TECHNICAL REGULATION

Rules concerning the obligation to provide information	**Regulation no.**	**:**	**TF 4**
(Unauthorized translation of a regulation in Danish)	**Date**	**:**	**2006.06.26**
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Pursuant to Section 10 of the Promotion of Trade and Industry Act, cf. Consolidated Act No. 992 of 8 December 2003, as subsequently amended most recently by Act No.430 of 6 June 2005, and further to Statutory Order on Accreditation of Laboratories to Testing, etc., and to GLP Inspection, it is hereby provided:

Part 1
Scope and Objective

Section 1. This Technical Regulation applies to all accredited laboratories.

Section 2. The rules concerning the obligation to provide information define how laboratories fulfil the requirements in Statutory Order on Accreditation of Laboratories to Testing, etc., and to GLP Inspection, so that DANAK is given sufficient time to react to circumstances that may have an influence on whether the conditions for the specific accreditation are still fulfilled.

(2) This Regulation also concerns the provision of other information for the use of DANAK's surveillance.

Part 2
Rules concerning the obligation to provide information

Section 3. The obligation to provide information includes the submission of:

1) quality manual and information for use in relation to DANAK's visit at the laboratory,
2) information on participation in laboratory intercomparisons, and
3) information on conditions that may be important for maintaining the accreditation.

(2) Special requirements may be stipulated in the conditions for accreditation concerning the laboratory's obligation to provide information.

Section 4. DANAK's copy of the laboratory's quality manual, cf. section 3, subsection 1, no. 1), shall at latest be updated by sending in supplements and corrective sheets to the manual before surveillance, reassessment or other agreed visits. In cases where the manual consists of several levels or parts, the overall and general parts shall be sent in. Specific parts, such as test instructions, shall be submitted to the extent agreed between the laboratory and DANAK.

Section 5. Before each surveillance and reassessment visit the laboratory shall submit detailed information on:

1) the amount of accredited testing and calibration performed since the last visit, and
2) the amount of testing and calibration performed since the last visit within the scope of accreditation, but which has not been reported as accredited.

(2) The amount should be stated in terms of number of assignments within the various fields of accreditation.

Section 6. Updated information on the laboratory's participation in comparative testing, cf. section 3, subsection 1, no. 2), shall be submitted before each surveillance and reassessment visit.

Section 7. The laboratory shall, cf. section 3, subsection 1, no. 3) currently send in information to

DANAK about conditions that may have an influence on maintaining of the accreditation, for instance:

1) changes in organizational conditions, management or other key functions,
2) essential changes in the laboratory's fundamental policies or quality procedures,
3) limitations in the laboratory's service to clients due to long-term absence of staff, lack of equipment or to other causes,
4) non-conforming results in intercomparisons, and relating hereto, the laboratory shall send in information about corrective actions,
5) serious complaints against the laboratory's activities as an accredited laboratory and about any claim for compensation against the laboratory, and
6) circumstances that have or may have significant influence on the laboratory's operations, including insolvency, suspension of payments or bankruptcy.

Part 3
Coming into Force

§ 8. This Regulation shall come into force on 10 July 2006.
(2) This Regulation replaces Technical Regulation No. 4 of 6 November 2000.

Danish Safety Technology Authority, 26 June 2006.

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Jan Roed