



**L'accréditation OLAS :
La preuve de la compétence**



OFFICE LUXEMBOURGEOIS
D'ACCREDITATION ET DE
SURVEILLANCE



International News

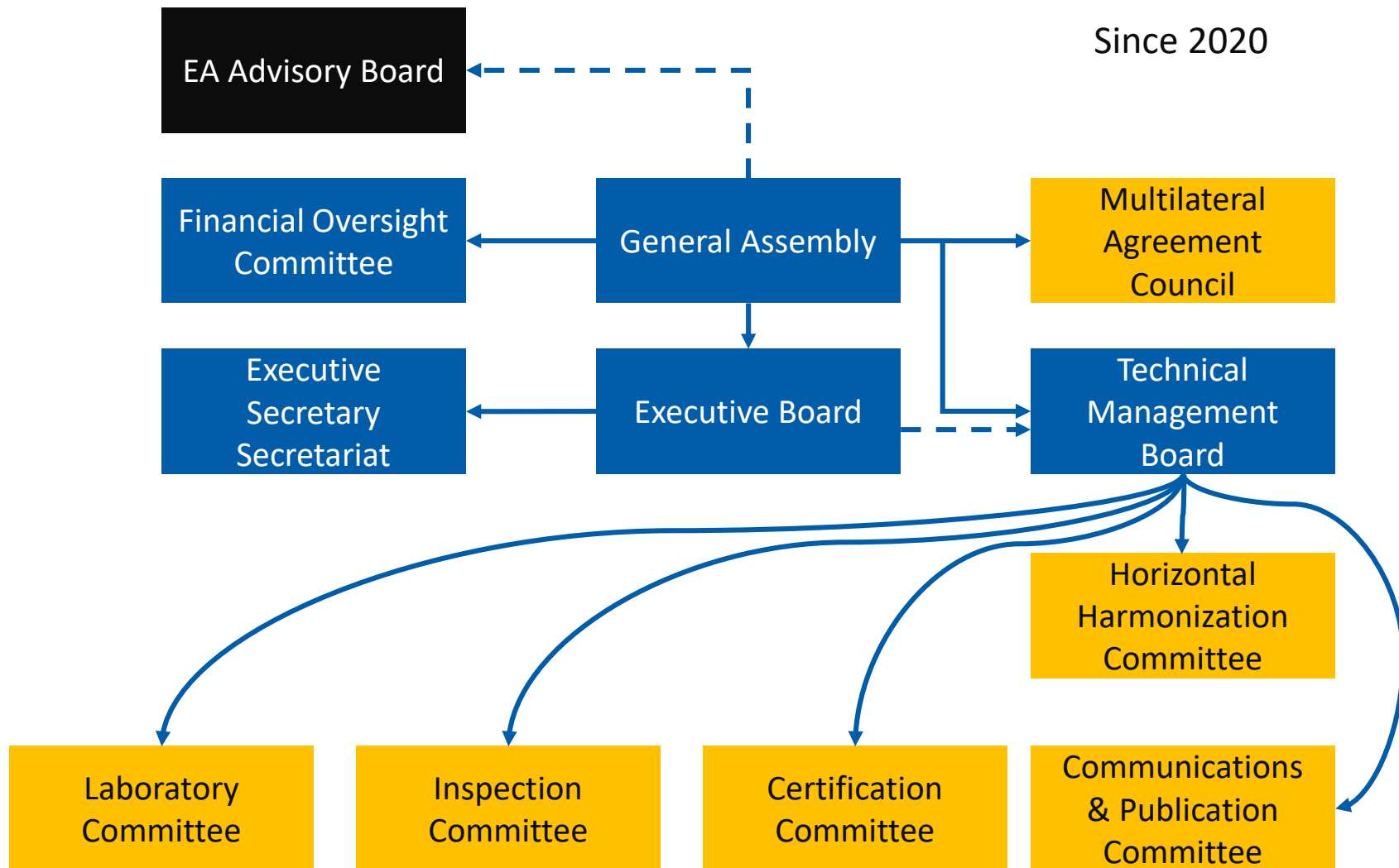
Paul Dax

JCA

14 October 2022

Welcome · Bienvenue · Willkommen

ILNAS





- **Since November 2021 (50th EA GA)**
- **4 categories of members**
- **A Members** are NABs from a:
 - Member state of EU or EFTA
 - State that has candidate status for EU or EFTA
- **B Members** are NABs from a:
 - State identified as potential candidate for EU or EFTA
 - Member state of the Council of Europe and signatory of a trade agreement
- **C Members** are NABs from a:
 - Member state of the Council of Europe not covered by categories A or B
 - Country identified by the EU as a country of particular importance
- **D Members** are NABs that are full members of another regional accreditation body organization



- Different voting rights for the different member types
- A members: voting rights in the general assembly and all EA committees on all topics
- B members: voting rights in the general assembly and all EA committees on all topics, except in relation with the articles of association of EA, rules of procedure of EA or with regard to the EU
- C members: no voting rights in the general assembly, same voting rights as B members in EA committees
- D members: no voting rights

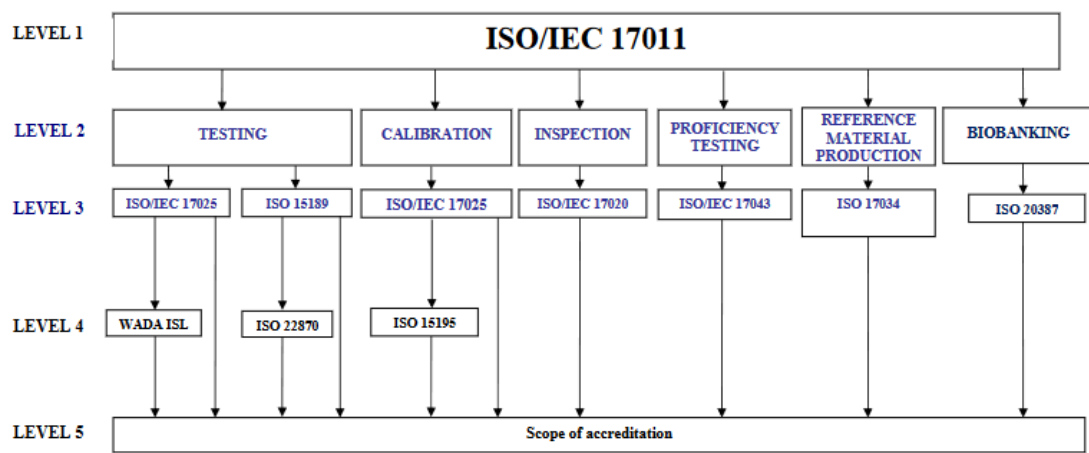


- EA has proposed to set up a **database for technical experts** (ongoing discussion)
- NABs should be able to add new experts to the database
- NABs can search for specific competence and contact experts
- But: EA Members do not agree on how to set up the database
- EA Members seem to prefer to add their accreditation managers as contact persons for specific technical domains, which would then propose technical experts on demand



EA Resolution 2021 (50) 11

- Extension of EA MLA for biobanking (upon referencing of the standard in the EU OJ)
- Biobanking is new level 2 conformity assessment activity
- Standard is EN ISO 20387:2018 (level 3)
- See also ILAC-R6:06/2022





EA Resolution 2022 (51) 04

The General Assembly, acting upon the recommendation from the Executive Board, agrees that EA considers it contrary to reasonableness and fairness if any EA member does not also comply with the EU sanction regulations. **EA members cannot offer accreditation services to Conformity Assessment Bodies in particular established in Russia and Belarus if these bodies are listed in the EU sanctions list.** Compliance with EU sanction regulations shall be deemed as an **obligation** according to paragraph 5 of EA-1/17 EA Rules of Procedure. The Executive Board may suspend a member if it does not fulfil its obligations to EA.



EA Resolution 2022 (51) 12

[...] approves that:

“The preferred standard for accreditation of **clinical pathology** is EN ISO 15189. Clinical pathology in this context is understood to contain **examinations of tissues or cell material** for the **purpose of diagnosis and eventual therapy recommendations**. It also includes the examinations of the natural deceased by means of **autopsies**. It is **not** to be understood as **forensic examinations or forensic autopsy**.

However, if the accredited services include further steps of diagnosis and eventual therapy recommendations, EN ISO/IEC 17020 could be considered to be also appropriate [...]”



- Ballot open since 15 July 2022 till December 2022
- Identified issues:
 - Alignment with recent CASCO standards
 - Item inspected
 - Independence and impartiality
 - Personnel involved in inspection
 - Management system
 - Annex A

Source: ISO CASCO – Systematic review of ISO/IEC 17020 – Accompanying information



- Alignment with recent CASCO standards
 - Align to ISO/IEC 17000:2020 with regards to the definition of inspection and the functional approach
 - Align with more recent standards like ISO/IEC 17025 and ISO/IEC 17021-1
 - Inclusion of requirements to risk of inspection

Source: ISO CASCO – Systematic review of ISO/IEC 17020 – Accompanying information

➤ Item inspected

- No definition in the current standard
- Difficulties when judging on impartiality and/or independence issues regarding the item inspected



Source: ISO CASCO – Systematic review of ISO/IEC 17020 – Accompanying information



- Independence and impartiality
 - No definition of independence in the standard, but inclusion of non-dated definition from ISO/IEC 17000 which is not in line with the use in ISO/IEC 17020
 - There is a need to redefine or clarify the different types (A, B or C) of inspection bodies

Source: ISO CASCO – Systematic review of ISO/IEC 17020 – Accompanying information

- Personnel involved in inspection
 - No definition in the standard
 - Creates confusion when defining competence requirements



Source: ISO CASCO – Systematic review of ISO/IEC 17020 – Accompanying information

➤ Management system

- The extent of internal audits for the annual audit is not defined
- It is also not clear if the 12-month frequency could be increased in accordance with the 2nd sentence of clause 8.6.4



Source: ISO CASCO – Systematic review of ISO/IEC 17020 – Accompanying information

➤ Annex A

- For type C inspection bodies, the standard should further clarify how safeguards may be put in place, when one person performs both the inspection and other activities on the item inspected



Source: ISO CASCO – Systematic review of ISO/IEC 17020 – Accompanying information



- Since the beginning of the pandemic, remote evaluations, assessments and audits get a lot of attention
- Many initiatives to define rules:
 - Standard ISO/AWI TS 17012, under development (remote audits of management systems)
 - EA-2/02 S4 G for remote peer evaluations
 - IAF MD 4:2022 for remote auditing/assessing
 - ...



- There still remain uncertainties
- Some domains are ill suited (e.g. inspection activities)
- Can not replace on site activities, might be used in alternation

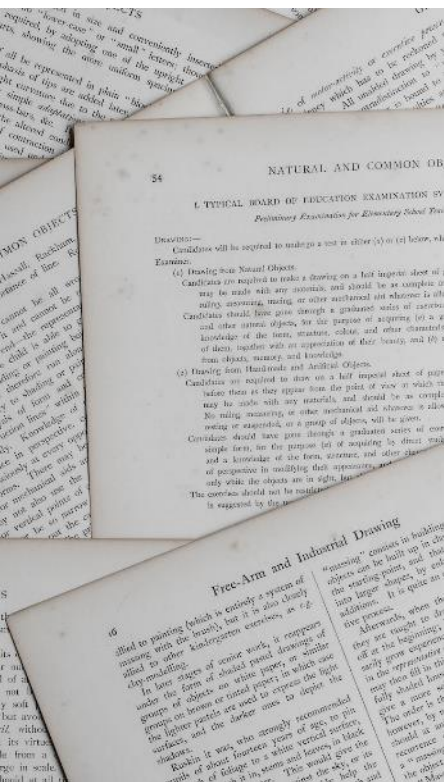
➤ IAF MD 25:2022 – Criteria for evaluation of conformity assessment schemes (similar to EA-1/22 A):

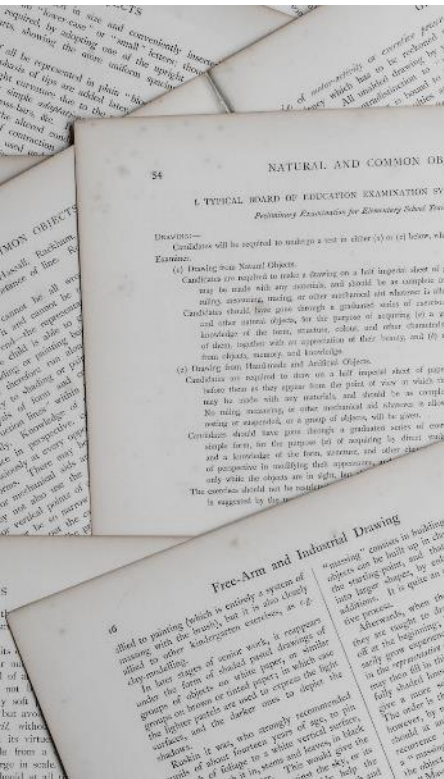
- used for schemes from scheme owners, not legal schemes
- Application from 7th January 2024

➤ IAF MD 26:2022 – Transition requirements for ISO/IEC 27001:2022:

- transition period of 3 years
- AB assessments 6 months after publication month (10/2022)

➤ IAF ID 14:2022 – Guidance on the determination of audit time for integrated audit of multi-site management systems





- EA-2/17 M:2020 – EA Document on Accreditation for Notification Purposes
 - Defines new rules for mandatory accreditation standards for EU directives
 - OLAS has started the transition period of CABs to these standards
 - End of transition period: April 2023



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Thank you · Merci · Danke

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