

## 40<sup>th</sup> Meeting on Sept. 29<sup>th</sup>/30<sup>th</sup>, 2020 (Web-Meeting)

### 1. Welcome, Apologies

Participants have been welcomed by the Chair Kevin Belson (UKAS)

### 2. Protocol for Remote Meeting

All participants have been named to check if every delegate was participating.

### 3. Approval of Agenda

Agenda has been approved

### 4. Approval of Minutes of 38<sup>th</sup> Meeting & Matters arising

Minutes of previous meeting (2019-09) in Berlin has approved (including comments of RvA and IIOC). There are no minutes from in 2020-03 because this has been cancelled.

### 5. EA-CC Responsibilities

Chair has updated the actual situation with respect of implementation plan to the EA Strategy 2025. With respect of the new EA-structure this will be discussed separately (see agenda item 11).

Also, the terms of references and the rules of procedure has been presented.

### 6. Harmonization session on Questions & Answers

#### a. EA-CC Questions submitted to 40<sup>th</sup> meeting:

- *Question with respect to all standards*

Question by TURKAK: Is it possible to perform a full/initial certification audit remotely?

Answer: In theory: yes, but in reality it will not be possible to perform a full/initial certification remotely which is also depends on the scope and its scheme specific requirements. (see also IAF MD 4)

- *Question with respect to ISO/IEC 17021*

Question by ACCREDIA: Does shift work has to be taken into account to reduce the effective number of personnel for the calculation of audit-time? (see also IAF MD 5 cl. 2.3.1, 2.3.4 and 3.7)

Answer: It is not a systematic reduction factor in any case. It depends on some special factors and may lead to reduction of audit time. For example, if the processes are the same in each shift it can be taken into account to reduce the effective number of personnel (but not more than 30 %). If the processes are different in each shift it cannot be taken into account.

Question by IPAC: If a certified company has been rent a site for a long time period (e.g. for 20 years) is that a permanent or a temporary site of the certified company? (see also IAF MD 1 cl. 2.2 and 2.3)

Answer: yes because of the long-time period this is a permanent site, even the period time is limited.

Question by EAK: IAF MD 17 cl. 4.2.8 states that also for non-critical codes accreditation shall be granted only if some requirements are fulfilled. This includes also a witness-audit which means that the CAB has to have a client for this scope even the CAB is not accredited for this scope at that time.

Answer: is postponed until revision of IAF MD 17, but if the scope of the CAB is extended it can be also assessed by the qualification of the auditors and reviewing the documents and records of the audit (only for non-critical scopes).

Question by PCA: Is it acceptable that a MSCB (management system certification body) certifies another MSCB according to ISO 9001 on another scope than MS certification (e.g. training or research)?

Answer: ISO/IEC 17025 cl. 5.2.4 does not permit the certification of other MSCBs. It is necessary to certify just a (internal separate) organisation unit which deals with training or research (but it must be clear that the management system of the certification activities are not included).

Question from RvA: Audit time can be reduced by the effective number of personnel. This can be done if there is personnel with similar or repetitive processes (IAF MD 5 cl. 2.3.4). Does this repetitive function also include personnel with higher trained or qualified skills (like in medicine activities, architecture etc.)?

Answer: question transferred to IAF TC.

Question by EUROLAB (transferred from EA-LC): Can a laboratory be certified by another CAB according to ISO 9001?

Answer: ISO/IEC 17025 and ISO 9001 are different in its purpose. The standard ISO/IEC 17021 does permit certification of management systems according to ISO 9001, but it has to be cleared that certification of the management system is different from accreditation of the laboratories competence. But there is consensus meaning and some big concerns with respect of a misuse of such certificates.

- *Question with respect to ISO/IEC 17024*

Question from CIA-client: A client of CIA complains that it is not possible in Czech Republic to get an accreditation for certification of welders according to ISO 9606-1 cl. 9.3 (c) whereas this is possible in other countries.

Answer: CIA was not amused about this question from client, because this clause is not within the the only responsibility of the CAB but also of the certificate user or the employer. The question will be transferred to EA-MAC.

- *Question with respect to ISO/IEC 17065*

Question by Accredia: In ISO/IEC 17065 cl. 4.3.3 the note permits CABs to decline an application if the client is participating in illegal activities. So, now the question is what does the note mean by »illegal activities«?

Answer: Illegal activities are just mentioned in a note and the note says »can« decline. So, this is not a requirement. The mentioned clause of the standard describes requirements according to non-discrimination. So, the CAB can reject an application, because certification is not outside the law and if the CAB is aware of the illegal activity it can not be forced to accept the application. It is not necessary to check the criminal activity.

Question by UKAS: ISO/IEC 17065 cl. 6.2.1 and 6.2.2.1 refer to requirements for resources. Can these requirements also be taken for verification/validation (as in ISO/IEC 17029)?

Answer: Same principles cannot be taken if validation/verification according to ISO/IEC 17029 is part of a product certification according to ISO/IEC 17065

#### b. EA-CC Questions submitted in previous meetings

Question by OLAS: Do any NABs have any experience with the accreditation according to ISO/IEC 17065:2012 (or other) of TABs (Technical Assessment Bodies acc. to regulation 305/2011/CRP)? Do any NABs have any experience with the process of designation and monitoring of TABs in their country?

Answer: Some NABs have experience in accreditation of TABs, other just with assessing them without accreditation. Some NABs opinion is that TABs activity 1 is writing product standards which is not accreditable, while for TAB activity 2 (ETA) could be accredited because TAB is certifying manufactures to an EAD exactly as NBs are certifying manufactures to a hEN.

Question of TURKAK: ISO 9712 makes some requirements for certification of NDT personnel control and documentation. Is it possible to transfer certificate from one CAB to another? Can a candidate receiving a certificate from a CAB according to EN ISO 9712 standard apply to another CAB for certification renewal?

Answer: Actual there are no rules for transfers of certificates under ISO/IEC 17024. Both CABs shall work under the same scheme and the documents shall be equivalent. A TFG will be established and the results also discussed with IAF.

#### c. Status of EA FAQs

Final version of Q&A from Meeting 39 will be published on EA website.

#### d. Structure of the Review Panel

Review panel will be still Salih Yuksel TURKAK (convener), Edelio Gago ENAC, Adriana Lekakou ESYD, Leonardo Omodeo-Zorini IIOC and Nathalie Saveant COFRAC.

## **7. Information Panel 1**

### **IAF work (just information)**

#### a. IAF meetings

IAF mid-term meetings – Beijing – April 2020: Cancelled

IAF Annual meetings – Montreal – 27 Oct. - 5 Nov. 2020: Cancelled

#### b. Specific IAF Items

IAF MDX on CAS

IAF MDX on Duration of AB Assessments

IAF WG Audit Time

PL 3 – Expansion of Scope of the IAF MLA – significance to the EA-CC

MD 6

c. Review of recent/revised/under revision IAF MD documents

N/A

d. ISO CASCO Clarifications

- Review of recent clarifications

**8. Closed Discussion (for AB members only)**

Experience exchange on COVID remote activities. Because of “closed discussion” stakeholders were not permitted to attend this discussion.

**9. Harmonization activities**

- a) EA-6/02 revision (“EA Guidelines on the Use of ISO/IEC 17065 and ISO/IEC 17021 for Certification to EN ISO 3834”) has been done and is out for 60 days comment period
- b) Certification scheme for persons when certification is performed according to ISO 9606-X or ISO 9712 which is sometimes with respect to the PED. This has been discussed with the EC and a TFG was created. A short presentation of the results of the TFG has been given. Some elements of ISO 9606 which are in contradiction to a 3<sup>rd</sup> party certification (validity of certification is extended by declaration of the employer organization and also the renewal of the certification can be based on the employer declaration). Because of this some NABs have strong doubt that this can be a 3<sup>rd</sup> party certification. So, the scheme owner (for PED this is the EC) has to analyse this aspect in detail. But this was under a strong discussion, because some NABs are arguing that there should be no differences by using the same standard. Further EA will discuss the conclusion with ISO and CEN. This seems to be similar also in person certification of NDT personnel.
- c) Guidance document for ABMS: actual no EA-CC guidance document based on some NABs guidance documents has been prepared
- d) Blended Assessments post COVID – what will be the new norm? What procedures need to remain in place and what will be in future. Remote and traditional audits will be done both for regular audits in future. Even IAF MD 4 gives requirements for remote audits, e.g. UKAS is preparing an own guidance document based on the actual experience and a lot of other NABs are doing similar things. So, this may lead to a harmonised EA document.
- e) IAF FAQs are developed especially for COVID crisis. Maybe it would be helpful to generalize it so that it also can be used in future after COVID crisis. This is in discussion in IAF TC actually.
- f) In 2020-10 there will be a one-day joint workshop with HHC in order to review of schemes and selection of standard.
- g) COVID Return to Work schemes which seems to be more of interest for IBs
- h) For IAF MD 8 (“Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)”) some information for the regulatory authority and witnessing requirements has been given. ISO/IEC 17011 cl. 7.9.3 requires that the time between 2 on-site assessments shall not exceed 2 years whereas IAF MD 8 cl. 7.9.3 requires that surveillance assessments shall be done at least once per year.
- i) In ISO 27006 it is mentioned that you can add referencing conformity assessment documents in MS scopes if it is clearly that these documents are not part of the certification. The NABs are concerned about this, because it may lead to some worse situation. It seems to be better that instead of mentioning these reference conformity standards a product certification should be used.

- j) How to enforce rules on use of logos if for example the CAB lose the accreditation within its validity time of e.g. a product certification? Is it possible to enforce the CAB in that case to exchange the accredited certification by a non-accredited certification? It would be good to find an agree about harmonization of this aspect.
- k) Systemic review of ISO/IEC 17021-1: decision is that this standard will not put under revision and maintain without any changes.
- l) Because UKAS has made the experience that CABs reduce audit time because of exclusion “design” from ISO 9001 scopes it is not permitted in UK anymore to exclude “design”, just identifying it as not applicable. IAF MD 5 cl. 8 v) is identifying “client is not ‘design responsible’” as an audit time decreasing factor. In 9001 scopes “design” should not be mentioned as “excluded” but as “not applicable”.
- m) Remote audits: Postponed to end of meeting but time was running out so that it couldn't discussed.

## 10. Information Panel 2

- a. WG Food: A short oral report has been given with respect of the last remote-meeting from 2020-05. The EA-3/12 publication and status of revision of the EU-Regulation on organic Production has postponed. Also, the EA-3/XX: “EA policy for accreditation of certification activities under PDO/PGI/TSG, wine products, spirits and aromatised wine products” is still in work. The revision of EA-6/04 is still on hold too. There is some progress on ISO 22003, especially 22003-1 (application under ISO/IEC 17065) but a decision has not been made on WD2. There are some new approaches by scheme owners to sign individual agreements with its NAB.
- b. WG Environment: An oral report according to meeting held in Vienna, Austria in 2019-11 has been given. The meeting in 2020-04 in Helsinki, Finland has been cancelled. In 2020-10 a remote meeting is planned.
- c. Network-Group (NG) EU-ETS: A presentation has been given concerning the update on NG organisation and its activities in 2019 (EU-ETS, MRV-shipping, CORSIA, DG-Clima, EMSA, IAF) as well as its working programme 2020. Annual meeting has been cancelled for 2020 but a web-meeting is planned 2020-10 an 2020-11. (Presentation have to be shut down because of bad web-connection of German NAB representative and presentation will be shared afterwards)
- d. WG ICTDS: a brief report shows that there were no activities so far

## 11. Information Panel 3

EA Structure: an update concerning the implementation of the new EA structure has been given

EA activities: the EA-GA resolutions from 2020-05 have been presented with respect to EA-CC

Standardization activities: actual standards activity with respect to EA-CC are ISO 29001 (“Petroleum, petrochemical and natural gas industries — Sector-specific quality management systems — Requirements for product and service supply organizations”), the implementation of ISO 17029 (“General principles and requirements for validation and verification bodies”) and ISO 17033 (“Ethical claims and supporting information — Principles and requirements”).

Regulatory activities: an update concerning the revision of EA-2/17 (“Accreditation for Notification Purposes”) has been given (handled by EA-HHC).

Transitions: just a reminder of key dates for existing transition programmes has been mentioned

## **12. EA-CC planning and outcomes**

- a. The approved EA-CC Work Plan for 2020 was presented
- b. The EA-CC Work Plan for 2021 was prepared for next EA-GA
- c. Updated EA-CC Decision Log has been presented

## **13. Summary & Conclusions**

- a. Recapitulation of actions agreed have not been summarised
- b. Report and Proposed Resolutions for the next EA GA has been prepared but not presented

## **14. Next Meetings**

- 24-25 March 2021, to be held remotely
- 28-29 September 2021 in Zagreb, Croatia, hosted by HAA