
ONE VOICE
THE DEFINITION
OF THE PREFERRED
ACCREDITATION STANDARD
EUROPEAN
ACCREDITATION

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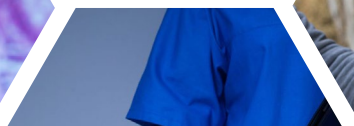

PREAMBLE

EA is the European Association of National Accreditation Bodies (NABs) and recognised by the European Commission (EC) according to Regulation (EC) No 765/2008 as the European Accreditation Infrastructure.

Pursuant to the Articles of Association, but also to the General Guidelines for the cooperation between EA, EC, EFTA, and the Competent National Authorities, EA has the following main tasks:

- Peer evaluation of the NABs,
- Harmonisation of accreditation throughout Europe,
- Cooperation with and support of the European Commission, its Departments (DGs) and Agencies as well as EFTA and other stakeholders relevant for the European Quality Infrastructure.

The harmonisation of accreditation throughout Europe is essential in order to ensure trust in certificates issued by accredited conformity assessment bodies by regulators, industry, consumers, and other parties using conformity assessment results.
Harmonisation of accreditation is also important for conformity assessment bodies of having a level playing field in Europe when offering the conformity assessment services.

The harmonisation of accreditation starts with the selection of the best suitable accreditation standard for a specific conformity assessment activity. It is one important pillar regarding the EA Policy on “One Voice” set out in document EA-1/23.

Note: The preferred standards for the accreditation of conformity assessment bodies in the regulated harmonised sectors are set out in EA-2/17 EA Document on Accreditation for Notification Purposes.
The definition of the accreditation standard in conformity assessment schemes, established by private scheme owners, is part of EA-1/22 EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members.

Pursuant to EA-1/23 harmonisation is needed (one voice principle) whenever a situation arises in which different standards for the accreditation of conformity assessment bodies (so-called level 3 standards) are used or could be used by NABs for the same activity. But first it should be decided whether such a case constitutes a case for application of the one voice principle.

Only comparable situations should be analysed for the preferred standard. Significant differences in the usage of conformity assessment activities might lead to different and incomparable situations thus making the choice of a preferred standard simply impossible or inadequate. These cases should not be subject to the search for a preferred standard and should be considered as being incomparable.

EA has identified the following sectors, where EA NABs are using for the same activity different standards for the accreditation of conformity assessment bodies:

1. Medical examination: EN ISO 15189 vs EN ISO/IEC 17025
2. Sampling as a stand-alone activity: EN ISO/IEC 17025 vs EN ISO/IEC 17020
3. Forensic activities / autopsy: EN ISO/IEC 17020 vs EN ISO/IEC 17025
4. Clinical pathology: EN ISO 15189 vs EN ISO/IEC 17020
5. Reference Material Producers: EN ISO 17034 vs EN ISO/IEC 17025
6. Legal metrology: EN ISO/IEC 17025 (calibration) vs EN ISO/IEC 17025 (testing) vs EN ISO/IEC 17020
7. Non-destructive testing: EN ISO/IEC 17020 vs EN ISO/IEC 17025
8. Food and feed sector: EN ISO/IEC 17065 vs EN ISO/IEC 17021-1
9. Forrest schemes: EN ISO/IEC 17021-1 vs EN ISO/IEC 17065

These cases have been evaluated by EA in order to decide whether one specific standard shall be applied by EA national accreditation bodies and if agreed, which shall be the best suitable standard for the accreditation.

Note: Even in case that another standard than the preferred one can be applied by national accreditation bodies, only the preferred standard shall be recommended to scheme owners, including the European regulator, for application, when preparing schemes/legislations.

This report includes the evaluation results for the first 9 sectors/activities identified for harmonisation. It shall support NABs when selecting the standard for the accreditation of a conformity assessment body and EA peer evaluators when evaluating a NAB. It can be of interest also for the conformity assessment bodies, stakeholders, and other interested parties.
The report will be updated as soon as other sectors/activities have been identified for harmonisation.

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1 - MEDICAL EXAMINATION: ISO 15189 VS ISO/IEC 17025

EA Resolution 2022 (52) 12
The General Assembly, acting upon the recommendation of the Technical Management Board and based on the endorsement from the Horizontal Harmonization Committee, approves that:
The preferred standard for the accreditation of medical laboratories is EN ISO 15189. For distinct activities, which are not direct patient-related, EN ISO/IEC 17025 can also be used. That applies also to the case, that a national regulator requires the accreditation of a medical laboratory according to EN ISO/IEC 17025.

EN ISO 15189: Medical laboratories - Requirements for quality and competence

EN ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

According to EA Resolution 2022 (52) 13, the General Assembly allows for the implementation of this Resolution an implementation period of five years.

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2 - SAMPLING AS A STAND-ALONE ACTIVITY: EN ISO/IEC 17025 VS EN ISO/IEC 17020

EA Resolution 2022 (52) 11
The General Assembly, acting upon the recommendation of the Technical Management Board and based on the endorsement from the Horizontal Harmonization Committee, approves that:
The preferred standard for the accreditation of bodies performing sampling as a stand-alone activity is EN ISO/IEC 17025. EN ISO/IEC 17020 could be considered to be also appropriate provided that all the corresponding requirements of the preferred standard are used as additional requirements within the accreditation process.

Note: This resolution amends EA Resolution 2015 (35) 20.

EN ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

EN ISO/IEC 17020: Conformity assessment - Requirements for the operation of various types of bodies performing inspection

According to EA Resolution 2022 (52) 13, the General Assembly allows for the implementation of this Resolution an implementation period of five years.

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3 - FORENSIC ACTIVITIES / AUTOPSY: EN ISO/IEC 17020 VS EN ISO/IEC 17025

The Technical Management Board approved on 16 September 2022 that there is no need to define a preferred accreditation standard for forensic autopsy and other forensic activities.

EN ISO/IEC 17025 and EN ISO/IEC 17020 can be applied for the accreditation of laboratories performing forensic autopsy or other forensic activities, unless a scheme owner defines the standard which shall be applied for a specific activity.
ILAC-G19 Modules in a Forensic Science Process provides additional information to determine the best suitable standard for a specific forensic activity.

EN ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

EN ISO/IEC 17020: Conformity assessment - Requirements for the operation of various types of bodies performing inspection

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4 - CLINICAL PATHOLOGY: EN ISO 15189 VS EN ISO/IEC 17020

EA Resolution 2022 (51) 12
The General Assembly, acting upon the recommendation of the Technical Management Board and based on the endorsement from the Horizontal Harmonization Committee, 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 provided all the requirements of the preferred standard are used as additional requirements within the accreditation process."

EN ISO 15189: Medical laboratories - Requirements for quality and competence

EN ISO/IEC 17020: Conformity assessment - Requirements for the operation of various types of bodies performing inspection

According to EA Resolution 2022 (52) 13, the General Assembly allows for the implementation of this Resolution an implementation period of five years.

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5 - REFERENCE MATERIAL PRODUCERS: EN ISO 17034 VS EN ISO/IEC 17025

The Technical Management Board approved on 22 November 2021 that there is no need to identify the preferred accreditation standard. The level of guaranty offered by a Reference Material certificate issued by a Reference Material Producer accredited according to EN ISO 17034 and by a calibration certificate or testing report delivered by a laboratory accredited according to EN ISO/IEC 17025 are different.

EN ISO 17034: General requirements for the competence of reference material producers

EN ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

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6 - LEGAL METROLOGY: EN ISO/IEC 17025 (CALIBRATION) VS EN ISO/IEC 17025 (TESTING) VS EN ISO/IEC 17020

The Executive Committee approved on 09 September 2020 that there is no need to identify the preferred accreditation standard for legal metrology.

Note: Until December 2020, the former Executive Committee was responsible for decisions regarding the need of identifying the preferred standard for accreditation.

The evaluation of the preferred standard in metrology covered two different areas, legal metrology, and 'normal' metrology.
In legal metrology, the preferred standard for accreditation cannot be identified by EA, because there are significant differences in national legislations. More harmonisation regarding the accreditation of conformity assessment bodies in legal metrology can only be achieved by harmonised legislations.
The evaluation of 'normal' metrology could not demonstrate that there is a significant number of instruments or situations where different accreditation activities (ISO/IEC 17025 calibration vs ISO/IEC 17025 testing) have been applied by the NABs. Therefore, it has been agreed that the EA Laboratory Committee shall further analyse the possibilities of providing advice for individual instruments / situations regarding the preferred accreditation standard.

EN ISO 15189: Medical laboratories - Requirements for quality and competence

EN ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

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7 - NON-DESTRUCTIVE TESTING: EN ISO/IEC 17020 VS EN ISO/IEC 17025

The Executive Committee approved on 24 November 2020 that there is no need to identify the preferred accreditation standard for Non-Destructive Testing (NDT).
The evaluation demonstrated that the choice of the best suitable accreditation standard is mainly based on the type of conformity assessment activity to be accredited. NDT can be performed in a laboratory or on the client's site. Furthermore the question, whether professional judgement / interpretation of the results shall be covered by the accreditation, has an impact on the selection of the best suitable accreditation standard.

EN ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

EN ISO/IEC 17020: Conformity assessment - Requirements for the operation of various types of bodies performing inspection

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8 - FOOD AND FEED SECTOR: EN ISO/IEC 17065 VS EN ISO/IEC 17021-1

The Technical Management Board approved on 01 September 2021 that there is no need to identify the preferred accreditation standard in the food and feed sector. It is the responsibility of the scheme owner to define the best suitable conformity assessment activity and accordingly the standard which shall be applied for the accreditation of Conformity Assessment Bodies.

EN ISO/IEC 17065: Conformity assessment - Requirements for bodies certifying products, processes and services

EN ISO/IEC 17021-1: Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements

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9 - FORREST SCHEMES: EN ISO/IEC 17021-1 VS EN ISO/IEC 17065

The Technical Management Board approved on 02 February 2022 that there is no need to identify the preferred accreditation standard. It is the responsibility of the scheme owner to define the best suitable conformity assessment activity and accordingly the standard which shall be applied for the accreditation of Conformity Assessment Bodies.

EN ISO/IEC 17065: Conformity assessment - Requirements for bodies certifying products, processes and services

EN ISO/IEC 17021-1: Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements

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