

## **Information on accreditation for**

- **Testing**
- **Calibration**
- **Medical examination**
- **Production of reference materials**
- **Provision of proficiency testing**
- **Biobank processes**

## **The accreditation process – step by step**

## **This publication describes**

1. DANAK
2. Accreditation
3. The accreditation process for the areas mentioned on the front page, with the applicant's and DANAK's roles

### **1. DANAK**

DANAK, The Danish Accreditation Fund, is the national accreditation body appointed by the Danish Safety Authority under the Ministry of Industry, Business and Financial Affairs. DANAK is a non-profit company.

DANAK performs accreditation *in the laboratory area* within

- testing
- calibration
- medical examination
- production of reference materials
- provision of proficiency testing
- biobank processes

DANAK also accredits companies, as described in a separate document, to carry out:

- certification of management systems, products, and persons
- inspection
- validation and verification
- EMAS verification

DANAK further performs the following tasks on behalf of other Danish authorities:

- inspection in accordance with OECD rules on GLP (Good Laboratory Practice).
- authorisation and notification of companies under the EU Construction Products Regulation.

## **2. Accreditation**

### **2.1 Purpose of accreditation**

Many companies and authorities need impartial and reliable documentation that their products or services meet specified requirements and regulatory provisions. The company can obtain this documentation by using accredited services.

### **2.2 Accreditation is ...**

An accreditation is a recognition of the applicant's professional competence, organisational structure, impartiality, facilities, and equipment in relation to the requirements of one or more harmonised international standards, and that the company's quality management system is well-functioning and documented.

A comprehensive list of the assessment basis can be found on DANAK's website.

As a general rule, accredited companies must use DANAK's accreditation mark on reports and certificates for accredited services. To maintain confidence in the accreditation mark and what it stands for, there are rules for using it. The conditions are set out in DANAK's accreditation regulation AB 2.

In agreement with DANAK, accredited companies can also use the ILAC MRA symbol together with DANAK's symbol. This is documentation that the company is accredited by an accreditation body that has signed the international agreements on mutual recognition of accredited reports and certificates.

Accreditation is usually granted for a 4-year period.

### **2.3 Payment**

All costs at DANAK in connection with case processing, assessment activities and maintenance of accreditation are covered by the applicants and the accredited companies.

The current price list is available on DANAK's website.

## **3. Accreditation process**

An accreditation process will consist mainly of the following phases:

### **Preparation**

### **Application**

### **Visit**

### **Reporting and processing nonconformities**

### **Decision on accreditation**

### **Maintaining accreditation**

### **Renewal**

### **Termination**

## **3.1 Preparation**

Before applying, it is possible to have a free orientation meeting, so that the applicant is equipped to review all requirements and interpretation documents and thereby can assess whether the established quality management system can meet all accreditation requirements.

Already from the moment the decision to apply for accreditation is made, it is an advantage to start working with the accreditation requirements in the daily routines. This includes, among other things, that procedures and reporting of services meet the accreditation requirements.

## **3.2 Application**

DANAK's application form must be completed and can be downloaded at [www.danak.dk](http://www.danak.dk). An application will be treated confidentially by everyone participating in the accreditation process. It is also ensured that the requirements for impartiality for DANAK's assessment team are met.

A lead assessor (case officer) will be appointed to be responsible for the accreditation process – including the appointment of other participants in the assessment team. It shall consist of a lead assessor and one or more technical assessors.

A technical assessor has professional knowledge and insight into the accreditation area applied for. The assessors work on a consultancy basis for DANAK and are recruited from universities, authorities, hospitals or private companies. Applicants will be informed of who DANAK will use as a technical assessor and will have the opportunity to object to their capacity.

The submitted documentation is reviewed to assess whether it is sufficient to meet the accreditation criteria (own procedures, relevant standards and DANAK's accreditation regulations). The applicant is notified of significant deficiencies or ambiguities and is then given the opportunity to send revised or supplementary material.

### **3.3 Visits**

#### *Pre-visit - informative assessment (optional)*

In consultation with DANAK, the company decides whether a preliminary visit is needed to assess whether the basis is good enough to carry out the actual visit. Usually, pre-visits are not necessary.

#### *Accreditation visits*

During the visit, which will be carried out at all addresses where the company carries out accredited activities on a permanent basis, the administrative and technical parts of the quality management system will be reviewed. DANAK will, if possible, attend the parts of the applicant's practical work that will be covered by a future accreditation. The purpose is to assess the suitability of the quality system and professional competence.

If deficiencies or nonconformities have been found in relation to the company's own documentation or the assessment basis mentioned in section 2.2, these will be entered into DANAK's nonconformity database.

At the final meeting, the company is presented with the result of the assessment and the nonconformities are reviewed. The nonconformities are expected to be closed within 3 months in order for the completed assessment to be relevant (updated).

After the visit, a report will be written for the visit. The report briefly summarises the outcome of the assessment of the assessment team.

### **3.4 Reporting and processing of non-conformities**

#### *Reporting*

After the visit, DANAK prepares an assessment report, the conclusion of which includes the assessment team's recommendation on accreditation or rejection as well as a description of the scope of accreditation. The company can always object to the conclusions of the recommendation, processing of nonconformities and assessment report within a set time limit.

#### *Processing of nonconformities*

Nonconformity processing takes place in DANAK's customer portal. For each nonconformity, the company describes: the cause, extend, proposals for correction and corrective actions, and attaches any documentation for implementation. In special cases, DANAK carries out a follow-up visit to verify that the changes made are sufficient. DANAK closes nonconformities when answers are judged to be sufficient.

### **3.5 Decision on accreditation**

DANAK's accreditation committee evaluates the recommendation, assessment reports and other case material. The Committee decides whether accreditation may be granted, possibly subject to special conditions, or whether it is refused.

The accreditation shall take effect from the date of the decision. The decision is the legally valid document, and the accreditation period is usually 3 years (4 years in subsequent periods).

Together with the decision on accreditation, or shortly after, the applicant will be sent an accreditation document, with the accreditation number, the area of accreditation and the accreditation period. If the scope of accreditation is limited in relation to what has been agreed with the applicant during the accreditation process, information shall also be provided on the possibility of appeal.

The accreditation will be published on DANAK's website, just as it will appear on the website when an accreditation has ceased or suspended.

### **3.6 Maintaining accreditation**

#### *Surveillance during the accreditation period*

Regular surveillance visits are carried out, usually at 12-month intervals in the first period and at 16-month intervals in subsequent periods.

The surveillance visits, which include all addresses where the company carries out accredited work on a permanent basis, are carried out to assess whether the company continues to meet the requirements for accreditation.

The scope of assessment during a surveillance visit is generally less extensive than for an accreditation visit or a renewal visit (re-accreditation).

After surveillance visits, an assessment report will be prepared, and any nonconformities will be entered into the customer portal in the same way as when processing the application. Responses must be made within an agreed deadline, usually 1 month, and nonconformities must be closed within 3 months.

#### *Suspension or withdrawal of accreditation*

Non-conformities detected at surveillance visits, or otherwise, may be of such a serious nature that the lead assessor of the accreditation recommends suspension or withdrawal of the accreditation or parts of it. A decision to suspend or withdraw in whole or in part is taken by an accreditation committee on the basis of a recommendation from the lead assessor, nonconformities notified to the company, the company's comments and any other relevant material. The company will also be informed of the possibility of appealing the decision.

However, a company may itself request total or partial suspension of accreditation, e.g. due to the absence of key employees.

A suspension can last a maximum of 6 months.

Suspension or withdrawal will be published in DANAK's register of accredited companies on [www.danak.dk](http://www.danak.dk).

#### *Change of accreditation area*

Changes or extensions of the scope of accreditation may be made at any time during the accreditation period.

The company must send an application for extension or change, with a description of the new area and with documentation of the company's competence in the area and of any changes to procedures, etc.

DANAK reviews the material and assesses whether the change requires an assessment visit and the assignment of a new technical assessor.

The Accreditation Committee shall decide on extension or refusal on the basis of a recommendation from the Lead assessor. If the extension is granted, the applicant will have a decision or an addendum to the decision extended to include the new area.

### **3.7 Renewal**

For an accreditation to be maintained, the renewal process must be completed before the end of the existing accreditation period.

The case management for renewal largely follows the procedure for processing new applications, i.e. visit(s), reporting, closure of any nonconformities, and the accreditation committee's decision on accreditation for a new term.

At the assessment it is taken into account that DANAK has continuously assessed the accredited activities.

Renewal is usually granted for a period of 4 years.

### **3.8 Termination**

If the company chooses not to renew the accreditation, it expires at the end of the accreditation period. The Company may also choose to request that parts of an accreditation cease with immediate notice. If the entire accreditation is to be terminated, this must be done with 6 months' notice.

After the accreditation has ended, the company also has the obligations it has signed in the application, including confidentiality of customer relationships.

