



## **Information about DANAK accreditation for**

- **Testing**
- **Calibration**

## **The Accreditation Process - Step by Step**

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### Information about the accreditation process for

- Testing
- Calibration verification

#### **About accreditation**

**DANAK** - which is an abbreviation for Dansk Akkreditering (Danish Accreditation) - is Denmark's national accreditation body. DANAK grants accreditation to laboratories performing testing and calibration and to firms for certification, environmental verification and inspection.

Many Danish firms have a need for having their products and services tested by Danish laboratories whose impartiality and technical competence are recognised both nationally and internationally. This requirement is covered by laboratories which have been granted accreditation by DANAK.

An accreditation is a formal recognition of a laboratory's technical competence, organisational structure and impartiality in relation to the requirements in one or more international standards.

The basis for accreditation of laboratories is to be found in the international standard DS/EN ISO/IEC 17025, Danish statutory orders, technical regulations and guidelines issued by DANAK indicating how the standards should be interpreted and how to ensure compliance with the accreditation requirements.

The basic conditions for a firm to obtain accreditation are:

- technical competence
- impartiality
- a well-functioning and documented quality system
- legal identity

## The Accreditation process - step by step

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### The accreditation process

An accreditation process consists of the following main phases:

#### **Application**

- Initial review of documentation

#### **Accreditation visit at the laboratory**

- Visit
- Drafting visit report

#### **Accreditation**

- Letter of acceptance
- Issue of accreditation document

#### **Surveillance visit**

#### **Application for renewal/reaccreditation**

## The individual phases in the accreditation process

### Before application

Before sending in the application, the applicant may obtain general information about accreditation from DANAK, both in the form of information material and possibly a free briefing meeting. For the actual application for accreditation DANAK's accreditation forms should be used. They can be obtained from DANAK or downloaded from DANAK's website: [www.danak.dk/products](http://www.danak.dk/products) from DANAK/application forms.

### Initial phases

An application will always be treated confidentially by all persons participating in the process and DANAK will ensure that the requirements of legal capacity have been complied with.

When the application is received by DANAK, a lead assessor (case officer) will be appointed to be responsible for the accreditation process - including selection of a team of assessors. This will consist of the lead assessor, who - in cooperation with one or more technical assessors - will undertake the assessment of the laboratory.

A technical assessor is a person who possesses broad technical expertise and insight in the accreditation field applied for, and who has undergone DANAK's special training as technical assessor. Technical assessors are called in from educational institutions, public authorities or private firms. Laboratories that apply for accreditation are always informed about who DANAK is going to use as technical assessor so that any objections concerning legal capacity can be submitted in writing to DANAK.

## The Accreditation process - step by step

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### Review of the application and documentation material

Assessment of the application. DANAK reviews the applicant's quality system and other documentation forwarded in order to assess whether the technical and organisational conditions for complying with the requirements of the relevant standards have been met. The applicant will be informed about any deficiencies or lack of precision, and the applicant may then submit new or supplementary material before an audit visit to the laboratory is agreed.

### 'Audit' at the applicant's premises - accreditation visit

During the visit, which is carried out at all addresses where the laboratory carries out testing or calibration, relevant administrative routines, the quality system, staff qualifications, method list, etc., will be reviewed. Testing or calibrations routines with the laboratory's equipment and premises will be reviewed by the technical assessors. In connection with this the assessors will often observe selected testings or calibrations.

If deficiencies or occurrences of non-compliance in practice in relation to the documentation or accreditation rules are ascertained, so-called non-compliance reports will be drawn up for the individual situations.

A non-compliance report is a description of the conditions ascertained that are not in accordance with the laboratory's own documentation, requirements in standards or accreditation rules. The laboratory's representatives sign Letter of acceptance the non-compliance forms and make proposals for corrective actions, which must be approved by the lead assessor.

During the accreditation visit it will not normally be necessary to agree a deadline for the implementation of corrective actions. However, they must be commenced and their implementation documented not later than six months after the accreditation visit. If this has not taken place, DANAK reserves the right to carry out a follow-up visit.

At the meeting of assessors, which takes place after the assessment, the assessment team will determine what recommendation should be submitted to the laboratory at the final meeting.

After the visit DANAK will draw up an assessment report.

The conclusion of the assessment report incorporates the recommendation to DANAK's management concerning acceptance or refusal of accreditation to the laboratory. In some cases the recommendation will set out special terms (conditions) for acceptance.

### **Closing phase**

During this phase of the accreditation process any occurrences of non-compliance will be 'closed' This is effected by DANAK approving the documentation for implementing the described corrective actions - possibly in connection with a follow-up visit.

## The Accreditation process - step by step

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When all occurrences of non-compliance have been satisfactorily corrected, a letter of acceptance will be drawn up describing the field for which accreditation can be granted. The letter of acceptance also serves as a contract between the laboratory and DANAK concerning the laboratory's accreditation.

### Accreditation

DANAK's management will deal with the recommendation in the assessment report and the applicant's comments, if any - and will determine the conditions for granting accreditation. The applicant will be informed of the decision in a letter of approval/refusal. When the applicant has accepted the letter of acceptance, the accreditation document will be forwarded.

Accreditation for testing and calibration may be granted for a period of up to 5 years.

When the laboratory has been granted accreditation, this will be published on DANAK's website and in DANAK Nyt.

### Mark

Accredited firms have the right to use DANAK's mark on reports and certificates for accredited services to show that accreditation has been granted. In order to maintain confidence in this 'seal of approval' rules have been laid down for use of DANAK's accreditation logo. The conditions are stated in DANAK's technical regulations and are designed to ensure that the logo is used in a manner that cannot give rise to misunderstandings regarding the scope of accreditation.

### Surveillance during the accreditation period

Regular visits are carried out during the accreditation period. These visits, which comprise all addresses at which the laboratory carries out accredited services, are made to ensure that the laboratory continues to meet the requirements.

During the visits it is assessed whether the laboratory continues to comply with the accreditation requirements – also including that the laboratory is adhering to its quality system and is currently updating it, that the laboratory has implemented internal audit, managerial evaluations and so on.

Reviews of the laboratory' documentation in connection with a surveillance visit are, however, generally less comprehensive than in connection with application and renewal (re-accreditation).

In connection with the surveillance, a report will be drawn up describing any occurrences of non-compliance in the same way as when dealing with the application. Corrective actions must be carried out within an agreed time limit that normally must not exceed three months.

## The Accreditation process - step by step

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### Voluntary suspension

Some occurrences of non-compliance may, however, result in the assessment team stating during the visit that they will recommend to DANAK that the laboratory shall suspend certain activities until the corrective actions to remedy non-compliance have been approved. It will be possible for the laboratory within a very short time limit to comment on the recommendation, which will subsequently be considered by DANAK.

A firm may also voluntarily suspend its accreditation - or parts thereof. This may take place in the case of organisational changes that affect the firm's technical competence or in connection with replacement of equipment or rebuilding.

### Suspension or withdrawal of accreditation

Any occurrence of non-compliance ascertained in connection with surveillance may on rare occasions be of such a serious nature that during the visit the team of assessors will inform the laboratory that it will recommend suspension or withdrawal of the accreditation, or parts thereof.

On the basis of the report from the surveillance visit and the accredited laboratory's response DANAK will decide whether the occurrence of non-compliance is of such a nature that the accreditation shall be suspended for a period or be wholly or partly withdrawn.

Suspension or withdrawal will be published on DANAK's website.

### Change of field of accreditation

Change/extension of a specific field of accreditation may take place at any time during the accreditation period. The laboratory must submit a request for extension/change with a description of the new accreditation field and with documentation of the laboratory's competence in this field.

DANAK will review the material submitted and determine whether the change necessitates an assessment visit, attachment of another technical assessor, etc.

After consideration of, among other things, the firm's competence in the new field, a decision will be made regarding acceptance/refusal of the change.

### Renewal/re-accreditation

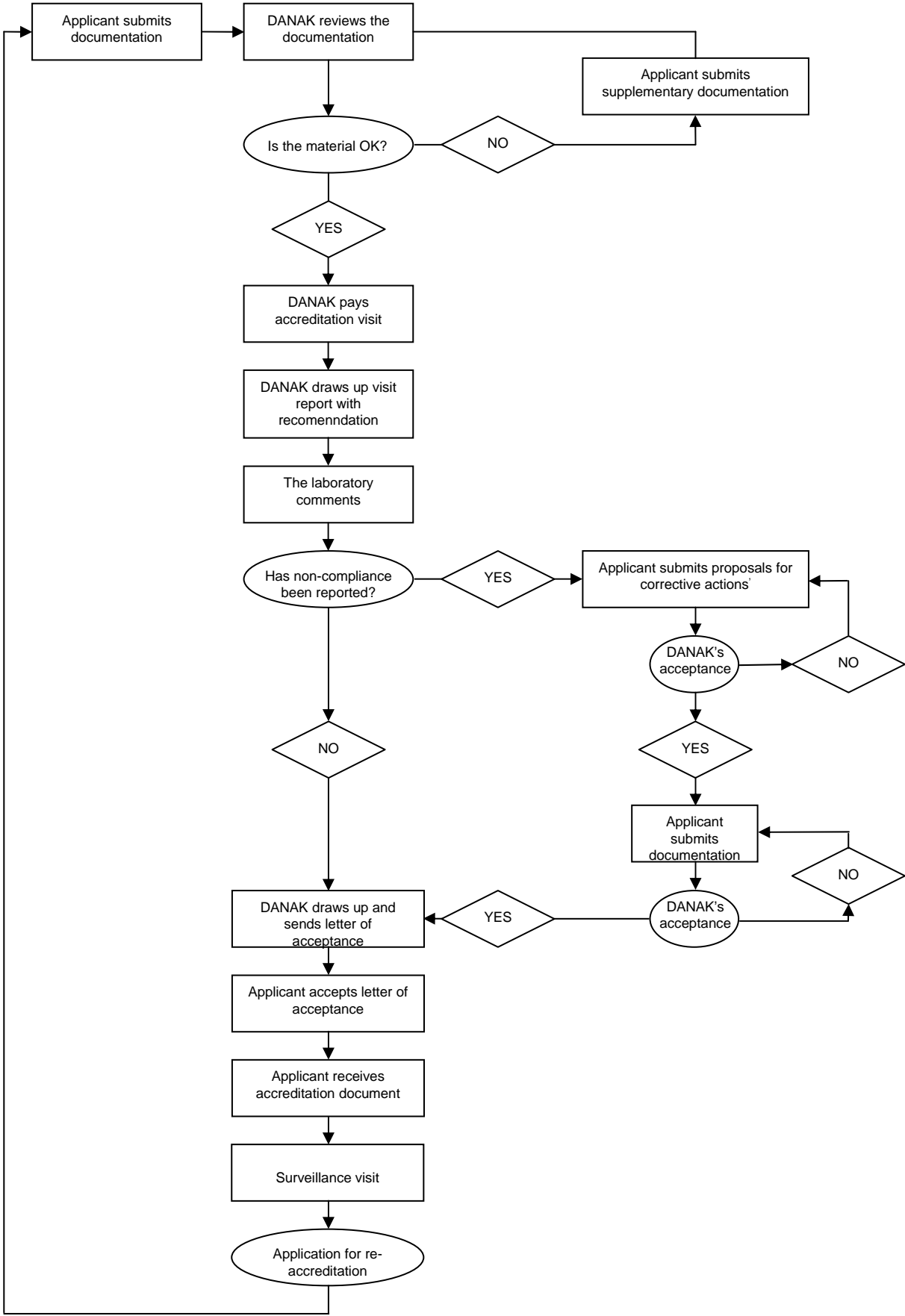
The case procedure for a renewal largely follows the procedure for handling new applications.

The assessment will naturally take into account the fact that DANAK has been conducting on-going surveillance of the accredited activities. Thus the last surveillance visit before the accreditation expires may be combined with the renewal visit.

### Payment

DANAK is run as a non-profit organisation. All DANAK's costs in connection with case processing, assessment activities and maintenance of the accreditation will be covered by the applicant or accredited firms. Collection of administration fees and case processing take place in accordance with the statutory order on DANAK's prices (fees) for accreditation, etc.

# The Accreditation Process – step by step



<sup>4</sup> Accepted only in special cases