1. Application

To achieve international recognition of accreditations, DANAK is a co-signer of agreements in European Accreditation (EA), International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF). Maintenance to these agreements is conditioned on compliance with international standards for accreditation as well as documents from EA, ILAC and IAF.

This accreditation regulation shall ensure that schemes within product, system and person certification as well as inspection meet the requirements for application under accreditation, cf. ISO / IEC 17011: 2017 item 4.6.3 and EA-1/22, and that requirements in schemes do not conflict with the above accreditation standards and other documents.

2. Scope of accreditation

2.1 This accreditation regulation covers new, amended and existing schemes. The requirements distinguish between Danish and international schemes, just as the ownership of the scheme is included. Schemes shall be approved in accordance with the requirements of this AB in order that accreditation can be obtained and maintained for these.

2.2 In this document a scheme, cf. ISO / IEC 17000, is to be understood as a documented and publicly available set of requirements which stipulates the following:

- The subject of conformity assessment;
- The requirements with which conformity is determined;
- The manner in which compliance is determined such as testing, inspection, verification, validation or auditing;
- Any special requirements for the certification or inspection body;
- Any specific applications or interpretations of ISO/IEC 17011.

2.3 A Scheme Owner (SO) can be an authority or a private company.

2.4 There is no need to evaluate internationally recognized schemes such as accreditation to EU directives or regulations as well as schemes approved by EA, ILAC or IAF for use under multiple accreditations. DANAK can inform about which schemes this covers.

2.5 Regardless of whether a scheme is assessed to meet requirements to be used for accreditation, DANAK is not obliged to offer the service.

2.6 DANAK charges payment for the evaluation of schemes on the basis of a written agreement on evaluation. However, for simple schemes such as those applicable to Weighers and measurers, the evaluation will be very simple and will be included in the assessment of the Conformity Assessment Body (CAB).

For simple changes to executive orders, DANAK will be able to provide consultation responses without an agreement being established.

3. Requirements for scheme owner

3.1 A SO shall be an unambiguous identified legal entity. SO shall be responsible for the layout and operation of the scheme, including having a mandate to amend documents of requirements.

3.2 In cases where a SO desires a scheme to be approved for accreditation, the following is required:

1) SO shall enter into an agreement with DANAK regarding evaluation of the scheme in relation to accreditation in accordance with one of the recognized accreditation standards (see 4.2 1) c).
2) After DANAK's approval of a scheme, SO shall, upon any subsequent change to the scheme, request DANAK for approval before the entry becomes effective.
3) SO shall have a process for informing CABs about changes in the scheme and for establishing transitional rules for CABs and certified/inspected/applicant companies.

3.3 In cases where it is a CAB (or a group of these) that desires a scheme to be approved for accreditation, and where it is not possible to get a SO to carry out the process cf. 3.2, the following is required:

1) CAB shall enter into an agreement with DANAK regarding the evaluation of the scheme;
2) After DANAK's approval of a scheme, the CAB(s) accredited to the scheme shall in the event of any subsequent change to the scheme request DANAK's approval of the change before it can be accredited to a new version.

4. Requirements for the scheme

4.1. Below is an overview of relevant standards and guidelines.

	Inspection	Person certification	Product certification	System certification
ISO/IEC 17007 Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment	X	X	X	X
ISO/IEC 17020 Conformity assessment — Requirements for the operation of various types of bodies performing inspection	X			
ISO/IEC 17021-1 Conformity assessment — Requirements for bodies providing audit and certification of management systems				X
ISO/IEC 17024 Conformity assessment — General requirements for bodies operating certification of persons		X		
ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services			X	
ISO/IEC 17067			X	

Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes				
Appendix 1 in this AB Guidelines for choosing product or system certification as a basis for the scheme.			X	X

4.2. Requirements for the scheme:

1) Requirements for developing the scheme:
   a) The purpose of the scheme shall be stated, as well as it shall be clear to whom it is addressed;
   b) There shall be coherence between the stated purpose of the scheme and the technical requirements;
   c) It shall be evident which standard (17020, 17021-1, 17024 or 17065) the scheme is based on. The requirements shall be unambiguously described both the technical requirements for the company as well as the requirements for the CAB's performance of tasks;
   d) The requirements shall not exclude clauses in the standards in item c) or be in conflict with the requirements in the standards;
   e) There shall be documentation of validation of the scheme;
   f) All documents of requirements shall be publicly available;
   g) When changing the scheme, a date shall be set for when the new version become effective as well as transitional rules for conversion from old to new version of the scheme;
   h) Documents of requirements shall be available in Danish and/or English.

2) The scheme's requirements for CAB:
   a) Scheme owner can make requirements regarding CAB's performance of the task e.g. regarding time spent, audit or inspection interval, auditors/inspectors competences and regarding the training of auditors/inspectors.
   b) Scheme owner can stipulate that CABs shall be registered with the scheme owner;

3) The scheme's requirements for the accreditation body:
   a) The scheme owner cannot normally formulate requirements for the accreditation body's work, e.g. regarding expectations for the frequency of witnessed assessments, competencies of assessors, etc.;
   b) If EA-approved schemes require such special requirements that go beyond the requirements of ISO/IEC 17011:2017, these shall be approved by EA's general assembly before they can become effective.

4.3 For person certification the requirements in ISO/IEC 17024:2012 item 8 shall also be met.

5. Application for approval of scheme

5.1 Application for approval can be put forward by

a) scheme owner (company or authority) or

b) a Danish compliance assessment body (CAB) seeking accreditation to the scheme.

5.2 The Following is forwarded to DANAK:

a) the scheme's documents of requirements

b) documentation that the scheme has been evaluated with the requirements for conformity assessment for a type of accreditation, cf. 4.2, and

c) documentation that the scheme is in compliance with the requirements of section 3 of this AB.

5.3 Evaluation of scheme for national approval:
For applications where it is only desired that DANAK can accredit to a scheme, the form for the national scheme (simplified EA form), which can be found at www.danak.dk under "About accreditation / application forms" is filled in. DANAK may request further information in connection with the evaluation. If 5.2 b) or c) has not been implemented, DANAK will be able to perform these against payment.

5.4 Evaluation of scheme for the purpose of EA approval so that accreditation can be made to the scheme in other countries:

1) The request for evaluation must be submitted by the scheme owner, and it must be stated that DANAK is requested to act as a Home Accreditation Body (hAB) in relation to the scheme, cf. EA-1/22, ie. performs assessment on behalf of all accreditation bodies;
2) The scheme and documents of requirements shall be constructed in accordance with EA-1/22
3) An EA form shall be completed. It can be found on www.danak.dk under "About accreditation/application forms".
4) DANAK then informs EA that the scheme is under evaluation. The procedure for evaluation and approval by EA is evident in EA-1/22.
5) After EA approval, the scheme will appear on EA's list of approved schemes. The list is not publicly available.

6. DANAK's evaluation

6.1 DANAK will perform evaluation of schemes that have not previously been evaluated and approved by DANAK, EA or IAF. Modification of a scheme that has not been previously approved is in this connection equated with a new scheme.

6.2 DANAK will reassess previous DANAK-approved schemes when the overall requirements for CABs or accreditation bodies have changed in relation to those effective at the time of approval. If several CABs use the same scheme, they can ask the scheme owner to agree on an evaluation with DANAK or enter into an agreement with DANAK on a joint sharing of costs and results.

6.3 DANAK will assess existing schemes that have been accredited and have not been evaluated within the last 4 years. The evaluation will be carried out in connection with the re-accreditation of the CABs that apply

the scheme. Here the principles of 6.2 will be followed. DANAK establishes a transitional arrangement, and the evaluation process might be simplified. For national schemes accepted before 21 May 2015, DANAK will in connection with re-accreditation assess the need for evaluation. Evaluation will also be carried out at changes to the scheme or to the accreditation basis.

6.4 A positive result of an evaluation is a prerequisite for DANAK to be able to accredit to the scheme. In cases where DANAK is not responsible for the evaluation (see table at the end of this section), DANAK will await the result of the evaluation before a decision can be made on accreditation to the scheme.

6.5 DANAK performs the evaluation according to the categories of schemes shown in the table below.

When changing existing schemes, the same requirements for evaluation apply as for new schemes within the category.

Assessment of the specific scheme divided by category

Category	**Requirement for evalutaiton**
IAF approved scheme cf. IAF's list of schopes and subscopes	Non*
EA approved scheme cf. EA's list	When updating the evaluation is performed by hAB**
New schemes for EA approval	EA-1/22, performed by hAB**
Older EA scheme which was put in use before may 21 2015	EA-1/22, performed by hAB**
New EU requirements (regulation/directive)	The EA procedure described in EA-1/22 is handled by the EA Secretariat
Older EU requirements (regulation/directive) which are used for accreditation	Non*
New Danish scheme, only for use in Denmark (e.g. executive order)	Simplified Danish EA form (see item 5.3)
Danish scheme, only for use in Denmark, first accreditation before this accreditation notice became effective.	Simplified Danish EA form (see item 5.3) before re-accreditation of CAB. For schemes accepted before 21 May 2015, the need for evaluation will be assessed in connection with. re-accreditation. However, evaluation must be carried out by changing the scheme or the accreditation basis.
Older Danish executive order which is at present used for accreditation.	For schemes accepted before 21 May 2015, the need for evaluation will be assessed in connection with. re-accreditation. However, evaluation must be carried out when changes are made to the scheme or the accreditation basis.

* as IAF or EA has already made a decision ** hAB can, for example, be DANAK

7. References

ISO/IEC 17011:2017 item 4.6.3
EA-1/22

DANAK, June 17 2020

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Appendix 1: Guidelines for choosing product or system certification as a basis for the scheme. The document has been prepared under the auspices of EA: HHC M22 (Sept.2019)

Product or management system certification?

1 Summary

1.1 The most important differences between the certification of products and the certification of management system are:

- The **conformity declaration** in case of certification of products based on ISO/IEC 17065 applies to a specified product, service or process of an organisation and is based on the evaluation of these products, services or processes against specified requirements.
- The conformity declaration in case of certification of management systems specifies the type of management system (quality, environment, etc.) of the organization and the requirements (ISO 9001, ISO 14001, etc.).
- **Assessment activities** are fundamentally different. Certification of products, services or processes need testing of products, assessment of service delivery and/or inspection of processes whilst certification of management system is based on audits. Conducting these activities require specific competencies. In management system certification the certification body does not evaluate product conformity and is not required to be competent to do so.
- Process certification as meant in ISO/IEC 17065 is not a special type of management system certification achieved by auditing but needs specification of requirements for the production or service delivery processes and needs evaluation of those processes, most likely by inspection thereof.
- Product certification is intended to allow the producer to use a **certification mark** on the product, which is not allowed in management system certification.

1.2 In which case product certification or management system certification should be preferred is a question the interested parties should answer. These parties should consider the nature of the products or services and the risks associated with these.

1.3 Where the clients are able to clearly define product specifications and to evaluate the conformity of the products with these specifications themselves, one could conclude that certification of a quality system is appropriate to provide the level of confidence needed. If this is not the case, certification of the product is more likely to be the appropriate because the specifications are defined and made public in the scheme and the confirmation that the products comply is very much the responsibility of an independent and competent party (certification body). Market parties, including regulators should prevent that misplaced expectations are created by the system they establish.

1.4 The two golden rules for scheme developers shall be:

i) define an unambiguous declaration of conformity making clear what is certified against which criteria and;

ii) ensure the use of appropriate conformity assessment activities that justify this declaration of conformity.

2 Differences between product certification and management system certification

The differences can be looked at from two perspectives, namely from a market perspective where the certificate plays a role and from the perspective of the certification bodies that need to be accredited based on one of the standards ISO/IEC 17065 or ISO/IEC 17021-1.

2.1 The market's perspective

2.1.1 Management system certification

2.1.1.1 On certification of management systems, the introduction of ISO/IEC 17021-1 states:

Certification of a management system provides independent demonstration that the management system of the organization:

a) conforms to specified requirements;

b) is capable of consistently achieving its stated policy and objectives;

c) is effectively implemented.

Conformity assessment, such as the certification of a management system, thereby provides value to the organization, its customers and interested parties.

2.1.1.2 ISO 9000 (3.5.3) defines that a management system is a *set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives*. The second note given with this definition explains: *management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes*. The first and third note clarify that the management system should define its scope and purpose.

2.1.1.3 Thus, to be suitable for accredited management system certification, the management system shall include unambiguous requirements for:

1. Determination of the scope of the system;
2. (the establishment of) Policies (inclusive of practices, beliefs, rules) within that scope;
3. Objectives
4. Processes to *effectively* achieve the objectives
    a. Planning (P)
    b. Operational (D)
        i. Primary
        ii. Supportive
    c. Evaluational (C)
    d. Correctional (A)
5. Organisational structure, roles and responsibilities

Note: Following the ISO HLS generally ensures that the above aspects are covered in an appropriate manner.

2.1.1.4 The above means that a management system standard can include specific process requirements (such as sector specific good practices (e.g. 22000-2) or legal requirements), *as long as* the final conformity statement (certificate) explicitly and only refers to the management system being in compliance with the requirements.

Example:

When this is translated to a system for quality management, it is expected that a certified organization uses a quality system that complies with the requirements of e.g. ISO 9001 and has effectively implemented this system. I.e. the certification body has confirmed that organization has defined and implemented a set of interrelated or interacting elements to establish quality policies and objectives and has established processes to achieve these. In fact, the certificate is a statement on the ability of an organisation to meet intended results. Based on that, a client of that company may expect that the organization is able to determine the needs and expectation of the clients, to understand the desired product specifications, to master the processes to comply with the specifications, and to control that the delivered products comply with the requirements, agreed with the client. ISO 9001 however does not give specific criteria for product specifications, process requirements and control tools or for quality objectives, but requires the organization to establish those. The certification body will audit this system and declare that it complies with the requirements of ISO 9001. During the auditing process, the auditor will also look at the production process and verify (on sampling base) whether the organization abides by its own work instructions and procedures. When the auditor determines failures to achieve this, this will lead to nonconformities related to the management system. When the auditor detects conformity in the audit, his/her sampling has confirmed effective implementation of the system, but this will still not lead to a declaration on the conformity about the products, services or processes with specifications.

2.1.1.5 Being certified therefore does not mean[1]:

- *that the organization will always achieve 100% product conformity, though this should of course be a permanent goal.*
- *that the organization is providing a superior product, or that the product itself is certified as meeting the requirements of an ISO (or any other) standard or specification.*

2.1.2 Product certification

2.1.2.1 On the other hand ISO/IEC 17067, states:

4.2.1 The fundamental objectives of product certification are:
a) to address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfilment of specified requirements;

[1] Refer to ISO/IAF *Communiqué Expected Outcomes for Accredited Certification to ISO 9001*, website ISO

b) to allow suppliers to demonstrate to the market that their product has been attested to fulfil specified requirements by an impartial third party body.

4.2.2 Product certification should provide the following:
- confidence for those with an interest in fulfilment of requirements, and
- sufficient value so that suppliers can effectively market products.

2.1.2.2 In product certification, an impartial competent body confirms that the producer produces products that comply with specified requirements and as a result of this the clients may have confidence in that specified characteristic of the product. Product certification requires specified requirements for the product and definition of the conformity assessment methods to check conformity with these requirements.

2.1.2.3 These can also be requirements for the production or service delivery process. When the object of certification is to confirm that the final product has been produced under specified process characteristics and these are mentioned on the certificate, we speak of process certification. Thus, process certification is a specific type of product certification and not some sort of management system certification with addition of process requirements because process certification concerns the specific production process requirements which determines specific product characteristics. Three main purposes of process certification are distinguished:

a. The specified characteristics of a product describe the way the product is produced (e.g. sustainability or animal welfare criteria). It cannot be measured on the product whether it was the result of a process that takes into account animal welfare or sustainability criteria. To confirm by certification that the processes conform with these requirements requires the certification body to evaluate2 (inspect) these processes. The conformity declaration in such cases confirms that the product was the result of a process that conforms to specified requirements.

b. In certain cases, it is more efficient to evaluate the process than to evaluate the output (e.g. if destructive testing of the product is required to determine conformity of products). The welding process is an example of such types of processes that may be certified. The result is a declaration of the conformity of the welds made, by following a process in conformance with requirements.

c. In another type of process certification, the process and the output are both the object of certification (e.g. the object is to have the safety of work ensured in a high risk process). The certification body is certifying the output and the process confirming that the activities were conducted according to certain rules that should ensure safety. Examples would be the certification of the asbestos removal process or personal data security provided by certification in GDPR.

2.1.2.4 Process certification is not about supporting processes but about the primary production or service delivery processes that will ensure that the output conforms to the requirements of the client or other stakeholder. The evaluation by the certification body consists mainly of inspection of those processes and may be *supplemented* by audits of the management system that the producer has implemented to support its continued fulfilment of the requirements.

[2] The words ‘evaluate’ and ‘evaluation’ are used as overall terms for determining conformity of product, service or process with requirements as this is also the language in ISO/IEC 17065 (see definition 3.3 and clauses 7.4).

2.1.2.5 Certification of services often has many similarities with certification of processes because in the delivery of a service the client is part of the process. The requirements against which certification is performed could be requirements for the process. However, these should include requirements for processes in which interaction with the clients takes place. So it is very unlikely that in a certification scheme for services the certification body will not involve the clients in the evaluation process and will not observe the service delivery and thus the service delivery process.

2.1.2.6 In case of certification of services or processes, the selection of the appropriate evaluation method may be a challenge. The designers of a scheme need to establish the typical characteristics of a service including objectively measurable indicators and criteria, in order to define an appropriate assessment method. Customer satisfaction surveys, observation of services delivery and the use of *mystery guests* are methods that could be necessary. For process certification those characteristics of the process need to be defined that makes the process resulting in the products or services that meet the needs of the client. To evaluate conformity of a process with criteria the certification body will inspect the processes. In schemes this is often (incorrectly) referred to as auditing.

Example:

From the perspective of the objectives of the certification activity, the parties that are involved in this activity should question themselves whether they need a statement about the management system of the producer or a statement about product conformity. The following rationales may assist parties in answering this question:

A management system certificate and in particular a quality management certificate, like an ISO 9001 certificate, confirms that the client has implemented a quality system that conforms to the applicable standard (like ISO 9001). Based on that, a client of that organization may expect that the organization should be able to understand the need of the client and provide the product or service agreed with the client. The certified producer should be considered capable of delivering this product or service but this will only be the product needed by the client if the client was able and prepared to specify sufficiently what its need is. As the certification body is not confirming that the producer really delivers a product that conforms to these needs, because it did not evaluate the product, the client should be able to evaluate at the end whether the producer delivered the product the client asked for.

When a client is not capable to define the product specifications, due to the fact that the product needed is complex (a one-time purchase of a house or building, a one-time need for a soil sanitation service, etc.) and/or the client is not fully capable and prepared to determine at the end of whether the product conforms to its needs, product certification should be preferred.

2.2 The certification body's perspective

2.2.1 From the perspective of a certification body, important differences between ISO/IEC 17065 or ISO/IEC 17021-1 exist in the evaluation activities of the certification body and the competencies required to conduct these activities and also in the requirements for the use of marks and in the conformity declarations made by the certification body.

2.2.2 In case of management system certification, the certification body has to conduct audits to verify conformity of the system with the requirements (e.g. ISO 9001) and to check effective implementation of the management system. The conduct of audits needs other competencies than the testing of products, the assessment of service delivery or the inspection of processes.

2.2.3 For product certification, ISO/IEC 17065 mainly refers to other standards for the requirements for the conduct of the evaluation activities (and the related competences), for example ISO/IEC 17025 in case of testing and ISO/IEC 17020 for inspection. When applying ISO/IEC 17021-1, further additional documents should be *considered*, such as ISO/IEC 17021-3 on competences of QMS auditors and relevant IAF MDs. This should be decided by the scheme owner, dependent on the requirements on the supporting management system.

2.2.4 An important difference is the use of marks on products that may be allowed in case of product certification but not in case of management system certification. The need to advertise these specified criteria make a reasonable case for product certification. Adversely, avoiding the use of the logo on specific products, is an indicator that this scheme is not really about product or process certification.

2.2.5 The certification programmes for product certification and management system certification are also different. ISO/IEC 17021-1 requires the certification body to conduct initial certification audits, annual surveillances and after three years a recertification audit. Product certification is based on an initial evaluation of the product and additional requirements (process requirements, quality system requirements, etc.) and after that the activities may vary depending on the scheme. For example, ISO/IEC 17067 distinguishes six basic options for product certification schemes, varying from no surveillances after the initial test of a product sample to schemes where the certificates have a validity term connected with surveillance activities with product testing, process inspections and quality system audits.

2.2.6 The design of the scheme should be the result of the need for a certain level of confidence in the conformity declaration for the product and the nature of the products and the risks associated with it and thus, the explicit involvement of the parties that have an interest in the certificates.

2.2.7 The certification body shall avoid to declare on a certificate that a company complies with certain requirements. The conformity declaration[3] shall clearly state compliance of the management system of a company in case of management system certification in case of ISO/IEC 17021-1 or compliance of products, services or processes of an organisation in case of product certification based on ISO/IEC 17065.

2.2.8 The declaration shall be based on the activities performed by the certification body. Thus, if the certification body *only* performed audits (which apply as explained in the definition of ISO/IEC 17000 to management systems), the declaration cannot be about product conformity.

[3] Also refer to the definition of certification in ISO/IEC 17000:2006 (5.5) that states: “third-party attestation (5.2) related to products, processes, systems or persons”