

CERTIFICATION COMMITTEE

EA/CC FAQs

QUESTIONS ASKED AND ANSWERS GIVEN
AT THE CERTIFICATION COMMITTEE MEETINGS
FROM SEPTEMBER 2016 ONWARDS

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*The answers presented here represent the consensus view of the EA Certification Committee - they are intended for informational purposes and should not be used as official guidance for the implementation of the requirements of the standards concerned
When reading questions and answers take into consideration whether transition periods are on-going.*

1. Questions relating to ISO/IEC 17021-1 – Management Systems Certification

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Question 32.2 GFSI

GFSI is requiring Scheme owners to comply with their requirements like additional new audit items, but also to ‘audit’ all elements during every audit. This appears in contradiction with the methodology of MS certification as determined for QMS and EMS through IAF MD5 or FSMS through ISO/TS 22003, which applies the audit time reduction for surveillance and recertification audits (of 2/3 and 1/3 of the initial time respectively). Yet AB’s are giving with their accreditation logo’s the impression that auditing all elements is equally effective as covering them during the whole cycle. The most clean example is comparison of ISO22000 versus FSSC22000.

The question is:

- 1) How do we interpret that GFSI based schemes have to ‘audit’ all criteria whereas the methodology of MS certification applies the assessment of all criteria over the certification cycle which therefore allows to give a reduction for surveillance and recertification audits.
- 2) To enable the same amount of confidence to these different types of certification audits, should we require that these schemes apply a different time allocation scheme as well (i.e. above ISO/TS 22003)?

GFSI Guidance Document - Version 6.4 / November 2015 - Part II § 3.5.1 states :

“The scheme owner shall have a clearly defined and documented audit frequency programme, which shall ensure a minimum audit frequency of one audit per year of an organisation’s facility and has the scope to assess all elements of the scheme’s standard.”

General understanding of the clause and the sentence is that the requirements of assessing all elements lies with the audit programme and not with the annual audit (which is in the sentence the first requirement put on the audit programme). There are no contradiction between GFSI requirements and ISO/IEC 17021-1 ISO/TS 22003 and related IAF MD documents.

Question 32.3 Duration

Background:

ISO/IEC 17021-1:2015 does not specify requirements for audit time and audit duration. IAF-MD5 and e.g. ISO/TS22003 describe this in more detail. MD5 describes in §4.1 that audit duration (on-site) should not be less than 80% of the audit time indicating that planning and reporting should typically be <20% of the audit time. ISO/TS22003 is a bit clearer by mentioning that preparation (and reporting) are not included in audit time. In practice it is noted that CAB's consider to allocate time for reporting (else no report would be made), but time for planning and more importantly preparation of the audit team is not included (nor mentioned) and thus depends on the personal time of the team members.

Question:

Could it be considered to suggest an amendment to IAF-MD5 to identify whether preparation time is required, that this be justified and recorded, and potentially indicate a 'minimum'?

Clause 9.1.4 of ISO/IEC 17021-1:2015 specifies the overriding requirements for audit time and requires that 'for each client the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's management system.' This is confirmed by clause 0.6 of IAF MD 5 which states that 'notwithstanding the guidance provided by this document (MD 5) the time allocated for a specific audit should be sufficient to plan and accomplish a complete and effective audit of the client's management system.'

It is, therefore, clear that preparation time to plan an audit is required by both ISO/IEC 17021-1:2015 and IAF MD 5.

There will be evidence from witnessed audits and reports to determine whether or not the certification body has an effective process for planning audits. Providing the certification body has demonstrated an effective process for planning audits and is allocating sufficient on site time to accomplish a complete and effective audit, there is no need for it to separately justify and record planning time.

Question 32.4 2-Stage
Some of the wording of the standard ISO/IEC 17021-1, related to stage I and stage II, having to be considered as one audit, conducted in two stages (9.3.1.1) cause some interpretation problems.

It is stated in a NOTE under 9.3.1.2.1 that “Stage 1 does not require a formal audit plan (see 9.2.3).”

Secondly, 9.2.3.1 states that “The certification body shall ensure that an audit plan is established prior to each audit identified in the audit programme...”.

Related questions are the following:

1. What is required as the audit plan for a stage I? Is a telephone conversation acceptable?
2. Since the stage II audit is not a separate audit, a formal audit plan is not required either?
3. Or does this mean that the stage II audit (or the overall «initial audit») plan has to be prepared prior to stage I (i.e. prior to «the initial audit»), maybe in a more generic way, but with the objective that the stage I provides further focus/adaptation to this plan (ref. 9.3.1.2.2.f)?
4. Do the requirements for 9.2.3 (and more specifically 9.2.3.2) apply to the audit plan for a stage II (even though that is not a separate audit)? Particular attention is requested to the requirement in 9.2.3.2.a (objectives) which are quite different for a stage I (9.3.1.2.2) from a stage II ‘audit’ (9.3.1.3).
5. Can it be required that the CAB prior to the stage I at least will have to inform the client that prior to stage II an audit plan is prepared in line with the requirements of 9.2.3?
6. A note normally does not contain requirements; how then can a note make requirements not applicable (as is the case here)?

The sequence of clauses in ISO/IEC 17021-1 is as follows :

- § 9.1.3.2 and 9.3.3.1 : the initial audit (part of the audit programme) is a two-stage audit
- § 9.2.3.1: ... an audit plan is established prior to each audit identified in the audit programme to provide the basis for agreement regarding the conduct and scheduling of the audit activities.
- § 9.2.3.2 : “The audit plan shall be appropriate to the objectives and the scope of the audit.”
- § 9.2.3.2 and 9.2.3.3: give the elements to be found in each formal audit plan for each audit; It may come that some elements are not applicable/ necessary for stage 1.

Then an audit plan is required before the initial audit (then before stage 1) so that the organisation to be audited is aware of what is to be audited and when (“agreement regarding the conduct and scheduling of the audit activities”). The CB may choose to draft one unique plan for stage 1 and 2, in the form required per § 9.2.3.2 and 9.2.3.3, the plan addressing all elements of 9.3.1.2.2 and 9.3.1.3. If there is only one plan, it has to be reminded to the client that the plan may be adjusted after stage 1, following the conclusions of stage 1.

If the CB chooses to have a plan in 2 parts, one for stage 1, and then, after stage 1, one specific for stage 2, it may accommodate the form of the stage 1 plan, as all points of § 9.2.3.2 and 9.2.3.3 may not apply. What is captured in the NOTE , is not to say that a plan is not required but is only waiving the formal aspects of the plan.

From there answers to questions :

- 1) A plan (whether separate or not) is required but does not have to be formal, focusing on the objectives stated in § 9.3.1.2.2. If the plan is specific to stage 1 (where not the full team is present and not all elements are audited) it may waive some points of § 9.2.3.2 (c-d-e-f) as not yet identified at this stage, and of 9.2.3.3 (b-c). As does not have to be formal maybe an email or a phone call is acceptable. Records on what has been agreed with the client needed to demonstrate implementation of requirements (e.g. 9.2.3.1)
- 2) See above : stage 2 plan is required, whether specific or integrated in the global “initial audit” plan
- 3) An overall plan may be prepared before stage 1 (in other words the audit plan communicated before stage 1 may include the elements of stage 2), with the information known by the CB at this stage , to be reviewed after stage 1 conclusions
- 4) All apply
- 5) Yes, it has to be required in the case that the plan is not drafted in once
- 6) According to ISO, Information marked as “NOTE” is intended to assist the understanding or use of the document. The NOTE intends to waive the “formal aspects” of the plan and not the full requirement

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Question 32.5 2-stage

Some of the wording of the standard ISO/IEC 17021-1, related to stage I and stage II, having to be considered as one audit, conducted in two stages (9.3.1.1) cause some interpretation problems.

In 9.3.1.2.3, it is stated in a NOTE that “The stage 1 output does not need to meet the full requirements of a report (see 9.4.8). “

We do consider that the report of the “initial audit” in its totality (i.e. the full report prepared after conclusion of stage II), does need to comply with the requirements of 9.4.8. This means that it shall also include or refer to the “k) audit findings (see 9.4.5), reference to evidence and conclusions, consistent with the requirements of the type of audit” (i.e. findings, evidence and conclusions consistent with the requirements of stage I and stage II). So although the stage I findings don’t have to be reported immediately after the stage I in a report complying with all requirements of 9.4.8 (since then only “Documented conclusions with regard to fulfilment of the stage 1 objectives and the readiness for stage 2 shall be communicated to the client, including identification of any areas of concern that could be classified as a nonconformity during stage 2.” have to be reported), the stage I findings (positive and negative) should find their way into the overall “initial audit” report after stage II.

Please confirm that the above position, i.e. the report (whether consisting from several documents or not) in its totality shall comply with all requirements of 9.4.8 for both stage I and stage II audits.

In 9.3.1.2.3, it is stated that “Documented conclusions with regard to fulfilment of the stage 1 objectives and the readiness for stage 2 shall be communicated to the client, including identification of any areas of concern that could be classified as a nonconformity during stage 2.”

Actually “Documented conclusions” refers to “Stage I Audit Report” that does not need to meet the full requirements of a report as given in 9.4.8. That means not all items of audit report given in 9.4.8 are covered.

This report or “documented conclusions” shall be communicated before stage II. Since the standard is not saying “immediately communicated”, it can be communicated immediately or later stage I. However, it shall be communicated before stage II.

According to related requirements of the standard, the CB can prepare one “Initial Audit Report” consisting of two separate parts (e.g. Stage I and Stage II) or prepare two separate audit reports; “Stage I report” and “Stage II report”. In the second case, most of requirements of 9.4.8 should be covered including sub-item “k) “audit findings” since there is no need to report the conclusions of Stage I as “nonconformity”, just “identification of any areas of concern that could be classified as a nonconformity during Stage II” is enough.

Since the stage I “documented conclusions” shall be communicated in any format with the client of CB and these have to be based on findings (positive and negative), these (stage I findings) should find their way into the overall “initial audit” report after stage II provided that the conclusions are communicated with the client after or at the end of Stage I, and before Stage II.

<p>Question 32.6 2-stage Some of the wording of the standard ISO/IEC 17021-1, related to stage I and stage II, having to be considered as one audit, conducted in two stages (9.3.1.1) cause some interpretation problems. Clause 9.4.1 states that “The certification body shall have a process for conducting on-site audits. This process shall include an opening meeting at the start of the audit and a closing meeting at the conclusion of the audit.” Does this mean that the initial audit require only an Opening Meeting (meeting the requirements of 9.4.2) at the start of the stage I audit and a Closing Meeting (meeting the requirements of 9.4.7) at the end of the stage II audit (i.e. no Closing Meeting at end of stage I or Opening Meeting at the start of stage II)? These would seem like a silly consequence as these audits have clear and distinct objectives, i.e. both need full Opening and Closing Meetings.</p>	<p>Clause 9.4.2 of ISO/IEC 17021-1:2015 states that the purpose of the opening meeting is to ‘.....provide a short explanation of how the audit activities will be undertaken.’ Since the audit objectives and activities for stage one and stage two are different, the requirement of clause 9.4.2 can only be met if there is an opening meeting for each stage. The requirement of clause 9.4.7 relate to a formal closing meeting which includes the recommendation regarding certification. A formal meeting complying with clause 9.4.7 is, therefore, not required at the end of stage one. However, clause 9.4.3.1 requires the audit team leader to ‘....periodically communicate the progress of the audit and any concerns to the client.’ Clause 9.3.1.2.2 requires that an objective of stage one is to ‘....undertake discussions with the client’s personnel to determine the preparedness for stage two.’ Whilst a formal closing meeting, in accordance with clause 9.4.7 is not required at the end of stage one, there is clearly a need for a meeting with the client, at the conclusion of stage one, in order that the certification body can meet the requirement for communication with the client and the objectives of stage one.</p>
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Question 32.8 logos
 ISO/IEC 17021:2015, 8.3.1 denies any possibility of a labelling of products by an enterprise which is certified (only) with its management system.

In contrast, the PEFC rules allow the use of the logo “on product” for forest owners (see PEFC ST 2001:2008 , 7.2.1 : „The PEFC Logo can be used on-product by a PEFC Logo user with valid PEFC Logo usage licence for group B (forest owners and managers) and group C (forest related industries).“ This is also possible for the group members respectively members of the Regional Working Groups in Germany.

In practice, the mark of conformity is not placed on the wood coming from forests under PEFC management, but there is one possible exemption to be discussed: a sign marking the entrance of the forest under PEFC management as “This wood is different. Certified and managed based on the accepted PEFC standards. Please ask for wood and paper with the PEFC logo”. This statement is connected with the PEFC logo and the certification number.

This can be interpreted as incorrect logo use.

As far as the question is about the use of the phrase “This wood is different. Certified and managed based on the accepted PEFC standards. Please ask for wood and paper with the PEFC logo”, connected with the PEFC logo and the certification number (but no CB marks) as far as the mark of the CB is not used This statement is OK. There are no rules for the use of the Scheme owner marks (PEFC).

The PEFC document was prepared in 2008 and revised in 2010 and “PEFC ST 2001:2008”, date of entry into force is 2010-11-26. As a scheme owner, PEFC marks are different to CBs Marks.

PEFC selected ISO/IEC 17021-1:2015 as accreditation standard for “Sustainable Forest Management System” certification bodies. According to EA-1/22 requirements 3.5 and 3.6, the scheme owner shall not contradict or exclude any of requirements of ISO/IEC 17021-1:2015 as EA MLA Level 3 standard.

EA-1/22:

“3.5 The conformity assessment process described or chosen by the SO shall fall within the scope of one of the EA MLA Level 3 standards (see EA-1/06).

3.6 Scheme specific requirements placed on CABs by the SO shall not contradict, or exclude, any of the requirements included in the standard referred to in 3.5.”

All the above mentioned considers that the PEFC logo is not a third party mark of conformity, cl. 3.1, in ISO 17030 (“Conformity assessment. General requirements for third-party marks of conformity applies”).



Question 33.1 Impartiality

This relates to clause 5.2.7 of ISO 17021-1:

5.2.7 Where a client has received management systems consultancy from a body that has a relationship with a certification body, this is a significant threat to impartiality. A recognized mitigation of this threat is that the certification body shall not certify the management system for a minimum of two years following the end of the consultancy.

Several CBs accredited by a particular NAB use contracted auditors (not 'subcontractors,' but individuals contracted to work for the CB, under the CB's management system). Most of these auditors also provide consultancy. The NAB has, in the past, accepted that CBs could certify the management systems of clients who received consultancy from one of these contractors, as long as it was demonstrated that satisfactory controls were in place – transparency, different auditors, informing the impartiality committee, etc.

Clause 5.2.7 could be understood to mean that this practice can no longer continue.

However, it is proposed that this clause does not apply in the scenarios described above, because

- a) Clause 5.2.7 refers to 'a body,' and the consultancy here is provided by individuals; and
- b) Furthermore, clause 5.2.7 states that "A recognized mitigation of this threat is..." Because the word recognized is used, it means that there may be other ways of mitigating the threat; it is not mandated that the CB shall not certify the management system for two years.

Does the CC agree with the NAB's position?

An individual that has his/her own consultancy company would be considered as a body in terms of ISO/IEC 17021-1 and in this case clause 5.2.7 should be invoked and the "2 year" rule should be invoked, or a similar mitigation.

Question 33.2 OH@SMS EA-3/13M

As defined in EA 3/13 M: 2016 - G 9.2.1.3:

“Once the scope is defined, the OH&SMS shall include activities, products and services within the organization’s control or influence that can impact the organization’s OH&SMS performance.

Temporary sites, for example construction sites, shall be covered by the OH&SMS of the organization that has control of these sites, irrespective of where they are located. The need to visit such sites and the extent of sampling shall be based on an evaluation of the risks of failure of the management system to control the OH&S risks associated with the client’s operations (see clause B.9 of Appendix B)”.

Question:

Considering the same importance and dignity of all the workers of an organization, that can affect the organization’s OH&SMS performance, is it mandatory to include into the scope of the certificate all the sites of the organization?

In other words, can an organization decide to certify only a part of the organization, excluding some sites?

Example: An organization has 1 headquarter and a network of 10 sites.

The organization applies the OH&SMS only in the headquarters and in 5 sites.

Is it acceptable, or the company has to apply for the certification of the OH&SMS of the full organization?

In this case, it could be acceptable that the organization establishes a plan in order to certify all sites.

Clause G 9.2.1.3 of EA-3/13 relates to audit scope not scope of certification. EA-3/13 does not make any reference to whether or not all sites shall be included in the scope of certification. The core requirement is Clause 8.3.4 (g) of ISO/IEC 17021-1 which states that that the certified client ‘does not imply that the certification applies to activities and sites that are outside the scope of certification’. The existence of this requirement accepts that it is possible that not all sites are covered by the scope of certification. EA-3/13 provides no additional guidance to clause 8.3.4 of ISO/IEC 1702-11, therefore, it is acceptable that some sites could be excluded from the scope of certification.

The CB should report on the rationale/justification for not including all sites.

<p>Question 33.3 OH@SMS EA-3/13M As defined in EA 3/13 M: 2016 - G 9.2.1.3: "Once the scope is defined, the OH&SMS shall include activities, products and services within the organization's control or influence that can impact the organization's OH&SMS performance".</p> <p>Question: Considering that all the activities, products and services within the organization's control or influence can impact the organization's OH&SMS performance, is it mandatory to include into the scope of the certificate all the activities, products and services of the organization? In other words, can an organization decide to certify only a part of its activities, excluding some activities, products and services?</p> <p>Example: An organization produce cars and trains. The organization applies the OH&SMS only in the cars production. Is it acceptable, or the company has to apply for the certification of the OH&SMS of the full organization? In this case, it could be acceptable that the organization establishes a plan in order to certify all production activities, products and services.</p>	<p>Clause G 9.2.1.3 of EA-3/13 relates to audit scope not scope of certification. EA-3/13 does not make any reference to whether or not all activities, products and services shall be included in the scope of certification. The core requirement is Clause 8.3.4 (g) of ISO/IEC 17021-1 which states that that the certified client 'does not imply that the certification applies to activities and sites that are outside the scope of certification'. The existence of this requirement accepts that it is possible that not all activities, products and services are covered by the scope of certification. EA-3/13 provides no additional guidance to clause 8.3.4 of ISO/IEC 17021, therefore, it is acceptable that some activities, products and services could be excluded from the scope of certification</p> <p>However the OH&SMS should reflect the core activities of the organisation i.e. a manufacturing company should have the manufacturing activity as part of the OH&SMS, not just for example the office activities.</p> <p>The CB should report on the rationale/justification for not including all activities.</p>
<p>Question 33.6 Operational Control If a certification body does not have any agency, representative or branch office, is the Clause 6.2.2 still applicable to check their own operational controls? I mean, is 6.2.2 independent from Clause 6.2.1 or a subclause linked with it?</p>	<p>Clause 6.2.2 is independent and that it applies to the certification body's own operational controls as well as control of activities delivered by branch offices, partnerships, agents, franchisees, etc.,</p>

<p>Question 33.7 Organisational Control What does the following mean? “The person(s) [excluding members of committees (see 6.1.4)] assigned by the certification body to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with either the certification body or an entity under the organizational control of the certification body.” Who are these persons? Are these persons from the entities where explained in bullets a, b and c in the same clause? Or these persons can be different?</p>	<p>These persons can be from the entities explained in the bullets a,b,c and also persons employed by, or shall be under legally enforceable arrangement with either the certification body or an entity under the organizational control of the certification body. IAF Technical Committee Decision 15/10/02 is relevant to this question. It is acceptable for CB decision taking group to be composed of people who are hired as external personnel; provided the personnel meet the competence requirements outlined in ISO/IEC 17021 and ISO/IEC 17021-1 (e.g. section 7.2.8) and the CB has organizational and operational control outlined ISO/IEC 17021-1, section 6.2 as it relates to the decision making person/s. There are many examples today of this type of situation and ABs have found it acceptable in accordance with ISO/IEC 17021. Note: ISO/IEC 17021 (nor ISO/IEC 17021-1) does not differentiate between permanent and non-permanent staff.</p> <p>This means that the persons do not have to be from the entities listed in bullets a), b) and c), but that they shall be under a legally enforceable arrangement with the certification body or one of the entities listed in bullets a), b) and c) and must be under the certification body’s operational control.</p>
<p>Question 33.8 Operational Control What is the interaction between clause 6.2 and 7.5? Does status of an organisation having a relationship with the CB for performing any part of the certification activities of the CB fall in clauses 6.2.1 and 7.5.1? Under which circumstances such an organization does not fall in the clause 7.5?</p>	<p>Clause 6.2 is concerned with the certification body having operational control over its certification activities performed by its branch offices, joint ventures, agents and franchises etc.</p> <p>Clause 7.5 covers the certification body’s process for outsourcing (subcontracting) of any part of the certification activities to another organisation. Organisations listed in Clause 6.2 which are part of the certification body, for example branch office, joint ventures are not subject to the requirements of Clause 7.5. Organisations listed in Clause 6.2 which are not part of the certification body, for example some particular agents and franchises are subject to the requirements of Clause 7.5.</p>

<p>Question 33.10 Product References Primary Packaging Is it possible to use the statement (ref requirement 8.3 of ISO/IEC 17021-1:2015) on the primary packaging, the one that is in direct contact with the product like the tomato's can, or the milk bottle?</p> <p>The standard clearly stat that is not possible to add the certification mark on the packaging but is not so clear about the statement use.</p> <p><i>“A certification body shall have rules governing the use of any statement on product packaging or in accompanying information that the certified client has a certified management system. Product packaging is considered as that which can be removed without the product disintegrating or being damaged. Accompanying information is considered as separately available or easily detachable. Type labels or identification plates are considered as part of the product.”</i></p>	<p>It was agreed that according to the standard it is not possible to add the certification mark on the primary product packaging.</p> <p>Bottles are packaging material, so the statement can appear on the bottle. The statement must refer to the management system not to the product.</p>
<p>Question 33.11 Quoting of 17021 parts Relating to ISO/IEC17011: 2004 Clause 7.9.4 The accreditation body shall provide an accreditation certificate to the accredited CAB. This accreditation certificate shall identify (on the front page, if possible) the following: g) a statement of conformity and a reference to the standard(s) or other normative document(s), including issue or revision used for assessment of the CAB.</p> <p>The Question With the recent issuance of requirements document ISO/IEC17021-3: 2016 to support accreditation to ISO/IEC17021-1: 2015 EMS, do AB's have to make reference to this normative document on EMS accreditation scoping documentation in the same manner as Level 4 documents such as ISO27006.</p>	<p>This was discussed at the IAF Technical Committee meeting in Frankfurt in April 2017; the question has been raised before in 2014.</p> <p>IAF Decision log states</p> <p>Some ABs reference ISO/IEC 17021 on the certificate with the assumption that it includes the dash standards (e.g. ISO/IEC 17021-2) as it is applicable to the scope of accreditation, and they do not reference all the parts. The ABs feel this is appropriate because the foreword of ISO/IEC 17021 standard states, ISO/IEC 17021 consists of the following parts...</p> <p>Some ABs include all normative documents used in the assessment of the CB (per ISO/IEC 17011), including all individual parts of ISO/IEC 17021 (e.g. ISO/IEC 17021-2) and IAF MDs. One word of warning with including everything (including versions) is that it can become an issue of maintenance; however, it is the ABs decision on the level of detail included.</p> <p>The TC reached consensus that the ABs can decide how to manage the accreditation certificate on their own, recognizing accreditation certificates can vary in level of detail. “</p>

Question 33.14 medical Devices Scoping
 According to ISO 13485 standard it can be used by organizations involved in one or more stages of the life-cycle of a medical device, including design and development... Furthermore it can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies...) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of ISO 13485 or can be required by contract to confirm.
 In case the product cannot be unambiguously defined to be a medical device or any of the related products identified in the ISO 13485 but the manufacturer still wants to certified against ISO 13485 – is this acceptable or not?
 And more generally can ISO 13485 be used for certification purposes in the voluntary field outside the proper scope of the standard?

Supplier or external party shall demonstrate the intention of its “product” (item such a device, part incorporated in a device, raw material etc.) or service in the context of an application or use of a medical device.

- CAB (certification body) has to perform a contract review considering the elements stated in this answer (see below) including the national interpretation of medical devices performed by the national regulatory authorities (apply list of medical devices or family of medical devices). .
- Activity or product shall fall into the definition of (ISO 13485:2016 - 3 Terms and definitions - 3.11 medical device (see also source GHTF/SG1/N071:2012, 5.1 and 5.2 (□ note GHTF/SG1/N071: 2012 5.2 is not mentioned in ISO 13485:2016. Therefore, ISO 13485:2016 is not fully clear in the non-regulated field of IVD.

The supplier or external party seeking certification according to ISO 13485:2016 shall justify all not applicable clauses of ISO 13485:2016. The CAB shall critically audit the reason for not applying the requirements. Certification bodies shall always avoid certifying when it has some indication that a standard is applied in a way to only pretend compliance in the medical device field and in reality, it does not fit the encountered activity. The contract review of the supplier or external party shall always include an investigation of the purpose of the use of the ordered “product” or service.

Conclusion: If no clarity is reached the supplier or external party should better be certified against ISO 9001:2015 only. Therefore, there shall be no certification outside the proper scope of the standard ISO 13485:2016. The only difficulty lies in the evaluation of the boundary of the scope of the standard ISO 13485:2016 as it will contain some arbitrary components and perhaps some national particularities.

<p>Question 33.15 Consultancy 5.2.7 Where a client has received management systems consultancy from a body that has a relationship with a certification body, this is a significant threat to impartiality. A recognized mitigation of this threat is that the certification body shall not certify the management system for a minimum of two years following the end of the consultancy.</p> <p>Many CB's external auditors are owners of one man consultancy enterprises and the contracts with the CB are signed by the enterprise. We have understood the changes in wording of the standard in a way that in such cases the relationship constitutes a significant threat to impartiality as the contractor is the enterprise/body – not an individual and thus 5.2.8 does not apply.</p> <p>In addition we recently faced a case where at the same time the CB made an annual surveillance of ISO 9001:2008 certification by auditor X an external auditor Y of the same CB was giving consultancy to the same company for ISO 9001:2015.</p> <p>What would be your reaction in such cases?</p>	<p>Clause 5.2.8 refers to outsourcing (sub-contracting) and this is different to contracting-in external resources.</p> <p>An individual that has his/her own consultancy company would be considered as a body in terms of ISO/IEC 17021-1 and in this case clause 5.2.8 should be invoked and the CB should not outsource audits to them</p> <p>An individual used as a contracted-in external resource does not come under 5.2.8 however impartiality rules still apply in terms of ensuring previous relationships do not compromise the impartiality of the audit process.</p>
<p>Question 33.16 Annual Indicators IAF MD 15 defines the data an AB shall collect on an annual basis as indicators of CBs activities. The NAB has included the indicators in the request for information we regularly ask the CBs to provide before the assessment. However we have not received relevant information concerning “overdue audits”. According to the NAB’s experiences the CBs have not even defined when an audit is ”overdue” or any consequences of delayed/overdue audits. The NAB has raised a NC of this type of findings in several assessments.</p> <p>To be discussed: Have other NABs similar experiences or findings? What actions have been taken? An NC raised against MD15 documents?</p>	<p>IAF TC Dec log April 2016 (see below) shows some explanation about what is an “overdue audit” helping to the definition of overdue audits.</p> <p>The information is collected is for exploitation of the AB during assessments. There are no requirements at the IAF MD 15 about the need to define consequences of delayed/overdue audits. The indicators could provide an insight into the effectiveness of the Certification Body’s processes. The requirements about due date of audits are at the ISO 17021-1 : first surveillance (only for ISO 17021:2006 and 2011) second surveillance and recertification audit (each calendar year and before the expiry date of the certificate)</p>

CERTIFICATION COMMITTEE

Question 33.19

The CB shall periodically evaluate the performance of each auditor on-site. The frequency of on-site evaluations shall be based on need determined from all monitoring information available

Is there any upper limit of frequency (in years) recommended? (some CB perform yearly monitoring of audit personnel, other CB extend the frequency to many years.)

There is not any specified upper limit for on-site monitoring in ISO/IEC 17021-1:2015, IAF MD-10 and any other relevant normative documents. But, in practice the most of CBs perform at least one on-site monitoring every three years. According to ISO/IEC 17021-1:2015 clause 7.2.9 "There shall be a documented process for monitoring competence and performance of all persons involved, based on the frequency of their usage and the level of risk linked to their activities.". This frequency should be based on assignment frequency and the level of risk.

Another factor, linked to risk, which should be considered is the results of previous monitoring. It is reasonable to expect that auditors where issues have been identified are monitored more frequently than those where no issues have been raised.

In ILAC P15:07/2016 clause 6.1.9b, for inspection body' inspectors there is a limit saying that "at least once during the accreditation re-assessment cycle".

For ABs, ISO/IEC 17011:2004 clause 6.3.2 says that "Each assessor shall be observed on-site regularly, normally every three years."

Question	Consensus Position
<p>Is the performance of energy audits, in accordance with ISO 50002 or BSEN 16247, as well as environmental and/or energy management system certification <u>for the same client</u> considered to be an unacceptable threat to impartiality?</p>	<p>An energy audit may be used to support the “Energy review”, which is a key process and forms the basis for an energy management system according to ISO 50001. An energy audit according to ISO 50002 (or BS EN 16247) is defined as a “systematic analysis of energy use and energy consumption within a defined energy audit scope, in order to identify, quantify and report on the opportunities for improved energy performance”. Performing a full energy audit according to ISO 50002 or BS EN 16247 contains elements of management system consultancy, including the following examples:</p> <ul style="list-style-type: none"> • “establish and evaluate the current energy performance”; • “The energy auditor shall identify energy performance improvement opportunities based on analysis and the following: a) their own competency and expertise ... • “When reporting the energy audit results, the energy auditor shall: ... f) provide a prioritized list of energy performance improvement opportunities; ... g) suggest recommendations for the implementation of the opportunities.” • “The energy audit report shall include the following topics: d) opportunities for improving energy performance: 1) recommendations and the suggested implementation programme; 2) assumptions and methods used in calculating energy savings, and the resulting accuracy of calculated energy savings and benefits; 3) assumptions used in calculating costs of implementation, and the resulting accuracy; 4) appropriate economic analysis, including known financial incentives and any non-energy gains; 5) potential interactions with other proposed recommendations; 6) measurement and verification methods recommended for use in post-implementation assessment of the recommended opportunities;”. <p>Therefore, the performance of energy audits, in accordance with ISO 50002 or BSEN 16247, as well as environmental and/or energy management system certification for the same client is considered to be an unacceptable threat to impartiality. It is noted that providing EMS or EnMS certification to entities, related to the client where the Certification Body has provided an energy audit, who could use those energy audit results (i.e. through having a similar energy profile) shall also be considered to be an unacceptable threat to impartiality.</p> <p>When EnMS and EMS Certification Bodies demonstrate through their regular mechanisms awareness and mitigation of the risks to impartiality arising from the consultancy elements as listed above, the performance of energy audits at other clients is not considered to be an unacceptable threat to impartiality.</p>

2. Questions relating to ISO/IEC 17065 – Product Certification

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<p>Question 32,7 Other standards The question concerns certification schemes where inspection is (part of) the evaluation activities. Which independence criteria would apply to inspection bodies or individually hired inspectors?</p> <p>As certification and the inclusive components like inspection are a third party activity, we would assume that the requirements of ISO/IEC 17020: 2012 Clause 4.1.6.a / Clause A.1. apply in full.</p>	<p>It is for the certification scheme (and accordingly for the scheme owner) to specify the independence requirements applicable to the nature of the evaluation activity. So in general, inspection bodies type A, B or C might be specified to be used where inspection is (part) of the evaluation activities. In the other hand it is for the CB to demonstrate that both internal and external resources meet the independence requirements stipulated in the relevant standard.</p> <p>A) Individually hired inspectors (ISO 17065 6.2.1 internal resources)</p> <p>The requirements for personnel including the inspectors are described in the Standard.(ISO/IEC 17020:2012) regardless of the type (A, B or C) of inspection body from which they derive.</p> <p>B) Outsourced Inspection body (ISO 17065 6.2.2 external resources)</p> <p>ISO 17065 6.2.2.2 allows the CB to outsource activities to “non independent” bodies like the testing lab. of the client of the certification body. Certification is a third party activity, but Inspection as a part of the certification scheme may include “different parties” activities : from Type A inspection Bodies (third party inspection) , Type B and/or Type C inspection bodies (first party inspection for its parent organization).</p> <p>Type A inspection bodies may always be used for evaluation activities complying with the rest of requirements of the ISO 17065.</p> <p>The use of type B and C implies that the CB analyzes the potential conflicts of interest and adopts measures to eliminate or reduce it. Type B inspection bodies all should not be involved in the certification of its parent company but may be used for evaluation activities complying with the rest of requirements of the ISO 17065.The use of Type C inspection bodies as part of the evaluation may be used for evaluation activities complying with the rest of requirements of the ISO 17065 but this fact should be communicated in advance to the client of certification.</p> <p>Probably it is going to be easier for a CB to demonstrate independence when using Type A inspection bodies while it will require more work when using Type C inspection bodies.</p>
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Question 33.4 Discrimination

Clause 4.4 of ISO/IEC 17065 reads:

4.4.1 The policies and procedures under which the certification body operates, and the administration of them, shall be non-discriminatory. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this International Standard.

[...]

4.4.3 Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions.

During a recent assessment an assessor raised following NC against 4.4:

Within „certification case XYZ“, the fee was reduced without reason (compared to the fee schedule). The rules and procedures of the CB foresee such reductions but without reasoning.

(The CB is internationally active and subject to assessments of several AB. Furthermore, the reduction of the fee was decided on by a “non CL” office, not the accredited office itself.)

- 1) Does the EA CC support the interpretation that individual, “freeform” discounts of certification fees without reasoning and general applicability are not in line with the requirements of ISO/IEC 17065 and constitute a discrimination especially looking at equal treatment of clients?
- 2) More generally, what is the stance of the EA CC toward discounts and application of fee schedules? Are discounts acceptable? Under which circumstances?
- 3) Does the EA CC support a submission of this query to the ISO/CASCO?

A certification body does not have to charge all clients that are in the same condition the same fee. Offering discounts does not ‘impede or inhibit’ access by applicants, neither does it impose ‘undue financial or other conditions’.

The fees charged by a certification body are a purely commercial decision for the certification body and it is perfectly acceptable for a CB to charge different clients different fees, providing the certification process is applied equally to all clients. Certification bodies operate in a competitive environment. Most clients obtain multiple quotations for certification and cost will be one of the factors taken into account. Certification bodies need the flexibility to vary their fees in order to attract clients. There is no requirement in ISO/IEC 17065 for the CB to justify the reasons for the fees it charges or for applying a discount.

<p>Question 33.5 Group Certification EA 6/04 stresses that groups under an umbrella organization, where only this umbrella organization is certified, may NOT sell their products individually as certified.</p> <p>How is this issue dealt with in face of the fact, that at least GLOBALG.A.P. as a major scheme owner does allow group members to sell their products individually, due to market pressure in the US?</p> <p>What is the opinion of the EA CC in general in relation to group certificates, especially within product/process/service certification and their use by individual members?</p> <p>The reply will be the more important since a solid stance on this will be part of the revised EA 6/04.</p>	<p>In a group, certification is granted based on the sampling performed and based on the assessment that the group has done on all the operators that comprise it. An operator belonging to a certified group cannot receive an individual certificate (sub certificate) as far as it has not been evaluated.</p>
<p>Question 33.12 Notified Body Stating of Product Standards Is it possible for an accredited CB, when acting also as a Notify Body, to issue a certificate of conformity to the producer for a given type of product, without mentioning the product standards or specifications against which conformity has been demonstrated? Note for example the Lifts Directive: The Commission Communication 2016/C 138/03 published the list of harmonized standards to be used for the conformity assessment. So, the list of applicable standards is defined in the law, and anyone can access it. If the conformity certificate is a positive one (approval without exclusions) the absence of identification of the standards becomes administrative and may be omitted as long as the assessment report contains the details of the conformity assessment, including the standards used?</p>	<p>ISO/IEC 17065:2012 says that in 7.1.2 “The requirements against which the products of a client are evaluated shall be those contained in specified standards and other normative documents.” and in 3.10 “scope of certification identification of</p> <ul style="list-style-type: none"> - the product(s), process(es) or service(s) for which the certification is granted, - the applicable certification scheme, and - the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply” <p>If manufacturer choses non-harmonised product conformity standard, in this case they should conduct risk analysis and show its (non-harmonised standard) applicability and validity.</p> <p>On the other hand, in some EU directives, there is no defined harmonised standard for specific products and in this case, it is left to manufacturer’s decision to choose the most reevant product conformity standard or criteria.</p> <p>In both cases, the product conformity certificate should give reference to relevant standard or criteria (normative document). For other cases (when EU Directive mandates to use any harmonized product conformity standard), there is no need to give additional reference in the product conformity certificate</p> <p>NOTE All the technical specifications and standards (harmonized or not) of these products normally is a part of their technical files.</p>

<p>Question 33.17 Response to nonconformities</p> <p>Situation: The certification process in the CB is as follows :</p> <ul style="list-style-type: none"> - The CB auditor performs the audit and writes non conformities in case there are. His/her action stops after that. - The reviewer (technical officer inside the CB) is in charge of the follow up of the audit which includes analysis of the answers from the client to the nonconformities and recommendation on closing or not the nonconformity - The reviewer is in charge of reviewing other results from the evaluation process (e.g. test results) - This reviewer makes a recommendation for the certification - The certification decision is taken by the CB's Director <p>Question: Is the analysis of the answers from the client to the nonconformities (and opinion on closing or not the nonconformity) part of the audit or can it be considered as part of the review?,</p> <ul style="list-style-type: none"> - In other words is the analysis of the answers from the client to the non conformities is an evaluation task and shall be considered as an evaluation activity or is this analysis of client answers part of the evaluation process without being considered as an evaluation task belonging to evaluation activities? <p>Depending on the answer, is it fulfilling (or not) 7.5 requirements that the reviewer performs the analysis of the answers from the client to the non conformities raised in audit?</p>	<p>Clause 7.5.1 of ISO/IEC 17065 states "7.5.1</p> <ul style="list-style-type: none"> - The certification body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process." <p>Therefore in, an independent review is required. The review, acceptance and verification of answers to nonconformities is an evaluation activity and the individual performing these tasks cannot, therefore, perform the review required by clause 7.5.1 of ISO/IEC 17065.</p> <p>If the product certification scheme requires that the certification body performs management system auditing as part of product certification, it shall meet the applicable requirements of ISO/IEC 17021-1. The applicable requirements concerning handling the client's response to non-conformities are specified in Clause 9.5.2 of ISO/IEC17021-1 which states that prior to making a certification decision:</p> <ul style="list-style-type: none"> - that for any major non-conformities, the certification body has reviewed, accepted and verified the correction and corrective actions and - that for any minor nonconformities it has reviewed and accepted the client's plan for correction and corrective action. <p>In this case, the review and acceptance of the client's plan for correction and corrective action, in respect of minor non-conformities, is not part of the evaluation as there is no verification of the correction and corrective action, and the individual performing these tasks can perform the review required by clause 7.5.1 of ISO/IEC 17065</p> <p>.</p>
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Question 33.20 witnessing for CPR

In the area of Product Certification, the NAB performs demo witness assessments in the initial accreditation or scope extension assessments for the CABs that are not designated as NB yet by notifying authority and applied first time in the field of CPR (Reg.No. 305/2011) for a certain scope and makes decision about CAB's competence according to this demo witness assessment.

The question is whether CABs can use the reports and outcomes of this demo witness assessment as a basis for certification decision and issuing real certificate under CPR for relevant producer, after being accredited by NAB and being designated as Notified Body by authorities without performing a new audit to relevant producer?

Does any other NAB faced a similar case in their country and what is the general implementation about this issue in other EA member countries?

Note: The national authority requests the NAB's opinion about this issue and expects the NAB to determine some rules in accreditation procedures for preventing this issue.

When CPR came into force there was two options for the initial accreditation:

One possibility with DEMO witness assessment and the other possibility with conditional accreditation. The first possibility takes place in the initial accreditation for the CABs which are not notified.

If the AB follow all the procedures regarding accreditation then it is not needed new audit to the relevant producer after the Notification.(DEMO witnessing assessment) – however the NB would need to carry out a review to ensure that the processes used in the DEMO witnessed are still valid in terms of the processes under which the CAB achieved Notification.

The second possibility was a practice suggested by the European Union. This means accreditation shall be gained without witness assessment and under the condition that the first witness assessment will take place with the AB. (conditioning accreditation)

3. Questions relating to ISO/IEC 17024 – Certification of Persons

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Question 32.0 restriction

The situation concerns invoicing of an initial certification which can in the same CB follow 2 different routes :

- Registration directly to the CAB: payment of fees for initial and 1st surveillance in one go
- Registration via a training body (with which the CBs has an agreement): payment of fees in 2 steps part before the initial examination, the other part before the 1st surveillance
- The total amount of fees is the same in both cases

One possible interpretation of the case is that these provisions are not acceptable regarding § 4.3.3 and 4.3.4 as they lead to 2 different treatments of the certified person :

- In the first case, the applicant has to pay for the whole process no matter he/she succeeds in the certification or continue to work after the certification
- in the second case, under the same circumstances, the applicant will have paid only a part.

The CBs argues that :

- conformity to § 4.3.3 from the definition of fairness (3.16 fairness : equal opportunity for success provided to each candidate (3.14) in the certification process (3.1)) the CB argues that the difference of invoicing does not affect the opportunity of success
- Conformity to §4.3.4 : the CBs argues that
 - o The price is the same for all applicants
 - o The fact that there are 2 steps of invoicing is due to the fact as part of the initial exam can be included in some training financial support (which exist in some cases for helping working persons to go on professional training)
 - o Each applicant is informed of this possibility and can apply through a training body

Then the question is what interpretation of the 2 above is acceptable regarding (§4.3.3 and § 4.3.4 of the standard).

ISO/IEC 17024 states :

4.3.3 : *Policies and procedures for certification of persons shall be fair among all applicants, candidates and certified persons.*

4.3.4 : *Certification shall not be restricted on the grounds of undue financial or other limiting conditions, such as membership of an association or group. The certification body shall not use procedures to unfairly impede or inhibit access by applicants and candidates.*

There is no apparent breach of clauses 4.3.3 (the opportunities to be certified are the same by either of the two ways) or 4.3.4 (access is not restricted or limited arbitrarily (unfairly) to a candidate to the detriment of another), as long as both options are available to all and the relationship between the CB and the training organisations meets all other requirements of the standard.

Question 33.18 publicly available information
According to ISO 17024 cl 7.2.2, and 7.2.3, the only information that shall be publicly available without request, is that regarding the “scope” of the scheme (cl 8.2. a)) a general description of the certification process and the prerequisites (cl 8.2. e)).

Please give us your opinion (agreement or not with and if not, details for justification) on the following:

- a) the previous paragraph ,
- b) that the standard clearly excludes the required “competencies” of the person (cl 8.2 c) be publicly available without request, and
- c) Upon request, both the “competencies” (cl 8.2 c) and the “job description” (cl 8.2 b) shall be provided (this does not exclude the right of the scheme owner to be paid for that information (please note that this is the case of the Standardization Bodies)

As a preliminary, the standard has 3 different levels of diffusion regarding information :

- The one without request (4.3.1, 7.2.2 ,7.2.3, 9.2.2, 9.8.3, 9.9.2) to any one
- The one upon request i.e. to anyone requesting
- The one for applicants (9.1.1) : this is also upon request (through the application)

a. Not in agreement: we do not interpret the clauses like this: the minimum mandatory publicly available information are 8.2.a and 8.2.e). This doesn't prevent CBs to have other publicly available information if they wish to do.

b. Not in agreement (from answer to a))

c. Partial agreement: as per §9.1.1, the CB shall make available “the requirements for certification and its scope”. The “requirements for certification” of 9.1.1 are considered to be equal to the “c) required competence; » of 8.2.c. It is not nevertheless mandatory to give the 8.2.b, even upon request