

EA/CC FAQs

QUESTIONS ASKED AND ANSWERS GIVEN
AT THE CERTIFICATION COMMITTEE MEETINGS
FROM MARCH 2005 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 17011 – Providing accreditation to certification bodies

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QA 21-1

Applicability of EA-7/05 to ISMS

We would like to know if combined audits with ISMS can be conducted, using EA-7/05. ISMS seems to be very distinctive from QMS and EMS, so the overlapping of requirements is much less.

EA-7/05 can be applied, but the level of integration is expected to be much smaller than for QMS and EMS.

QA 17-1

§6.2 – Witnessing of Impartiality Committee

We consider that it is up to the AB (and not the CB) to decide by which means (assessment on-site, document review, witnessing, etc.) the AB will ascertain that the CB is fulfilling the requirements of ISO/IEC 17021. So an AB can legitimately decide that meetings of the Impartiality Committee need to be witnessed by the AB (e.g. if documental reviews do not provide sufficient assurance). Since some CBs are questioning this option, we'd like to confirm this view, and if any of you has the same requirement.

At 17th CC meeting:

The CC agreed that it is up to the AB to decide whether it wants to witness meetings of the Impartiality Committee.

At 18th CC meeting:

The CC confirmed the IAF TC Chair's opinion.

Chair IAF TC: I agree that an AB could request to witness a meeting of a CB's impartiality committee.

QA 21-2

Witness audit activity in assessment of QMS CBs

Is it necessary to audit all the EAC/IAF codes, subject of the scope of accreditation of QMS certification body, during a cycle of accreditation?

The accredited scope coverage during each accreditation cycle shall be assured through (namely) a combination of witnessing and office file reviews..

<p>QA 21-3 Choice of the enterprises subject to the witness audit in assessment of QMS CBs What are the best rules for the selection of the audited companies?</p>	<p>The main focus for selecting assessment for witnessing should be: the coverage of the CB scope; taking into account the choice of different auditors; and types of audits; and different countries</p> <p>The choice of the enterprises for the conduct of witnessing should be based on criteria such as:</p> <ul style="list-style-type: none"> • extent and complexity of the enterprise's activities (certification scope), • size of the enterprise (number of staff, shifts, etc), • any significant changes to the staff, organizational structure, processes, etc, • first time audited enterprise for initial certification, • previous performance of the certified enterprise in terms of the nature and significance of the non conformities raised, • significance of findings from the review of the CBs clients files, etc.
<p>QA 21-4 Accreditation scope of QMS CBs Shall certification bodies have (or not) certified company for each EAC/IAF code object of its accreditation scope?</p>	<p>It is possible for certification bodies to maintain competence for technical areas where it no longer has clients, however the AB would need to assess how technical competence is being maintained.</p>
<p>QA 21-5 Composition of the assessment team to evaluate QMS CBs Is it necessary to have a technical expert by EAC/IAF code among the assessment team?</p>	<p>The assessment team should include the technical competence needed to assess certification activities performed in certain EA/IAF sectors included in the CBs scope of accreditation. This can be achieved in several ways.</p>

QA 21-6**Use of AB mark**

For one year now we had a sectoral committee for discussion of improvement of ISO 9001 certification for somatic hospitals. The committee had approximately 20 members with representation from several hospitals, local hospital administration, National health inspectorate, one CB, AB and users. The outcome of the discussions have been 2 documents:

- Guidance to ISO 9001 for emergency care unit of somatic hospitals
- Requirements for accreditation body and certification bodies for somatic hospitals.

The last document has used elements from the food sector certification/accreditation; ISO 22003 and EA 3/11 Food Safety Management System – Scope of accreditation. The document is also in line with ISO 13485 for medical equipment.

Most of the document is not controversial. But some part of the document has met opposition among 1 or 2 CB active in the sector but not member of the sectoral committee. It is regarding requirements for the composition of the audit team and also number of mandays. For AB there are requirements for witnessing in each professional department before accredited certification.

We think the document is good and will improve ISO 9001 certification in somatic hospitals and also improve the AB control with the CB.

This was information. The question is: Can we make this document mandatory for all ISO 9001 certification in somatic hospitals? The consequence will also be that ISO 9001 certification of somatic hospitals using only ISO 17021, ISO 19011 and IAF MD 5 will no longer be allowed. 1 CB has said that if so, they will apply for accreditation with another AB.

Some in my AB says Yes. My opinion is No, I want the document to be Guidance only. My argument is that it will be against the IAF No More No Less Policy to make the document mandatory. It will be ok for the health authorities or a single hospital to require that those CB that perform the certification shall follow the requirements in the document, but we cannot prevent hospitals from choosing “normal” ISO 9001 certification.

If the extra requirements are not discriminatory and additional to 9001, this could create a different QMS scheme without preventing from offering the ‘normal’ ISO 9001 certification.

If the extra requirements relate to the interpretation or application of 17021, then the AB cannot offer a 17021 ‘normal’ and a 17021 ‘plus’ accreditation for any type or sector of certification.

However, the AB can discuss with the interested parties and conclude on a particular application of 17021 requirements for a given sector that must be applied to all CBs. The particular interpretation should be made clear to all interested parties.

<p>QA 13-1 17011 § 7.1 - Accreditation of progressive certification schemes</p>	<p>The CC made the following statement: a stage approach is principally possible based on normative documents provided that stages be clearly defined and the certificate clearly show which stage has been reached.</p>
<p>QA 21-16.b Reference to MS certification standards when they have been slightly modified For some management standards, i.e. ISO 14001 (November 2004) and ISO 13485 (July 2003), there were some modifications recorded in documents respectively named AC July 2009 and AC June 2007: should we consider it as an extension of accreditation? Should we precise it on the accreditation schedule?</p>	<p>It was agreed that as such modifications to MS certification standards are neither scheduled, nor mentioned in the scope of certification, they should not be treated as extensions to the scope of accreditation, unless changes are significant.</p> <p>However they will be checked during the next assessment if there are substantial changes.</p>
<p>QA 25-5 Use of the accreditation logo after accreditation on certificates issued by CABs When the AB grants the accreditation, the CAB can place the accreditation logo also on the certificates issued before the accreditation has been granted. This rule is valid for ISO 17021 and ISO 17024. How about ISO 17065 (specifically Type 1A of ISO 17067), ISO 17020, and ISO 14065?</p>	<p>The possibility for this is related to the ABs rules (each AB shall define its own rules and conditions) for the application of § 7.13 or 8.3 of ISO/IEC 17011, and not to any specific conformity assessment standard. Such provisions are not covered by ISO/IEC 17021 or ISO/IEC17024.</p> <p>The same rationale applies to ISO/IEC 17065 or ISO 14065: each AB shall establish its own rules for authorizing (or not) and under which conditions, this type of practice is allowed. As a minimum, the AB rules shall ensure that the accreditation criteria have been fulfilled for the re-issued certificates.</p> <p>This is also to be considered for suspensions. For information, some scheme owners, (e.g. IFS) have some rules on this topic.</p> <p>The certificate may be re-issued under accreditation once it has been verified that all accreditation requirements are fulfilled. The re-issuing date should be after the date accreditation was granted and for the remaining period of validity of the certificate.</p>

**QA 25-6
Cross-Frontier Policy**

1) Considering the new EA 02/13, is it correct to schedule in this way the assessment to be performed in the critical location?

	Country of the AB	Europe	Outside Europe
New accreditation (the CAB is accredited for no scheme)	Visit all the critical locations	Visit all the critical locations	Visit all the critical locations
Extension to a new accreditation or certification scheme (eg: CB accredited for QMS, is applying for EMS or Inspection)	It is not necessary to visit the critical locations. Perform a document review in order to see if the activity is managed homogenously in all the locations.	It is not necessary to visit the critical locations. Perform a document review in order to see if the activity is managed homogenously in all the locations.	It is not necessary to visit the critical locations. Perform a document review in order to see if the activity is managed homogenously in all the locations.
Surveillance	All the critical location has to be visited in the accreditation cycle at least once time, for at least 1 accreditation scheme , unless there is a justification (Eg: less than 50 certificates issued by that location with no complain / problem)	All the critical location has to be visited each year , for at least 1 accreditation scheme. <u>All the accreditation schemes has to be checked in the accreditation cycle.</u> These rules are in place, unless there is a justification (Eg: less than 50 certificates issued by that location with no complain / problem, witness already performed in that country, audit report provided by another AB signatory of EA / IAF MLA) See EA 2/13.	All the critical location has to be visited in the accreditation cycle at least once time, for at least 1 accreditation scheme , unless there is a justification (Eg: less than 50 certificates issued by that location with no complain / problem, witness already performed in that country, audit report provided by another AB signatory of EA / IAF MLA)

2) How about the non-critical location? Is it necessary to perform some kind of visit? If yes, which is the sample criteria?

3) How about the company that are performing some processes on behalf of the accredited CB (outsourcing – e.g.: auditing company, sales company..). Is it necessary to perform some kind of visit? If yes, which is the sample criteria?

One of the focuses of EA 2/13 is on how to proceed and cooperate among European ABs to perform the assessment of foreign multi-site CABs.

To determine which critical sites are to be assessed, IAF GD3 (current) and future IAF MD XX (under comment at the present time) shall be taken into account.

The country or the region where the site is located does not matter, as what is considered is the fact that a certificate is issued under one ABs accreditation (in the example ACCREDIA).

1) Answers to this question is under the responsibility of each AB fulfilling requirements of EA-2/13 (e.g. §5.6), IAF GD3 (§2.3) or, in the future, of IAF MD XX §3.

2) At present time no assessment is required. In the future, according to IAF MD XX this will have to be performed depending on the type of activity. It is to be noted that, the IAF MD XX, at this stage of redaction has cancelled the concept of critical and non critical site, but focuses on assessment of key activities no matter where and how they are operated.

3) This question is not related specifically to Cross Frontier. It is related to the assessment of CBs subcontractors. As far as I know there is no specific requirement for this, the subject has been noted for the 2013 work plan of CC

<p>QA 25-7 How to manage the transition to a new accreditation standard, if the CAB is suspended against the old one</p> <p>1) Is it possible to maintain the accreditation against an old accreditation standard if the CAB is suspended, and to do the transition assessment after the deadline fixed for the transition? E.g.: Certification body, accredited against ISO 17021:2006, suspended on 1st of December 2012, for 6 months. Deadline for transition from ISO 17021:2006 to ISO 17021:2011 is on the 1st of February.</p> <p>2) Is it possible to do the transition assessment in May, or is it necessary to do it before the 1st of February?</p> <p>3) Is it possible to issue a new accreditation certificate during the suspension?</p> <p>4) Is it possible to have in the market an accreditation certificate referring to an superseded accreditation standard.</p> <p>This rule should be applied similarly at the certification standard level (company suspended for ISO 9001 overlapping the transition period).</p>	<p>1) + 2) No, transition has to be made within the deadline. Suspending an accreditation cannot be used to postpone the deadline.</p> <p>If an accreditation is suspended close to the deadline for transition the CAB should be informed that the present standard will be superseded by the deadline for transition and conditions for lifting the suspension should cover this situation. An accreditation certificate that is suspended shall be withdrawn when the transition deadline is reached.</p> <p>It is up to each AB to decide how to handle situations where a CAB does not complete the transition by the deadline. The AB will need to decide how much assessment is necessary in order for a new accreditation certificate to be issued. Where the assessment is within a short period after the deadline, the AB may decide that a full assessment is not necessary.</p> <p>3) Yes, if the conditions for lifting the suspension have been fulfilled and in this case the requirements in the new version of the standard have been assessed with a satisfactory result.</p> <p>4) No, not once the transition deadline has been completed.</p>
<p>QA 25-8 Who is responsible for the certification? The AB or the CB?</p> <p>Is it possible for an AB to ask to a Certification body to suspend or revoke one certificate?</p>	<p>No, but suspension or revocation of one certificate may occur as a corrective action. It is not the AB responsibility to define corrective actions, but revoking or suspending an accredited certificate can be the appropriate solution for a finding raised by the AB.</p> <p>For example:</p> <ul style="list-style-type: none"> • Where it is found that the Certification Body has issued accredited certificates outside their accredited scope. In this case the AB is entitled to define the measures to be taken in order to comply with the use of the accredited logo. • Where there is evidence that the certification is unsound and the certified company's management system has significant failings that put the accreditation into disrepute. A finding should be issued and solved by the CB. <p>This second occurrence may be identified from, for example a witnessed assessment identifying major failings not being identified by the certification body.</p>

QA 25-15

Product – regulatory schemes

What happens if a regulatory scheme is against some requirement of ISO 17065?

Can the AB grant the accreditation? (please, consider that sometimes is the law that is asking for the accreditation for schemes that are, in some requirement, against the relevant accreditation standard. This can happen for Product, but also for other fields).

If the answer is yes, this accreditation is it still under the MLA?

If it is not under the MLA, is it necessary some kind of declaration of the AB (e.g.: in the accreditation certificate? In the list of accredited CAB?...)?

If a requirement of a scheme owner, whether private, public or regulatory, is contrary to ISO/IEC 17011 or contrary to a conformity assessment standard, the scheme shall not be accepted as falling under the EA MLA.

This is stipulated in the current EA 1/22 (formerly EA 2/11) section 4, specifically 4a) and 4.2

If accreditation is granted against part of a harmonized standard, it does not comply with the definition of accreditation in Regulation 765/2008.

Accreditation bodies should never offer partial accreditation against harmonised standards.

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

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QA 10-1

§ 5.2 – Ownership and impartiality

Ms X is a shareholder (more than 50%) of a management consulting company Y and a shareholder (less than 50%) for a company Z partner of a subsidiary B (not accredited) of CB A (accredited by an EA AB). She marketed and sold 2 services, one for consulting and one in view of a certification. I am writing "in view of a certification" because the certificate is delivered by the subsidiary (B) of CB A, the partner company acting as a marketing agency only, not supplying the certification services. It acts as an intermediary actually (but provides for the revenue...).

The question is: can the certificate issued in this context be covered by accreditation? Is not there a conflict of interest between the certification body and the marketing agency?

There is a conflict of interest in the described scenario, although it is a complex situation the conflict can clearly be seen. This scenario would not meet the requirements of ISO 17021.

QA 13-2

§ 5.1 - Different legal entities certified with a single certificate

Certificates are issued to an organization, as such where a single certificate is issued it must be demonstrated that the individual entities involved are directly related.

Generally certificates should be issued to individual legal entities and single certificates issued to a group of legal entities should be avoided.

QA 14-1

§9.2.3.1 - Preliminary audits and Stage 1 audits

Is it possible to consider that the **preliminary audit** be the initial audit step 1?

The preliminary audit is intended for a different purpose than the Stage 1 audit in that the preliminary audit is to assess the general readiness of an organization for assessment whereas the stage 1 audit is defined in terms of specific objectives.

However it is acceptable for the preliminary audit to also be the Stage 1 audit as long as it is identified as such and meets all of the requirements of ISO 17021: 2011 clause 9.2.3.1

<p>QA 14-2 § 7.4 - Updated information on auditors' consultancies of the standard requires that: "The certification body shall maintain up-to-date personnel records, including... and any relevant consultancy services that may have been provided..." many CB's have told me that this requirement is very difficult to comply with, as many auditors are subcontracted (or hired in) and this information about all consultancy provided is not known on a permanent basis, having this information on a permanent basis is impossible to realize.</p>	<p>The requirement provides that auditors shall declare conflicts of interest and corresponding records shall be kept. In practice declarations shall be made and records updated on a case-by-case basis each time the auditor is used, for the appropriate period. Records make it possible for the CB to demonstrate whether an external auditor has performed consultancy services in his/her other job</p>
<p>QA 14-3 §5.2 - third-party audits without certification The organization X asked a certification body to provide independent assessment of its QMS conformity according to ISO 9001 standard. The expected result of the assessment was a written report of nonconformities. (Certification was not required).</p> <p>Question a: Is it allowed (or clearly forbidden) to accredited certification bodies to provide third party audit (on request of any organization) in the accredited scope?</p> <p>Question b: If such audit (as described above) is provided, and later on Organization X decides to apply for certification, is there any restriction for accredited certification body to provide such a service</p>	<p>Answer a: It is forbidden to provide internal audit services to certified clients. Internal audit services can be provided to other organizations provided they are carried out outside the accredited activity on a third party basis. It is not a certification. The report should be clear as to its purpose and must not bear the accreditation mark.</p> <p>Answer b: It may be acceptable for the Certification Body to accept this situation but it would need to demonstrate that any internal audit activity previously offered will not compromise the impartiality and integrity of the certification process, in particular, internal audit previously undertaken by the certification body cannot be taken into account when assessing for certification purposes.</p>

QA 14-4

§8.2 - Certificate with(out) exclusions

What is the approach of EA CC members to the information stated in a certificate of QMS according to ISO 9001. This question concerns the information which should be in such a certificate when organization has excluded § 7.3 of ISO 9001. In the case when the organization does not carry out any design and development, shall the certificate express this fact?

E.g. a certificate shall include the statement

The company
has implemented and maintains
Quality Management System
applicable to a house construction

- 1) which was found to be in compliance with ISO 9001:2000 - excluding article 7.3. or
- 2) which was found to be in compliance with ISO 9001:2000 (the company does not perform a design and development) or
- 3) which was found to be in compliance with ISO 9001:2000 or
- 4) other statements.

We would like to know the usual way of giving information on the excluding of article 7.3 from QMS to the customers in other European countries and to harmonize our approach.

Answer:

It is recommended that the certificate should not have a negative statement. The statement on the scope has to be clear. Details shall be given in the quality document and the certificate shall not contain any misleading statement.

Clarification (Action Chair)

There is an IAF document IAF-PL-01-012:2001 Guidance on the Application of ISO 9001:2000 which requests a positive statement in the scope when the company is responsible for the design and development process.

It states under Guidance 3:

Certificates issued to ISO 9001:2000 shall state clearly in words the scope of the quality management system (QMS) in a way that will not mislead customers, and shall ensure that information is available for the user to determine which categories of product and product realization processes are included within the scope of certification/registration. In particular, scope statements shall be explicit in stating the responsibility for product design and development and other principal realization processes such as manufacturing, sales, and service.

.....

b) If the organization has responsibility for and realises or outsources the design and development process, the scope statement for certification/registration shall include the words 'Design of', 'Development of ...', or 'Design and development of'.

QA 15-1

§ 9.2.3.1.3.

When certification body conducts stage 1 audit at company's premises, if there is no non-conformity or concern area, is it possible that the stage 2 audit can be conducted the following day?

The CC confirmed that the standard does not forbid that the stage 2 audit starts immediately after stage 1 provided that there are no issues of concern in the organisation found during stage 1 and provided that the CB has set up the adequate rules on how to make the decision because it is the responsibility of the CB and not of the individual auditors to eventually decide on performing the stage 2 audit.

QA 15-1

§ 7.3 - Use of auditors from consultancy companies

In the last IAF TC it was decided (clause 7.7 in the minutes) that:

If the "body" contracted by the CB does not provide any management systems consultancy this would be ok. If the "body" contracted by the CB does provide management systems consultancy, it would not be ok.

.... The IAF TC had discussed this issue at its meeting in Vancouver in February 2004 (item 9.5 of the meeting summary). What ended up in § 5.8.5 of ISO/IEC 17021:2006 derived from this IAF TC decision.

In the case of a single person being the consultancy, if a CB and AB can confirm this is a single person, then it is reasonable to consider it ok to contract this person as an auditor according to ISO/IEC 17021:2006, §7.3. Means that consultants individuals can be used by CBs as auditors provided they did not provide consultancy services. However, in the case of body with several persons, it is not ok if this "body" also provides management systems consultancy. If a company of consultants, the CB cannot use one of the consultant from that company.

As I read it seems to mean that a CB cannot hire people from a consultancy company but can hire individuals being consultants. It seems to me quite a strange decision. In this respect our interpretation of § 5.2.8 is that a CB **do not outsource audits** if the contracted organization **restricts itself to provide to the CB personnel** for the performance of the activities that, according to ISO/IEC 17021, must be performed by audit teams (§ 9.2.3 to 9.2.5.1) or training activities (limited to lectures with no responsibility in the CB qualification process). In these cases we understand that 7.3 applies. Any other activity related to the certification process performed by the contracted organization or its personnel will be considered as outsourcing and therefore shall never be performed by an consultant (company or individual).

I would like to discuss this interpretation in the EACC and be sure of the interpretation because if the interpretation of IAF decision is that is a CB cannot hire people from a consultancy company it means a major change in the operation of many CBs in some countries.

Recognising that the decision of the IAF TC is unclear, the CC agreed that EA should request clarification from IAF.

Furthermore, the EA/CC confirmed that having a contract with a consultancy company to provide a defined auditor, provided there is no conflict of interest with the person or the employer, is using external auditors and not sub-contracting.

The issue was raised at the IAF TC in Bonn in March 2008. The TC confirmed that a contract has to be made with the individual and not with the company. Single person companies are acceptable. It is not acceptable that the payment is made to the company; it has always to be made with the individual.

QA 15-3

§ 9.6.2 - Withdrawal of certificates

A certified QMS client has a valid certificate which will end within a few months because it is the end of the three year cycle; the certification body intends to suspend that certificate (before its term) because the certified client declared that it intends to transfer the certification to another CB at the end of the 3 year cycle, and as such it does not see as adequate to make arrangements for the recertification audit with the current CB.

The current CB argues that this cancellation of the certificate before its term is in accordance with ISO/IEC 17021, §9.6.2. The client declares that it has still a contractual relationship with the CB, and is obliged to answer the CB enquiries regarding other issues, namely payment of fees, handling of complaints, etc.; the contract is still valid, they just don't want to renew it, so they don't accept the immediate cancellation of the certificate.

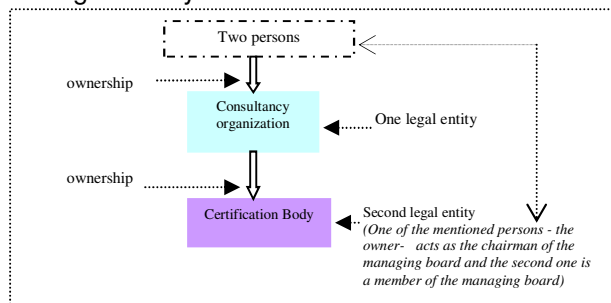
Validity of a certificate terminates at the expiry date unless re-certification is provided in due time. The fact that an organisation wants to move to another CB is in itself not enough justification for suspending a certificate. The fact that because of the change to another CB there is no re-certification visit organised, is also not in itself enough justification for a suspension to be decided before the expiry date. In addition, after the expiry date, a certificate is expired and cannot be suspended. Any audit by the new CB shall be an initial audit.

QA 15-4

§ 5.2 - Independence from consultancy companies

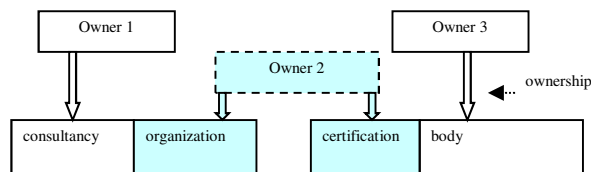
Case No 1

A **consultancy organization** (Ltd) is owned by two persons. This organization offers and provides management system consultancy. The consultancy organization is the exclusive owner of a certification body (joint-stock company) providing management systems certification.



Case No 2

A **consultancy organization** is owned by two persons. This organization offers and provides management system consultancy. One of these persons is also a 40 % owner of the certification body providing management systems certification.



In both cases, the employees of the respective consultancy organization are also hired (as individuals) by the mentioned CB to perform audits of management systems.

Does the particular situation (No 1 or No 2) constitute an unacceptable threat to impartiality of the certification body? Is it possible to manage conflict of interest in these cases or are the particular cases an example of a situation when a threat to impartiality cannot be eliminated or minimized?

There is nothing in ISO 17021 to specifically exclude the 2 organisational scenarios. However, the certification body cannot provide certification to organisations who have received consultancy from the related organisation and the AB would have to look very closely at how the risks to impartiality caused by the close relationship between the CB and consultancy are managed. The consultancy in both scenarios is a separate organisation and 5.2.8 of ISO 17021 clearly states that a CB shall not outsource audits to a management consultancy organisation so the CB cannot outsource audits to this consultancy organisation. This has been confirmed by IAF decisions 07/01/09 (Sydney) and 08/12/07 (Stockholm).

QA 15-5

§ 9.2.3.1.1 - Stage 1 audits off-site

The stage 1 audit shall be performed [...]

For most management systems, it is recommended that at least part of the stage 1 audit be carried out at the client's premises in order to achieve the objectives stated above.

We experience that many of the CB's interpret this last sentence as a real recommendation: something nice to know but not a real requirement of the standard. This means that these CB's never visits clients' premises for the stage 1 audit.

The CC recognised that on principle the standard allows the approach but it is the CB's responsibility to demonstrate that it has evaluated all the tasks mentioned under 9.2.3.1.1.
The CC is also of the opinion that it will be difficult to have a sound evaluation at least of objectives "b" and "f" without going on site.

QA 15-6**§ 9.1.15 - :Clearance of NCs**

The certification body shall confirm, prior to making a decision, that

a) the information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification;

b) it has reviewed, accepted and verified the effectiveness of correction and corrective actions, for all nonconformities that represent

1) failure to fulfil one or more requirements of the management system standard, or

2) a situation that raises significant doubt about the ability of the client's management system to achieve its intended outputs;

c) **it has reviewed and accepted the client's planned correction and corrective action for any other nonconformities.**

IAF GD2:2005 says:

G.3.5.3. Certification/registration shall not be granted until all nonconformities as defined in guidance G.1.3.1. have been corrected and the corrective action verified by the certification/registration body (by site visit or other appropriate forms of verification).

I know ABs have to use only annexes of IAF guidance during the transition period. Then I understand that there is no need to be granted any other nonconformities (for example: Minor Nonconformities) have been corrected and corrective action verified by CB for decision of certification according to ISO 17021 item 9.1.15.

According to the old guidance, all NCs had to be closed. With the new guidance, the requirement is that corrective actions have to be planned.

Before the CB can make a decision,

- for major NCs under b), effectiveness of corrective actions has to be checked.
- for minor NCs, verification can be left out and the CB must have reviewed and accepted the plan proposed by the customer applicant to certification.

<p>QA 16-1 § 5.3 – Assessment of liability and financing To what extent should a CBs assessment reach regarding ISO/IEC 17021 §§ 5.3.1 and 5.3.2 (liability and financing):</p> <p><i>Clause 5.3.1 The certification body shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.</i></p> <p><i>Clause 5.3.2 The certification body shall evaluate its finances and sources of income and demonstrate to the committee specified in 6.2 that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.</i></p>	<p>It is the task and responsibility of the CB to evaluate its risks and request professional support for evaluating the necessary steps to be taken to cover the risk (guarantee, amount of insurance).</p> <p>It is the Impartiality Committee role to investigate whether there is a financial threat and the AB's responsibility to ensure that the appropriate information is given to the IC and ensure that the IC has investigated it in an appropriate way.</p>
<p>QA 17-2 § 8.2 - Certification of third party inspection I have a query about the Joint Resolution issued by ILAC and IAF in Sydney. As you know this concerns the certification to accreditation standards. My query is this:</p> <p>Can a Certification Body issue an ISO 9001 Certificate where the scope of certification/registration is "Third Party Inspection Services"? There is no reference to ISO/IEC 17020 on the certificate.</p>	<p>CABs, except MS CBs, may be certified for their MS against ISO 9001 provided that the statement of the scope is not misleading, i.e. the scope makes reference neither to CB assessment standards nor to any 3rd party status.</p>

<p>QA 17-3 § 10 - Inconsistency between head and local offices' procedures I present to you one among the problems which we will encounter with the certification bodies in order to deliver your opinion.</p> <p>Indeed, the documentary system of a body has two levels: - a general level relating to the group "Holding" and - a local level for each entity constituent this group.</p> <p>The problem which arises is the inconsistency of the two levels with regard to the sectoral qualification criteria (for the 39 fields defined by IAF) of the QMS assessors: in the local procedure is less required than by the global procedure. They say in the branch that the experience in audits is sufficient to have the qualification in a given sector. In the entity they say that the global procedures were regarded as guidelines whereas it is mentioned clearly that they are applicable for all the entities.</p>	<p><u>At 17th CC meeting:</u> The CC agreed that: 1) the document control system in CBs has to assure there is a clear hierarchy of documents defining clearly which documents are applicable at what level; 2) the system has to ensure that there is no inconsistency or contradiction; 3) all documentation has to support the implementation of requirements of applicable standard, i.e. ISO/IEC 17021 in this case. Even if they are based on a hierarchy, all documents have to comply with ISO/IEC 17021.</p> <p><u>At 18th CC meeting:</u> The CC position can be summed up as follows: 1. An accredited legal entity has to fulfil the requirements of the relevant standard. It has to run an adequate management system which may be embedded in a larger one. Nevertheless the CB will have to demonstrate its compliance and the AB to verify it.</p>
<p>QA 17-4 §6.2 – Witnessing of Impartiality Committee We consider that it is up to the AB (and not the CB) to decide by which mean (assessment on-site, document review, witnessing, etc.) the AB will ascertain that the CB is fulfilling the requirements of ISO/IEC 17021. So an AB can legitimately decide that meetings of the Impartiality Committee need to be witnessed by the AB (e.g. if documental reviews do not provide sufficient assurance). Since some CBs are questioning this option, we'd like to confirm this view, and if any of you has the same requirement.</p> <p>Chair IAF TC: I agree that an AB could request to witness a meeting of a CB's impartiality committee.</p>	<p><u>At 17th CC meeting:</u> The CC agreed that it is up to the AB to decide whether it wants to witness meetings of the Impartiality Committee.</p> <p><u>At 18th CC meeting:</u> The CC confirmed the IAF TC Chair's opinion.</p>

<p>QA 17-5 §6.2.3 – Composition of Impartiality Committee A - This clause may leave the door open for a CB to invite interested parties, and if they say 'no', the CB will say that it fulfils the requirement. Our interpretation is that although not all interested parties may be represented, a minimum representation is needed, and at least some parties need always to be present. The requirement is not only to identify and invite, but to have a minimum number of interested parties represented. Otherwise we may end up with an Impartiality Committee composed by the CB and its clients, and we don't think that this would be appropriate.</p> <p>We also don't think appropriate that the CB can vote on the Impartiality Committee on any analysis of its own impartiality - this would be a threat to impartiality by self-interest - he can only present and explain.</p>	<p>As a minimum the committee should comprise representation from all relevant stakeholder groups e.g. certified clients, their customers, regulators, consumers, professional bodies. It should also cover representation to cover all of the management systems e.g. quality, environment, health and safety, etc. for which the CB offers certification. The CB should not be a member of the impartiality committee or vote at its meetings but it is acceptable and necessary for the CB staff to attend meetings.</p>
<p>QA 17-6 § 9.3.3 2nd sentence - Review of Corrective Actions by the audit team in surveillance audits The standard reads <i>"It may maintain a client's certification based on a positive conclusion by the audit team leader without further independent review..."</i>.</p> <p>This requires (always) a review of the client's corrective action plan by the audit team, and a review performed by the CB staff cannot be used as an alternative to this audit team review - because it mentions "further independent review", it implies that a review has been performed by the audit team.</p> <p>However, if NCs or other situations that may lead to the suspension or withdrawal of certification are declared, further independent review (by the internal or external CB staff) shall be performed.</p>	<p><u>At 17th CC meeting:</u> Statement is correct. It is allowed for the CB to review the NCs in addition because at the latest they have to be reviewed for the re-certification.</p> <p><u>At 18th CC meeting:</u> The CC agreed that corrective actions have to be reviewed by the audit team. An independent review by the CB staff can only be an additional review.</p>

<p>QA 17-7 § 9.4.2.2 - Recertification with (minor) NCs and corrective actions plan <i>"When, during a recertification audit, NCs or lack of evidence of conformity are identified, the CB shall define time limits for the correction and corrective actions to be implemented prior to the expiration of certification."</i></p> <p>This requires that CBs shall redefine (individually if needed) time limits for the correction and corrective actions of ALL NCs to be implemented by the client prior to the expiry of the certificate. If a client proposes a correction or a corrective action that is to be implemented after the expiry of the certificate, the CB cannot reissue the certificate, and take a positive decision before this has been implemented.</p> <p>Chair IAF TC: clause 9.1.15 applies for the initial certification decision and the recertification decision. This means that those NCs meeting 9.1.15b (a major NC) must be reviewed, accepted implemented and verified before certification or recertification can be granted. However, for NCs meeting 9.1.15c (a minor NC) the corrective action plan must be accepted before certification or recertification can be granted.</p>	<p><u>At 17th CC meeting:</u> Finally the IAF TC Chair's statement was agreed upon by the CC: <i>Clause 9.1.15 applies for the initial certification decision and the recertification decision. This means that those NCs meeting 9.1.15b (a major NC) must be reviewed, accepted implemented and verified before certification or recertification can be granted. However, for NCs meeting 9.1.15c (a minor NC) the corrective action plan must be accepted before certification or recertification can be granted.</i></p> <p><u>At 18th CC meeting:</u> Again the CC confirmed the IAF TC Chair's view.</p>
<p>QA 17-8 § 9.1.15 and § 9.2.5 - Certification decision Can a CB take a positive decision of certification today, and the client propose to implement correction and corrective actions (for NCs that are not 'major' as defined in 9.1.15.b) several months after the decision? In other words, can a CB take a positive certification decision without 'minor' NCs having actually been corrected, but under correction according to a plan?</p>	<p><u>At 17th CC meeting:</u> Finally the IAF TC Chair's statement was endorsed by the CC, for which "several months" means that the reasonable time should be kept short.</p> <p><u>At 18th CC meeting:</u> The CC agreed that a plan has to be accepted by the CB. But then what is the acceptable timeframe for corrective actions? The answer shall be based on common sense to be used to appraise timeframe.</p>

<p>QA 17-9 § 8.2.3 g - CB client's logo on the accredited certificate In our opinion, placing the logo of the client at the certificate is misleading for the public because it shows that the certified company is also approved (or simply accredited – because of the awareness of the public) by accreditation body.</p>	<p>This is covered by IAF decision 12/10/16 (Rio) which states that as the inclusion of a certified client's logo on a certificate is not prohibited by 17021 it is allowed providing it is not misleading.</p>
<p>QA 17-10 § 8.6.1 c - Price Lists publicly available We understand that this requirement is obligatory for accredited bodies, according to our understanding of the idea of 4.5 <i>Openness</i> and in connection with 8.6.1.c:</p> <ul style="list-style-type: none"> a. <i>Price List shall be publicly accessible;</i> b. <i>The best way to provide publicly accessible information (the only one from technical point of view) is a website (we think that each competent and serious body has possibility to use a website);</i> c. <i>if a body accepts negotiating of prices (not an assessment time), the information in that matter shall be publicly accessible – otherwise it is violation of non-discriminating activity of certification bodies.</i> 	<ul style="list-style-type: none"> a. The CC did not agree with this sub-point a) because it is not a requirement of the standard which requires that prices shall be available on request (ISO/IEC 17021 § 8.6.1.c) and for the clients – and that does not mean “publicly”. b. The CC agreed that Sub-Point b) is not a requirement of the standard ISO/IEC 17021, but it can be recommended. c. The CC agreed this Sub-Point c) is not a requirement of the standard ISO/IEC 17021.

<p>QA 17-11 § 8.1.3 - Granted and suspended information on the website We require from accredited bodies the information about granted, suspended or withdrawn certifications on the website for the public</p> <p>The above mentioned problems are very intensively discussed with certification bodies. The bodies which have foreign origin (for instance CB1; CB2; CB3, and so on) try to convince us that the requirements of other accreditations are much lower.</p> <p>We think it is necessary to agree among MLA signatories a common approach to those selected problems because it threatens harmonization of the European Accreditation System, especially with reference to the Regulation 765/2008.</p>	<p>The CC agreed to endorse IAF TC's statement made in Stockholm as reflected in the TC minutes (Page 11): From the Minutes of IAF TC held in Stockholm: <i>the TC was asked for clarification on application of ISO/IEC 17021, clause 8.1.3, which requires a CB to "make publicly accessible" – rather than "make publicly accessible, or provide on request" as in 8.1 and 8.3 – information on certifications granted, suspended, or withdrawn.</i></p> <p><i>Mr. Dougherty said there is no requirement in ISO/IEC 17021 as to how a CB would make information publicly accessible. One means of doing so could be by removing information from a Web site, for example, in the instance of removing the name of a suspended CB from an online directory. He acknowledged there were drafting anomalies, such that the WG intentionally used "publicly accessible" in all instances but did not intentionally ensure that "or provide on request" followed that phrase in every instance. The greatest debate in the WG was on directories and the WG would love to see directories on CB Web sites; this has been resisted because CBs fear poaching of clients based on publication of certificate expiry dates.</i></p> <p><i>The conclusion is that there is no requirement that any information must be put on a web site.</i></p>
<p>QA 18-1 § 8.2 - Scoping on ISO 9001 certificates CB Clients' scopes using EA codes and commercial brands A - Is it only allowed to put the EA main scope on the certificate or may also all other scopes which are applicable for the customer be put on the certificate?</p> <p>A bis - And about the mention of a commercial brand on certificates?</p> <p>CB certificates using commercial brands B - Accreditation certificate: I have a request to mention a certification brand as part of the certification standard which has to appear on the accreditation certificate (ISO/IEC 17011 § 7.9.5 a) 2). What the CB would like us to write is: "Certification of QMS under CB and custom brands" Do you think this is acceptable? From my point of view it is not, as it is not ABs function to communicate about CBs commercial brands.</p>	<p>A - The Chair summed up the point as follows: 1. It is not acceptable that only EA scopes are mentioned on ISO 9001 certificates. 2. If the certified body is also certified for activities being outside the accredited scope, there should be two different certificates, or a single one clearly identifying the activities that are not covered.</p> <p>A bis – It is acceptable for commercial brands to be expressed in the scope of a certificate as long as the certification body can demonstrate that the commercial brand is included in the assessed scope.</p> <p>B - The CC agreed that the accreditation certificates should mention the accreditation standard and no other potentially misleading information. Accreditation certificates should not contain commercial brands.</p>

QA 19-1 & QA 20-1

§ 5.1.2 Contract between client and CB

The case: one CB with branch offices, grants certifications (in the specific case it is for EN 9100, aerospace) to suppliers based in foreign countries. For these files, the enforceable agreement for certification is signed between the supplier and the CB branch office which is based in the foreign country or in the geographic area of that country (as defined by the CB).

The question: does this situation comply with 5.1.2 of ISO/IEC 17021?

5.1.2 of ISO/IEC 17021: *"The certification body shall have a legally enforceable agreement for the provision of certification activities to its client. In addition, where there are multiple offices of a certification body or multiple sites of a client, the certification body shall ensure there is a legally enforceable agreement between the certification body granting certification and issuing a certificate, and all the sites covered by the scope of the certification."*

§ 5.1.2 Responsibilities and authorities of accredited CB unit and local CB unit

In ISO 17021 it has been defined that the customer agreement shall be made by the accredited unit. By making this strictly in this way there will be confusion amount customers ("why I should make an agreement with another company compared to one I have negotiated the agreement"). And at same time I have asked situation in other countries using foreign accreditations => there has not been this requirement.

The Committee agreed that a legal contract should exist between the legal entity issuing the accredited certificate and the certified client

The CC confirmed that neither the contracting nor the certificate issuing can be subcontracted. Both have to be concluded with the accredited legal entity.

QA 20-2

§ 6.2.2 a) - Composition of the Impartiality Committee

Requires that the CB must include

“representation of a balance of interests such that no single interest predominates (internal or external personnel of the CB are considered to be a single interest, and shall not predominate)”.

One interpretation is that each member of the committee must be formally nominated by his/her organisation, as being an official representative of that organisation. The CAB has to demonstrate that each member of the committee is representing an interest, and not him/herself. The only way for the member to do that is to be appointed by an organisation.

The other interpretation is that we are looking at a balance of *interests* on the committee, not specifically *representatives of organizations*. And therefore it is not appropriate to demand that each member on the committee is formally representing an organisation (for example, a microbiologist from a hospital would not necessarily represent the hospital, but would represent the interests/competencies in the field of microbiology).

As these views are quite different from each other, we would appreciate the opinion of the CC on which approach to take.

The CC agreed that the normal expectation is that the CB identifies all interested parties for the Impartiality Committee and that the representative organisations nominate a suitable individual to take part. If no representative can be found for a specific interested party the CB should at least demonstrate that it has tried to find a representative. Representation of individual members should be clear.

QA 21-8

§ 8.4.1 - Use of 9001 logo on products or packages

ISO/IEC 17021 requests in clause 8.4.1 that a certification mark is not allowed to be applied on a product or product packaging as long as the consumer could interpret it as product conformity.

ISO/IEC 17021:2006, clause 8.4.1:

A certification body shall have a policy governing any mark that it authorizes certified clients to use.

This shall assure, among other things, traceability back to the certification body. There shall be no ambiguity, in the mark or accompanying text, as to what has been certified and which certification body has granted the certification.

This mark shall not be used on a product or product packaging seen by the consumer or in any other way that may be interpreted as denoting product conformity.

One of our big certification bodies is asking, if the application of its certification marks on an old clothes bag (1), a paper bag for fried chicken (2) or a tooth brush packaging (3) can be accepted regarding the fact that the mark is clearly mentioning "certified management system - ISO 9001"?

In our view, the requested use of the mark is acceptable for the old clothes sack (1), because nor the sack itself nor the possible content (= old clothes) may be a risk for the consumer, if by mistake he interprets it as product conformity. For the tooth brush and the paper bag for fried chicken the use of the mark is not acceptable.

We would like to know, how other ABs handle this clause of ISO/IEC 17021 and the meaning of the EA CC on this subject.

The conclusion from the EA/CC is that the standard does not allow the use of the mark in the three cases presented.

QA 21-9

§ 8.2.3 - Identification of scope of certification in accredited certificate

ISO/IEC 17021 requests in clause 8.2.3 that a certificate shall identify amongst other things the name and geographic location of the certified client and the scope of certification with respect to product, process etc., as applicable at each site.

ISO/IEC 17021:2006, clause 8.2.3:

The certification document(s) shall identify the following:
a) the name and geographic location of each client whose management system is certified (or the geographic location of the headquarters and any sites within the scope of a multi-site certification);
f) the scope of certification with respect to product (including service), process, etc., as applicable at each site;

One of our big certification bodies is mentioning on its certificates as scope of certification "Whole Organization". If a client is a multi-site organization, operating from several sites, all sites covered by the certification are listed in an additional document as integrated part of the certificate, according to paragraphs a) and f) of clause 8.2.3.

In its "Certification Contract", the CB requests from his clients to identify to him any new site and that these sites are not allowed to mention certification before they have been audited.

We would like to know, how other ABs handle this clause of ISO/IEC 17021 and the meaning of the EA CC on this subject.

If the activities covered by the certification scope are clearly described, and the certificate refers to the document where the sites are listed, it would be acceptable.

<p>QA 21-10 § 9.1.1 and 9.4.1.1 - Recertification and surveillance Some Certification Bodies use a model for surveillance, where organisations are visited every 6 months. When this model is used, the recertification visit alone is performed as a normal surveillance audit and a document review of the Quality System, but not all clauses in the relevant standard, i.e. ISO 9001, are covered by the audit.</p> <p>The recertification visit/audit and the last surveillance audit then together cover all of the requirements in the management standard. With regard to MD 5 will the time needed for the last 2 surveillance audits together be 2/3 of the time needed for the certification audit.</p> <p>Is this acceptable according to ISO 17021 to perform surveillance audits every 6 month and to let the recertification audit consist of the recertification visit/audit and the last surveillance audit? See e.g. ISO 17021 section 9.1.1 and 9.4.1.1.</p>	<p>Yes, if with the set of the two visits (recertification + last surveillance) it can be demonstrated that all the requirements of the relevant normative document have been evaluated (§ 9.4.1.1) and if all along the cycle, the sum of durations of audits complies with IAF MD5.</p>
<p>QA 21-11 §9.1 - Remote audits It is not clear when this kind of audit might be performed. IAF MD5 states that it is authorized to perform 30% of phase 1+2 as remote, but ISO/IEC 17021 prohibits such an audit for phase 2 (9.2.3.2) and for surveillance (9.3.2.1).</p> <p>It looks like the 2 statements are contradictory.</p>	<p>ISO/IEC 17021 does not prohibit a remote audit. The phase 2 and surveillance visits must have physical on-site audit activities. Some audit activities can take place remotely using CAAT, as approved by the AB. The remote activities duration must comply with IAF MD5 and IAF MD4.</p>

QA 21-12

§ 5.2.5 - MS conflict of interest

In Europe, the following directive applies - *European Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work* (with the relevant corrigendum).

The aim of this Directive is to ensure a higher degree of protection of workers at work through the implementation of preventive measures to guard against accidents at work and occupational diseases, and through the information, consultation, balanced participation and training of workers and their representatives. The Directive has been included into the national regulation of each Member States by 31 December 1992, with little amendments.

On the basis of this regulation OHSAS 18001 has been developed and published.

So, according Art. 7 of European Council Directive 89/391/EEC, "*the employer shall designate one or more workers to carry out activities related to the protection and prevention of occupational risks for the undertaking and/or establishment....If such protective and preventive measures cannot be organized for lack of competent personnel in the undertaking and/or establishment, the employer shall enlist competent external services or persons*".

The point is if these external services can be provided by accredited Certification Bodies.

In our opinion this is not acceptable, because it is against ISO 17021 clause 5.2.5 "*The certification body and any part of the same legal entity shall not offer or provide management system consultancy.*"

The CAB cannot provide consultancy service to its certified clients, and to whichever organizations not yet certified.

It is agreed that the scenario described is not acceptable.

QA 21-13

8.1.3 and 8.3 – Publicity accessible

We and the CAB's have a difference of opinion about the meaning of the meaning of ISO 17021 – 8.1.3 and 8.3

8.1.3 read:

...shall make publicly accessible information about certifications granted, suspended or withdrawn

8.3 read:

...shall ..make publicly accessible, or provide on request ..a directory of valid certifications

The discussion focuses on the requirement for putting suspended and withdrawn certificates on the internet (website of the CAB). The CAB's are very unwilling to do so. They do not like to publish actively negative news on their clients with the risks of claims from that client.

Are other AB's confronted with this issue?

Is there a shared interpretation on this issue?

For instance by answering the following questions:

- Requires "make publicly available" an action from the CAB. Does this mean that the CAB has to publicise this information in a magazine or on its website?

- Is the addition in 8.3 "or provide on request" limited for the directory of certified clients only or can the standard be interpreted as that the 8.3 addition "or provide on request" also is valid for the publication of certifications granted, suspended or withdrawn as mentioned in 8.1?

- Means "make publicly available" always that it can be on request and is the 8.3 addition "or provide on request" just is an extra explanation of the meaning of "make available"?

These questions have been discussed in IAF TC some time ago (TC-64-08, see Stockholm meeting).

There seems to be no reason to change the interpretation given – "making publicly available" means that it is not necessary to have a request to access the information, and the CB can choose the means for achieving this.

<p>QA 21-14 §9.1 - Requirement for a preliminary certification before issuing another certificate We are confronted in the evaluation of a national certification scheme with the requirement of having another specific management system certificate. No alternative way is offered in the scheme. There is also a national management system certification scheme with the requirement for a specific type of inspection report. Also no alternative way is offered.</p> <p>Does the EACC find this kind of tying acceptable?</p>	<p>This could be acceptable when the pre-requisite for a prior distinct MS certification can be justified technically, and if neither discrimination nor monopoly towards some clients or the accepted MS certificates is created.</p>
<p>QA 21-15 § 8.4 - Use of certification mark Could client which is a bakery certified for management system for production and distribution of food use certification mark on their cars as it is shown on the picture?</p>	<p>The policy is that the product and its packaging of a certified MS cannot bear the certification logo. If the van is to be interpreted as a promotional media for a certified MS, and not the final product, it would be acceptable, otherwise, no.</p>
<p>QA 21-16.a § 5.1 - Penalty for change of CB Is it allowed for a certification body to apply a penalty (e.g.: 25% of the overall amount of the certification contract), if the client decide to change the certification body during the certification cycle, or also at the end of the certification cycle? In other words, if the certified company wants to change the CAB, at whatever time, than can the CAB apply a penalty for this?</p> <p>This seems to be not in line with the rationale of IAF MD 02 (Transfer of accredited MS certification), however we found no specific requirement about that in ISO 17021.</p>	<p>ISO/IEC 17021 has no requirements regarding the financial arrangements between CBs and their clients. These arrangements are discussed and set by each CB with its clients, and ABs should not be involved in this aspect of those contractual relationships.</p>

QA 21-19

§5.2 - Requirement for a certificate before issuing another certificate

We are confronted in the evaluation of a national certification scheme with the requirement of having another specific management system certificate. No alternative way is offered in the scheme.

There is also a national management system certification scheme with the requirement for a specific type of inspection report. Also no alternative way is offered.

Does the EACC find this kind of tying acceptable?

This could be acceptable when the pre-requisite for a prior distinct MS certification can be justified technically, and if neither discrimination nor monopoly towards some clients or the accepted MS certificates is created.

QA 22-1

§ 8.3 - Directory of Certified Clients

We have received from a multinational CB (XXX) a letter in which the holding establishes a general position to comply with ISO 17021 cl. 8.3. This is said to be done via the holding website, where a Directory of Certified Clients is made available, where a given certificate can be confirmed valid or not, by company name or certificate ID.

Furthermore, a Note that says "if you Have Any questions in relation to your specific search or Directory of Certified Clients XXX, Please contact your local XXX office "

We think it may generally provide compliance to ISO 17021 § 8.3. , with an obvious reservation: the mechanism, the results and that Note should also be accessible in our language (in my case).

IAF TC held in Epson, 8-9 March, calls for the accreditation bodies to enforce the CBs to comply with cl. 8.3 of ISO 17021, showing a clear concern about that. As far as this is involving most of the EA ABs (and IAF as well) we think that this issue could be submitted to discussion in the EA CC.

We think it is more than a "process to verify certificates" so it will be also in line with the ISO response to a recent request for interpretation (question 2b) of this clause 8.3, which states that a "process to verify certificates" on its own does not comply with cl. 8.3 but if it does for clause 8.1.4.

We recommend publishing a directory of the valid certifications of our accredited certification bodies at the website (it is not obligatory but desired) – we think it is the best way to put in practice the rule 4.5 – *Openness*.

It was confirmed that a CB shall provide, upon request, a full directory of its certified clients, as agreed at the last IAF TC meeting. Providing details of individual clients can be found, by whatever means, it is satisfactory.

Whether this directory is available on the CB's website, or by other means, is for each CB to decide, providing it is publicly available, upon request as a minimum.

A means of checking the validity of certificates does not replace the need for a directory.

The directory shall be made available in the appropriate national language(s).

QA 22-2

§ 9.1.10.1 - Certification body report for each audit.

Question 1: Is it required to give the report (including 9.1.9.6.1 Audit findings summarizing conformity and detailing nonconformity) to the client?

Question 2: Is it required to give the FULL report (including 9.1.9.6.1 - Audit findings summarizing conformity and detailing nonconformity) to the client?

Question 3: Is it required that the Client has to sign / accept the audit report? (*9.1.9.8.1 Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed*).

Question 4: *9.1.10.2 The audit report shall include...i) audit findings, evidence and conclusions, consistent with the requirements of the type of audit.*

Does it mean that is required to write also the evidence of conformities, and not only the evidences of NON conformities?

Answer 1: Yes, clause 9.1.10.1 requires a report to be provided for each audit.

Answer 2: Yes, all of the information listed in clause 9.1.10.2 shall be included in the report.

Answer 3: No. The client has to acknowledge that the non-conformities are understood and agree the timescale for responding, but this does not mean that they are accepted. Unresolved issues shall be recorded in the report.

Answer 4: Yes. However, how detailed the evidence of conformity shall be, remains for further discussion. The evidence of non-conformities shall be more detailed than that of conformity, which can be summarized.

QA 22-3

§ Table A1

Question 1: What is the definition of each “*Knowledge and skills*” requirements listed in the table?

Question 2: Is technical expertise required for the function of “Conducting the application review” regarding “Knowledge of client products, processes and organization”?

See what is written under the Table A.1.

Question 3:

7.1.2 - The CB shall have a documented process for determining the competence criteria for personnel involved in the management and performance of audits and certification. (...) Annex A specifies the knowledge and skills that a CB shall define for specific functions.

So, is it necessary to specify the knowledge and skills of ALL personnel, according to Annex A, or only for the specific functions listed in Annex A.

Question 4: Which is the difference between *Knowledge of client business Sector* and *Knowledge of client products, processes and organization*? See the example below:

- Scope of the certified organization: design and manufacture of motor vehicle electrical equipment, such as generators and alternators.
- Knowledge of client business Sector: automotive sector in general (NACE 29 Manufacture of motor vehicles, trailers and semi-trailers)
- Knowledge of client products, processes and organization: Manufacture of electrical and electronic equipment for motor vehicles (NACE 29.31)

So, it means, that the auditor / contract reviewer has to be competent exactly in the process / product written in the scope of the certificate. The qualification criteria seem to be very similar to product certification.

Answer 1: There is no definition. Table A1, 1st column only gives expectations and a general understanding. “Knowledge and skills” are dealt with in ISO 17024.

Answer 2: Yes, but not as much as for auditing. Table A1 give qualitative criteria for competence; quantitative criteria may differ.

Answer 3: Yes, the knowledge and skills of ALL persons involved in certification and audit processes shall be specified, even if these persons have functions other than those listed in Table A1, when these functions are influencing the certification and audit processes.

Answer 4: The competence required for contract review is the same level as for auditing. The examples relating to the automotive sector are relevant illustrations.

<p>QA 22-4 § 9.1.14 - Decision making personnel <i>The certification body shall ensure that the persons or committees that make the certification or recertification decisions are different from those who carried out the audits.</i> Question 1: Is it allowed that some of the members of Committee for impartiality participate in the certification or recertification decisions (e.g. as technical experts)? Question 2: Is it allowed that the people that conduct the application review make the certification or recertification decisions?</p>	<p>Answer 1: Yes, but self-interest risks shall be identified and managed. Answer 2: Yes, this is not forbidden by the standard. People shall only be different for the audit.</p>
<p>QA 22-5 § 8.2.2 - Dates on a certification document. Question 1: Does it mean that is possible that the date written on the certificate (effective) is one date after the certification decision? Question 2: 9.1.1.2 (...) <i>The three-year certification cycle begins with the certification or recertification decision. 8.2.3 The certification document(s) shall identify (...) c) the expiry date or recertification due date consistent with the recertification cycle.</i> So, does it mean that the effective date written on the certificate, if it is different from the date of the decision, is not to be taken into consideration in order to calculate the expiry date of the certificate? The expiry date has to be calculated 3 years after the decision. Question 3: Does it mean that 8.2.3 <i>The certification document(s) shall identify the following: b) the dates of granting, extending or renewing certification, AND (in this case) ALSO the effective date?</i> Question 4: Is it required to write ALWAYS on the certificate the date of the initial granting?</p>	<p>Answer 1: Yes. The standard is clear: validity begins when the decision is made. The certificate can be issued at a later date (effective date), but validity time would be shortened accordingly. The effective date on the certificate cannot change the validity period starting on the decision date. Answer 2: Yes. The effective date on the certificate cannot change the expiry date, which is based on the decision date. Answer 3: [...] OR the certificate validity date to be identified as the effective date. Answer 4: No, but It is possible upon request..</p>

<p>QA 22-6 § 9.1.1.2 - Expiry dates for certification <i>(...) The three-year certification cycle begins with the certification or recertification decision. 8.2.3 The certification document(s) shall identify (...) c) the expiry date or recertification due date consistent with the recertification cycle.</i> Is it to be intended that is up to the CAB to decide if the expiry date is 3 years after the certification decision (that can be different from the effective date of the decision), or 3 years after the recertification decision? Or, is it to be intended that if there is a recertification decision, then this is the date that must be taken into consideration to calculate the expiry date of the certificate?</p>	<p>Answer (as modified at 23rd CC Meeting): Please refer to the decision made at the IAF TC meeting held in 2009 in Mumbai.</p>
<p>QA 22-7 & QA 14-5 § 9.1.1 and § 9.3.2.2 - Surveillance intervals <i>Surveillance audits shall be conducted at least once a year</i> Is it to be intended once a solar year (so, it is possible to have 1 audit in January, and then 1 in December of the following year – it means after 24 months), or once in a year time (so, 1 audit in January, and the second one within January of the following year)? § 9.1.1 and § 9.3.2.2 surveillance audits frequency: regarding the requirements stating an annual frequency for surveillance audits, how to interpret the sentence of § 9.1.1: "<i>The determination of the audit programme and any subsequent adjustments shall consider the size of the client organization, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits.</i>" Does it mean that some flexibility about this annual period could be thought?</p>	<p>The IAF decision is based on the calendar year. In-between time can be longer than 12 months, but the second surveillance would take place earlier.</p> <p><u>Clarification of the point raised:</u> there is a requirement for annual surveillance visit audit. There is another requirement that provides for flexibility. One CB stated that the clause would allow for some flexibility with regard to frequency and leaves space for adjusting the audit program over the cycle. Is this acceptable?</p> <p><u>Answer:</u> The standard defines the minimum frequency. More is possible not less. The clause shall read for the calculation to cover days on site + other annual surveillance activities. Flexibility is allowed but within a one year period. There must be at least one annual visit.</p> <p><u>Finally:</u> the Audit program can allow for flexibility within the minimum annual surveillance. If the organisation performs badly, the CB may increase the frequency and content of the surveillance activities.</p>

<p>QA 22-8 § 9.2.3.1.1 - Stage 1 audits before MS completed <i>The stage 1 audit shall be performed....g) to evaluate if the internal audits and management review are being planned and performed...</i> Is it necessary or not that the internal audit / management review must have been fully planned and <u>completed</u> BEFORE stage 1? If this is the understanding, if the CAB does not have evidence that the internal audit / management review was fully planned and <u>completed</u>, then is it not possible to plan the stage 2 audit?</p>	<p>There is no requirement in 9.2.3.1.1 g. for the internal audit to have been completed. Stage 1 should be used to see that an effective internal audit process is implemented and underway.</p>
<p>QA 22-9 § 8.1.4 - Means to confirm validity <i>On request of any party, the certification body shall provide the means to confirm the validity of a given certification.</i> Does it mean that the Certification Body, if requested by the interested parties (including customers or competitors of the certified organization), shall provide any relevant records that support a specific certification process? (e.g.: audit checklists, audit evidences, audit plan, etc.). If yes, is it necessary that the CB maintains all relevant records for the entire period of the certification validity? If not, what exactly does this requirement mean?</p>	<p>No. The “means” to be provided by the CBs is the mechanism to confirm validity of certificates, not the supporting evidence. It is the validity of certificate, not the validity of the certification decision, which shall be confirmed here.</p>
<p>QA 22-10 § 9.2.3.2 - Stage 2 audit location Small organizations in the service business, with 1 or 2 employees, may have their entire Quality System and all quality records on a Laptop. The organization carries out the services at their clients premises. The address of such a company may be the owner’s private address, where no activities are said to be carried out. Is it possible for the Certification Body to perform Stage 2 audit either at the Certification Body’s office or at another address different from the owner’s address mentioned above?</p>	<p>Yes, it is quite possible.</p>

QA 25-3

§9.1- Scope of IAF MD4 and use with MD1

- 1) Is IAF MD4 applicable to all kinds of management system certifications?

We agree that it is applicable to ISO 9001, But is it also applicable for ISO 22000, ISO 14001 and ISO 50001 certifications where the direct viewing and evaluations of situations seems more required for a sounded audit?

- 2) IAF MD4 and IAF MD1 (multisite): how to implement those 2 documents in the case several sites of an organization are far and a CB wants to operate CAAT techniques?

Is the clause 1.2.6 ("In addition to the requirements in ISO/IEC 17021, clause 9.3.2.2, regardless of the use of CAAT, the organization shall be physically visited at least annually.") applies for each and every sampled site?

IAF MD1 should first be applied and then IAF M D4 clause 1.2.3 ("If remote auditing activities represent more than 30% of the planned on-site auditor time, the certification body shall justify the audit plan and obtain specific approval from the accreditation body prior to its implementation") should be applied to each sampled site?

1. There is nothing in MD 4 to suggest that its application is limited to certification against any specific management system standards, therefore, it can be applied to all forms of management systems certification. Clause 1.2.6 states that regardless of the use of CAAT the organization shall be physically visited at least annually and this provides ample opportunity for any necessary direct viewing or evaluations of on-site situations.
2. First apply MD 1 and then apply MD 4 to each site. Clause 5.3 of MD 1 specifies the requirements for determining auditor time for multisite organizations and this shall be used first to calculate the total auditor time (on-site plus CAAT). Whether some sites in the sample selected can be audited entirely by CAAT will be dependent on variables such as the management system standard, the processes performed on the site, the risks, the scope of certification etc. It may be acceptable to audit using CAAT a sales office of an ISO 9001 certified organization, whereas a site of a manufacturing company certified to ISO 14001 may need to be visited. The physical on-site time spent on individual sites may, however, be reduced within the limits of MD 4 where CAAT is used. The critical point is that the total audit time (on-site plus CAAT) is in accordance with clause 5.3. Clause 1.2.4 requires the certification body to indicate in the audit report the extent to which CAAT has been used and how it contributes to audit effectiveness and efficiency. The accreditation body must satisfy itself that the certification body's audits, whatever combination of audit techniques have been used, are effective.

QA 25-4

§ 9.1 - Implementation of MD5 for shifts

How can one calculate the effective number of personnel for the audit day calculation (IAF MD05), when the company works on a shift basis?

Example - Transportation company.

Head Office: 50 people

Shift 1 - 100 people

Shift 2 - 200 people

Shift 3 - 300 people

1) The effective number of personnel is calculated as the sum of all people (50 + 100 + 200 + 300 = 650)

2) Considering that a significant proportion of staff carries out a

similar simple function it is possible to apply an appropriate reduction of number of personnel in accordance with point 2.3 of IAF MD05. If we consider 40% (*) of reduction the effective number of personnel will be: 50 + (600 - 40 %) = 50 + 360 = 410

In the above case it is not possible to apply the following decreasing factor of an audit duration (see point 8.1 of IAF MD 05): "Low complexity activities: identical activities performed on all shifts with appropriate evidence of equivalent performance on all shifts based on prior audits (internal audits and CAB audits)" because it has been already applied as a reduction to calculate the effective number of personnel.

(*) How is it possible to calculate a numerical reduction limit? What criteria should be applied?

Given the importance of uniformity in this matter we need to know your opinion on whether an approach favouring reduction, in cases where it can be demonstrated that the work carried out is a similar simple function (such as in transportation or assembly lines), or whether it is preferable to follow a non reductive policy.

The approach to man-day allocation for shift work depends very much upon the individual organization, what happens on the shifts, how they are supervised and other factors.

Firstly the overall requirement to take into consideration is from ISO/IEC 17021: 2011 clause 9.1.4.1 which states 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."

MD5 is a mandatory tool for providing a start point and helping determine if the time allocated is reasonable but it is the above requirement that the Certification Body has to demonstrate overall, whatever MD5 allows. The time allocation should not be purely based on the MD5 tables but by using MD5 in support of the ISO 17021 requirement.

MD5 clause 3.5 specifically covers shifts and states that: For QMS audits, Figure QMS 1 provides a visual guide to making adjustments from the basic audit times and provides the framework for a process that should be used for audit planning by identifying a starting point based on the total effective number of personnel for all shifts. Where product or service realization processes operate on a shift basis, the extent of auditing of each shift by the CAB depends on the processes done on each shift, and the level of control of each shift that is demonstrated by the client. The justification for not auditing each shift shall be documented."

And in section 8 one possible reason for reduction of audit time is shown as "Identical activities performed on all shifts with appropriate evidence of equivalent performance on all shifts based on prior audits (internal audits and CAB audits).

Section 2.3 refers to reduction where a significant proportion of staff carry out a simple function, this is irrespective of whether they are working on a shift basis or not.

There is no justification for reduction simply because they are working on shifts.

If they are carrying out the same simple function on a shift and there is evidence of equivalent performance (see above) then the reduction factors can apply as stated (but not twice).

However it could equally be argued that shift work presents an additional risk meaning that it may be necessary in some cases to allocate more time to the audit to cover shift working.

<p>QA 25-9 § 5.2 - Recognized consultants using CB's logo One certification body is operating a 'Recognised Consultant Scheme' which is a list of consultants that are recognised by this CB and these consultants are allowed to using a logo that gives the CB's name and stating that they are 'recognised consultants'. We think that this is not in conformity with clause 5.2.9 of ISO 17021 as there is a definite link between the consultants and the CB and also we see the use of the CB's name as marketing.</p> <p>For the consultants to be included on the CB's list the 'ISO consultants who have proven themselves in audit situations'</p> <p>The website of the CB states that 'Certification will not be simpler, easier, faster or less expensive if a recognised consultant is used'.</p> <p>Does the CC agree that this is not allowed under ISO 17021?</p>	<p>As the recognized consultants use the certification body's logo, the certification body's activities may be linked with the services of an organisation that provides management system certification, which contravenes clause 5.2.9 of ISO/IEC 17021. Although the certification body may state that certification will not be simpler, easier, faster or less expensive if a recognized consultant is used, use of the word 'recognised' could indicate that the certification body endorses the competence of the consultant. Despite the certification body's disclaimer, clients could believe that there are distinct benefits in using a recognized consultant as they have the certification body's endorsement (recognition).</p> <p>There are, however, situations where certification bodies may provide potential clients with a list of possible consultants. Providing the certification body does not endorse the competence of the consultant, informs the client that it is their responsibility to choose the most suitable consultant from the list and makes it clear that certification would not be simpler, easier, faster or less expensive if one of these consultants was used, then is acceptable. The critical difference is the use of the certification body's logo and of the term 'recognised' which indicates the certification body's endorsement of the consultant's competence.</p>
<p>QA 25-11 § 9.1.2.3 - Audit Plan ISO/IEC 17021:2011 cl. 9.1.2.3 requires that audit plan shall include or refer to f) roles and responsibilities of the audit team members and accompanying persons.</p> <p>Is it understood that accompanying persons should be written namely or is it enough to write e.g. representative of sales department?</p>	<p>"Accompanying persons" are part of the audit team and not of the audited company.</p> <p>It is required that their role and responsibility (observers, guides, experts...) shall be recorded.</p> <p>Nothing is required by the standard related to the names of the client's representatives. Nevertheless, for the audit team traceability shall be insured in the report which shall include "identification of the audit team leader, audit team members and any accompanying persons;" (§ 9.1.10.2 g)</p>

QA 25-12

§ 8.4.1 - Use of CB's mark in products

§ 8.4.1 of ISO/IEC 17021 states that: "A certification body shall have a policy governing any mark that it authorizes certified clients to use.... This mark shall not be used on a product or product packaging seen by the consumer or in any other way that may be interpreted as denoting product conformity."

We have asked our CBs to ask their clients to add near the statement of MS certification a clear mention like "only Management System is certified, and this certification does not indicate conformity of the product" in situations where when the product is seen by the consumer.

The case we are facing is that a CB declares that this is to be done in case of B to C market but not in case of B to B market as the user in a B to B relation is not a consumer (in the sense of "end consumer").

Is this acceptable?

No, if the product or product packaging is marked with a statement of MS certification without any accompanying text it does not matter whether it is a B to C or B to B market relationship. It may still be interpreted as denoting product conformity.

QA 25-13

§ 8.3 - Directory of certified clients

§ 8.3 indicates : “The certification body shall maintain and make publicly accessible, or provide upon request, by any means it chooses, a directory of valid certifications that as a minimum shall show the name, relevant normative document, scope and geographical location (e.g. city and country) for each certified client (or the geographic location of the headquarters and any sites within the scope of a multi-site certification).

2 Questions :

1. What is the definition of a directory? Is it a list? Or is it an organized way to present elements which if correctly handled gives a list?
2. Is the CB authorized to “qualify” who request this directory, i.e.; to select to whom it might or might not provide this directory (e.g. not for competitors). The answer might appear obvious but one of our “international” CBs told us that this requirement was not implemented in some other countries.

1. A directory is any means, as determined by the CAB, of providing the information listed in § 8.3 of ISO/IEC 17021. It might not be simple list. It may have different forms.
2. ISO/IEC 17021 says “make publicly accessible or provide upon request” it does not say anything about right of CB to refuse such request. It is a service to their clients and the public to “not hide” information on the certificates the CAB has issued. No refusal to supply a directory is acceptable according to the standard. There is a NOTE that the directory remains the sole property of the certification body, so the CAB could have enforceable arrangements with the party asking for the directory to prevent its misuse in any way.

ISO/IEC 13485

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QA 13-3 & QA 14-6

Is it possible to certify against ISO 13485 a distributor/retailer that is not a manufacturer but simply an entity for selling medical devices?

The certificate against ISO 13485 does not say anything about product conformity; it states that QMS of the organization complies with the requirements of the mentioned standard. All the certified organizations have to comply with all (100%) the requirements laid down in ISO 13485. We would like to know, why EA CC anticipates that certified organizations operating only trade do not comply with all requirements. We could go as far as to say, that the statement written in Draft Minutes of the 13th meeting of the Certification Committee – item 12 e) ISO 13485 undermines the trust in accredited certification by the wording allowing, that certified organizations do not meet all requirements set in the standard.

This matter was subject to an IAF decision number 12/10/14 which agreed: -

1. That it is allowed to certify management systems for activities such as wholesale and retail trade, transport and service of medical devices for compliance with ISO 13485.
2. MD9 does not currently apply to services and needs to be amended to include service.

QA 25-2

ISO 13485 specifies “requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.”

Is consultancy activity included in those “related services”? Is it acceptable for any kind of consultancy to manufacturers? If this is acceptable, what will the CB audit and what will we be witnessing?
We were not able to find this activity in the annex A (which details the technical areas) in IAF MD 9.

The activities which it is possible to be certify are listed in IAF MD 9:2011 Annex A (or IAF MD 8:2011 Annex 1).

Furthermore based on the draft minutes from the IAF TC 2012 in Rio, the consensus of the IAF Technical Committee recorded as Decision Number 12/10/14 was:

1. that it is allowed to certify management systems for activities such as wholesale and retail trade, transport and service of medical devices for compliance with ISO 13485, and
2. MD9 does not currently apply to services and needs to be amended to include service.
3. The TC requests the 13485 WG to amend MD9 for further review by the TC.

Consultancy to manufacturers is not an activity that is possible to certify against ISO 13485.

ISO 3834 & EA-6/02

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QA 21-7

EA-6/02 document provides the basis for an assessment of a welding process and instructions how to deal with all welding related activities. In the field of QMS certification, there is no doubt about its application if we accredit CABs for certification according to ISO 9001 in connection with ISO 3834. In this case certificates contain reference to the both mentioned standards.

My question concerns assessment of CABs operating in the field of EA codes - 17,18,20,21, 28,29,34, where welding can be applied however CABs issue certificates containing only declaration of ISO 9001 conformity - there is no reference to ISO 3834 on the certificate. For a better understanding, this is a case e.g. when company welds for a building construction besides other processes included in QMS and applies just for ISO 9001 certificate.

Is it legitimate, in this case when welding is applied, to require all instructions set in EA 6/02 to be met by CABs operating in mentioned branches? And furthermore, should ABs require CABs to assess this special process in accord with ISO 3834 unless any QMS certificates contain reference to these standards?

It is not required to assess implementation of EA-6/02 except when ISO 3834 is explicitly quoted in the accreditation certificate.

ISO/TC 22003

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QA 16-2
Auditors' competence

I would really appreciate to have your opinion on the meaning of the word "equivalent" in the paragraph that follows:
Paragraph 7.2.4.4 concerning "auditors' work experience", namely:

Can it be recognized as "the equivalent" to the indicated in the above-mentioned paragraph auditor' activities, during accreditation, as follows:

1. Full-time Professor at the University of Food Technologies-;
2. Lecturer on the subjects of: Food Engineering, QMS and SMS, Bachelor` and Master` degree at the University;
3. Head of the Scientific and Research Sector at the University;
4. Head of the Accredited Testing Laboratory for Food and Equipment;
5. Head of Consultancy Team for Development and Implementation of QMS and SMS;
6. Chief of the Department of Food Equipment;
7. Research Associate at the Canning Research Institute

In principle the listed experience is an acceptable starting point for initiating the qualification process for an auditor in the food sector.

A question remains open concerning knowledge and experience with food production processes for which the information available is not sufficient to have a clear opinion.

QA 21-17
Auditors' competence

Client applied for accreditation of certification of FSMS. ISO/TS 22003 sets very precise requirements for personnel involved in the certification activities. Among other requirements, for a first qualification of an auditor the certification body shall ensure that the auditor has a minimum 5-years of full-time work experience in the food-chain-related industry (some examples of such industry would be highly appreciated) which may be reduced by one year if auditor has appropriate education.

5 years of full time work experience in food chain related industry is one of the basic requirements on food auditors. ISO/TS 22003 sets this requirement for each single auditor, not for audit team. Personnel without this full time experience from previous years cannot work as a food auditors, such personnel can work e.g. as an expert.

QA 21-18

Audit team with only experts

CB has qualified an auditor who fulfils all requirements of clause 7.2.4 except abovementioned working experience clause and we raised nonconformity about qualifying person who is not fulfilling the requirements of ISO 22003 cl.7.2.4.4.

In its reaction to that NC the CB worked out another interpretation of rules and according to that the audit team competence as a whole must meet all requirements set to auditors instead of individual auditors.

The qualification of abovementioned auditor was approved with precondition that in audit team the auditor's lack of working experience must be covered by additional technical expert who has sufficient work experience in food-chain-related industry.

In fact, now the audit team consists only of technical experts. Is it acceptable?

Is there any requirement that audit team must include auditors and cannot be comprised of technical experts only?

An audit team is defined as one or more auditors conducting an audit, supported if needed by technical experts.

An expert is defined as a person who provides specific knowledge or expertise to the audit team. There is nothing about assessment carried out by an expert. An expert does not conduct any assessment. The team consisting only of experts would not be able to provide assessment – such team does not meet the definition of an audit team.

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

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QA 25-1

§4.2 Impartiality and trade associations

- a) Does the provision of preferential pricing to groups of customers (those belonging to a trade association or similar) present a threat to impartiality?
- b) If the Trade Association agrees to publicise the Certification Body concerned to its members, does this present an unacceptable risk to impartiality?
- c) If the Trade Association (not the members) is linked to the Certification Body e.g. by common ownership, does this present an insurmountable issue with regard to impartiality?

If a CB, with majority ownership held by an Association, certifies companies which are members of that Association, this does not in itself constitute an unacceptable threat to impartiality, if:

- the list of certified company members of the Association owned by the CB, is made available to the AB
- the CB deals with these threats in the risk analysis, specifying effective countermeasures on a number of levels (e.g.: persons doing the contract review, performing the audit and taking the decisions shall not have an operative role within the owner association)
- the CB also offers its services to companies not linked with the owner association
- any discount is applicable, it shall not be a significant amount
- the risks to impartiality are kept rigorously under control
- the average time taken by the CB to handle the certification process is the same for all of its clients (connected or not to the owner association)

Another factor to be considered is the percentage of certified clients that are members of the owner association and what percentage of the CB's revenue created by these clients?

Question (c)

- It is not a case of whether the association has the majority of the shares or not, it is also not related to 5.2.3 but to 5.2.2 and should be considered as a major threat to impartiality which shall be eliminated/ minimized. The committee for impartiality should provide its opinion.

QA 25-10

§7.6 Decision on Product Certification

A testing laboratory and a product certification body operate within one legal entity. The testing laboratory operates as a subcontractor of laboratory testing for the certification body. Is it permissible for the same person to sign a Test Report used in the evaluation of a product and make decisions on certification of the same product (System 1a of ISO/IEC Guide 67)? The evaluation was performed another person. Is it in compliance with 4.2f) of EN 45011:1998 and G.4.2.26 of IAF GD5, or with 7.6.2 of ISO/IEC 17065?

NO, it is not allowed. IAF GD 5; G 4.2.6. is clear that the person signing the test report cannot make the certification decision for the same product. Nevertheless, this person could be part (member) of a Committee making the certification decision.

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

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QA 9-2

§ 6.2.2 - Monitoring of examiners

- Is monitoring of the examiners necessary?
- Is it possible, to monitor the examiners on a sampling basis (which means that some examiners might be not monitored)?
- What is an appropriate monitoring cycle for examiners?

- Yes.
- No.
- Normally between 3 to 5 years.

QA 9-3

§ 4.3 - Certification based solely on diploma or document review

Is it possible - in the framework of an ISO 17024 accreditation that the initial certification processes of juridical experts is solely limited to:

- a. a verification of the adequacy of the diploma of the expert against the discipline for which the expert applies a certification?
- b. A + a documentary evaluation of the gained experience of the expert, based on information from the applicant or his employers?

The requirement in ISO/IEC 17024 is that requirements for assessment are defined by the scheme and developed by the scheme committee. However clause 9.2.3 requires that “The assessment shall be planned and structured in a manner which ensures that the scheme requirements are objectively and systematically verified with documented evidence to confirm the competence of the candidate.” And so the CB would need to be satisfied that whatever method is used demonstrates that the person meets the competence requirements.

QA 25-14.a

§5.2 - Questions related to the training

Question 1.1

Par. 5.2.1 The recognition/approval of training by the certification body shall not compromise impartiality or reduce the assessment and certification requirements.

Can an applicant who has completed training (according to the scheme) participate in a smaller examination than another who had not been undergone training?

Question 1.2

Par. 5.2.2 However, the certification body shall not state or imply that certification would be simpler, easier or less expensive if any specified education/training services are used

Can we assume that common marketing activities between CB and training providers are not against this clause by default?

See also 5.2.3c

Question 1.3

Par. 5.2.3 b : is this related also to the economic policy of the CB (except from the other resources) ? If yes how deep can we go?

Par. 5.2.3 d : the existence or not of alternative training and moreover with an equivalent outcome is chaotic

Par. 5.2.3 e : for example if the name of the candidate isn't disclosed to the examiner and decision maker somehow, is this in line with the clause? Is this also a solution for par. 6.1.8?

Question 1.4

Is it possible that the CB is mainly a training institute; meaning that the core service is training and the certification of the people is actually the final step of its services? Take as example a vocational training institute which wants to be a CB. Of course the CB provides all the commitments about impartiality, confidentiality etc

Answer 1.1

No, clauses 5.2.1 and 5.2.2 state that the assessment and certification requirements cannot be reduced because any training is recognized or approved or that certification would be simpler, easier or less expensive if any specific education/training services are used.

Answer 1.2

It depends on the marketing message. It would be acceptable to state that "Training company LTD" offers a course for welders seeking certification under the "Welding scheme" offered by "CB International Ltd. " A problem would arise if the message implies that the certification activity may become simpler, easier or less expensive if some a specific training service is selected, for example, " Get welding certification in one week only with our coordinated training course (Monday to Thursday) plus certification exam (Friday)"

Answer 1.3

5.2.3. b) "all processes" is clear and what is required is "to ensure confidentiality, information security and impartiality are not compromised " so the processes to be investigated are all those that can impact on the areas mentioned above.

" Economic policy" is not a specific process but "sales " could be an example of a process to be investigated (see above for question 1.2)

5.2.3.d) The investigation shall be done by the CB and they have to demonstrate that equivalent training does not exist. Anyway afterwards the marketplace can also show how accurate the investigation was

5.2.3 e) NO, the criteria don t offer alternative routes.

Second question : NO it is not enough to ensure impartiality for the examination process (the internal candidate can easily know almost all the questions and right answers for the exam)

Answer 1.4

Yes, if complying with § 5.2.3.and the rest of criteria linked to conflicts with training

QA 25-14.b

§8 - Questions to the scheme development

Question 2.1

Ch 8. : how far the assessment team can go? In what extent the team can object the requirements stated in the scheme?

Question 2.2.

Par. 8.3 c surveillance methods and criteria (if applicable);
So it is possible not to have surveillance at all? Is it possible to have as surveillance process a self-declaration of continuing work experience or should it be a 3d party attestation?

Answer 2.1

An AB cannot refuse to accept a scheme simply because they do not like it, but they should ensure that the scheme meets the requirements of the standard.

The AB assessment team should be assessing all of the 'Shall' requirements of section 4 and the scheme has to meet all of these in order to be acceptable for accreditation. This includes the stated process requirements and the need for the scheme to have been developed with the involvement of appropriate experts, and interested parties and the alignment of assessment mechanisms with competence requirements, etc.

Answer 2.2

There is no requirement for all schemes to have a surveillance element, specific clauses regarding surveillance are stated as "if required by the scheme" or "if applicable", and therefore it is the scheme development process that will define whether surveillance activities are a requirement and what form the surveillance will take.

Recertification however is compulsory.

QA 25-14.c

§9 - Questions to the certification process requirements

Question 3.1

Is par. 9.2.6 actually talking about transfer of certification?
Moreover is it possible for a CB to use examination results of another CB to issue certificate in case that the equivalence is checked?

Question 3.2

Par. 9.6.5 In accordance with the certification scheme, recertification by the certification body shall consider at least the following:
“Consider” means that the CB shall endorse in his rationale of recertification all of the 6 elements? Or at least one of them?

Question 3.3

Par. 9.9.9 The complaints-handling process shall be subject to requirements for confidentiality, as it relates to the complainant and to the subject of the complaint
Is there a meaning in this requirement that the CB shall not disclose the complainant also to the certified person in question for example?

Answer 3.1

§ 9.2.6, is not justifying “transfer “: “work performed by another body” is different to “certificates” issued previously
“examination results of another CB” is possible under 6.3 “outsourcing”

Answer 3.2

“consider” means “to think of especially with regard to taking some action “ and “consider at least” is not adding anything. It means “think about the six elements with regard to taking some action” but again there is no requirement to choose alone or more of them.

Answer 3.3

The requirements for confidentiality include disclosure of the person making the complaint, written permission must be obtained from the complainant before their name can be given to the CB”

QA 25-14.d

§10 - Questions to the MS requirements

Question 4

§ 10.1 gives two options : without and with 9001

In option b what is the extent of our assessment?

I could see three sub-options in this case:

b1 The CB has a 9001 system in place with his self declaration that this MS is effectively implemented and maintained

b2 The CB has a 9001 system in place certified by a non accredited CB

b3 The CB has a 9001 system in place certified by an accredited CB

The depth and extent of the AB's assessment should differ in my opinion. Meaning that the AB shall focus in full at the MS requirements in option a and options b1&b2, instead of option b3, where the AB's assessment should be lighter because of the higher level of confidence in this case.

Answer 4

These are options for design and implementation of the MS of the CB but there are not options for the assessment by the AB.