

Webinar for standard drafters of 2018-11-06 Questions & answers

Conformity Assessment

Questions asked by the Attendees	Answers from the Presenter
In CPR AVCP 1, can a laboratory be notified?	Yes it can. It will depend on the standard and whether there is a task for a notified laboratory for that specific product standard (reflected in AVCP system decision/delegated act).
The conformity assessment responsibility can be given to one party, e.g., first-party?	Requirements for the object shall be written in a way, that the responsibility for the performance of the conformity assessment can be taken by any party (neutrality principle).
A Conformity Assessment made by one party can be used as basis for the assessment made by another party e.g. EN 206 identity testing)?	The Conformity Assessment tools i.e. testing, inspection and certification are meant to be applied in a modular way. For instance, using test results as basis for certification or certified components for inspection purposes.
Related: can you give an example of a requirement mentioned in a Conformity Assessment?	One example is EN 13369:2018: "this document specifies the requirements, the basic performance criteria and the Assessment and Verification of Constancy of Performance (AVCP) for unreinforced, reinforced and pre-stressed precast concrete products."
What is wrong with demanding that an independent party should do the assessment?	Requirements for the object shall be written in a way, that the responsibility for the performance of the conformity assessment can be taken by any party (neutrality principle).
Do I understand correctly that any requirements for the Conformity Assessment should be written down in a document, separate from the standard?	The requirements should be available in a separated deliverable.
What is the difference between validation and verification?	Validation and verification as conformity assessment tools apply to claims as objects of assessment. Claims referring to events not yet occurred can be confirmed by validation. Claims referring to events that have already occurred can be confirmed by verification.
In CEN/TC452 the object of assessment	Without going into detail, we could suggest to consider providing a service or a process and therefore you would need to specify the specific requirements (e.g.



is an assistance dog; There was no conformity assessment body responsible for animals listed in your slide. I am most interested in all information that will help us draft conformity assessment requirements for assistance dogs.	for the training) to be assessed.
Why is not only one body that will take care of the accreditation?	The European regulation 765/2008 foresees one accreditation member per member state.
The standards are written by an EU country why only one organization can do the accreditation?	The European regulation 765/2008 foresees one accreditation member per member state.
Could you clarify the comments on slide 23 clause 10.2 please - the Clause states when required by a contract or in provisions in the place of use, surely this is not breaching the neutrality principle it is following the principles you laid out earlier in the presentation?	The neutrality principle needs to be followed in the standard, even if contractual situations or legal provisions, can impose the intervention of certification bodies.
I toughed that the Keymark certification was replaced by ENEC?	The KeyMark certification is still valid. Please check our website: https://www.cen.eu/work/keymark/Pages/default.aspx
The bodies that needed to be assessed did not want to spend much time and money for the assessment and preferred a 3rd body that was not to strict in order to prevent a fail and a re-assessment. the 3rd parties knew that and were not as strict as they should have been, in order to get more work.	Not knowing in detail the case, this seems a clear case where the main requirements of the standard and or the conformity assessment scheme in place was not followed.
Question on slide 15: does this mean that testing apparatus should (shall) not be too complex and expensive, because then 1st party assessment is not (practically) possible anymore?	The slide 15 refers to neutrality principle and nothing about complexity of testing and assessment procedures.