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<b>Evaluering af ordninger/schemes i forhold til akkreditering</b>	Nr.	:	AB 21
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## 1. Formål

For at opnå international anerkendelse af akkrediteringer er DANAK medunderskriver af aftaler i European Accreditation (EA), International Laboratory Accreditation Cooperation (ILAC) og International Accreditation Forum (IAF). Opretholdelse af disse aftaler er betinget af, at internationale standarder for akkreditering samt dokumenter fra EA, ILAC og IAF følges.

Det skal med denne akkrediteringsbestemmelse sikres, at ordninger, inden for produkt-, system- og personcertificering samt inspektion opfylder kravene til anvendelse ved akkreditering, jf. ISO/IEC 17011:2017 pkt. 4.6.3 og EA-1/22, og at krav i ordninger ikke er i modstrid med ovennævnte akkrediteringsstandarder og andre dokumenter.

## 2. Anvendelsesområde

**2.1** Akkrediteringsbestemmelsen omfatter nye, ændrede og eksisterende ordninger. I kravene er der skelnet mellem danske og internationale ordninger, ligesom ejerforholdet til ordningen indgår. Ordninger skal være godkendt efter kravene i denne AB for, at der kan opnås og opretholdes akkreditering til disse.

**2.2** En ordning skal i dette dokument jf. ISO/IEC 17000 forstås som et dokumenteret og offentligt tilgængeligt sæt af krav som fastlægger følgende:

- Emnet for overensstemmelsesvurdering;
- Kravene som der skal bestemmes overensstemmelse med;
- Måden der bestemmes overensstemmelse på såsom prøvning, inspektion, verifikation, validering eller auditering;
- Eventuelle særlige krav til certificerings- eller inspektionsorgan;
- Eventuelle specifikke anvendelser eller fortolkninger af ISO/IEC 17011.

**2.3** En ordningsejer (Scheme Owner, SO) kan være en myndighed eller en privat virksomhed.

**2.4** Der er ikke behov for evaluering af ordninger, der er internationalt anerkendt såsom akkreditering til EU-direktiver eller -forordninger samt ordninger, der er godkendt af EA, ILAC eller IAF til anvendelse under flere akkrediteringer. DANAK kan informere om hvilke ordninger, det omfatter.

**2.5** Uanset om en ordning vurderes at opfylde krav til at kunne anvendes til akkreditering, er DANAK ikke forpligtet til at tilbyde ydelsen.

**2.6** DANAK opkræver betaling for evaluering af ordninger på grundlag af en skriftlig aftale om evaluering. For simple ordninger som dem, der er gældende for Vejere og målere vil evalueringen dog være meget enkel og indgå i bedømmelsen af overensstemmelsesvurderingsorganet (Conformity Assessment Body, CAB).

For simple ændringer til bekendtgørelser vil DANAK kunne give høringsvar, uden at der oprettes aftale.

## 3. Krav til ordningsejer

**3.1** En SO skal være en entydigt identificeret juridisk enhed. SO skal være ansvarlig for udformning og drift af ordningen, herunder have mandat til at ændre kravdokumenter.

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**3.2** I de tilfælde, hvor det er SO, der ønsker, at en ordning godkendes til akkreditering, kræves følgende:

- 1) SO skal indgå aftale med DANAK om evaluering af ordningen ift. akkreditering efter en af de anerkendte akkrediteringsstandarder (se 4.2 1) c).
- 2) Efter DANAKs godkendelse af en ordning, skal SO ved enhver efterfølgende ændring af ordningen anmode DANAK om godkendelse inden ikrafttrædelse.
- 3) SO skal have en proces for orientering af CABs om ændringer i ordningen og for fastsættelse af overgangsregler for CABs og certificerede/inspicerede/ansøgende virksomheder.

**3.3** I de tilfælde, hvor det er et CAB (eller en gruppe af disse), der ønsker at en ordning godkendes til akkreditering, og hvor man ikke kan få SO til at gennemføre processen jf. pkt. 3.2, kræves følgende:

- 1) CAB skal indgå aftale med DANAK om evaluering af ordningen;
- 2) Efter DANAKs godkendelse af en ordning, skal den/de CABs, der er akkrediteret til ordningen ved enhver efterfølgende ændring af ordningen, anmode DANAK om godkendelse af ændringen, inden der kan akkrediteres til en ny version.

#### 4. Krav til ordningen

**4.1.** Nedenstående er en oversigt over relevante standarder og retningslinjer.

	Inspektion	Person-certificering	Produkt-certificering	System-certificering
ISO/IEC 17007 Overensstemmelsesvurdering – Vejledning i udarbejdelse af normative dokumenter, der kan anvendes til overensstemmelsesvurdering	X	X	X	X
ISO/IEC 17020 Overensstemmelsesvurdering – Krav til forskellige typer inspektionsorganer	X			
ISO/IEC 17021-1 Overensstemmelsesvurdering – Krav til organer der foretager audit og certificering af ledelsessystemer				X
ISO/IEC 17024 Overensstemmelsesvurdering – Generelle krav til organer, der udfører certificering af personer		X		
ISO/IEC 17065 Overensstemmelsesvurdering – Krav til organer, der certificerer produkter, processer og serviceydelser			X	
ISO/IEC 17067			X	

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Overensstemmelsesvurdering - Grundprincipper for produktcertificering og retningslinjer for produktcertificeringsordninger				
Bilag 1 i denne AB Retningslinjer for valg af henholdsvis produkt- eller systemcertificering som grundlag for ordningen			X	X

#### 4.2. Krav til ordningen:

- 1) Krav til udformning af ordningen:
  - a) Formålet med ordningen skal fremgå, ligesom det skal være klart, hvem den henvender sig til;
  - b) Der skal være sammenhæng mellem ordningens erklærede formål og de tekniske krav;
  - c) Det skal fremgå, hvilken standard (17020, 17021-1, 17024 eller 17065) ordningen er baseret på. Kravene skal være entydigt beskrevet, såvel tekniske krav til virksomheden som krav til CAB's udførelse af opgaver;
  - d) Kravene må ikke udelukke punkter i standarderne i pkt. c) eller være i modstrid med kravene i standarderne;
  - e) Der skal være dokumentation for udført validering af ordningen;
  - f) Alle kravedokumenter skal være offentligt tilgængelige;
  - g) Ved ændring af ordningen skal der være fastsat dato for ikrafttræden af ny version samt overgangsregler for konvertering fra gammel til ny version af ordningen;
  - h) Kravedokumenter skal foreligge på dansk og/eller engelsk.
- 2) Ordningens krav til CAB:
  - a) Ordningsejer kan stille krav til CAB's udførelse af opgaven fx omkring anvendt tid, audit- eller inspektionsinterval, auditorers/inspektørers kompetencer og om træning af auditorer/inspektører;
  - b) Ordningsejer kan fastsætte krav om, at CABs skal registreres hos ordningsejer;
- 3) Ordningens krav til akkrediteringsorganet:
  - a) Ordningsejer kan normalt ikke udforme krav for akkrediteringsorganets arbejde fx omkring forventninger til hyppighed af markbesøg, kompetencer hos assessorer mm;
  - b) Såfremt der ved EA-godkendte ordninger ønskes sådanne særlige krav, der går ud over kravene i ISO/IEC 17011:2017, skal disse godkendes af EAs generalforsamling, før de kan træde i kraft.

**4.3** For personcertificeringsordninger skal kravene i ISO/IEC 17024:2012, pkt. 8 desuden opfyldes.

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## 5. Ansøgning om godkendelse af ordning

5.1 Ansøgning om godkendelse kan fremsættes af

- a) ordningsejer (virksomhed eller myndighed) eller
- b) et dansk overensstemmelsesorgan (CAB), der søger akkreditering til ordningen.

5.2 Følgende fremsendes til DANAK:

- a) ordningens kravdokumenter,
- b) dokumentation for, at ordningen er sammenholdt med kravene til overensstemmelsesvurdering for en type akkreditering jf. pkt. 4.2, og
- c) dokumentation for, at ordningen er sammenholdt med kravene i afsnit 3 i denne AB.

5.3 Evaluering af ordning med henblik på national godkendelse:

Ved ansøgning, hvor der alene ønskes, at DANAK kan akkreditere til en ordning, udfyldes skema om national ordning (forenklet EA-skema), som findes på [www.danak.dk](http://www.danak.dk) under ”Om akkreditering/ansøgningskemaer”. DANAK kan i forbindelse med evalueringen bede om yderligere oplysninger. Hvis 5.2 b) eller c) ikke er gennemført, vil DANAK kunne udføre disse mod betaling.

5.4 Evaluering af ordning med henblik på EA-godkendelse, så der kan akkrediteres til ordningen i andre lande:

- 1) Anmodningen om evaluering skal fremsættes af ordningsejer, og det skal fremgå, at DANAK anmodes om at agere som Home Accreditation Body (hAB) i forhold til ordningen jf. EA-1/22 dvs. udfører bedømmelse på vegne af alle akkrediteringsorganer;
- 2) Ordning og kravdokumenter skal være udformet i overensstemmelse med EA-1/22.
- 3) Der skal udfyldes et særligt EA-skema, som kan findes på [www.danak.dk](http://www.danak.dk) under ”Om akkreditering/ansøgningskemaer”.
- 4) DANAK orienterer herefter EA om, at ordningen er under evaluering. Procedure for evaluering og godkendelse hos EA fremgår af EA-1/22.
- 5) Efter EA-godkendelse vil ordningen fremgå af EAs liste over godkendte ordninger. Listen er ikke offentligt tilgængelig.

## 6. DANAK's evaluering

6.1 DANAK vil udføre evaluering af ordninger, der ikke tidligere er evalueret og godkendt af DANAK, EA eller IAF. Ændring af en ordning, der ikke tidligere er godkendt, sidestilles i denne forbindelse med en ny ordning.

6.2 DANAK vil foretage en genbedømmelse af tidligere DANAK-godkendte ordninger, når de overordnede krav til CABs eller akkrediteringsorganer er ændrede i forhold til de på godkendelsestidspunktet gældende. Hvis flere CAB benytter samme ordning, kan disse bede ordningsejeren om at aftale evaluering med DANAK eller indgå en aftale med DANAK om en fælles deling af omkostningerne og resultatet.

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**6.3** DANAK vil bedømme eksisterende ordninger, som der er akkrediteret til, og som ikke er evalueret inden for de sidste 4 år. Evalueringen vil blive udført i forbindelse med re-akkreditering af de CABs, der anvender ordningen. Her vil principperne i 6.2 blive fulgt. DANAK fastsætter en overgangsordning, ligesom evalueringsprocessen kan være forenklet. For nationale ordninger accepteret før 21. maj 2015 vil DANAK ifm. re-akkreditering vurdere behovet for evaluering. Evaluering vil desuden blive gennemført ved ændring af ordning eller akkrediteringsgrundlag.

**6.4** Positivt resultat af en evaluering er en forudsætning for, at DANAK kan akkreditere til ordningen. I de tilfælde, hvor det ikke er DANAK, der skal varetage evalueringen (se tabel sidst i dette afsnit), vil DANAK afvente resultatet af evalueringen, før der kan tages beslutning om akkreditering til ordningen.

**6.5** DANAK udfører evalueringen efter de kategorier af ordninger, der fremgår af tabellen nedenfor.

Ved ændring af eksisterende ordninger gælder samme krav til evaluering som for nye ordninger inden for kategorien.

#### Bedømmelse af den enkelte ordning, opdelt efter kategori

Kategori	Krav til evaluering
IAF-godkendt ordning jf. IAFs liste over scopes og subscopes	Ingen*
EA-godkendt ordning jf. EA's liste	Ved opdatering udføres evaluering af hAB**
Ny ordning til EA-godkendelse	EA-1/22, udføres af hAB**
Ældre EA-ordning, der blev taget i brug før 21. maj 2015	EA-1/22, udføres af hAB**
Nye EU-krav (forordning/direktiv)	EA-procedure beskrevet i EA-1/22, varetages af EA-sekretariatet
Ældre EU-krav (forordning/direktiv), som er anvendt til akkreditering	Ingen*
Ny dansk ordning, kun til brug i Danmark (fx bekendtgørelse)	Dansk forenklet EA-skema (se pkt. 5.3)
Dansk ordning, kun til brug i Danmark, første akkreditering før ikrafttræden af denne akkrediteringsmeddelelse.	Dansk forenklet EA-skema (se pkt. 5.3), inden re-akkreditering af CAB. For ordning accepteret før 21. maj 2015 vil behov for evaluering blive vurderet ifm. re-akkreditering. Evaluering skal dog gennemføres ved ændring af ordning eller af akkrediteringsgrundlag.
Ældre dansk bekendtgørelse, der pt. anvendes til akkreditering	For ordning accepteret før 21. maj 2015 vil behov for evaluering blive vurderet ifm. re-akkreditering. Evaluering skal dog gennemføres ved ændring af ordning eller af akkrediteringsgrundlag

\* idet IAF eller EA har taget stilling tidligere

\*\* hAB kan fx være DANAK

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## 7. Referencer

ISO/IEC 17011:2017 pkt. 4.6.3  
EA-1/22

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**Bilag 1:** Retningslinjer for valg af henholdsvis produkt- eller systemcertificering som grundlag for ordningen. Dokumentet er udarbejdet i EA-regi: 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;

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- 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



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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 organization 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<sup>1</sup>:

- *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;*

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<sup>1</sup> Refer to ISO/IAF *Communiqué Expected Outcomes for Accredited Certification to ISO 9001*, [website ISO](#)

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*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:

- 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 evaluate<sup>2</sup> (inspect) these processes. The conformity declaration in such cases confirms that the product was the result of a process that conforms to specified requirements.
- 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.
- 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.

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<sup>2</sup> 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).

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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.

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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<sup>3</sup> 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.

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<sup>3</sup> 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”