

Information on DANAK accreditation for

- **Testing**
- **Calibration**
- **Medical examination**
- **Certification of reference materials**
- **Proficiency testing**

The accreditation process – step by step

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This publication describes

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1. DANAK

DANAK, The Danish Accreditation Fund, is the national accreditation body, appointed by the Danish Safety Technology Authority under Ministry of Business and Growth. DANAK is a non-profit organisation.

DANAK accredits *companies* to perform

- certification of management systems, products and persons
- inspection
- environmental verification
- CO₂-verification
- certification of reference materials
- provision of proficiency testing

DANAK accredits *laboratories* for

- testing
- calibration
- medical examination

In addition, DANAK carries out the following tasks on behalf of Danish authorities:

- Inspection in accordance to OECD's rules for GLP (Good Laboratory Practice)
- Authorization and notification of bodies in accordance with the EU Construction Product Regulation

2. Accreditation

2.1 Purpose of accreditation

Many companies and public authorities have a need for impartial and reliable documentation testifying that their products or services comply with specific requirements and legislative provisions. This documentation may be obtained by the company by using accredited services.

2.2 Accreditation is ...

An accreditation is a recognition of the applicant's technical competence, organisational structure, impartiality, facilities and equipment in relation to the requirements in one or more harmonized international standards and that the company's quality system functions effectively and has been documented.

A complete list of the basis for assessment can be found at DANAK's website.

Accredited companies shall as a main rule use the DANAK accreditation mark on reports and certificates for accredited services. In order to maintain confidence in the accreditation mark and what it stands for, there are rules for its use. The conditions can be found in DANAK Accreditation Regulation AB2

By agreement with DANAK, accredited companies can also use the ILAC-MRA mark together with the DANAK accreditation mark. This documents that the company is accredited by an accreditation body which has signed the international agreements on mutual recognition of accredited reports and certificates.

Accreditation is normally granted for a 4 year period.

2.3 Payment

All DANAK's costs in connection with case processing, assessment activities and maintenance of the accreditation shall be covered by the applicant and the accredited companies.

The current pricelist can be found at DANAK's website.

3. Accreditation process

In general, the process mainly consists of the following stages:

Preparation

Application

- Documentation review

Visit at company

- Possible pre-assessment visit
- Accreditation visit

Finishing

- Drawing up assessment report
- Handling non-compliances

Granting accreditation

- Accreditation committee
- Decision on accreditation
- Accreditation document issued

Maintaining accreditation

Surveillance during the accreditation period

- Review of documentation
- Visit
- Preparation of assessment report
- Handling non-compliances

Renewal

- Documentation review
- Suspension or withdrawal of accreditation
- Preparation of assessment report
- Handling non-compliances

Finishing

- Preparation of assessment report
- Handling non-compliances

Decision about renewal

- Accreditation committee
- Decision on renewal of accreditation
- Issuing new accreditation document

Other

- Changes can be handled continuously or in connection to visit
- Termination
- Suspension or withdrawal of accreditation

3.1 Preparation

Before sending in the application, the applicant can obtain information about accreditation from DANAKs such as:

- Information material with general information on accreditation and specific conditions regarding the area of accreditation in question.
- A free information meeting so that the applicant is equipped to go through all the requirements and interpretation documents and to evaluate if the established quality system is able to fulfil all the accreditation requirements.

When the decision on applying for accreditation has been taken, it can be an advantage for the applicant to start working on the requirements in the daily routines. This includes among other things that procedures and reporting of services meet the requirements for accreditation.

3.2 Application

The DANAK application form can be downloaded at www.danak.dk. An application will always be treated confidentially by all persons participating in the process of accreditation, and it will be ensured that the requirements for impartiality in DANAK's assessment team are met.

DANAK will appoint a lead assessor (caseworker) to be responsible for the accreditation process - including selection of the other members of the assessor team. Apart from the lead assessor this consists of one or more technical assessors.

A technical assessor is a person who possesses technical expertise and insight into the scope of accreditation concerned, and the person has completed DANAK's special training for technical assessors. Technical assessors work on a consultancy basis for DANAK and are recruited e.g. from universities, hospitals, public authorities or private companies. Applicants will always be informed about who DANAK is going to use as technical assessors and will have the possibility to object in relation to their impartiality.

DANAK will review the documentation sent forward in order to determine if it is adequate with regard to meeting the accreditation criteria (own procedures, relevant standards and DANAK Accreditation Regulations). The applicant will be informed about any deficiencies or lack of precision and will then be able to send in revised or supplementary material.

3.3 Assessment visits

Pre-assessment visit

In collaboration with DANAK, the company decides on the need for a pre-assessment. This visit allows for a review of whether the company meets the criteria of accreditation and for a discussion of the technical requirements prior to the actual assessment at the accreditation visit. Most companies are accredited without a pre-assessment visit.

Accreditation visit

During the visit that will take place at all addresses where accredited activities services are carried out on a permanent basis, relevant administrative routines, the quality system, staff qualification, method list etc. will be assessed. Rooms, equipment, technical documentation and competence will usually be assessed by the technical assessors. In this connection the assessors will often witness how tasks within the applied scope of accreditation (for instance calibration, testing or medical examination) are carried out in practice.

The assessment team will hold an assessor meeting at the end of the visit, and decide which observations constitute non-compliances with the accreditation criteria and if the company can be recommended for accreditation, once the non-compliances have been handled in a satisfactory way.

At the final meeting with the company, the assessment team will present its non-compliances and recommendation. A deadline for corrective actions for the non-compliances found will be agreed upon. In case corrective actions have not been carried out and documented at the latest 6 months after the assessment, it can be necessary for DANAK to carry out a follow-up assessment.

3.4 Finishing

Preparation of assessment report

After the visit, DANAK will draw up an assessment report, which together with the recommendation and handling of non-compliances form the basis for decision on accreditation, to be taken by the accreditation committee. The company always has the possibility to object to the conclusions in the recommendation, handling of non-compliances and the assessment report within a specific time limit.

Handling non-compliances

The company shall send documentation on implementation of corrective actions for the non-compliances found. The non-compliances will be 'closed' by DANAK's approval of the documentation, and, in special cases, by carrying out a follow-up visit in order to ensure that the implemented changes are adequate. Non-compliances are registered in DANAK's non-compliance database where all subsequent communication take place.

3.5 Granting accreditation

Accreditation committee

When all non-compliances have been corrected in a satisfactory way, the lead assessor will draw up an internal note for DANAK's accreditation committee with a recommendation on whether an accreditation can be issued. The note is part of the documentation from the case processing together with a draft for a decision on accreditation.

Decision on accreditation and issuing accreditation document

DANAK's accreditation committee handles the recommendation and documentation and determines if accreditation can be granted. The decision will be forwarded to the company together with an accreditation document which states the scope of accreditation and the period of validity.

Accreditation is usually granted for a period of 4 years.

When the company is accredited, it will be published on DANAK's website and in the DANAK newsletter.

3.6 Maintaining accreditation

Surveillance during the accreditation period

DANAK will determine the number of ordinary surveillance visits when granting and renewing accreditation, which are planned to take place at the company during the accreditation period. The starting point is surveillance visits with an interval of 12 months for accreditations without a shown stability and efficiency for the quality system. In any case, the interval between surveillance visits cannot exceed 2 years, but the most usual for experienced laboratories is intervals of 16 months.

The surveillance visits that include all addresses, at which the company carries out accredited work on a permanent basis, are carried out in order to ensure that the company continues to comply with the requirements. The extent of assessment at a surveillance visit is in general more limited than during an accreditation visit or a renewal visit.

Visit report

During a surveillance visit, a recommendation on maintaining the accreditation is drawn up, followed by a more detailed assessment report.

Handling non-compliances

In case non-compliances are observed, they will be entered into DANAK's non-compliance database in the same way as at an accreditation visit. The corrective actions must be implemented within a time limit agreed upon, which normally cannot exceed 3 months.

3.7 Renewal

The procedure for a renewal largely follows the procedure for handling new applications, but at the assessment it is taken into account that DANAK has been conducting on-going surveillance of the accredited activities.

In order to maintain the accreditation, the renewal process – including visit, reports, closure of non-compliances and decision on accreditation for a new period – must be completed prior to the expiration of the current accreditation period.

Renewal is usually granted for a period of 4 years.

3.8 Change

Change of accreditation may take place at any time during the accreditation period. The company submits a request for a change of the accreditation, e.g. with a description of the new accreditation scope and a documentation for the company's competence in this area and enters the relevant data in DANAK's database for method lists or measurement capability.

DANAK will review the material received and evaluate if handling the change can be done administratively or if there is a need for an assessment visit, involving a new technical assessor etc.

Minor changes within the current area of competences (for instance inclusion of new methods in this area) can often be handled in a simplified process without involving the accreditation committee, but will require that the laboratory receives an amendment to the previous decision on accreditation. Extensions with new areas of competence will usually follow the process for new accreditations and might require a new decision and a revised accreditation document.

3.9 Other

Expiry

If the company chooses not to renew the accreditation, it will expire at the end of an accreditation period. The company can also request that part of an accreditation expire immediately. In case the complete accreditation is to expire, a notice of 6 months must be given.

Suspension or withdrawal of accreditation

Non-compliances observed at surveillance or in another way may be of such serious nature that the lead assessor will recommend suspension or withdrawal of the accreditation, or parts thereof. A decision on whole or partial suspension or withdrawal will be taken by an accreditation committee on basis of a recommendation from the lead assessor and will contain a complaint guide.

This does not apply, however, if the company itself has requested complete or partial suspension of the accreditation, for instance caused by breakdown of equipment or lack of essential employees. In such cases a suspension can normally be made administratively.

A suspension lasts 6 months as a maximum.

Suspension or withdrawal will be published in the register of accredited laboratories at www.danak.dk.

