

# **Krav til præstationsprøvning Revideret ILAC P9 og udkast for revideret AB3**

Akkrediteringsdagen 10. og 13. juni 2024  
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## Revision af ILAC P9

- ILAC P9 blev sendt i høring hos medlemmerne
  - 1. gang juli 2019
  - 2. gang januar 2021 (under COVID19)
- I årene 2020-2022 var alle ILAC møder remote og AIC chair bestemte sig for at afvente genoptagelse af normal mødeaktivitet.
- ILAC P9 blev sendt i høring for 3. og sidste gang august 2023, og efter hektiske drøftelser tilrettet og sendt til afstemning ultimo 2023.
- ILAC P9 blev vedtaget januar 2024 og implementeringsfristen er 1 år.

## 2. Udkast revideret ILAC P9

- 1) A PT provider, accredited to ISO/IEC 17043 [10] by an AB signatory of the ILAC MRA for PT providers
- 2) A PT provider, accredited to ISO/IEC 17043 [10] by an AB non-signatory of the ILAC MRA for PT providers
- 3) Participation in an ILC, which is organized for other purposes than determining laboratory competence (ISO/IEC 17043[10], Introduction points h-j) and that has been evaluated and confirmed to be in accordance with ISO/IEC 17043 [10]:
  - h) evaluation of the performance characteristics of a method – often described as collaborative trials;
  - i) assignment of values to reference materials and assessment of their suitability for use in specific test or measurement procedures; and
  - j) support for statements of the equivalence of measurements of National Metrology Institutes through “key comparisons” and supplementary comparisons conducted on behalf of the International Bureau of Weights and Measurement (BIPM) and associated regional metrology organizations.
- 4) Organisation or participation in competent ILC’s organized, in accordance with the requirements of ISO/IEC 17043 [10], to determine the performance of accredited organisations by comparison with results of other laboratories.

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## ILAC P9:01/2024

8) The AB shall define its process on the use of PT and/or ILCs other than PT. The process shall include, at least, the following:

....

d) how the AB ensures that the CABs have appropriate evidence of the competence of the PT provider or the organization providing ILCs other than PT (see Appendix A).

## ILAC P9:01/2024

AB3 NYT 3.9 Laboratoriet skal vælge kompetente udbydere af præstationsprøvning og have passende vidnesbyrd for udbyderens kompetence. Akkrediterede præstationsprøvningsprogrammer omfattet af EA's MLA og ILAC's aftale om gensidig anerkendelse (ILAC Arrangement) opfattes som leveret af en kompetent udbyder. I andre tilfælde og/eller ved sammenligning med andre laboratorier lægges vægt på nedenstående punkter, **hvor relevant og muligt**:

- At referenceværdier overholder krav om metrologisk sporbarhed jf. afsnit 4;
- At laboratorier, der sammenlignes med, er akkrediteret indenfor det relevante område;
- At sammenligningen kræves af myndigheder;
- At relevante krav i DS/EN ISO/IEC 17043 tages i betragtning;

## ILAC P9:01/2024

P9 item 5 pkt. 1): Taking into consideration the outcome of the **CAB's risk assessment**, participation in PT and/or ILCs other than PT is considered, by ISO/IEC 17025:2017 as mandatory when available, appropriate and deemed necessary. For ISO 15189:2022, participation in PT is considered mandatory when available, appropriate and deemed necessary.

*Nyt krav i AB3*

3.8 Laboratoriet skal udarbejde planer for deltagelse i sammenlignende prøvninger og opretholde registrering heraf. Planerne skal udformes på en sådan måde, at det er muligt at vurdere, om omfanget dækker akkrediteringsområdet på relevant vis **og i henhold til identificerede risici**....

## Næste skridt

- AB 3 sendes i høring medio 2024.
- Udover de viste ændringer er der nyt Bilag 2, som er en decideret oversættelse af appendix i ILAC P9.
- Udgivelse forventes medio efteråret 2024.

