
General regulation for accreditation of companies

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1. Application

1.1 This accreditation regulation applies to companies which applies for accreditation from DANAK, The Danish Accreditation Fund (hereafter DANAK) or are accredited by DANAK.

1.2 Companies mentioned in item 1.1 may be established in Denmark as well as abroad.

2. Requirements and regulations for accreditation**Accreditation criteria**

2.1 In order to be accredited by DANAK or to maintain an accreditation from DANAK the company shall meet the accreditation criteria included in:

- a. Executive Order No. 913 of 25 September 2009 regarding accreditation of companies;
- b. relevant international standards for the accreditation scope including mandatory guidelines and interpretations issued by EA, ILAC and IAF etc.;
- c. DANAK's general regulation for accreditation of companies and relevant specific accreditation regulations;
- d. any supplementary requirements in directives, laws, executive orders and other specific regulation documents depending on the specific accreditation area.

2.2 A list of the accreditation criteria mentioned in item 2.1 is published on the DANAK web-site.

2.3 DANAK will notify the accredited companies in case the criteria in the documents mentioned in item 2.1a-c are amended and inform about the deadline for implementation of the amendments.

Further requirements for accreditation

2.4 Applicants and accredited companies are obliged to provide DANAK with all necessary information needed for processing an application for accreditation and for maintaining, change and renewal of an accreditation, upon request.

2.5 Accredited companies shall use DANAK's accreditation mark or refer to accreditation in accordance with the regulations in executive order on accreditation of companies and DANAK's accreditation regulation AB 2 "DANAK's accreditation mark and reference to accreditation".

2.6 Accredited companies must not use the accreditation in such a way that it may bring discredit on DANAK and shall only declare that they are accredited with regards to the activities, which are covered by the scope of accreditation.

2.7 At DANAK's enquiry on complaints about the company related to accreditation the company shall assist with investigation and resolution.

2.8 Accredited companies must not offer certification according to the standards used for accreditation e.g. DS/EN ISO/IEC 17025 or DS/EN ISO 15189.

2.9 Accreditation is granted to one legal entity and the accredited activities shall be carried out by this. However, sub-contractors can be used in accordance with the accreditation criteria for the specific area.

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2.10 Special criteria apply if foreign companies apply for accreditation. If the national accreditation body for the applied scope of accreditation is comprised by a multilateral agreement (MLA) from European cooperation for accreditation (EA), International laboratory Accreditation (ILAC) or International Accreditation Forum (IAF) the applicant will normally be referred to apply at the national accreditation body.

2.11 An accreditation can only include one accreditation standard. However, standards or other normative documents used in combination with this (for instance ISO 22870 in combination with ISO 15189 or ISO/TS 22003 in combination with ISO/IEC 17021) can be included. DANAK will also consider whether the applied areas are so different that it might be appropriate to divide into several accreditations.

2.12 For each accreditation the company shall appoint one contact person who is responsible for communication and coordination with DANAK.

3. Accreditation, change and extension of accreditation area and renewal of accreditation

Application

3.1 Application for accreditation is made by sending a completed application form which can be found at the DANAK web-site. Documentation as listed in the application form shall be attached. The application form and the documentation may be sent electronically.

Management system – documentation

3.2 Applicants shall forward a copy of the company's management system (quality management system) and a list of standards and procedures or give DANAK access to an electronic version of the management system.

3.3 If an electronic quality system is used DANAK shall have access to all relevant parts of the management system or to a copy in a version that has a functionality which will make an adequate assessment possible. DANAK will not require general access to the registrations of the company, including the registration of personal data, and DANAKs access to these should, if at all possible, be restricted. DANAK will not copy personal data, included in the registrations of the company.

3.4 If the accreditation shall only apply to a part of a company's activities and the company's management system covers additional activities, it shall clearly be indicated (e.g. from an overview) which parts of the system that are valid for the area of activities the accreditation shall cover.

Granting accreditation

3.5 DANAK determines an accreditation area, which specifies the services the company may provide under its accreditation, on basis of the application and of the DANAK assessment. If the company performs accredited assessment activities on more than one address the addresses shall be evident from the accreditation and where some accredited services are not performed on all addresses it shall be evident which parts of the accreditation scope that are performed on the specific addresses. On addresses where assessment activities are not performed DANAK will, together with the company, determine which of these that are relevant to note.

3.6 Accreditation is granted to the company for a period determined by DANAK.

3.7 The duration of an accreditation period is usually four years.

Change and extension of scope of accreditation

3.8 Application for change or extension of an accreditation may take place at any time after accreditation is granted. The company shall send a clear description of the applied, with relevant documentation for the change or extension of the accreditation. Regarding flexible scope, the relevant DANAK accreditation regulation applies.

3.9 At application of extension of accreditation scope, DANAK, determines based on a risk analysis, whether a visit or eventual assessment of practical performance of the new service will be required, cf. item 5.4 regarding extra ordinary surveillance visits.

Renewal of accreditation

3.10 Before the expiration of the accreditation period, cf. item 3.7, the company will be informed that DANAK is planning a renewal visit in order to grant the company a new accreditation period. The company will also be informed of a deadline for informing DANAK, in case the company does not want to renew the application.

3.11 Visits in connection with renewal of an accreditation are conducted in accordance to section 4 and will normally be undertaken 3-6 months before the expiration of the accreditation.

3.12 Time for visit is agreed upon with the company or decided by DANAK if necessary.

3.13 In case the process of granting a new accreditation period has not been finished before the end of the current period DANAK may – under certain circumstances – administratively extend the current accreditation period. The total accreditation period cannot extend 5 years.

4. DANAK's assessments of applications and accreditations

4.1 At reception of an application DANAK evaluate whether the scheme applied for, cf. overview on DANAK's website, is included by DANAK's established scopes of accreditation or whether it is a new area. If it is a new area it will be evaluated whether DANAK wishes to establish the new area and whether the scheme fulfil the requirements for accreditation (unambiguous requirements). If this is not the case the application will be rejected.

4.2 DANAK appoints an assessment team to manage the assessment. DANAK can also invite observers to join the assessment team. The company may object to the appointed assessment team before a fixed deadline. In case of assessments at addresses abroad, DANAK can ask the national accreditation body to perform the assessment, according to the co-operation in the organisations mentioned in item 2.10.

4.3 Applicants and accredited companies are obliged to receive visits from assessment teams cf. item 4.1, in connection with the handling of application, change and renewal of accreditation and in connection with surveillance for maintaining the accreditation.

4.4 DANAK shall have access to assess all the company's premises where accredited activities are per-

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formed or are desired to be performed. From the received information the assessment team will evaluate, based on a risk assessment, which premises to be visited.

4.5 DANAK shall have access to assess a representative number of staff in order to evaluate the applicant's competence within the accreditation scope applied for.

4.6 If non-conformities are found they will be processed as described in section 7.

4.7 When companies, during an application process or as part of corrective actions, send data to DANAK on employee competences or other kinds of documentation, this documentation shall not include CPR-numbers or specific data e.g. on state of health or union membership. DANAK will acknowledge receipt of data regulated by GDPR while confirming to delete the received documentation when the assessment has been carried out.

4.8 DANAK complies with the EU General Data Protection Regulation (GDPR), EU Regulation 2016/679. In cases where accredited companies or applicants deems it necessary, for the party to send relevant documentation to DANAK, DANAK can enter into an agreement with the party on DANAK's handling of the data.

4.9 Applicants and accredited companies are obliged to ensure that DANAK is able to assess how the company perform their tasks at their customers.

4.10 If fraudulent behaviour is found when DANAK is processing the application, if the company deliberately gives false information or if the company withholds information DANAK will reject the application and terminate the assessment process.

5. Maintaining accreditation

5.1 It is a condition that an accredited company complies with the accreditation criteria cf. section 2, as well as the conditions for the accreditation, in order to maintain its accreditation. The accredited company shall at any time be capable of demonstrating competence within the complete scope of accreditation. This can be documented by referring to activities carried out during the past years and by providing updated documentation for competence.

5.2 DANAK performs periodic surveillance visits during the accreditation period (ordinary surveillance) in order to evaluate the companies' continuous fulfilment of the accreditation criteria and terms.

5.3 When granting and renewing an accreditation, DANAK determines the number of ordinary surveillance visits to be planned at the company during the accreditation period. The plan includes visit to the accredited company's addresses and participation in the company's visits to the field, so that the area of accreditation is evaluated in the accreditation period.

The basis for accreditations is yearly surveillance visits during an accreditation period. The last surveillance visit will be replaced by a renewal visit if the company wish to renew their accreditation.

The interval between the surveillance visits is decided based on a risk assessment where the following will be looked into:

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- a. the documented stability the company's services has reached;
- b. the demonstrated effectiveness of the management system;
- c. the complexity of the accreditation area.

The maximum interval between visits cannot exceed two years.

5.4 DANAK may conduct extra ordinary surveillance visits at the accredited companies when a risk assessment indicates the need, i.e. in connection with:

- a. application for changes in the accreditation area for an accredited company, cf. item 3.8;
- b. incidents comprised by an accredited company's duty of information, cf. section 6;
- c. information from a third party to DANAK about irregularities in delivered accredited services;
- d. verification of the company's implementation of corrective action(s), cf. item 7.3 and 7.4.

5.5 Companies that perform accredited activities in the field shall upon request from DANAK forward complete lists of planned activities. On the basis of these DANAK will plan participation in the visits of the company.

5.6 Time for ordinary and extra ordinary surveillance visits, including participating in the company's visits to the field, is agreed upon with the company or decided by DANAK if necessary.

6. Information duty

6.1 Accredited companies are obliged to inform DANAK about all changes in the conditions on which the accreditation is based and which are significant for maintaining the accreditation. Including:

- a. Changes in organizational conditions like ownership, management or other key functions;
- b. significant changes in the company's basic politics and quality procedures;
- c. limitations in the company's accreditation area as consequence of long absence of key staff or serious conditions against the company's activities which have or may have significant influence on the operation of the company, including insolvency, suspension of payments or bankruptcy;
- d. changes in the company's domicile and localities;
- e. changes in the company's resource situation;
- f. shortage or defective equipment which means that accredited activities have to be discontinued for a longer period;
- g. differing results in comparison tests or
- h. other conditions which may influence the company's ability to meet the accreditation criteria:

See item 3.8 and 3.9 regarding request for change of accreditation area.

6.2 Accredited companies shall upon request give DANAK access to documents as stated in section 3.2-3.4.

7. Non-compliances from the accreditation criteria for an accredited company

7.1 If non-compliances from the agreed accreditation criteria are found in connection with a visit or another type of surveillance, the company shall perform the following:

- a. Analysis of extent;

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- b. Correction for securing that the non-conformities are rectified for the whole extent
- c. Analysis of cause
- d. Corrective actions for securing that similar non-conformities do not occur

If it is assessed that there is no need for corrections or corrective actions the reasons for this shall be stated.

7.2 A time-limit for performing actions will be determined by DANAK , cf. item 7.1 and will usually not exceed 3 months.

7.3 The actions mentioned in section 7.1 must be approved and the implementation verified by DANAK.

7.4 DANAK can withdraw or suspend all or parts of an accreditation cf. section 8 in case the actions stated in section 7.1 have not been implemented within the time-limit.

7.5 DANAK can withdraw or suspend all or part of an accreditation, cf. section 8 upon establishing non-compliances that are believed to cause that the accredited services do not meet the criteria for accreditation

8. Suspending and termination of an accreditation

Suspending an accreditation

8.1 DANAK may suspend an accreditation, or parts of the accreditation area with a time-limit for remedy of ascertained violations or ascertained non-compliances of accreditation criteria or conditions, cf. statutory order on accreditation of companies.

8.2 The accredited company can also ask DANAK to suspend the accreditation or parts of the accreditation area for a period of up to 6 months, should the company e.g. not be competent to deliver a specific service during a period of time.

8.3 DANAK informs the accredited company about the consequences of the suspension which will include:

- a. that the specific accredited services may not be conducted;
- b. demand of withdrawal of already issued accredited reports or certificates where relevant;
- c. publication at the DANAK web-site and
- d. potential information to relevant authority or others.
- e. that, immediately after the suspension, affected costumers are informed hereof and about related consequences.

Termination of the whole or of parts of an accreditation

8.4 If the conditions causing a suspension of the accreditation or parts of the accreditation area are not rectified within the time-limit, the accreditation will terminate or the accreditation area will be reduced.

8.5 DANAK can withdraw an accreditation, if the conditions for the accreditation are no longer fulfilled or in case of gross or repeated violation of the conditions cf. executive order on accreditation of companies. If fraudulent behaviour is ascertained or if the company deliberately gives false information or withhold information DANAK will, furthermore, withdraw the accreditation.

8.6 The accredited company can request an accreditation to terminate completely or partly, for example if an

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activity is no longer performed or if the complete accredited area is terminated.

8.7 At termination of the whole or of parts of an accreditation DANAK shall assess if the accredited activities carried out until the termination meet the accreditation criteria. DANAK determines if this assessment shall be carried out at a visit or by assessing documentation sent by the company.

9. DANAK publication of accreditations

9.1 DANAK is responsible for securely storing all received information.

9.2 DANAK publishes accreditation areas and status for current accreditations at its web-site together with contact details, including the contact person of the accredited company.

9.3 DANAK upholds confidentiality about all other information about the applicant or the accredited company, however, information will be passed on to other accreditation bodies, cf. section 4.2. Sufficient information will be provided for the foreign accreditation body to complete an assessment on an enlightened basis and e.g. focus on points chosen by DANAK.

9.4 If a company applies for accreditation to a foreign national regulatory basis DANAK must ensure in cooperation with the foreign national accreditation body where the regulatory basis is issued, that DANAK has access to the necessary information and expertise. Hereby, DANAK will pass on information to other accreditation bodies stating that there are applications in an area.

9.5 DANAK provides information about registered data to persons from other accreditation bodies that participate in EA evaluations of DANAK.

9.6 All persons who gain access to DANAK's information have signed a non-disclosure agreement.

9.7 If companies desire a special statement on confidentiality DANAK has a statement, which can be forwarded.

10. Complaints

10.1 A company can make a complaint about a DANAK-decision by asking DANAK at the latest four weeks after the company has been informed about the decision to conduct a new evaluation of the case. Should the time-limit for making the complaint expire on a Saturday, Sunday or a holiday, the time-limit will be prolonged to the following working day.

If the new handling of the case does not lead to a fully compliance with the company's complaint, the decision can be brought to 'Klagenævnet for Udbud' the official Danish Complaints Committee of Tenders.

10.2 Regarding complaints of matters other than DANAK's decisions, DANAK will handle the complaint and inform the complainant about the result. Should DANAK receive complaints about accredited companies, the complainant will normally be asked as a first step to contact the accredited company.

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11. Payment

11.1 DANAK charges payment for activities connected with accreditation. The pricelist is published on DANAK's website.

11.2 When applying for accreditation the applicant becomes obligated to pay for DANAK's services. DANAK can suspend the accreditation if payment is not received, cf. the pricelist.

12. References

Section in AB 1	Document with requirement	In AB 1	Document with requirement
2.1-2.2:	17011 section 4.2a)+8.2.1b)	4.6:	Ref. to section 7
2.3:	17011 section 8.2.3	4.7-4.8:	GDPR
2.4:	17011 section 7.2.1+7.2.2	4.9:	17011 section 4.2d)+e)
2.5:	17011 section 4.3.1a)+8.2.1b)	4.10:	17011 section 7.2.4
2.6:	17011 section 4.2f)+g)+h)	5.1-5.3:	17011 section 7.9.2+7.9.3
2.7:	17011 section 4.2k)	5.4:	17011 section 7.9.5
2.8:	IAF/ILAC JGA7-07	5.5-5.6_	17011 section 4.2c)+d)
2.9:	17011 section 7.2.1	6.1-6.2:	17011 section 4.2i)
2.10:	EA-2/13	7.1-7.2:	17011 section 7.6.8
2.11-2.12:	DANAK	7.3:	17011 section 7.6.9
3.1:	17011 section 7.2.1	7.4-7.5:	17011 section 7.11
3.2-3.4:	17011 section 7.2.2	8.1-8.7:	17011 section 7.11
3.5:	17011 section 7.8.1c)+d)	9.1:	17011 section 8.1.1
3.6-3.7:	17011 section 7.9.1	9.2:	17011 section 7.8.1
3.8-3.9:	17011 section 7.10	9.3:	17011 section 8.1.1 + EA-2/13
3.10-3.13:	17011 section 7.9.4	9.4:	EA-2/13
4.1:	17011 section 7.3	9.5:	EA-1/17
4.2:	17011 section 7.4.1	9.6-9.7:	DANAK
4.3:	17011 section 4.2c)+7.4.2	10.1:	17011 section 7.13
4.4-4.5:	17011 section 4.2c)	10.2:	17011 section 7.12
		11:	17011 section 4.2j)

This accreditation regulation comes into force 17 September 2019. Any differences between the Danish and the English version of this document are not intended, but in case of doubt with respect to the correctness the version in Danish should be consulted.