

TECHNICAL REGULATION

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This is a translation of a regulation in Danish, coming into force on 28 November 2007. Any differences between the Danish and the English version of this regulation are not intended but in case of doubt with respect to the correctness of the English translation, the Danish language version should be consulted.

Pursuant to Section 10 of the Promotion of Trade and Industry Act, cf. Consolidated Act No. 992 of 8 December 2003, as subsequently amended by Act No.1464 of 22 December 2004, and further to Statutory Order on Accreditation of Laboratories for Testing, etc., and for GLP Inspection, and Statutory Order on Accreditation of Companies for Certification of Persons, Products and Systems and for Inspection and for Environmental Verification (EMAS), it is hereby provided:

Part 1 **Scope and Objects**

§ 1. This Technical Regulation concerns accredited laboratories, certification bodies and inspection bodies plus CO₂ and environmental verifiers.

§ 2. The Regulation contains provisions on the use by accredited companies of DANAK's accreditation mark.

(2) A company's use of DANAK's accreditation mark is documentation that the company is accredited by DANAK.

(3) Accredited laboratories may, according to an agreement with DANAK, use the ILAC MRA mark together with DANAK's accreditation mark.

(4) Certification bodies that are accredited for certification of quality management systems, environmental management systems or products, may, according to an agreement with DANAK, use the IAF MLA mark together with DANAK's accreditation mark.

(5) The ILAC MRA mark or the IAF MLA mark together with DANAK's accreditation mark is the accredited company's documentation that the laboratory or certification body is accredited by an accreditation body that has signed the international agreements on mutual recognition of accredited reports and certificates (the ILAC agreement or IAF agreement).

§ 3. Accredited companies may use DANAK's accreditation mark when the accreditation is granted by DANAK.

(2) The ILAC mark or IAF mark may be used when a written agreement is concluded with DANAK to this effect.

(3) Applicants for accreditation may not use DANAK's accreditation mark.

(4) Any use of DANAK's accreditation mark must cease immediately on termination of the accreditation.

(5) In the case of suspension or voluntary suspension of an accreditation, DANAK decides on the company's possibilities for continuing to refer to DANAK's accreditation, including revocation of already issued accredited reports and certificates.

(6) It is the accredited company's responsibility that DANAK's accreditation mark, the ILAC mark and the IAF mark are used in accordance with the rules of this Technical Regulation.

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Part 2

DANAK's logo, accreditation mark, the ILAC mark and the IAF mark

§ 4. DANAK's logo for accreditation consists of "Royal crown + DANAK" as shown. The logo is a registered trademark no. FR 1993 00027 (ref. copy of the register from the Danish Patent and Trademark Office).



(2) DANAK's accreditation mark consists of the logo mentioned in (1) above and the company's field of accreditation and the registration no. at DANAK.

(3) DANAK has established the following abbreviations for the fields of accreditation:

- i. TEST: Testing laboratories;
- ii. CAL: Calibration laboratories;
- iii. EXAM: Medical laboratories;
- iv. SYSTEM: Management systems;
- v. PERSON: Personnel certification;
- vi. PROD: Product certification
- vii. INSP: Inspection bodies
- viii. DK-V: Environmental verification

(4) In connection with the granting of accreditation to a company, DANAK decides what fields of accreditation shall be covered by the accreditation, and the company is given a registration no. at DANAK.

(5) If a company has two or more fields of accreditation, the accreditation mark for the area covered by the accredited service shall be used.

§ 5. DANAK's accreditation mark is shown in Appendix 1 and shall be used in the shown colours or in a monochrome reproduction. The accreditation mark must be used in the shown size or in another smaller or larger version that retains the relative proportions of the elements.

§ 6. Instead of DANAK's accreditation mark, accredited companies may refer to their accreditation by using the following text on accredited reports and certificates: "Accredited by DANAK under registration number xxx to respectively "testing", "calibration", "medical examination", "certification of management systems", "certification of personnel, "certification of products", "inspection" or "environmental verification" (for environmental verification "DK-V" is added in front of the registration number. See § 4 (4) regarding registration number.

(2) The provisions of this regulation concerning use of DANAK's accreditation mark also apply to reference to accreditation, see (1).

§ 7. If an accredited laboratory wishes to enter into agreement with DANAK concerning use of the ILAC mark together with the DANAK mark, a contract shall be signed to this effect.

(2) The ILAC mark and DANAK's accreditation mark are in the following designated as "the

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combined laboratory mark”.

(3) The combined laboratory mark is shown in Appendix 2 and shall be used in the shown colour or in another monochrome reproduction. The combined laboratory mark must be used in the shown size or in another smaller or larger version that retains the relative proportions of the elements.

§ 8. If an accredited certification body, according to § 2 (4), wishes to enter into agreement with DANAK concerning use of the IAF mark together with the DANAK mark, a contract shall be signed to this effect.

(2) The IAF mark and DANAK's accreditation mark is in the following designated as the “combined certification mark”.

(3) The combined certification mark is shown in Appendix 3 and shall be used in the shown colour or in another monochrome reproduction. The combined certification mark must be used in the shown size or in another smaller or larger version that retains the relative proportions of the elements. The combined certification mark must, however, not be smaller than 2 cm. (symmetrical version) or 4.8 cm (asymmetrical version).

Part 3

General rules concerning DANAK's accreditation mark, etc.

§ 9. DANAK's accreditation mark, the combined laboratory mark or the combined certification mark must only be reproduced together with the company's own logo and name and must not be more prominent than these.

(2) The company's logo and name or other information about the accredited company must not give rise to any misunderstanding as to who is accredited and thereby covered by the registration no. or as to what is covered by the accreditation.

§ 10. All accredited services must be reported to the clients on documents (laboratory reports, inspection reports, certificates, attestations, etc.) carrying DANAK's accreditation mark and registration no. as well as the logo and name of the accredited company.

(2) If the accredited company has entered into an agreement with DANAK concerning use of the ILAC mark or the IAF mark, accredited companies may instead of DANAK's accreditation mark use the combined laboratory mark, see § 7, or the combined certification mark, see § 8, for the reporting of accredited services, see (1) above.

(3) If the client has requested in writing not to receive reporting on documents that refer to the accreditation as stated in (1) or (2) above, the accredited company may in exceptional cases accept this. The accredited company must be able to present documentation from the client.

Furthermore, special circumstances may form the basis for agreement with DANAK concerning omission to use the accreditation mark.

(4) However, tasks of the type referred to in (3) above must be treated and registered as accredited services.

§ 11. In addition to use on accredited reports and certificates, DANAK's accreditation mark may

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also be used by accredited companies on other documents in association with the accreditation, for instance, letters, tenders for accredited services, information and advertising material, websites, etc. DANAK's accreditation mark must not be used on business cards.

(2) In addition to the use described in § 10 (2), the combined certification mark and the combined laboratory mark may be used by respectively accredited laboratories according to § 7, and accredited certification bodies, according to § 8, on other documents as stated in (1) above. The combined marks must not be used on business cards.

(3) If DANAK's accreditation mark, the combined laboratory mark or the combined certification mark is used on other material than accredited reports and certificates, see (1) or (2) above, the services covered by the company's accreditation shall be indicated.

(4) If the accredited company has more than one DANAK accreditation, its letters and other material that have a common feature for all the accreditations may be provided with DANAK's accreditation mark or the combined certification mark, possibly with a description of the accredited service for each registration number. The accreditation mark, the combined laboratory mark or the combined certification mark shall contain all accreditation fields and registration numbers, see the description in § 4.

§ 12. DANAK's accreditation mark, the combined laboratory mark or the combined certification mark, see § 9 (1) and (2) must not be used in such a way as to give the impression that DANAK, ILAC or IAF has issued the report, the certificate, attestation, or has approved the system, product or service etc. covered by the document.

§ 13. Accredited companies must not use the logos of other accredited companies for their services, for instance, sub-contracted services together with their own reference to DANAK's accreditation.

(2) If a sub-contractor has delivered results that are reported in a test report, calibration certificate, examination report, inspection report/certificate, etc. it must clearly appear, either directly or in an appendix, who the sub-contractor is and what report (with ID no.) the sub-contracting is based on.

Part 4

Specifically on testing, calibration and pharmaceutical analysis

§ 14 Where calibration certificates contain results that are not covered by the laboratory's accreditation, these must constitute only a minor part of the reported results, and these results must be distinctly marked. The certificate shall be endorsed with the following, or a similar declaration:

Calibrations and results marked <...*...> in this calibration certificate are not covered by the laboratory's accreditation".

(2) Where test reports or examination reports contain results that are not covered by the laboratory's accreditation, it shall appear clearly from the reports what tests or analyses have been carried out during the accreditation.

(3) If a report/certificate contains results, that are associated with the assessment, and which are not an integral part of the accredited testing method, calibration method or examination method,

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these results must be marked e.g. by the use of a different typeface, and the following or a similar statement must be included:

“The marked statements in this test report/calibration certificate/examination report are not covered by the laboratory's accreditation”.

(4) The statements referred to in (1), (2) and (3) above shall be written preferably at the beginning or on the first page of the test report/calibration certificate/examination report, or where reference to the accreditation is made, or where the accreditation mark or combined laboratory mark is used, and in such a manner that the attention of readers of the report/certificate cannot avoid being drawn to the statement.

§ 15. Where customer demands, standards, regulations, etc. require reporting of results on specific forms, an application may be made for DANAK's approval of the forms being furnished with the accreditation mark or combined laboratory mark - always provided that the forms comply with the accreditation requirements for reporting.

§ 16. If a report/certificate is produced as electronic print-out, which does not allow the application of an accreditation mark or combined laboratory mark, the report/certificate may be provided with the accreditation mark or the combined laboratory mark, or may in a paper-bound version be inserted in a folder provided with the accreditation mark or the combined laboratory mark together with an unambiguous identification of the inserted report/certificate, or may subsequently be marked with the accreditation mark or combined laboratory mark by means of a stamp or similar permanent marking.

§ 17. The accredited company may not permit others to use DANAK's accreditation mark or combined laboratory mark.

Part 5 Specifically on certification

§ 18. DANAK shall approve the rules of the accredited company for a certified company's use of reference to the fact that it has an accredited certificate.

(2) A combination of the certification body's logo and name together with DANAK's accreditation mark shall be used.

(3) It must be clear from the accredited company's rules for the use of its own name and logo and DANAK's accreditation mark that these must not be used for products or services, or in connection therewith, in a manner that can lead to misunderstanding as to what the certificate covers.

§ 19. The accredited company's rules and conditions for certification must contain provisions to the effect that the certified company will cease referring to an accredited certificate and will withdraw documents carrying DANAK's accreditation mark when a certificate has expired or is withdrawn. The accredited company must take appropriate steps to enforce that provision.

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§ 20. The accredited company must have rules and procedures including contractual stipulations that ensures the enforcement of its provisions for the use of DANAK's accreditation mark and makes intervention against misuse possible.

Certification of quality management systems, environmental management systems or products

§ 21. For companies that have been accredited for certification of quality management systems, environmental management systems or products, and which have entered into an agreement with DANAK concerning use of the combined certification mark, the rules in § 18 (2) and (3) and §§ 19 and 20 shall also apply to the combined certification mark.

Certification of products

§ 22. Where the product certification covers the accredited company's inspection of the ongoing production and control of products, the rules may permit marking of the products and their packaging with DANAK's accreditation mark together with the accredited company's logo and name, always provided that it clearly appears that DANAK has not approved the product.

(2) If the product certificate only certifies approval to the effect that type testing has shown compliance with the specifications, the rules can permit that the firm uses DANAK's accreditation mark together with the accredited company's logo and name in commercials etc., provided that it clearly appears that the certificate covers the type testing only, and that the type testing has not been approved by DANAK.

Part 6 Specifically on inspection

§ 23. The accredited company must have rules and procedures, including contractual stipulations concerning the enforcement of its provisions to ensure that inspected companies do not use DANAK's accreditation mark or reference to accreditation, and to make intervention against misuse.

§ 24. Where inspection reports/certificates contain results that are not covered by the company's accreditation, these must constitute only a minor part of the reported results, and these results must be clearly marked. The report/certificate shall be endorsed with the following or a similar declaration:

“Inspections and results marked <...*...> in this report/certificate are not covered by the company's accreditation”.

Part 7 Specifically on environmental verification

§ 25. Attestation of environmental statements must be made on a form bearing DANAK's accreditation mark and the environmental verifier's own logo and name.

(2) The attestation form must contain the following, or a similar, reservation: “The verifier has verified the original version of the environmental statement in <...language ...>. The verifier cannot vouch for translations into other languages”.

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§ 26. The accredited company must state in the contract terms that translations of the environmental statement shall be endorsed as follows: "The environmental verifier's attestation applies to the <...language...> version", stating the original language of the environmental statement - or a similar statement.

§ 27. The accredited company's report on the review of the company and its environmental statement must be provided with a clause stating that it may only be published in extract when the extract has been approved by the accredited company.

Part 8 Coming into Force and rules for transition

§ 28. This Regulation shall come into force on 15 December 2007.

(2) This Regulation replaces Technical Regulation No. 1 of 2 March 2005.

(3) Accredited environmental verifiers can use the DANAK accreditation mark allowed up to the publishing of this regulation on reports for accredited services according to § 10 until the 15 March 2008 and on other types of documents according to § 11 until the 15 December 2008.

The Danish Safety Technology Authority, 28 November 2007.

Carsten Sørig

/

Karen Rud Michaelsen

APPENDICES:

Appendix 1: DANAK's accreditation mark

Appendix 2: Combined laboratory mark

Appendix 3: Combined certification mark

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DANAK's accreditation mark

Colours

Pantone 186 C

[Mark]

B/W:

100% black

Version asymmetrical

When the mark (Royal crown + DANAK) is 4 cm wide, the accreditation field and Reg. no. are printed in 6 point ARIAL.

[Mark]

If the mark is used in other sizes the subtext is enlarged or reduced correspondingly.

Version symmetrical

When the mark (Royal crown + DANAK) is 2.65 cm wide, the accreditation field and Reg. no. are printed in 6 point ARIAL.

[Mark]

If the mark is used in other sizes the subtext is enlarged or reduced correspondingly.

When using the accreditation mark for environmental verification "Reg.no." is omitted.

[Mark]

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Combined laboratory mark

Colours DANAK

Pantone 186 C

Version asymmetrical

[Mark]

B/W:

100% black

Colours ILAC

Pantone 293 C

B/W

100% Black

[Mark]

Version asymmetrical

When the mark (ILAC + DANAK) is 7 cm wide, the accreditation field and Reg. no. are printed in 6 point ARIAL.

If the mark is used in other sizes, the subtext is enlarged or reduced correspondingly.

Version symmetrical

[Mark]

[Mark]

When the mark (ILAC + DANAK) is 2.65 cm wide, the accreditation field and Reg. no. are printed in 6 point ARIAL

If the mark is used in other sizes, the subtext is enlarged or reduced correspondingly.

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Combined laboratory mark

Colours DANAK

Pantone 186 C

[Mark]

B/W:

100% black

Colours IAF

Pantone

Dark blue:

Pantone 2747

[Mark]

Light blue:

Pantone 299

Version asymmetrical

[Mark]

[Mark]

When the mark (IAF + DANAK) is 7 cm wide, the accreditation field and Reg. no. are printed 6 point ARIAL.

If the mark is used in other sizes, the subtext is enlarged or reduced correspondingly. HOWEVER, the mark should be at least 4.8 cm wide.

Version symmetrical

When the mark (IAF + DANAK) is 3 cm wide the accreditation field and Reg. no. are printed in 6 point ARIAL.

If the mark is used in other sizes, the subtext is enlarged or reduced correspondingly. HOWEVER, the mark should be at least 2 cm wide.