

## TECHNICAL REGULATION

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### Granting and Maintaining Accreditation

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Pursuant to Section 10 Subsections (2) and (3), and Section 16 Subsection (4), of the Promotion of Trade and Industry Act, cf. Statutory Order No. 323 of 25 April 1996, and further to Statutory Orders issued by the Danish Agency for Trade and Industry on accreditation of laboratories for technical testing, etc.; on accreditation of companies, etc., for certification of persons, products and systems, and for inspection; and on accreditation for the certification of environmental management systems and for environmental verification, the following provisions are laid down:

#### **Part 1 Delimitation and Objects**

§ 1. This Regulation concerns applicants for accreditation as well as accredited laboratories, certification bodies, inspection bodies and environmental verifiers, subsequently collectively referred to as "accredited bodies".

§ 2. The general conditions for granting and maintaining accreditation as well as the rules for suspension and withdrawal of accreditation are contained in the above-mentioned Statutory Orders. This Technical Regulation provides a more detailed description of the general conditions.

#### **Part 2 Granting Accreditation**

§ 3. (1) Any granting of accreditation is conditional upon the fulfilment of all criteria in the relevant Statutory Orders, Technical Regulations, and standards.

(2) All corrective actions occasioned by deficiencies or non-compliance observed in the assessment are subject to approval by DANAK before accreditation is granted.

(3) Where special conditions so warrant, DANAK may decide that the rectification of deficiencies and non-compliances may be carried out after the granting of accreditation if such deficiencies and non-compliances do not concern the criteria that must be fulfilled in order to qualify for the carrying-out of the accredited activities.

#### **Part 3 Maintaining Accreditation**

§ 4. (1) Maintaining the accreditation is conditional upon the accredited body observing the rules and conditions for the accreditation; upon its continued possession of the necessary professional qualifications; and upon the accredited services being performed in a correct and professionally qualified manner; and upon it being shown that the requisite experience is available for the performance of the tasks.

(2) Compliance with the conditions for accreditation is monitored by DANAK, e.g., by means of regular visits.

§ 5. (1) Where non-compliances or deficiencies are observed in the quality system or in other aspects of the basis for accreditation, rectification must be initiated at once and performed within a time-limit approved by DANAK.

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(2) The associated corrective actions are subject to approval by DANAK and must be performed within a time-limit approved by DANAK. The maximum time-limit accepted is generally three months.

§ 6. (1) Where non-compliances or deficiencies are observed which cause a considerable reduction of quality of the professional level of the accredited services, such non-compliances or deficiencies must be rectified by corrective actions before the relevant services are continued.

(2) The non-compliance report or assessment report must state that recommendation has been made to the management of DANAK that it is a condition for maintaining the accreditation that the accredited services in the relevant area be temporarily suspended until the corrective actions have been carried out and approved by DANAK. Any comments on the recommendation on the part of the accredited body shall be appended to the non-compliance report or assessment report.

(3) DANAK will then notify the accredited body of the conditions for maintaining the accreditation in the relevant area, and the deadline for carrying out the corrective actions.

(4) The conditions for maintaining the accreditation will typically be that:

- \* no reports, certificates, attestations, etc., be issued within the relevant area of accreditation;
- \* affected accredited services be temporarily suspended until the corrective actions have been carried out and approved by DANAK;
- \* no new assignments be commenced until the corrective actions have been carried out and approved by DANAK.

### Part 4

#### Voluntary Suspension and Suspension

§ 7. (1) An accredited body may request that an accreditation be suspended for a given period of time for the whole area of accreditation, or part thereof, if the accredited body is unable to comply with the rules and terms for the accreditation, including that it no longer possesses the necessary professional qualifications within the relevant area.

(2) Voluntary suspension of an accreditation may be granted for periods of up to six months. Exceeding such period, the accreditation is regarded as withdrawn, which shall be notified to the accredited body in writing.

§ 8. (1) Where gross or repeated violations are observed of rules and conditions issued in connection with the accreditation, or where the accredited body no longer meets the conditions for being accredited, the consequences will be as stated in the Statutory Orders, including suspension of the whole or part of the accreditation with a deadline for rectification of the deficiencies.

(2) When the violations concern matters that affect the whole area of accreditation, the total accreditation will be suspended.

(3) Before any suspension is implemented, the accredited body shall be given an opportunity to make a statement. A time-limit shall be fixed for such statement.

§ 9. (1) Where the matters criticised in connection with the suspension have not been rectified and approved by DANAK within a fixed time-limit, the accreditation will be withdrawn for the area covered by the suspension.

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(2) An accreditation which has been withdrawn cannot be restored until DANAK has ascertained, by a new assessment of the entire basis for the accreditation, that all the conditions for accreditation are fulfilled.

### **Part 5** **General Deficiencies and Non-compliance**

§ 10. (1) The following acts and omissions are general examples of deficiencies and non-compliance that will result in a recommendation for suspension, cf. ' 8 above:

- \* failure to perform, or inadequate performance of, corrective and remedial action within a fixed time-limit of the non-compliance and deficiencies referred to in ' 6 hereof;
  - \* repeated deficiencies or non-compliance in matters previously criticised in reports;
  - \* changes in staff that will cause a lack of professional qualification within a major or minor part of the area of accreditation, and where the accredited body has not requested voluntary suspension of the accreditation pursuant to ' 7 hereof;
  - \* observed unacceptable professional level of accredited activities carried out;
  - \* lack of attestation of reports, certificates and other material by persons authorised to sign - where DANAK has made this a condition;
  - \* persons who are authorised to sign retire or are posted to areas outside the scope of accreditation, and no replacement approved by DANAK is available;
  - \* the issuance of an accredited report, certificate, etc., outside the scope of accreditation;
  - \* failure to carry out mandatory cancellation or rectification of erroneous reports or certificates, etc.;
  - \* DANAK's request for necessary information for the purpose of the supervision of the accreditation is not complied with before the agreed deadline;
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- \* failure to inform DANAK of changes in matters on which the accreditation is based and which may have an impact on the maintenance of the accreditation - including any change in legal status - and will therefore require DANAK's acceptance before being implemented;
  - \* serious abuse of DANAK's logotype or of reference to accreditation;
  - \* failure to pay due charges; and
  - \* the filing of a petition in bankruptcy.

### **Part 6** **Accreditation for Testing and Calibration**

§ 11 (1) Within the areas of accreditation for testing and calibration the following examples of deficiencies and non-compliances, in addition to those listed in ' 10 above, will be regarded as serious enough to give rise to a recommendation for suspension of the area of accreditation affected:

- \* use of poorly maintained reference material;
- \* measurements made with measuring equipment without documented traceable calibration to standards primary, where such calibration is possible;

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- \* testing with the use of defective test equipment, and where the result was not subsequently corrected towards the customer;
- \* calibration or testing made under circumstances (such as environmental conditions) that may significantly affect the accuracy;
- \* calibration or testing not made in accordance with approved or documented methods;
  
- \* comparative calibrations/performance tests that have shown that the results from the laboratory differ significantly, and that corrective action has not led to satisfactory results;
- \* lack of appropriate and well-maintained equipment;
- \* refusal to participate in mandatory recognised proficiency testing; and
- \* lack of test experience for specific methods.

### Part 7

#### Accreditation for Certification, Inspection and Environmental Verification

§ 12. (1) Within the accreditation systems for certification and inspection, the following examples of deficiencies and non-compliances, in addition to those listed in ' 10 above, will be regarded as serious enough to give rise to a recommendation for suspension of the area of accreditation affected:

- \* Certification carried out by an audit team/assessment team without proper qualifications and routines within the relevant commercial sector; and
- \* repeated lack of documented traceable calibration of own measuring equipment to standards of primary.

### Part 8

#### Coming into Force

§ 13. This Regulation shall come into force on 17 June 1997; as of the same date, Technical Regulation No. 2 of 9 July 1996 shall be repealed.

Danish Agency for Development of Trade and Industry, 13 June 1997.

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Mette Holst

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 Bjarne Bang Christensen

#### Appendices:

None.