

Information on accreditation for

- **Certification of products,
persons and management systems**
- **Inspection**
- **Environmental verification (EMAS)**
- **CO₂-verifikation**

The accreditation process – step by step

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This publication describes

1. DANAK
2. Accreditation
3. The accreditation process describing the roles of the applicant and DANAK

1. DANAK

DANAK, The Danish Accreditation Fund, is the national accreditation body, appointed by the Danish Safety Technology Authority under the 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 manages the following tasks on behalf of Danish authorities:

- Inspection in accordance with 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 harmonised 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 IAF MRA-mark together with the DANAK accreditation mark. Furthermore, inspection companies can use the ILAC mark together with the DANAK 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 accreditation are covered by the applicants 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

Visit

Corrective actions and final report

Decision on accreditation

Maintaining accreditation

Renewal

Expiry

3.1 Preparation

Before sending in the application, the applicant can obtain information about accreditation from DANAK s 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 be treated confidentially by all persons participating in the accreditation process. It will also be ensured that the requirements for impartiality in DANAK's assessment team are met.

The forwarded documentation will be reviewed in order to determine if it is adequate with regard to meeting the requirements for accreditation (own procedures, relevant standards and DANAK Accreditation Regulations). The applicant will be informed about any deficiencies or lack of precision and revised or supplementary material can then be submitted.

A lead assessor (caseworker) will be appointed to be responsible for the accreditation process - including selection of the other members of the assessor team, which will include one or more external experts.

An 'expert' is a person who possesses technical expertise and insight in the accreditation area applied for. They work on consultancy basis for DANAK and are recruited from e.g. universities, public authorities, hospitals or private companies. The applicant will be informed about who DANAK is going to use as expert and given the opportunity to object in relation to their impartiality.

3.3 Visit

Initial visit – informative assessment (optional)

In collaboration with DANAK, the company decides on the need for an initial visit in order to determine if the basis for conducting a so-called office visit is adequate. An initial visit is a primary review of the organization, quality system and registrations. An initial visit is normally not called for.

Office visit

During the visit, which is carried out in the main office as well as in branch offices at home and abroad, if any, relevant administrative routines, the quality system, staff qualifications, etc., are reviewed. DANAK will, if possible, check those aspects of the applicant's work that will be comprised by a future accreditation. The purpose is to assess the suitability and professional level of the quality system.

If deficiencies or non-compliances are detected in relation to the company's own documentation or the basis for assessment, mentioned in item 2.2, these are entered into DANAK's non-compliance database.

At the closure meeting the company is presented with the result of the assessment, and the non-compliances will be reviewed.

After the visit, a report about the office visit will be drawn up. The report briefly summarizes the result of the assessor team's assessment.

Witness – assessment of the applicant in practice

A field visit is a witness of the applicant's practical performance of certification, inspection or verification. One or more field visits will take place to ensure implementation and efficiency of the quality system, also including that the procedures for appointing an audit team ensures the necessary professional competence in the team.

After the field visit an assessment report will be sent to the applicant and in case of non-compliances these are entered into DANAK's non-compliance database. The non-compliances are expected to be closed within 3 months in order for the assessment performed is still relevant (updated).

3.4 Corrective actions and final report

During this stage of the accreditation process any non-compliance will be 'closed' and DANAK will draw up a final report from the office and witness.

Handling non-compliances

The company will describe proposals for corrective actions in the database for non-compliance and enclose any documentation for implementation. The non-compliances will be 'closed' by DANAK's approval of the documentation and in special cases a follow-up visit to verify that the implemented changes are adequate

In some cases it can be appropriate to deal with the process in two steps so that DANAK receives documentation for the suggested actions (such as suggestion for changed text in the procedures) in the first step and receives documentation for implementation of the actions in the second step.

Final report

When handling of non-compliances is completed, the applicant receives a final report where the conclusion, among other things, will contain the assessment team's recommendation on accreditation or refusal. In some cases accreditation may contain specific terms (conditions) for the accreditation.

It will be possible for the applicant to comment on the final report before the case is handed over to the DANAK accreditation committee for final decision.

3.5 Decision on accreditation

DANAK's accreditation committee evaluates the recommendation in the final report and possible comments from the applicant, as well as assessment reports and other material. The committee decides if accreditation can be granted, maybe on specific conditions, or if it should be refused.

The accreditation comes in to force at the date of the decision which DANAK forwards to the applicant. The decision is the legally binding document, and the accreditation period is normally 4 years.

Together with the letter of decision on accreditation, or shortly after, the applicant receives an *accreditation document* listing the number of the accreditation, the scope of accreditation and the period of accreditation. Should the scope of accreditation however, be limited in relation to what has been agreed upon during the accreditation process, information on possibility for complaints will be included.

The accreditation will be published on DANAK's website and in the DANAK newsletter.

3.6 Maintaining the accreditation

Surveillance during the accreditation period

Regular surveillance visits will usually take place with a 12 months interval, however, the first surveillance usually 6-9 months after accreditation has been granted.

The surveillance visits includes office and field (witness) visits and are carried out in order to ensure that the company continues to comply with the requirements for accreditation.

The extent of the assessment at a surveillance visit is in general more limited than during an accreditation visit or a renewal visit (re-accreditation).

At the surveillance visit an assessment report is drawn up and any non-compliance is entered into the non-compliance database in the same way as by treatment of the application. Any corrective actions shall be carried out during an agreed time limit, normally not exceeding 3 months.

Suspension or withdrawal of accreditation

Any occurrence of non-compliances ascertained in connection with surveillance, or in another way, may be of such serious nature that the lead assessor in charge of the accreditation will recommend suspension or withdrawal of the accreditation, or parts thereof. A decision on a complete or partial suspension or withdrawal will be taken by an accreditation committee, based upon recommendation from the lead assessor, non-compliances communicated to the company, their comments and other possible material. The company will be informed on the possibility to object to the decision.

A company can, however, also on its own request a complete or partial suspension of the accreditation, for instance in case of lack of key employees.

A suspension lasts 6 months as a maximum.

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

Change of scope of accreditation

Change or extension of a specific scope of accreditation may take place at any time during the accreditation period.

The company must submit a request for extension or change with a description of the new area and with documentation of the company's competence in this field

DANAK will review the material and assess if the change requires an assessment visit and a new expert.

The accreditation committee will make the decision on extension or refusal on basis of the recommendation from the lead assessor. Should the extension be granted, the applicant will receive a new accreditation document with the new scope.

3.7 Renewal

The renewal process must be completed prior to the expiry of the current accreditation period in order to maintain the accreditation.

The procedure for a renewal is almost identical with the procedure for new applications: visit, report, closure of possible non-compliances and the accreditation committee's decision on accreditation for a new period.

The assessment will take into account that DANAK has been conducting on-going surveillance of the accredited activities.

Renewal is usually granted for a period of 4 years.

3.8 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 6 months warning must be given.

Even after expiry of the accreditation, the company maintains the commitments signed by the company in the application, including confidentially on customers.

