



For IEC use only

CAB/2034B/CC

2020-10-26

INTERNATIONAL ELECTROTECHNICAL COMMISSION

CONFORMITY ASSESSMENT BOARD

SUBJECT

Comments received on CA in ISO/IEC FDIS 27034-4

BACKGROUND

1. The CAB was invited to comment on document: CAB/2034/DC (which was subsequently replaced by CAB/2034A/DC due to an error on the cover page, where the number of the standard was incorrectly indicated as 17034-4 instead of 27034-4).
2. END OF COMMENTING: 2020-10-23

Total comments received : 8

3. The CAB Secretariat has also attached the comments received from the CAB subgroup that first reviewed the document.

ACTION

CAB is invited to note the comments.

COMMENTS

Member	Sequence	Comments
Cole, Martin (CA)	1	I agree with the CAB subgroup that this document has a number of serious problems and should not have moved to FDIS. a
Cole, Martin (CA)	2	I'm not sure the wording pf the recommendation is correct. The vote on final approval for this FDIS stage needs to be withdrawal immediately or all votes should be negative. (It's difficult to stop documents once they've reach FDIS)
Cole, Martin (CA)	3	The recommendation should be to either withdrawal the FDIS or for all member bodies to vote negative (which will return it to the MT) so that further development can take place to correct the concerns noted (by others) before resubmitting it as an FDIS.
Hirata, Masayuki (JP)	1	CAB JP member supports the recommendation from the CAB subgroup. But, ISO/IECFDIS 17034-4 is the mistake of ISO/IECFDIS 27034-4.
Imgrund, Gerhard Johannes (DE)	1	We are in favour of stoppning the development of this publication.
Nava y Uribe, Rafael Luis (MX)	1	I agree with CAB subgroup recommendation
Nava y Uribe, Rafael Luis (MX)	2	Also I agree to make a formal recommendation to SMB
Selva, Pierre Andre (FR)	1	CAB FR Member supports the CAB position : to stop the further development of this ISO/IEC 27034-4 standard
Sterling, Joan E. (US)	1	The US supports the recommendation of the CAB sub group and the SMB to reject this document, and supports the comments of the CASCO Secretary
Vagdia, Rajeev (GB)	1	Support the recommendation from the CAB subgroup and to make a formal recommendation to SMB to stop the development of this publication.
Wennersten, Fredrik Per (SE)	1	Dear All, just a small comment reflexing a typing error. The CAB document is called and referring to 17034-4 but the standard in question is called ISO/IEC 27034-4?

Selection of comments received from a CAB focus group.
2020-10-08

Comments on ISO/IEC FDIS 27034-4 itself:

...the concerns raised by Sean in his comments seem to be documented enough to not allow such a standard be published as it is.

Based on a cursory review of this document it is not a technical standard but a conformity assessment document.

The document is directed at (future) scheme owners and how they are to apply the requirements of the related technical standards within this series which should be able to stand alone. Sean notes a number of challenges and inconsistencies in the materials. Of particular note, while this is a document related specifically to validation/verification, it does not even list ISO/IEC 17029 as a normative reference. ISO/IEC 17029, on the other hand, already references a number of considerations for scheme owners related to validation/verification schemes. There are additional references to personnel certification which is by definition a third party system and would not meet 'neutrality principle' definition in Clause 33.1 of the Directives.

While it is not clear in my cursory review if the requirements of ISO/IEC Directives Part 2 and the IEC Supplement use of CA are not in compliance with the 'neutrality principle' of Clause 33.1 in other regards, I have the following notes related to our CA guidance materials

(https://www.iec.ch/standardsdev/resources/CA/documents/Guidance_for_CA_when_writing_standards.pdf)

- Clause 4 appears to not have been met: "Such documents shall not include requirements related to conformity assessment other than requirements which are necessary to provide repeatable and reproducible conformity assessment results." The numerous references to scheme and scheme owners do not meet the spirit of this requirement.
- Clause 4.1 states that requirements or recommendations concerning 'specific conformity assessment systems or schemes to be applied' shall not be contained in normative documents.
- Based on this consultation with CAB, Clause 4.4 states 'IEC/TCs should avoid spending resources in specifying CA requirements as in the end the standard will likely fail approval, or the standard may need to be modified when IEC editors become aware of a conflict with the Directives.'
- Clause 33.2 specifically states that 'Committees shall not develop documents providing general requirements for conformity assessment schemes and systems.' These are left to CASCO and CAB. This document has numerous references that do not meet this requirement.
- Per 4.6 (as well as 4.8 and 4.9), these materials should have consulted with CASCO and CAB 'prior to commencement of the work'. It should be noted that validation/verification are keywords that should have triggered early action as identified in Annex A1.

The fact that this work is so far along is unfortunate. Allowing it to proceed would be against the requirements of the Directives and set precedence for such work which is explicitly not allowed.

The ISO/IEC FDIS 27034-4 document is riddled with terminology that should never be in an IEC standard. Examples of words that should immediately raise red-flags are listed in Annex 1 of the document *Conformity Assessment Aspects in Normative Documents - Guidance for IEC standards writers* which can be obtained here https://www.iec.ch/standardsdev/resources/CA/documents/Guidance_for_CA_when_writing_standards.pdf

I agree with all the concerns... [given above].

Comments on what to do with ISO/IEC FDIS 27034-4:

...it becomes evident, that it would be difficult to discuss only several aspects of the document, or several line/sentence. It seems the whole concept of the document is intend to be like a CA Scheme document.

We need to send the stop message very clearly, and include an explicit request that ISO don't go it alone. If we don't stand firm then it will suggest that we don't really care, and encourage wrong future actions.

I fully agree [to the previous statement]

It would be beneficial for IEC and ISO to stand united with the [ISO/IEC] Directives in making a single decision.

Comments on the ISO/IEC Directives process for such issues:

This is an illustration of the failure of the system, which I think would be beneficial to address properly by ISO/IEC/JTC1 so this type of problem does not continue in the future.

I somewhat disagree with [the] comment "This is an illustration of the failure of the system..." [just above].

Yes, this was not caught early in the development process, but it was caught.

The new process that was negotiated with SMB, TMB, and the CASCO Secretariat has caught this now, but the process was not in place at an earlier stage of the development of this standard.

I agree that the process is not yet perfect, but it is a big step forward, and without it, this standard would have gone straight through to publication without a hitch.

All of this draws into question the correct application (over many years) of the ISO/IEC Directives.

It is certainly clear that more work needs to be done to ensure an improved process with clear responsibilities related to adherence to the Directives by both ISO and IEC.