

Information on accreditation to

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

The accreditation process – step by step

October 2023

This publication describes

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
- validation and verification
- environmental verification

DANAK also accredits *laboratories*, as described in another document, to perform:

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

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 Construction Product Regulation from EU

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. The company may obtain this documentation 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. 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 AB 2.

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 document states 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 DANAKs 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 DANAKs website.

3. Accreditation process

In general, the process consists of the following stages:

Preparation

Application

Visit

Handling of any nonconformities 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 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 requirement 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 DANAKs 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 re-vised 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

pre-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 nonconformities 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 nonconformity database.

At the closure meeting the company is presented with the result of the assessment, and the nonconformities 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, validation 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 nonconformities these are entered into DANAK's nonconformance database. The nonconformities are expected to be closed within 3 months for the assessment to be relevant (updated).

3.4 Corrective actions and final report

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

Handling nonconformities

The company will describe answers including corrective actions in the database for nonconformities and enclose any documentation for implementation. The nonconformities 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 nonconformities 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 and a description of the extent of accreditation. 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 accreditation committee in DANAK for decision on accreditation.

3.5 Decision on accreditation

DANAKs 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, eventually on specific conditions, or if it should be refused.

The accreditation comes into 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. 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.

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.

The accreditation will be published on DANAKs website as well as any termination or suspension.

3.6 Maintaining the accreditation

Surveillance during the accreditation period

Regular surveillance visits will usually take place with a 12-month interval.

The surveillance visits include 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 a surveillance visit an assessment report is drawn up and any nonconformity is entered into the nonconformity database in the same way as by treatment of the application. Answers shall be carried out within an agreed time limit, normally 1 month and nonconformities shall normally be closed within 3 months.

Suspension or withdrawal of accreditation

Any occurrence of nonconformities 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, nonconformities communicated to the company, their comments and other relevant 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 may last 6 months as a maximum.

Suspension or withdrawal will be published in the register of accredited companies at DANAKs website.

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, including documentation of the company's competence in this field and of any changes in procedures etc.

DANAK will review the material and assess if the change requires an assessment visit and a new technical 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 decision and 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 any nonconformities 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-month warning must be given.

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