

GUIDELINE

**Information about accreditation and
use of calibration labels by calibration laboratories**

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1. REFERENCES

DS/EN ISO/IEC 17011, 8.3.
Technical Regulation no. 1.

2. DELIMITATION

This guideline applies to all testing laboratories accredited for testing, calibration and medical examination. The guideline replaces the previous guideline RL 4 dated 20. June 2001.

3. OBJECT

DANAK's guidelines express DANAK's interpretation of relevant sections in accreditation standards, etc. with a view to ensuring harmonisation of the conditions imposed on accredited laboratories.

The object of this guideline is to describe what accredited laboratories may write about DANAK in accredited testing and examination reports, calibration certificates and other material where the laboratory wishes to inform about accreditation. Proposals for suitable texts are provided in Danish as well as English.

Guidance in the use of calibration labels is also provided for calibration laboratories.

4. SUGGESTION FOR INFORMATION TEXTS

4.1 Danish text

DANAK

Den Danske Akkrediterings- og Metrologifond – DANAK – administrerer den danske akkrediteringsordning på grundlag af en aftale med Sikkerhedsstyrelsen under Økonomi- og Erhvervsministeriet, som er ansvarlig for lovgivningen om akkreditering i Danmark.

De grundlæggende akkrediteringskriterier er beskrevet i henholdsvis DS/EN ISO/IEC 17025 "Generelle krav til prøvnings- og kalibreringslaboratoriernes kompetence" og i DS/EN ISO 15189 "Medicinske laboratorier – Særlige krav til kvalitet og kompetence". DANAK anvender fortolkningsdokumenter til de enkelte krav i standarderne, hvor det skønnes nødvendigt. Disse vil hovedsageligt være udarbejdet af "European co-operation for Accreditation (EA)" eller "International Laboratory Accreditation Co-operation (ILAC)" med det formål at opnå ensartede kriterier for akkreditering på verdensplan. Sikkerhedsstyrelsen udsteder desuden tekniske forskrifter udarbejdet af DANAK vedr. specifikke krav til akkreditering, som ikke er indeholdt i standarderne.

For at et laboratorium kan være akkrediteret kræves blandt andet:

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- at laboratoriet og dets personale skal være fri for enhver kommerciel, økonomisk eller anden form for pression, som kan påvirke deres uvildighed,
- at laboratoriet har et dokumenteret ledelsessystem og en ledelse, der kan sikre, at dette følges og vedligeholdes,
- at laboratoriet råder over teknisk udstyr og lokaler af en tilstrækkelig standard til at kunne udføre den ydelse, som laboratoriet er akkrediteret til,
- at laboratoriet råder over personale med såvel faglig kompetence som praktisk erfaring i udførelsen af de ydelser, som laboratoriet er akkrediteret til,
- at der er indarbejdet faste rutiner for sporbarhed og usikkerhedsbestemmelse,
- at akkrediteret prøvning, kalibrering eller medicinsk undersøgelse udføres efter fuldt validerede og dokumenterede metoder,
- at akkrediterede ydelser udføres og rapporteres i fortrolighed med rekvirenten og i overensstemmelse med dennes behov,
- at laboratoriet skal registrere forløbet af akkrediteret prøvning, kalibrering eller medicinsk undersøgelse således, at dette kan rekonstrueres,
- at laboratoriet er underkastet regelmæssigt tilsyn af DANAK,
- at laboratoriet skal have en forsikring, som kan dække laboratoriets ansvar i forbindelse med udførelsen af akkrediterede ydelser.

Rapporter, der bærer DANAK's akkrediteringsmærke, anvendes ved rapportering af akkrediterede ydelser og viser, at disse er foretaget i henhold til akkrediteringsreglerne.

4.2 English text

DANAK

The Danish Accreditation and Metrology Fund - DANAK - is managing the Danish accreditation scheme based on a contract with the Danish Safety Technology Authority under the Danish Ministry of Economics and Business Affairs who is responsible for the legislation on accreditation in Denmark.

The fundamental criteria for accreditation are described in DS/EN ISO/IEC 17025: "General re-

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quirements for the competence of testing and calibration laboratories”, and in DS/EN ISO/IEC 15189 “Medical laboratories – Particular requirements for quality and competence” respectively. DANAK uses guidance documents to clarify the requirements in the standards, where this is considered to be necessary. These will mainly be drawn up by the “European co-operation for Accreditation (EA)” or the “International Laboratory Accreditation Co-operation (ILAC)” with a view to obtaining uniform criteria for accreditation worldwide. In addition, the Danish Safety Technology Authority issues Technical Regulations prepared by DANAK with specific requirements for accreditation that are not contained in the standards.

In order for a laboratory to be accredited it is, among other things, required:

- that the laboratory and its personnel are free from any commercial, financial or other pressures, which might influence their impartiality;
- that the laboratory operates a documented management system, and has a management that ensures that the system is followed and maintained;
- that the laboratory has at its disposal all items of equipment, facilities and premises required for correct performance of the service that it is accredited to perform;
- that the laboratory has at its disposal personnel with technical competence and practical experience in performing the services that they are accredited to perform;
- that the laboratory has procedures for traceability and uncertainty calculations;
- that accredited testing, calibration or medical examination are performed in accordance with fully validated and documented methods;
- that accredited services are performed and reported in confidentiality with the customer and in compliance with the customer’s request;
- that the laboratory keeps records which contain sufficient information to permit repetition of the accredited test, calibration or medical examination;
- that the laboratory is subject to surveillance by DANAK on a regular basis;
- that the laboratory shall take out an insurance, which covers liability in connection with the performance of accredited services.

Reports carrying DANAK’s accreditation mark are used when reporting accredited services and show that these have been performed in accordance with the rules for accreditation.

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5. CALIBRATION LABELS USED BY CALIBRATION LABORATORIES

In order to inform customers on the calibration status for equipment and to ensure correct reference to the calibration certificate accompanying the equipment the equipment may be supplied with a label.

5.1 Where to put the label

The label should be put somewhere visible to the user of the instrument. If the label can not be put on the equipment it may be put on the container of the equipment or similar. Outdated labels should be removed.

5.2 Layout of calibration labels

The layout of a calibration label may be as illustrated below.



When the calibration label contains DANAK's accreditation mark or the combined mark reference is made to DANAK's TF nr. 1.

Equipment no., date of calibration and certificate no. should be filled in by the laboratory and controlled by the signatory to the calibration certificate.

The label should not make reference to a date of next calibration.

The label should be made of a sufficient durable material, stick the surface where it is put or otherwise attached to the equipment.

6. Entry into effect

The guideline comes into effect on 24 May 2005.

DANAK, 11. May 2005

Jesper Høy

Allan Munck