surveillance visits at all their localities by DANAK's assessment team consisting of leading assessors and appointed experts. The accredited body is

moreover obliged to ensure that assessment visits can include the accredited body's activities at companies, etc.

Document control

§ 7. Where an accredited body's quality management system covers various activities, it shall clearly be indicated (e.g. from an overview, etc,) which parts of the system are applied for the individual activities.

§ 8. Superseded parts of the quality system (in paper or electronic version) shall be kept as long as it is required (by any legislation in the area), however for a minimum period of 5 years.

§ 9. For quality systems that exist in electronic versions it shall be ensured that only personnel with authority to approve the individual parts of a system have access to make changes to these parts

§ 10. When changes are made to the quality system, clear information shall be given about the changes either by written notice or by marking of the changed text. In addition users of the system shall be advised that changes have been made.

Data security in electronic reporting

§ 11. In electronic transmission of accredited certificates, reports, etc. the accredited body shall ensure that the following are documented:

1) integrity (that no changes have been made to the reported data),
2) authenticity (that the report has been sent from the accredited body), and
3) imperativeness (that the accredited body can document the content of the report when it was sent).

(2) It shall be ensured that the requirements in relevant standards regarding confidentiality are met.

(3) When using "digital signature" in connection with the transmission of reports between the accredited body and its customers, no further documentation is required, if a »certified« key system is used. When other kinds of system are used to ensure secure transmission DANAK shall verify the accredited body's documentation of the effectiveness of these systems.

Other general requirements

§ 12. The accredited body is obliged to after notification from DANAK and within a time limit stipulated by DANAK to make changes in the basis for the accreditation as a consequence of changes of the accreditation criteria.

Part 2

Provisions regarding accreditation to certification

Documented traceable calibration.

§ 13. Where compliance with specifications is verified by measurement, the measuring equipment shall be calibrated for this purpose. There shall be documentation for the traceability of the measuring equipment's calibration to an accredited calibration laboratory recognised by EA or

ILAC, a primary laboratory or national reference laboratory if such a laboratory exists in the area. Moreover, uncertainty of measurement shall have been determined.

(2) The certification body and the certified company's documentation for traceable calibration must be based on certificates, etc. from other companies or laboratories that are accredited for calibration of measuring equipment in question.

(3) The certification body shall check that the certified company's transfer of the traceable calibration internally is correctly documented by means of calibration procedures and internal registrations.

Certification of management systems

§ 14. Accreditation for certification of management systems in respect of food safety requires documentation for the composition of the audit team for certification and surveillance, covering professional qualifications and including:

1) business sector knowledge, including familiarity with legislative requirements for the type of company concerned,
2) education in and updated knowledge of food microbiology and hygiene within the type of enterprise in question,
3) professional experience in the field of food production.

(2) The procedures of the certification body shall include an evaluation of the applicant's risk assessment.

§ 15. Certification bodies shall ensure that companies have been informed that there must be documentation for compliance with public legislative requirements, any agreements or outstanding matters that might be relevant for the certification prior to the auditing of their management systems.

§ 16. A certificate for a company's management system shall contain:

1) the name and address of the company's headquarters and addresses covered by the certification, possibly with a reference to an annex to the certificate,
2) a specification of the product, services and other activities available to customers from the company and covered by the management system,
3) the system standard and other normative documents, if any, with supplementary requirements,
4) the extent of the certified management system,
5) the name and logotype, if any, of the certification body, cf. Technical Regulation TF1 on DANAK's accreditation mark and reference to accreditation,
6) DANAK's mark, cf. Technical Regulation 1 concerning DANAK's accreditation mark and reference to accreditation, and
7) the date of coming into force and period of validity of the certification.

(2) Where it is appropriate and cannot lead to misunderstanding as to the fact that the certificate is for the management system only, DANAK may in special cases allow indication of legal requirements, product standards or other normative documents required to be fulfilled by the products.

Product certification

§ 17. The testing that the certification body carries out itself or arranges to be carried out must be performed as accredited testing or with documentation for compliance with relevant requirements in

DS/EN ISO/IEC 17025 concerning General requirements for the competence of testing and calibration laboratories.

§ 18. When controlling quality management in connection with product certification the assessment shall be carried out as at accredited system certification in compliance with the relevant requirements in DS/EN ISO/IEC 17021 concerning Conformity assessment - requirements for bodies performing audit and certification of management systems.

§ 19. Inspections that the certification body carries out itself or arranges to have carried out shall be performed as accredited inspection or with documentation for compliance with the relevant requirements in DS/EN ISO/IEC 17020 concerning General criteria for different type of bodies carrying out inspection.

§ 20. Where initial testing of the product is part of the conditions for certification, and the test can only be carried out on a prototype or the like, an examination of products from the production run must be made immediately after the start of production to confirm the result of the initial test on the prototype.

Part 3

Provisions regarding accreditation for inspection

§ 21. Inspection bodies shall know the accuracy of the measured inspection results or have reference to the accuracy of any measurements carried out and on request inform their customers thereof.

(2) Where within the context of the inspection assignment, the inspection body makes readings on measuring equipment of other parties, this must be clearly stated in the report, and as far as practicable the equipment must be clearly identified.

(3) Exact determination of properties shall be performed as accredited testing or with documentation for compliance with relevant requirements in DS/EN ISO/TEC 17025 concerning General requirements for the competence of testing and calibration laboratories.

Part 4

Coming into force

§ 22. This Regulation comes into force on 15 October 2007.

(2) Statutory Order 9584 of 29. November 2002. Technical Regulation. Provisions for certification and inspection bodies TF14 shall is repealed.

Danish Safety Technology Authority, 28. September 2007

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