

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 requirements 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.

Danak guidelines for RL 4 of 2005.05.11