

## Result of online voting and comments

OIML-CS/SC 7

**p 6: New OIML Document Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology**

**PG phase: 1 CD circulated to PG for vote and comment**

Deadline: 2022-04-04

Status: Closed

Voted Yes: 8

Voted No: 0

Abstain: 0

| Country        | Action    | Comment           |
|----------------|-----------|-------------------|
| AUSTRALIA      | Voted Yes | Comments provided |
| CANADA         | Voted Yes | Comments provided |
| FRANCE         | Voted Yes |                   |
| GERMANY        | Voted Yes |                   |
| INDIA          | Voted Yes |                   |
| JAPAN          | Voted Yes | Comments provided |
| SLOVENIA       | Voted Yes |                   |
| UNITED KINGDOM | Voted Yes | Comments provided |

## Template for comments and convener's observations

Date:2022-04-05

Document: OIML-CS\_SC7\_P6\_N010

Project: OIML-CS/SC 7/P 6

| Country Code <sup>1</sup> | Part | Clause/ Subclause | Paragraph/ Figure/Table                      | Type of comment <sup>2</sup> | Comments   | Proposed change  | Convener's responses   |
|---------------------------|------|-------------------|--|------------------------------|--|--|--|
| 0001<br>CA                |      |                   |  | ge                           | Canada will vote yes for the 1CD new OIML Document D xx Guide for the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities under the OIML-CS with the understanding that if required the additional requirements that were identified in PD-03 will be added to the final document |  | Noted. Addressed by responses to comments 0002 and 0011.   |
| 0002<br>AU                | I    | Preamble          | Para 6                                       | Ge                           | Considering the recent work of the Maintenance Group of the OIML-CS in reviewing OIML-CS PD-03, we suggest the following clauses of ISO/IEC 17065 are included in the 6 <sup>th</sup> paragraph of the preamble: 4.1.2, 4.1.3, 4.4, 4.6, 5.2, 7.4, 7.5, 7.6, 7.11 and 7.13.6.                            | Update the 6 <sup>th</sup> paragraph with the following clauses of ISO/IEC 17065: 4.1.2, 4.1.3, 4.4, 4.6, 5.2, 7.4, 7.5, 7.6, 7.11 and 7.13.6.   | Agreed. Amended to align with the revised PD-03.   |
| 0003<br>JP1               | I    | Introduction      | G.0.-2                                       | ed                           | "Amplifications" seems to be a typo.<br>"This Document includes <u>amplifications</u> of ISO/IEC 17020 in Part I, and..."  | Suggest correcting "amplifications" to "applications" as follows.<br>"This Document includes <u>applications</u> of ISO/IEC 17020 in Part I, and..."   | Partially agreed. Changed to "elaborations".   |
| 0004<br>JP2               | I    | 1                 | G.1.-2                                       | te                           | Add "claiming their status with conformance to the requirements of ISO/IEC 17020" for clarity and correctness since the majority of the Issuing Authorities would still claim their competence through conformance to ISO/IEC 17065.<br><br>Furthermore, take our comment JP3 into consideration.        | Insert "claiming their status with conformance to the requirements of ISO/IEC 17020" to the text as follows.<br>" <i><u>Inspection Bodies</u></i> are OIML Issuing Authorities <b><i>claiming their status with conformance to the requirements of ISO/IEC 17020</i></b> under the OIML-CS.  | Partially agreed. A reference to G.3.5-1 has been included, with some additional text included in G.3.5-1. |
| 0005<br>JP3               | I    | 4                 | G.4.1.6-1 and others throughout the document | ed                           | Distinguish "inspection bodies that are OIML Issuing Authorities under the OIML-CS" from the general term "inspection bodies". Using capitalized "Inspection Bodies" for the OIML purpose and "inspection bodies" for the general term may work.   | Use "Inspection Body" for the first one since it is for the OIML-CS.<br><br>"The <b><i>Inspection Body</i></b> must be a third-party (type A) inspection body to be an OIML Issuing Authority under the OIML-CS."<br><br>Furthermore, change to " <b><i>Inspection Body</i></b> " throughout the document for those used in the meaning specific for the purpose of the OIML-CS. | Agreed.  |
| 0006<br>JP4               | I    | 7                 | G.7.1.5-1                                    | Te/ed                        | The statement is not relevant to 7.1.5.<br>It is related to G.4.1.2.2-1 of Part II, however, the same statement already exists there.  | Delete G.7.1.5-1.  | Agreed.  |

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<sup>2</sup> Type of comment: ge = general te = technical ed = editorial

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|---------------------------|------|-------------------|-------------------------|------------------------------|---|--|---|
| 0007<br>JP5               | I    | 7                 | G.7.1.6-3               | ed                           | <p>The content of paragraph one and two are the same.</p> <p><i>Any adjustment or modification during the type evaluation process shall be authorised by the inspection body. Such adjustment or modification may be performed by the manufacturer.</i></p> <p><i>During the type evaluation process the manufacturer is not authorized to perform any adjustment and/or modification without authorisation of the inspection body.</i></p> | <p>Since the wording of the second paragraph is better, delete the first paragraph.</p> <p><del><i>Any adjustment or modification during the type evaluation process shall be authorised by the inspection body. Such adjustment or modification may be performed by the manufacturer.</i></del></p> <p><i>During the type evaluation process the manufacturer is not authorized to perform any adjustment and/or modification without authorisation of the inspection body.</i></p> | Agreed.   |
| 0008<br>JP6               | I    | 8                 | G.8.2.4-2               | ed                           | <p>It seems unclear what “and results received from applicants, from subcontractors or from signatories of a mutual arrangement/ agreement OIML-CS” means upon this specific document statement.</p>  | <p>Delete “and results received from applicants, from subcontractors or from signatories of a mutual arrangement/ agreement OIML-CS” in the last dot point of G.8.2.4-2 as shown below.</p> <p><i>• procedures for accepting and handling test reports. and results received from applicants, from subcontractors or from signatories of a mutual arrangement/ agreement OIML-CS.</i></p>  | Not agreed. The text is the same as the corresponding clause in D 32.   |
| 0009<br>UK                | I    | G.8.6.2-1         | 1                       | te                           | <p>There are additional requirements in PD-05 (e.g. content of type evaluation report) and PD-07 (various transitional arrangements)</p>  | Add PD-05 and PD-07  | Agreed.<br><i>Note: A corresponding amendment to D 32 is required.</i>  |
| 0010<br>UK                | I    | G.8.6.3-1         | 1                       | te                           | <p>This clause relates to the audit themselves rather than the audit programme. The first part is a repetition of G.8.6.2-1 (although not entirely), the second part would be better under 8.6.5 (f - the results of the audit are documented).</p>   | <p>Change G.8.6.3-1 to No OIML guidance</p> <p>Add G.8.6.5-1: For inspection bodies that are OIML Issuing Authorities under the OIML-CS the internal audit programme shall take into consideration the requirement to report annually to the OIML-CS Management Committee.</p>   | Partially agreed. 8.6.3 has been changed to “No guidance”, and the text “the requirement to report annually to the OIML-CS Management Committee” has been added to G.8.6.2-1. |
| 0011<br>AU                | II   |                   |                         | Ge                           | <p>Include the following clauses of ISO/IEC 17065 in Part II of this Document:</p> <p>5.2, 7.4, 7.11 and 7.13.6.</p>  | <p>Include the following clauses of ISO/IEC 17065 in Part II of this Document:</p> <p>5.2, 7.4, 7.11 and 7.13.6.</p>   | Agreed.   |

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|---------------------------|------|----------------------|----------------------------|---------------------------------|---|--|--|
|                           |      |                      |                            |                                 | The OIML guidance should be aligned with that specified in OIML D 32:2018.  | The OIML guidance should be aligned with that specified in OIML D 32:2018.   |  |
| 0012<br>JP8               | II   |                      |                            | Te/ed                           | 5.2 of D 32 is important to safeguard impartiality of inspection bodies.  | Cite the entire section of 5.2 of D 32.<br><br><i>OIML guidance to subclause 5.2.1 (G.5.2.1-1)<br/>G.5.2.1-1 The mechanism which safeguards impartiality may result from general provisions concerning the organization of public administrations.<br/>5.2.2 No OIML guidance<br/>5.2.3 No OIML guidance<br/>5.2.4 No OIML guidance</i>  | Agreed.  |
| 0013<br>JP7               | II   | 7.5.1                |                            | Te/ed                           | Under the ISO/IEC 17065, the certification body is required to place two personnel to perform the evaluation and review.<br><br>7.5.1 of ISO/IEC 17065:2012 states as follows:<br><i>7.5.1 The certification body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process.</i><br><br>Since ISO/IEC 17020 does not have such requirement to inspection bodies, we need to clarify within this document that the "Inspection Body" also needs to have at least two personnel; one for evaluation and the other for review, since we have no "OIML guidance" in D 32. | Place a Note that ISO/IEC 17065 requires two or more person in order to keep the IAs claiming competence through ISO/IEC 17020 to be aware of the requirement in ISO/IEC 17065.<br><br><i>Note: ISO/IEC 17065:2012 requires two or more personnel for the evaluation and review.<br/>"7.5.1 The certification body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process."</i> | Not agreed. Although there is no specific OIML guidance for this subclause in D 32, the requirement specified in ISO/IEC 17065, 7.5.1 will apply to the inspection body. |

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