BIML 10 No. 433/RG 2010.06.01

Note to CIML Members

Subject: Revision of OIML R 126 - OIML TC 17/SC 7 projects p1 and p2
Breath alcohol analyzers

Dear Colleagues,

The fifth Committee Draft (5 CD) of OIML R 126 was circulated to TC 17/SC 7 Members at the end of 2008 for comments. Considering the number of comments received, a meeting of TC 17/SC 7 was held on 17–18 September 2009 in Gaithersburg (USA); further to the conclusions of this meeting, a sixth Committee Draft (6 CD) was drawn up by the Secretariat.

At this meeting, TC 17/SC 7 Members agreed to risk launching, in parallel, the vote on the 6 CD among TC 17/SC 7 P-Members to transform it into a Draft Recommendation, and also the preliminary online ballot among CIML Members, to speed up the approval phase in an attempt to be in a position to submit the revision to the CIML for approval at its 45th Meeting in September 2010.

Sixteen TC 17/SC 7 P-Members voted; the results of their vote are summarized below:

- 7 P-Members voted “yes”;
- 6 P-Members voted “no”;
- 3 P-Members did not vote.

Thirty-four CIML Members voted at the level of the preliminary online ballot. The results of their vote are summarized in Annex 1 of the present Circular.

According to the Directives for the OIML Technical Work (OIML B 6-1, 3.4.4), *two-thirds of the P-Members shall vote in favor of the draft to register the Committee Draft as a Draft Recommendation*; this was not the case for the above results.

Considering the results of the votes among TC 17/SC 17 Members, those of the parallel preliminary online CIML ballot and the number of comments received (please refer to the synthesis in Annex 2 of the present Circular), the TC 17/SC 7 Secretariat has decided to proceed to a seventh Committee Draft (7 CD) to be circulated among TC 17/SC 7 Members for vote and comments in September 2010 for a three-month consultation.

This 7 CD will be drawn up on the basis of the replies to the comments received (both at TC 17/SC 7 and CIML levels). Please find in Annex 2 the synthesis of the comments and the Secretariat’s replies.

It is expected that the amendments proposed will contribute to the acceptance of the Draft Recommendation by P-Members and allow it to be submitted to the CIML for approval at its 46th Meeting in 2011.

…/ cont'd

In the meantime, if the decision of TC 17/SC 7 Members confirms the acceptance of the Draft Recommendation, it will be submitted for a preliminary online CIML ballot in January 2011 (three-month consultation).

Please do not hesitate to contact us if you require any additional information.

Yours faithfully,

Mrs. Régine Gaucher
Project Leader
BIML Contact for TC 17/SC 7

ANNEX 1
Preliminary online ballot - synthesis of votes

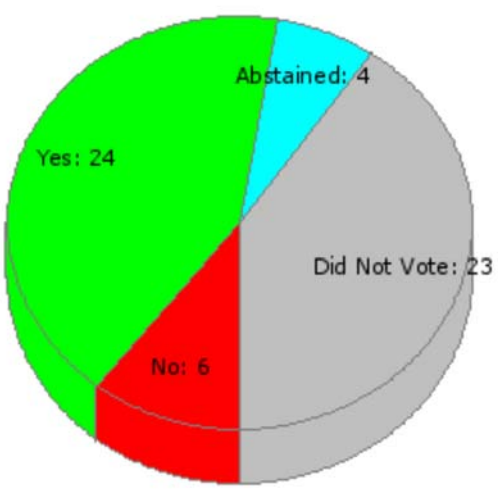
Project Number 58 (Revision of OIML R 126 Breath alcohol analyzers)

Deadline: 2010-03-31

AUSTRALIA voted No (Comments)
AUSTRIA voted No (Comments)
IRELAND voted No (Comments)
NETHERLANDS voted No (Comments)
UNITED KINGDOM voted No (Comments)
UNITED STATES voted No (Comments)

BELARUS voted Yes
BRAZIL voted Yes
BULGARIA voted Yes
CANADA voted Yes
CROATIA voted Yes
CYPRUS voted Yes
FRANCE voted Yes
GERMANY voted Yes (Comments)
KAZAKHSTAN voted Yes (Comments)
KENYA voted Yes (Comments)
KOREA (R.) voted Yes
P.R. CHINA voted Yes (Comments)
POLAND voted Yes (Comments)
PORTUGAL voted Yes
ROMANIA voted Yes
RUSSIAN FEDERATION voted Yes
SERBIA voted Yes
SLOVAKIA voted Yes
SLOVENIA voted Yes
SOUTH AFRICA voted Yes
SPAIN voted Yes (Comments)
SWITZERLAND voted Yes
TANZANIA voted Yes
VIET NAM voted Yes

DENMARK Abstained
ISRAEL Abstained
MONACO Abstained
NEW ZEALAND Abstained (Comments)



Countries who did not vote (23)

ALBANIA, ALGERIA, BELGIUM, CUBA, CZECH REPUBLIC, EGYPT, FINLAND, GREECE, HUNGARY, INDIA, INDONESIA, IRAN, ITALY, JAPAN, MACEDONIA (F.Y.R.), MOROCCO, NORWAY, PAKISTAN, SAUDI ARABIA, SRI LANKA, SWEDEN, TUNISIA, TURKEY.

ANNEX 2

CIML and TC 17/SC 7 comments on CD 6	
Comments on:	**Revision of OIML R 126: Breath alcohol analyzers**

Country	Document clause	Comments	Secretariat's replies
Australia	General comment	Most of the issues listed are editorial and not fatal. The vote against progression of 6CD to Draft Recommendation stage is due to the large number of changes required. The 6CD file distributed to Australian stakeholders, that the majority of comments relate to, was the zip file attached in the Members voting page of the OIML website. This was found to be slightly different to 6CD distributed by email 18/12/09. The latter file was not investigated with the same amount of detail.	Noted. The large number of changes you mentioned in the 6CD were discussed and agreed at the meeting in September 2009. The differences between the marked version circulated among TC 17/SC 7 Members and the clean version circulated for the preliminary CIML ballot are due to errors when converting the MSWORD marked version in PDF. Apologies for the inconvenience.
Austria	General comment	Austria votes NO, but if our proposals are included in the final document, we will vote YES. For an evidential test 2 measurements have to be carried out. Austria is of the opinion that this rule should be added in Part 1 chapter 5, metrological requirements. Austria suggests to make also additional tests with test gases with different pressures (back pressure), there should also be some test procedures in Part 2, (Performance tests), each test shall comply with the maximum permissible error requirement; Austria suggests the pressure steps: 12 hPa, 25 hPa and 50 hPa. Breath alcohol analysers shall have a device or an additional device (mouth pipe) to detect or to avoid sucking... Austria suggests including a new requirement to avoid or to detect sucking instead of blowing. (see original R126, edition 1998)	Noted The number of measurements to be conducted is out of the scope of the Recommendation. This shall be defined in the national regulation related to alcohol consumption. The issue related to the back pressure was discussed at the meeting in 2008 and again in 2009 as mentioned in the minutes. Since no proposal was sent by the German delegation, the text related to back pressure has not been modified (maintained as it was in the 5CD) 6.16 of R126:1998 has been moved to 8.2 of the 6CD.

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Country	Document clause	Comments	Secretariat's replies
Kazakhstan	General comment	It is necessary to indicate the concentration of alcohol in exhaled air in milligrams per cubic decimeter	Not accepted. However this does not prevent national regulations from specifying other units as specified in the third paragraph of 4 (6CD).
Spain	General comment	Our vote is positive but we suggest including information about the recommended test for initial and subsequent verifications. In the scope of the Recommendation it is stated that: "The purpose of this Recommendation is to enumerate the minimum metrological specifications and tests applicable to type approval, initial verification, and in-service verification of quantitative breath alcohol analyzers recognizing national differences in legal systems." But all references to this information have been removed except for mpe, we think it is really important for harmonization to make a recommendation about the test that should be performed.	Accepted. The last sentence of the last paragraph of the scope will be modified as follows: "*The purpose of this Recommendation is to enumerate the minimum metrological specifications and tests applicable to type approval of quantitative breath alcohol analyzers recognizing national differences in legal systems. It also gives guidance for establishing metrological specifications for initial and in-service verifications*." It is not the purpose of OIML Recommendations to specify tests to be performed at initial and subsequent verifications.
New Zealand	General comment	New Zealand is concerned that six P-Members of TC17/SC7 have voted 'No' to draft 6CD *Revision of R126 Breath Alcohol Analyzers.* In New Zealand the law enforcement authority using *Breath Alcohol Analyzers* has equivalent methodologies to their Australian counterparts. As a result we support and endorse the comments they have made on this document. At this stage New Zealand has abstained from voting until such time as the comments submitted by economies on 6CD have been considered and responded to by TC17/SC7.	Noted.

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Country	Document clause	Comments	Secretariat's replies
Poland	General comment	The text needs some technical redaction, e.g. : - temperature ranges (humidity etc) and uncertainties should be in brackets (23 ± 5) °C; - points should be written and referred to in the same way: (a) or a); - publication addresses should be written in the same way, with or without the date e.g. D31; use "breath alcohol analyzers" or "EUT", witch is appropriate, instead of "measuring instrument"	Noted. Will be under the responsibility of the BIML on final editing.
P.R. China	General comment	In my opinion, some items in the recommendation may be not tested. For example, the short–term drift and long-term drift. Because this device may not be in continues use for several hours.	Not accepted. Between the two series of 10 measurements for each type of drift, the instrument may be either powered on or off.
P.R. China	General comment	Test method is not according with conditions of measurement, which can not ensure the accuracy of the measurement. For as test gas volume （2±0.3）L, which is not the driver's expiration gas volume.	Not accepted. 2 L has been chosen to be representative of the mean value to comply with breath expiration of both women and men.
P.R. China	General comment	The test apparatus used in lab may be difficult in tracings, The accuracy and repeatability and stability of the alcohol gas generated from it changes with temperature , time in operation, flow rate of out-gas, and so on. So the accuracy and stability of the test gas can not be insured.	Not accepted. Several countries have longstanding experience with the implementation of OIML Recommendations in their national regulations. Experience shows that test facilities may fulfil the uncertainty requirements specified in the 6CD (which are greater than those specified in OIML R 126:1998).
United Kingdom	General comment	Such a specification should be strict enough that any instrument complying with it will produce analytical evidence that is capable of withstanding even the most challenging defence attack. For this reason we strongly believe that plateau monitoring breath sampling with mouth alcohol detection, and a high specificity to ethanol are basic requirements.	Not accepted. This was discussed at the last TC 17/SC 17 meeting and it was decided to maintain the alternative as defined in Annex A considering the general requirement in 6.3.4. In addition, if we limit the requirement to plateau monitoring, it will be technology dependent.
United Kingdom	General comment	This document, taking into account developments in technology, should reflect greater capability than the previous document, not less.	Noted. See previous reply.

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Country	Document clause	Comments	Secretariat's replies
United States	General comment	The US must vote no at this time even though we are appreciative of the Secretariat's efforts. The US cannot support the current software requirements in R126. We understand that they were just added to the document in the 6CD. We did discuss and the minutes reflect a decision at the meeting that the minimum examination levels would be A without code walkthrough and software module testing. In addition we feel that software separation would be beneficial to isolate the core metrological software from the state specific subject measurement requirements both of these should be controlled but the control is exercised at different levels type approval and in the state programs both levels have version control. See specific comments on Terminology, 6.4 and 11.3.3.	According to the reply to your comment on 11.3.3, level A will be included as a minimum examination level for all the software requirements. See reply to the United Kingdom on 6.4. Whatever the software structure, the whole software is considered as legally relevant. In the event that the software is divided into several parts (some of which are not legally relevant), the software examination would require the examination of the code of the various parts to validate the legally relevant ones; this is in contradiction with a level A examination.
Australia	1	Remove "for the purpose of establishing compliance with national policy for fighting against alcohol abuse". Application of instruments might not be limited to national regulatory authorities.	The current wording was agreed at the last meeting. It does not exclude the use of the specifications at local level (e.g. internal regulations at workplaces).
Australia	1	Reword the final paragraph to: "The purpose of this Recommendation is to enumerate the minimum metrological specifications applicable to type approval, initial verification and in-service verification of quantitative breath alcohol analysers recognizing national differences in legal systems. Guidelines for type approval tests are included." In 6CD it is ambiguous whether the tests for initial verification and in-service verification are included.	Accepted. See reply to Spain on general comments.
Austria	2.12	2.12 Measurement error (VIM 2.17 (1) ….. change to (VIM 2.16); In the VIM 3 / 2008 the definition of Measurement error is under point 2.16	Accepted.
Austria	2.18	Significant fault … change to "Significant fault (OIML D11, 3.10)"; refer to ID 11	Accepted.
Austria	2.20	Intrinsic error… change to "Intrinsic error (OIML D11, 3.7)"; refer to ID 11	Accepted.

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Country	Document clause	Comments	Secretariat's replies
United Kingdom	2	There are a large number of small typographical errors particularly capital letters and full stops missing.	The BIML has now decided to use the ISO rule for terminology. This is why each definition starts with a lower case letter and why there is no full stop (period) at the end of the definition.
United Kingdom	2.6	Replace "…in opposition…" with "…as opposed…"	Accepted.
United Kingdom	2	"reference value" is not defined but is used e.g. in 5.2.1 and 5.2.2 (OIML R126 1998 used "true value"). "reference value" of course is different to "reference conditions" given in 11.4.1 *which is also not defined;*	The general principle adopted is to avoid repetition in definitions so long as they already exist in the generic documents. Consequently, the definition of "reference value" has not been repeated in the Recommendation since it is included in the VIM (5.18) which is mentioned in the bibliography. This is the same for the definition of "reference conditions" which is in 3.15 of OIML D 11 and in the VIM (4.11). OIML D 11 is also mentioned in the bibliography.
United States	2	Please add appropriate definitions to section 2 on software. Definitions were not added for OIML software terminology in D31. ADD at least; 3.1.29 Legally relevant Software/hardware/data or part of the software/hardware/data of a measuring instrument which interferes with properties regulated by legal metrology, e.g. the accuracy of the measurement or the correct functioning of the measuring instrument. 3.1.30 Legally relevant parameter Parameter of a measuring instrument, electronic device, or a sub-assembly subject to legal control. The following types of legally relevant parameters can be distinguished: *type-specific parameters* and *device-specific parameters*. 3.1.31 Legally relevant software part Part of all *software modules* of a measuring instrument, electronic device, or sub-assembly that is legally relevant.	The general principle adopted is to avoid repetition of definitions which already exist in other Publications referred to in the Recommendation. OIML D 31 is listed in the bibliography.
Australia	2.4	Change "used" to "use" Editorial	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Kenya	2.4	delete "Used" and replace with "use"	Accepted.
United States	2.4	breath alcohol analyzer intended for **used** inside or outside buildings and in mobile applications… Editorial. New text: breath alcohol analyzer intended for **use** inside or outside buildings and in mobile applications…	Accepted.
United States	2.17	Abbreviations Suggest adding "BAA" to list of abbreviations used in this document as it appears in section 6.1.1 and others. Editorial New text: "BAA Breath Alcohol Analyzer"	Not accepted. There is no need for such an abbreviation. For readability, the complete name of the instrument is more appropriate.
United States	2.19	Plateau of Alcohol the plateau is the time in which the alcohol concentration is stabilized **within 99 % of the reference value** (see annex B2) This statement is incorrect; the plateau of alcohol occurs regardless of the reference value and indicates the measured value as determined by the BAA. Whether or not the plateau is representative of the reference value remains to be determined. New text: Plateau of Alcohol the plateau is the time in which the alcohol concentration is stabilized *and corresponds to the alcohol concentration representative of alveolar breath, generally obtained in the last third of the time of an exhalation (see annex B2).*	Not accepted. However, we suggest changing the definition to: *"Plateau of alcohol* *The plateau starts when the alcohol concentration (representative of the alveolar air) reaches 99 % of the true value of the gas used for testing and remains stable (see Annex B2)."*
Australia	3	6CD distributed by email 18/12/09 states: "A breath alcohol consists in general of three stages.." Insert "analyzer" after "alcohol". 6CD distributed by email on 18/12/09 differs slightly from 6CD zip file attached to the members voting page in the OIML website. The other file does not contain this particular error.	See reply to the US comment below.

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Country	Document clause	Comments	Secretariat's replies
United States	3	Description of the instrument A breath alcohol consists in general of three stages:" Editorial. New text: "Description of the instrument A breath alcohol *analysis [or test]* consists in general of three stages:"	Accepted.
United Kingdom	3.1	A mouthpiece should <u>always</u> (not "Usually…") be used for sampling whenever the subject's lips/mouth have to come into contact with part of the device in order to provide a sample. This paragraph contradicts Section **8.2**	Accepted.
Kenya	4	Delete "Admisibly" and replace with "Admisibility"	Accepted
Germany	5.2.1	Change the description into an equation: "…error shall be: (reference value – 0,9 mg/l)/2 for …" If this is not possible change the text into an unambiguous one as for example "…shall be half of the difference of the reference value and 0,9 mg/l for …".	Accepted. The current wording is ambiguous and has been misunderstood. It will be modified as follows: "$\frac{reference value}{2} - 0{,}9 mg/l$ *for all mass concentration greater than 2 mg/l"*
The Netherlands	5.2.1	MPE's are not suitable for The Netherlands. Stage / Current NL legislation / OIML 6CD R126 type-evaluation: 0,01 mg/l / 0,02 mg/l or 5% initial verification: 0,02 mg/l or 4% / 0,02 mg/l or 5% periodical re-verification: 0,025 mg/l or 5% / 0,03 mg/l or 7,5%	Noted.
Germany	5.2.2	Change the description into an equation: "…error shall be: (reference value – 1,35 mg/l)*3/4 for …" If this is not possible change the text into an unambiguous one as for example "…shall be three quarter of the difference of the reference value and 1,35 mg/l for …"	Accepted. The current wording is ambiguous and has been misunderstood. It will be modified as follows: "$reference value \times \frac{3}{4} - 1{,}35 mg/l$ *for all mass concentration greater than 2 mg/l"*
Kenya	5.2.2	Delete "whiwhever" and replace with "Whichever"	Accepted

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Country	Document clause	Comments	Secretariat's replies
Austria	5.3	We do not accept that the measured value of the three digits has to be rounded down to two digits. We would prefer mathematical rounding and not to round down because this is common practice in all other fields of legal metrology and techniques.	Not accepted. Considering the use of the instrument to fight against alcohol abuse, the general policy used for commercial transactions (mathematical rounding) is not appropriate. Rounding down is favors the person submitted to the control.
Germany	5.5.1	Change "from 0,00 mg/l " into "at 0,00 mg/l"	Accepted.
Austria	5.5.2.1	……at 0,40 mg/L shall be less than 0,01 mg/L in 4 hours. We can not accept this high value of short-term drift, because the maximum permissible error (MPE) is 0,02 mg/L (or 5 % of the reference value of mass concentration. We suggest: " ……at 0,40 mg/L shall be less than 0,0051 mg/L in 4 hours."	Not accepted. The type approval tests related to the drift is not a simulation of the in-service drift. It is not correlated to the periodic verification requirement. These tests have not been modified and are identical to those defined in OIML R 126:1998.
Austria	5.5.2.2	……at 0,40 mg/L shall be less than 0,02 mg/L in two months. We can not accept this high value of long-term drift, because the maximum permissible error (MPE) in service is 0,03 mg/L (or 7,5 % of the reference value of mass concentration). If we allow a drift of about 0,01 mg/L per month, the instrument will have an error of about 0,06 mg/l in six months and this is more than the MPE in service. In Austria we have a re-verification period of 2 years (with an additional check every 6 months by the manufacturer) , and the instruments shall fulfil the requirements of MPE in service during the use of the instruments. But if we allow a drift of 0,01 mg/l per month, this can not be fulfilled. We suggest: " ……at 0,40 mg/L shall be less than 0,01 mg/L in two months."	
United Kingdom	5.6.2	The criterion has changed from 4% in R126 1998 to 0.010 mg/L because a choice of upper range concentrations is given in **11.4.4.1c.** This choice could give ambiguous results – see comment in **11.4.4.1c**	See reply to 11.4.4.1.c)

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Country	Document clause	Comments	Secretariat's replies
Ireland	5.7	Multiple Indication Devices The meaning of this heading is not clear. If it is to be retained there is a problem with the spacing. We suggest that it should be deleted as this point is covered in 6.5.1.4.	Not accepted. This clause is general whereas 6.5.1.4 is limited to printing devices.
United Kingdom	5.8	Does not make explicit that all the physical influence factors should be tested **separately**, in contrast to Section 5.10.1.3 and R126 1998 annex B.	Accepted. The following sentence will be added: *"These provisions apply separately to each influence factor and to each error determination."*
United Kingdom	5.8.1.j (also 11.4.4.13)	Allows different hydrocarbons to be used as long as their concentrations are methane equivalent. This may give **different** results depending on the choice of hydrocarbon from C1 to C8, and aliphatic or aromatic. **This does not produce uniformity of test results**. Our suggestion is that methane is not selected, even though it is dominant in most atmospheres, but propane is selected specifically. Methane is generally prevalent in the open atmosphere but in other spaces, e.g in a vehicle other hydrocarbons may dominate and these will usually have a bigger effect on an infrared analyser.	Not accepted. The conditions specified are conventional and aim to verify that the instrument operates appropriately.
Australia	5.8.1	Footnote marker (1) is possibly missing. If not, then elaborate on which values are to be selected by the National Authority as indicated by the last row of the table. It is unclear which values the last row in the table is referring to.	The note will be deleted since there is no selection.
Poland	5.8.1	Linkage with (1) missing. Which values are to be selected by the National Authority?	The note will be deleted since there is no selection.
United States	5.8.1	Final row in table contains the text: "(1) These values are to be selected by the National Authority." Unassigned footnote – no corresponding note enumerated in text; US believes this reference used to be associated with ambient temperature Delete this text from the table or identify the note in the text.	The note will be deleted since there is no selection.

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Country	Document clause	Comments	Secretariat's replies
Austria	5.8.2	Condition of exhalation: We can not accept the given values. We prefer the values: Exhaled volume: greater than or equal to 1,5 l, Back pressure: does not exceed 15 hPa at a flow rate of 12 L/min), Flow rate: greater than or equal to 0,10 L/s, Exhalation time. Greater than or equal to 3 s. Austria would prefer a maximum back pressure of 15 hPa (at a flow rate of 12 L/min) to avoid discussions. In Austria, some tests showed that persons whose value of the pressure of breath is smaller or equal to 15 hPa are not able to drive a car. So Austria would prefer a lower limit of pressure to avoid discussions with persons refusing to blow into the breath analyser because the pressure drag is too high.	Not accepted. These figures were discussed at the last TC 17/SC 7 meeting.
United Kingdom	5.8.2	Why is a 5s minimum exhalation time defined here? A person with a small FVC who was blowing well above the minimum flow rate, could exhale enough breath to reach alveolar air in under this time.	The conditions specified are conventional and aim to cover most human behaviour.
Germany	5.10.1	Table 5.10.1.2 – change "duration" into "number of cycles". The word cycles in the following columns can be deleted in this case.	Not accepted. It conforms to the wording of 10.2.2 in D11:2004.
United States	5.10.1.1 11.4.5.8	Text within tables is inconsistent. Decide on use of lowercase, Sentence Case, or ALL CAPS in table headers and column identifiers. Editorial.	Will be checked at final editing.
Ireland	5.10.2	Physiological influence quantities The list of potential interfering substances has been reduced from 9 to 4. The following substances have been excluded: acetaldehyde, toluene, ethyl acetate, diethyl ether and methane. We believe that the best approach is for an expert sub committee to examine whether the current scientific literature supports a decision to include or exclude these substances from the list. In the absence of such a knowledge based decision, our view is that all 9 substances should be retained on the interfering substances list.	Not accepted. The list was agreed at the last meeting. A sentence has been added under the table to allow national regulations to specify additional substances to be tested.

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<table>
<tr><th>Country</th><th>Document clause</th><th>Comments</th><th>Secretariat’s replies</th></tr>
<tr><td>The Netherlands</td><td>5.10.2</td><td>An even larger problem is caused by the MPE for interfering substances:
<table><tr><td>Current NL legislation</td><td>OIML 6CD R126</td></tr><tr><td>0,01 mg/l</td><td>0,1 mg/l</td></tr></table>
As can be observed above the MPE in OIML R126 is 10 times larger than in NL legislation. The MPE is so large that persons could be fined or even
worse could be sentenced to imprisonment because of an interfering substance. For NL this is completely unacceptable.
To solve this problem NL has proposed in an earlier stage (and Germany had a similar proposal) to introduce accuracy classes.
We still strongly feel that it was an omission that this proposal was not voted upon during the meeting of TC 17/SC 7 in 2008 in Paris.</td><td>Noted.

Not accepted. This will not solve the problem.

Not agreed. The value is that of R 126:1998 and nobody requested any change. Only the number of interference substances has been changed.</td></tr>
<tr><td>United Kingdom</td><td>5.10.2 (Table)</td><td>The inclusion of only 4 Interfering Substances is not enough to ensure that the device has a proven specificity to ethanol. At the very least this Table should include all of the substances listed in the 1998 document – although experience may suggest a case for others to be included as well (e.g. Methyl iso-butylketone which is the solvent phase of many incapacitant sprays).</td><td>Noted. The table is the result of the discussions at the last TC 17/SC 7 meeting. See also reply to Ireland on 5.10.2.</td></tr>
<tr><td>United Kingdom</td><td></td><td>as well as any suggestion that mouth alcohol can be detected by double sampling [this does not get round the double-burp defence, which I did encounter with the 3000].</td><td>Not understood. No reference to any section in the CD6 has been provided.</td></tr>
</table>

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Country	Document clause	Comments	Secretariat's replies
Germany	5.11	"… to maintain an *adequate* stability …" change "*adequate*" into a more technical/ objective term or delete this word. "The stability of the metrological characteristics is well defined and such an adjective leads to personal interpretations	Accepted. "adequate" will be deleted.
United Kingdom	5.11	What is meant by the first sentence in this clause? By specifically mentioning the "…provisions in 5.8 to 5.10…", you are implicitly saying that the provisions in 5.1 to 5.7 and 5.11 do not need to be "…met durably.".	Partially accepted. References to the following section will be added: 5.2, 5.4, 5.5, 5.6.
United Kingdom	5.11	Verification period should be defined in Section 2 or at least be referred to specifically in this clause	Partially accepted. The following sentence will be added: *"The verification period is defined under the responsibility of the National Authorities (periodic or subsequent verifications)."*
Austria	6	We are missing requirements on the printing device as in the former CD	Not accepted. Requirements on the printing device are in 6.5.1.
Austria	6	Breath alcohol analysers shall have a device to detect or to avoid sucking. Austria suggests including a new requirement to avoid or to detect sucking instead of blowing. (see original R126, edition 1998) – see general comments.	See reply to your general comment
Austria	6	6.9.2 of OIML R 126 1998 was deleted. There is a big difference, if the instrument checks its operation only when it is switched on, as it is now in CD1, or if the breath alcohol analysers check correct operation automatically both before and after each measurement – see 6.9.2 of OIML R 126 1998. We suggest reinserting " 6.9.2" in the new CD version. – These instruments are usually used for evidential purpose. Therefore the security level shall be very high!	Not accepted. This has been included in the second paragraph of 6.3.

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Country	Document clause	Comments	Secretariat's replies
Austria	6.1.1	…….of 0,427 mg/L shall be reported as 0,42 mg/L in measuring mode), that is rounded down. We do not accept that the measured value of the three digits has to be rounded down to two digits. We would prefer mathematical rounding and not to round down because this is common practice in all other fields of legal metrology and techniques. - See also comment to 5.3	See reply to your comment on 5.3
Poland	6.1.1	6.1.1 Display: "In measuring mode, the minimum breath alcohol analyzer display shall be to indicate at least two digits (e.g. measured value of 0.427 mg/L shall be reported as 0.42 mg/L in measuring mode) that it rounded down." Is it correct ? In R126:1998 is "the display in normal operation shall consist of the display in metrological testing (to 0.001 mg/L) rounded down to 0.01 mg/L (e.g. a measured value of 0.427 mg/L shall be displayed as 0.42 mg/L in normal operation)."	Yes, this is correct. The requirement is the same as that in OIML R 126:1998.
Australia	6.2	The reference to clause 6.3 should be replaced with 6.4. Clauses 6.3.3 does not relate to data transmission. Editorial. 6CD distributed by email on 18/12/09 differs slightly from 6CD zip file attached to the members voting page in the OIML website. Only the file attached in the members OIML website contain these errors	See reply to your general comment.

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Country	Document clause	Comments	Secretariat's replies
United States	6.3.1	Warm-up time Under reference conditions (11.4.1), the breath alcohol analyzer shall be capable of attaining the measuring mode: ▪ in less than 15 minutes after being switched on, Inconsistency; Change necessary for document correctness. The warm-up time was to be determined by the manufacturer as already recognized in section 11.4.4, wherein the following precondition is noted: "normal electric power supplied and 'on' for a time period equal to or greater than the warm-up time specified by the manufacturer." New text under section 6.3.1: Warm-up time Under reference conditions (11.4.1), the breath alcohol analyzer shall be capable of attaining the measuring mode: *after a warm-up period specified by the manufacturer* after being switched on,	Partially accepted. Suggest changing the proposal to: *"after a warm-up period specified by the manufacturer* (without being greater than 15 minutes) after being switched on,…"
Ireland	6.3.3	Continuity of the exhalation. The phrase "in the rated operating conditions" has been inserted. I have no record of this being agreed and am unclear as to its significance. This point is also covered in 5.8.2 Conditions of exhalation.	"in the rated operating conditions" means that the requirement is applicable within the whole measuring range and the whole ranges of influence factors as defined in 5.8.
United States	6.3.3	Continuity of the exhalation "The exhalation shall be considered interrupted if the flow is below **0.1 L/s.**" The minimum flow rate that an instrument can detect is a function of the instrument design. This requirement should therefore allow for the manufacturer's minimum detectable flow rate. New text: "The exhalation shall be considered interrupted if the flow is below *0.1 L/s or the minimum flow rate for the device as provided by the manufacturer.*"	Not accepted. See reply to 11.4.4.1. The conditions specified are conventional and aim to cover most human behavior in terms of flow rate and duration of the exhalation. See also 5.8 of CD6.

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Country	Document clause	Comments	Secretariat's replies
Germany	6.3.4	Add " If not, other ways to avoid influences by alcohol in the upper respiratory tract (e.g. a mandatory waiting time) shall be incorporated."	Not accepted. 6.3.4 defines a general requirement; examples to fulfil this requirement are given in Annex A.
United Kingdom	6.4	What, precisely, is NOT allowed with the limitation now placed by 6.4?	The meaning is that whatever the structure of the software (separate modules operating together), the whole software is considered as legally relevant. Suggestion for modification: change the second sentence to "*In the event of a software separation as described in 5.2.1.2 of OIML D 31: 2008 [7] , the whole software is considered as legally relevant*"
United States	6.4	The proscription against software separation is not realistic. In the simplest terms the instrument software takes a sample reading and displays or prints the value. In the case of an arrested subject there is an ensemble of measurements leading to the decision of intoxication. 2-3 subject measurements, several air blanks as well as measurement of a reference sample such as a wet or dry gas, this is controlled by software. In the US the sequence of these subject tests and the format of the printed results is codified in state law. We believe there can be different levels of "legally relevant " software which are controlled at different levels of the metrology system. If we controlled all the software at national type approval then we would not allow for state specific variations. This would be a problem going from one country to another in the acceptance of type approval. Delete second sentence. The whole software of the breath alcohol analyzer should be considered as legally relevant. ~~Software separation as described in 5.2.1.2 of OIML D 31:2008 [7] is not allowed.~~	Accepted. See reply to the United Kingdom Noted Noted See reply to the United Kingdom
Germany	6.4.1	Change "…e.g. CRC16…" into "…**at least CRC16 (preferred higher)**…"	Accepted

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Country	Document clause	Comments	Secretariat's replies
United States	6.4.1	Software identification The checksum algorithm shall be a normalized algorithm e.g., the CRC16 algorithm is an acceptable solution for this calculation Specifying a checksum is too design specific. See modified 6.4.1 **6.4.1** Software identification (D 31:2008; 5.1.1 [7]) The identification shall be inextricably linked to the software itself and shall be calculated, then presented or printed, on command or displayed during operation or at start up. A checksum algorithm or equivalent is an acceptable solution for this requirement The software identification and the means of identification shall be stated in the type approval certificate.	See reply to Germany. CRC16 is only an example and does not prevent other algorithms from being used. Not accepted. The algorithm must be normalized. For instance …… are also acceptable. These additional examples will be included in the text.
Austria	6.4.2.3	……If necessary for the purpose of verification, the current parameter settings should be able to be displayed or printed. We suggest changing to: "For the purpose of verification the current parameter settings should be able to be displayed or printed. "	Accepted.
Austria	6.5	A requirement how long the printout is readable is missing. Austria suggests: Printouts shall remain readable for 12 month.	This was discussed at the TC 17/SC 7 meeting and it was decided that the readability requirement may depend on the national legislation. Not accepted.
Germany	6.5.1	change ".. that are *out of* the legal control" into " that are not **under** legal control.."	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Ireland	6.5.1	Printing device. I have no record that this section was discussed. This section should include a clear statement that it shall not be possible to print out a measurement result if the instrument checking facilities detect a significant fault or malfunction. (see CD5 6.6.1). The reference to ink (6.5.1.5) is not relevant where a thermal printer is used.	This section was discussed at the meeting and recorded in the minutes. This is covered by the general requirement in 6.3, e.g. if an error is detected, no measurement and consequently no printout are possible. Accepted. *"If applicable"* will be added at the end of the first bullet.
Kazakhstan	6.5.1.1	While specifying the printed data it is need to add information on time and date of measurement.	Accepted.
Germany	6.5.2	add at the beginning: 6.5.2.1 "**The breath alcohol analyzer may store measurement data for further applications under legal metrological control. In such a case, the requirements defined below apply (6.5.2.2 to 6.5.3.4).**"	Accepted.
Ireland	6.5.2.3	The intention of the phrase "Confidential keys employed for protecting data shall be kept secret and secured in the breath alcohol analyzer. Means shall be provided whereby these keys can only be input or read if a seal is broken." is not clear. Our view is that the use of a physical seal e.g. a tamper evident label is not a suitable instrument safeguard in this context.	Not accepted. This is the general requirement of 5.2.3.3 in OIML D 31. A physical seal is sufficient considering the use of the instrument by law enforcement bodies.
Germany	6.5.3.2	Include the sentence: "**It is necessary to apply cryptographic methods.**" between the paragraphs.	Not accepted. This is the general requirement of 5.2.3.4 in OIML D 31. This comment could be appropriate in the revision of OIML D 31.
Australia	6.5.3.3	6CD specifies: "Stored data may be deleted when compliance with national policy for fighting against alcohol abuse is demonstrated." Simplify this clause to improve clarity. i.e. Consider replacing with: "Stored data may be removed when no longer legally required" Demonstration of "compliance with national policy for fighting against alcohol abuse" is ambiguous. It should not be used as the criteria for which stored results can be deleted.	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Germany	6.5.3.3	Please clarify, this is ambiguous. If it is meant that the measurement values may be deleted if it is under a certain limit, please say it clear in technical terms!	Accepted. See reply to Australia.
Ireland	6.5.3.3	The current wording "when compliance with national policy for fighting against alcohol abuse is demonstrated." while appropriate for the scope of this OIML Recommendation, does not appear to be in keeping with language used within this document. Suggested alternative is "Stored data may be deleted only by authorised personnel."	See reply to Australia. Not accepted. This is out of the scope of the Recommendation.
United Kingdom	6.5.3.3	The primary use of these devices is for Road Traffic law enforcement – not "...fighting against alcohol abuse…". This is a different and very specific health issue.	Accepted. See reply to Australia.
Germany	6.5.3.4	Change 6.5.3.4 into "If the data according to 6.5.3.3 were deleted and when the storage …" because 6.5.3.3 is no requirement ("may be deleted").	Accepted with editorial modifications.
United States	6.5.4	Data transmission Omission; Insert language as discussed at September 2009 meeting 6.5.4. **Data transmission** 6.5.4.1. The measurement shall not be inadmissibly influenced by a transmission delay. 6.5.4.2. If network services become unavailable, no measurement data shall be lost. The measurement process should be stopped to avoid the loss of measurement data.	See 6.3.2 of the minutes of the September meeting: "After extensive discussions, it was decided to develop a new proposal which could define minimum requirements taking into account the fact that national regulations may also require more severe requirements. The minimum requirements would be suggested on the basis of: • software identification, • fraud protection, taking into account the fact that the breath alcohol analyzer is an instrument which: • displays the measurement result, • may print the measurement result, • may store the measurement result in its memory." Considering the new proposal, 6.5.4 has been deleted.

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Country	Document clause	Comments	Secretariat's replies
United States	6.5.5	Separation of electronic devices Omission; Insert language as discussed at September 2009 meeting 6.5.5. Separation of electronic devices (See D 31:2008; 5.2.1) 6.5.5.1.Metrologically critical parts of a breath alcohol analyzer shall not be inadmissibly influenced by other parts of the measuring system. 6.5.5.2.Electronic devices of a breath alcohol analyzer that perform legally relevant functions shall be identified, clearly defined, and documented. They form the legally relevant part of the breath alcohol analyzer. 6.5.5.3. During type testing, it shall be demonstrated that the relevant functions and data of subassemblies and electronic devices cannot be inadmissibly influenced by commands received via the interface. This implies that there is an unambiguous assignment of each command to all initiated functions or data changes in the electronic device.	See section 6.3.2 of the minutes of the September meeting: "After extensive discussions, it was decided to develop a new proposal which could define minimum requirements taking into account the fact that national regulations may also require more severe requirements. The minimum requirements would be suggested on the basis of: • software identification, • fraud protection, taking into account the fact that the breath alcohol analyzer is an instrument which: • displays the measurement result, • may print the measurement result, • may store the measurement result in its memory." Considering the new proposal, 6.5.5 has been deleted.
Australia	8.1	6CD specifies:" Each individual instrument shall be accompanied by an instruction manual for the users." Change this clause to: "An instruction manual for users shall be made available for each individual instrument." It should be the customer's choice whether they want an instruction manual with each instrument. Some customers might not want 250 manuals to be supplied with their order of 250 instruments. For user instructions, many companies are applying web-based electronically controlled documents. There will be less waste if unwanted instruction booklets and CDs are not produced. This philosophy is in line with report by Awosola, M; OIML Bulletin; L1 [1] 22-23.	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Ireland	9	Sealing. See comments in 6.5.2.3 above. Reference is made to an air filter in this section. It is clear that the intention is to ensure that an air filter may be changed without breaching the instruments security system. However the intention of the sentence "If the air filter is not installed, the breath alcohol analyzer shall deliver an error message, and no measurement shall be possible." is not clear. Is it related to a manufacturers requirement for an air filter to be present and for the instrument to be disabled if an air filter is not installed or is it related to the consequences of breaking the security seal?	The requirement in the antepenultimate paragraph aims to secure the measurement in case the breath alcohol analyzer approved for use with air filters is used without. Consequently, to clarify the specification we suggest combining and changing the paragraph as follows: "*If the breath alcohol analyzer is equipped with air filters, the manufacturer shall design the device in such a way that it is possible to change the filters without breaking a security seal.* *When air filters are not installed, the breath alcohol analyzer shall deliver an error message, and no measurement shall be possible….."*
Germany	11.1	change in the first sentence"… at least *one* unit" into ".. at least 2 units" (reason: for statistical reasons, testing should always be done on a number of units and not only one) add in the first sentence"… represents the definitive type **for serial production** change in the third sentence: at least *one*.." into "at least **two**.."	Not accepted. In most OIML Recommendations only one sample is tested. The fact that the sample should represent the production is a general issue which is addressed in the revision of OIML B 3.
Australia	11.2	Second last paragraph should have 6.5.1, not 6.6.1. Editorial	Accepted.
Australia	11.3.1	Each item listed should also reference the clause that it relates to. To ease clarification regarding the details for each item on the visual examination list.	Accepted.
Australia	11.3.3	Change "examination level" in 6CD to "validation level" to be consistent with terminology applied in OIML D 31:2008. Also add a reference to clause 6.4. It is ambiguous what "examination level" is referring to. The validation level and procedures is not limited to clause 6.3 only. Clause 6.4 also contains relevant details.	Not accepted. OIML D 31 refers to "normal examination level" and "extended examination level". Adding 6.4 in the title of 11.3.3 is accepted.

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Country	Document clause	Comments	Secretariat's replies
Australia	11.3.3	The document specifies details in accordance with OIML D 31:2008 clause 6.4 (a). Will additional details under 6.4 (b) and (c) also be specified? i.e. how the evaluation of test results shall be performed and which result should be included in the test report and which should be integrated in the certificate. The testing regime outlined under 11.3.3 is extensive but guidelines have not been provided. Will this be included in a model test report format?	The details for 6.4 (b) are given in the appropriate sections of OIML D 31 which are repeated under the table, e.g. 6.3.2.1 for AD. For 6.4 (6), the records will be specified in the Evaluation Report Format on the basis of Annex B of OIML D 31. The Evaluation Report Format will be a separate OIML Recommendation which will be drawn up as soon as this draft is approved.
Austria	11.3.3	Fraud protection: Change Examination level A to level B	Not accepted. See reply to the United States. Level A will be used as a minimum level and does not prevent national regulations from specifying higher levels.
Germany	11.3.3	Add explanation of VTFM below the table.	Accepted.
Ireland	11.3.3	Remove blank table. Examination level (A or B) is not explained. (OIML D 31:2008 Section 8 ?) The abbreviation VTFM is not explained. Should it read VFTM –Validation by Functional Testing of Metrological functions? (OIML D 31:2008 clause 6.3.2.2)	Accepted. Reference to section 8 will be added in the title of the clause. Accepted.
Poland	11.3.3	Is it clear that the column title "Requirement" in the table refers to the OIML R126? Maybe "Requirements of R126" would be better. The numbering is very similar to the points of D31.	Accepted.
United Kingdom	11.3.3	How can certain parts of the software be tested independently of others, given the number of software and hardware inputs that the device checks? There is no requirement to check the hardware independently of the software. Also, to increase the requirements for software testing above the current "black box" testing, whilst reducing the requirements for Mouth Alcohol detection and Interfering Substance detection (both of which will have a larger effect on the accuracy of a reading) makes no sense.	No longer relevant. See reply to the United Kingdom on 6.4.

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Country	Document clause	Comments	Secretariat's replies
United States	11.3.3	Software examination levels were not changed to those decided at the meeting in September 2009. At that meeting the minimum examination levels were to be A for all requirements For the US, implementation of CIWT: and SMT: would be impossible and unwarranted at this time. Stored data in the US is strictly for breath testing program use and statistics in the US and is not legally relevant. The printed ticket is the endpoint of legality. Change the Examination Level to A as agreed at the meeting and delete CIWT and SMT.	Accepted. Level A will be taken into account for all the requirements and consequently CIWT and SMT will be removed.
United Kingdom	11.4.1	Does not define reference conditions for supply voltage, frequency etc. this is because the Guide covers DC and AC etc, but there should be some text to cover this.	Accepted. The following sentence will be added: "*During each test at reference conditions, the voltage and AC mains frequency (if appropriate) shall be maintained at their nominal values."*
United Kingdom	11.4.1	The cross interference tests using ANY hydrocarbon with methane equivalent will not be consistent – see comment at **5.8j** and **11.4.4.13**	There is no inconsistency. 11.4.4.1 is related to reference conditions used for the tests defined in 11.4.4.1. 5.8.j is related to influence factor tests under rated operating conditions. The test for the influence of hydrocarbon is defined in 11.4.4.13.
Australia	11.4.2	The first dot point states: "Annex B.1 ... and general excepted flow rate curves..." Replace "excepted" with "accepted", as in the 2nd dot point re Annex B.2. Editorial	Accepted.
United Kingdom	11.4.3.1	The delivered has reduced to 2L from 3L. This is too low and 3L should be reinstated.	Not accepted. The value was discussed at the last TC 17/SC 7 meeting.
United Kingdom	11.4.3.1	Requires the use of CO2 in the first paragraph, and then allows its exclusion later. Either the CO2 has an effect or not – if it does then it should be in the accuracy test 11.4.4.1 a) for example? Could the effect of CO2 not being present with incorrect ethanol cause a false pass?	This is correct. 11.4.4.1 will be deleted in the second bullet of the second set of bullets. 11.4.4.14 specifies the test for the influence of CO_2. In 11.4.4.1, since no particular conditions are defined, 11.4.3.1 applies and the tests are performed with 5 % of CO_2.

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Country	Document clause	Comments	Secretariat's replies
United Kingdom	11.4.3.1 (bullet point "dry gases…")	There are less allowances for using dry gases, and more exclusions, than in 1998 version. If water vapour is shown to have no effect, dry gas testing should be allowed	Noted.
United Kingdom	11.4.3.1	The reference to last numerical clause in this **11.4.4.1** is out of order. Is this a typographical error?	Accepted. See previous reply.
United Kingdom	11.4.3.1 (second set of bullet points)	The last part of this sentence is unclear – what repeatability tests with wet gases must be performed?	Accepted. Suggest the following modification to the first bullet: *" dry gases, which can be used for tests defined in 11.4.4.2, 11.4.4.6 through 11.4.4.14 and 11.4.5 (except 11.4.5.11 and 11.4.5.12) with a preliminary repeatability test performed with wet gases,* *Note: this preliminary repeatability test may consist of the repeatability test defined in 11.4.4.1."*
United Kingdom	11.4.3.1	the sentence " **in all cases**…" appears to be wrong as refers to a constant evolution of concentration and flow, which is surely contradictory to all tests in 11.4.4.2 which require specific and non constant profiles as does annex B.	Accepted. "except in 11.4.4.2" will be added after "In all cases…".
United Kingdom	11.4.3.1(final bullet point)	Insert "…measurement uncertainties of the…" before "…test facilities…"	Accepted.
United Kingdom	11.4.3.2	This point is ambiguous and confusing – the test apparatus must deliver all the profiles as specified in **11.4.4.2**, and not just the generalised requirements of **11.4.2**	Accepted with a modification of the wording as follows: *"…….shall be capable of delivering a test sample according to 11.4.3 and a breath profile described in 11.4.2."*
United Kingdom	11.4.3.2	What is the difference between test apparatus here and test facility in **11.4.3.3?**	Accepted. Terminology to be harmonized.
United Kingdom	11.4.3.3	This section implies you **need** only one of the 2 types of test facility, which is also called "apparatus" as in above! You need BOTH types of facility to do all the tests	You are correct. Suggest adding at the end (before the note – see below) the following sentence: *"For the complete test program, both types are needed."*

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Country	Document clause	Comments	Secretariat's replies
United Kingdom	11.4.3.3	There is a requirement here **for the first time** that the plateau (which you cannot do with Type1) shall be reached when half of the test volume has been injected. Does this, in principle, apply to all the tests in **11.4.4.2**? We do not believe it should. This is confusing and requires clarification. It also does not appear compatible with some of the requirements of **11.4.4.2** (e.g. a) 15 seconds for duration and 3 seconds for plateau). This is also not required in **11.4.3.1** where a constant flow rate is required.	Noted. For clarification, we suggest modifying the wording of the type 2 explanation in 11.4.3.3 as follows: *"Type 2: the apparatus delivers a test gas which is capable of fulfilling the breath profile as defined in 11.4.2."* We also suggest adding in 11.4.3.3 the following note: *"Note: For certain tests, the testing procedures may specify the use of one of the specific types indicated above ."* For example, for test 11.4.4.2 a), a type 1 or a type 2 may be used but for test 11.4.4.2 d), a type 2 shall be used. 11.4.3.1 defines the reference conditions. The object of the tests in 11.4.4.2 is to check the influence of variations of these conditions.
United Kingdom	11.4.4.x	All tests in this section state that "All functions shall operate as designed." How many tests are required to check this ?(Maximum allowable variations)	The sentence "All functions shall operate as designed." is a general sentence of OIML D 11. The details of the tests to be performed are defined in each table under the heading "Test" and the applicable MPE are repeated in each table under the heading "Maximum allowable variations." The appropriate requirements are defined in section 5 and are referred to in each appropriate section of 11.4.4.

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Country	Document clause	Comments	Secretariat's replies
United Kingdom	11.4.4.1 c) memory effects with *large* differences in concentrations	This clause is ambiguous particularly the last 2 sentences	Accepted. The wording shall be modified as follows: "*Memory effect with large differences in mass concentration* *The breath alcohol analyzer shall be subjected to an initial test that includes 10 measurements using test gas No. 2. The mean value of these 10 measurements is calculated.* *Then, the breath alcohol analyzer shall be subjected 10 times to the following cycle:* • *one measurement using test gas No. 7 or No. 8,* • *one measurement using test gas No. 2.* *Each of the individual measurements, whatever the concentration is, shall comply with the MPE as defined in 5.2.1.* *The mean measurement of the 10 measurements with test gas No. 2 during the cycle is calculated.* *The difference between the two mean errors calculated for test gas No. 2 shall be less than the limit specified in 5.6.1".*
United Kingdom	11.4.4.1 c) memory effects with *large* differences in concentrations	The penultimate sentence should make clear that the 2nd set of means is being tested	See reply above.

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Country	Document clause	Comments	Secretariat's replies
United Kingdom	11.4.4.1 c) memory effects with *large* differences in concentrations	Why is there a choice of test gas 7 or 8 when these may give different results and one might pass and the other might fail?	Suggest adding a note (at the end of the paragraph related to the memory effects with large differences in concentration) to explain that it is intended to use test gas No. 7 in the event that the maximum concentration of the measuring range is 2 mg/L and test gas No. 8 when the maximum of the measuring range is greater than 2 mg/L.
United Kingdom	11.4.4.1 c) memory effects with *small* differences in concentrations	All comments made for **11.4.4.1 c) memory effects with *large* differences in concentrations** also apply to this section.	See replies above. The modifications will be made accordingly.
Germany	11.4.4.2	from the second test on till chapter d): please change the plus sign into the plus-minus-sign!! chapter e) update the reference: "…conditions specified in **11.4.3.1…"** chapter e): add the flow rate for the first and second test, because it would be much easier to understand what has to be done	Accepted. Accepted. The characteristics of the injection as defined in the fourth test will be defined at the beginning of e) as a general requirement for the whole test.
Ireland	11.4.4.2	a) The symbol ± should replace the symbol +/= (plus sign over equals sign) in this and subsequent sections: b) c) d) e)	Accepted.
Poland	11.4.4.2	Chapter a) Second test should be "±" instead of "+" ; Chapter b) Should be "±" instead of "+" ; Chapter c) Should be "±" instead of "+" ; The term "…Initial flow rate…" should be replaced by the term "…initial flow rate…" ; Chapter d) Should be "±" instead of "+" ;	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Australia	11.4.4.2 b)	Clarify the last dot point in all 3 tests by replacing with the following: "Option 1- variation in the alcohol concentration as a function of time (plateau): no variation OR Option 2- duration of plateau: 4.5 s (The option for this condition shall be consistent across the first, second and third tests)." There is ambiguity in 6CD as the set-point for plateau duration varies over the three tests but the bracketed sentence that follows states that the same condition shall be maintained in the three tests. The "same condition" actually relates to the two options available: 1) no variation in alcohol conc as function of time, OR 2) duration of plateau is preset i.e. 4.5 s in the 1st test, 6 s in the 2nd test and 3 s in the 3rd test.	Suggest modifying the third and fourth bullets of 11.4.4.2: • *"variation of pressure as a function of time,* • *variation of alcohol concentration as a function of time".* Suggest clarifying the test conditions in a), b), c) and d) as follows: • "exhalation" to be changed to "injection" (in the title of 11.4.4.2 also); • Variation **of** the pressure as a function of time; • Variation of the alcohol concentration as a function of time: no variation (type 1 test apparatus) or plateau duration equal to 3 s (type 2 test apparatus). This change will be made with the appropriate values in b), c) and d).
United States	11.4.4.2 b)	Influence of flow rate and exhalation duration ▪ delivered volume: 1.5 ± 0.1 L, ▪ duration of injection: 10 ± 0.5 s, This test results in a flow rate of 0.15 L/s. This is higher than the proposed minimum flow rate of 0.1 L/s in section 6.3.3, thus, allowing for additional minimum flow rate values to be used by manufacturers. See additional comments above under section 6.3.3. New text under section 6.3.3: "The exhalation shall be considered interrupted if the flow is below *0.1 L/s or the minimum flow rate for the device as provided by the manufacturer*	11.4.4.2 b) is a metrological test and therefore shall be done within the rated operating conditions. Between 0.15 L/s and 0.1 L/s, the uncertainties of the test apparatus do not allow interruption at the exact value defined in 6.3.3 to be guaranteed. The test procedure defined in 11.4.4.2 e) is supposed to be adapted to the requirement in 6.3.3. Consequently, the proposal for the modification of 6.3.3 cannot be accepted.
Germany	11.4.4.3	in the third sentence: delete "… *in brief*.. "	Accepted.
Poland	11.4.4.3	The term "…5.8 a)…" should be replaced by the term "…5.8.1 a)…."	Accepted.
Germany	11.4.4.4	delete "… *in brief*..	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Ireland	New	TETRA (Terrestrial Trunked Radio) It was my clear understanding that CD 6 would include a requirement to test the instrument for immunity to TETRA. At the very least, a test method should be included as an Informative Annex.	Not agreed. We were not able to find appropriate information on this item. In addition since the revision of the OIML D 11 has started, this issue should be addressed in a more general aspect in this revision. No change at present in the CD.
Germany	11.4.4.5	delete "… *in brief*.. add in the last row of the table: " is determined once per day **under test conditions**…."	Accepted.
United Kingdom	11.4.4.5	This section refers to **5.8.1 b)** – but there are no tests specified there for "stationary analysers" with RH at 85%.	This test does not apply to stationary analyzers as indicated in 5.8.1 b).
Poland	11.4.4.6	The tolerance should be consistent with 11.4.1 – the term "860 hPa ± 10 hPa, 1060 hPa ± 10 hPa" should be replaced by term "860 hPa ± 20 hPa, 1060 hPa ± 20 hPa"	Not accepted for pressure at reference conditions. A tolerance of 20 hPa is not appropriate since there is no ambient pressure regulation. When testing at the extreme values of the rated operating conditions, the values are generated and regulated through the test facilities. The tolerance may be narrow.
Germany	11.4.4.7	delete "… *in brief*..	Accepted.
United Kingdom	11.4.4.7	This section refers to **5.8.1 d)** – but there are no vibrational tests for stationary analysers (in contrast to R126 1998 annex D3)	TC 17/SC 7 agreed to change the requirements considering the general principles defined in OIML D 11:2004.
United Kingdom	11.4.4.7	The term " precondition" and the associated requirement are unclear. What does it mean?	Accepted. To be changed into "Test conditions".
Germany	11.4.4.8	delete "… *in brief*..	Accepted.
Germany	11.4.4.9	delete "… *in brief*..	Accepted.
Germany	11.4.4.13	change the last sentence into: **This tests are applied to verify compliance with the provisions in 5.10**:	Not accepted: 5.2 applies (MPE shall be fulfilled).
United Kingdom	11.4.4.13	This section refers to **5.8.1 j**. The test allows any hydrocarbon with a methane equivalent concentration to be used; this will probably give **different** results for IR analysers depending on the choice of hydrocarbon, with possibly methane the best case. We suggest a named hydrocarbon is specified (e.g. propane) which is spectrally more close to many others – except methane.	Not accepted - see reply to 5.8.1.j.

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Country	Document clause	Comments	Secretariat's replies
Germany	11.4.5.1	delete "… *in brief*.. in the table: - in the first row delete the last sentence (Adjust the EUT…) because in 11.1 further adjustment during type approval tests are not allowed. - in the second row: enhance the explanation of Condition of the EUT, e.g: "The EUT shall not be readjusted at any time during the test. If a reset, caused by the indication of a significant fault, requires a readjustment, then it is allowed."	Accepted. Accepted. Not accepted. A reset is not a readjustment.
Germany	11.4.5.2	see complete comment on 11.4.5.1 and in the third row of the table : - what is meant with "factors"? Please find another formulation e.g. "ambient conditions" - specify the test gas to be used for the measurement cycle	Accepted for the first two comments. Not accepted for the third comment. Accepted with the following modification: "*Stabilize all factors at nominal reference conditions*" to be changed to: *"Influence factors shall be fixed at reference conditions as defined in 11.4.1".* This modification will also be applied to 11.4.5.1. The test gas to be used is specified in the first sentence of 11.4.5 and is the same for all disturbance tests.
United States	11.4.5.2	Conducted radio-frequency fields Frequency range: From 0,15 MHz to 26 MHz Editorial Frequency range: From *0.15* MHz to 26 MHz	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Germany	11.4.5.3	see complete comment on 11.4.5.1in the third row: and in the third row of the table: - change in the second clause: "The number of points of application on each surface will depend on the size of the instrument **and is to fix according to IEC 61000-4-2**. The tested points shall be described in the test report. - the 4. clause is misunderstandable. what is meant with "accessible in normal operation" better to specify this for each instrument type: stationary and mobile BAAs: every surface accessible without moving the instrument out of its position of normal use for portable BAA: all surfaces of the housing - in the last sentence: specify the test gas to be used for the measurement cycle	See reply in 11.4.5.2 for the first three comments. Accepted. Not accepted. This is the general wording applied in OIML Recommendations in order to cover all types of instruments and conditions of installation and use. Described in 11.4.5.
Germany	11.4.5.4	see complete comment on 11.4.5.1	See reply in 11.4.5.2 for the first three comments.
Germany	11.4.5.6	see complete comment on 11.4.5.1	See reply in 11.4.5.2 for the first three comments.
Germany	11.4.5.7	see complete comment on 11.4.5.1	See reply in 11.4.5.2 for the first three comments.

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Country	Document clause	Comments	Secretariat's replies
Australia	11.4.5.7	The numerical values for voltage dips and interruptions in 6CD differ to those in the referenced IEC standard. The referenced IEC standard contains explanatory graphs to clarify the voltage level that corresponds with each numerical value. 6CD should incorporate similar graphs or just adopt the exact numerical values in the IEC standard to avoid ambiguity. The notation for amplitude reduction in 6CD (100%, 100%, 30%, >95%) is correct but inconsistent with the notation in the following documents: OIML D11 (voltage dip reduction= 0%, 0%, 70%; short interruption reduction= 0%) The referenced IEC standard (voltage dip level or test level= 0%, 0%, 70%; test level for short interruption= 0%). The IEC standard contains explanatory graphs on voltage levels the 0% and 70% test level correspond to.	Not accepted. OIML D 11 and IEC standards are ambiguous. This presentation was adopted in agreement with the TC 5/SC 1 Secretariat (responsible for the revision of D 11) in all the Recommendations revised recently. It is the presentation currently indicated in the Draft Recommendation Format.
Australia	11.4.5.8	There were a few inconsistencies with the referenced ISO standard that we are highlighting in case they are not intentional: 24V system pulse 1 voltage is -100V instead of -600V (ISO test 1). Pulse 2b minimum number of pulses is 5000 instead of 10 (ISO test 2). Pulse 4 minimum number of pulses is 1 instead of >1 (ISO test 4) Possible editorial. Also amend clause 5.10.1.1. on pp 17 if required.	Will be checked before drawing up the 7CD.
Germany	11.4.5.8	see complete comment on 11.4.5.1	See reply in 11.4.5.2 for the first three comments.
Poland	11.4.5.8	The term "…in the IEC…" should be replaced by the term "…in the ISO…."	Accepted.

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<table>
<tr><th>Country</th><th>Document clause</th><th>Comments</th><th>Secretariat's replies</th></tr>
<tr><td>Germany</td><td>11.4.5.9</td><td>see complete comment on 11.4.5.1
and in the third row of the table:
- the description of the test for portable BAA is too short. Please specify the test in more detail
- the sentence "the height of fall given below is that of the opposite edge" is not understandable. please specify where to measure the height of fall, especially for the portable BAA</td><td>See reply in 11.4.5.2 for the first three comments.

Not accepted.

Not accepted.</td></tr>
<tr><td>United States</td><td>11.4.5.9</td><td>Mechanical Shocks
The height of fall given below is that of the opposite edge
<table>
<tr><td></td><td>Stationary</td><td>Mobile</td><td>Portable</td></tr>
<tr><td>Height of fall</td><td>25 mm</td><td>50 mm</td><td>1 m</td></tr>
<tr><td>Number of fall</td><td>1</td><td>1</td><td>3</td></tr>
</table>
The height of fall for a portable instrument is 1 m three times. If the instrument is operated from a carrying case then this test should be carried out with the instrument in the carrying case. Some portable instruments are designed to operate from hardened cases which are specifically chosen to protect the instrument in the event the system is dropped.
Allow for testing of portable devices to occur while contained within a protective case if so provided as part of a system by the manufacturer.</td><td>Accepted. This will be added in the heading "Condition of the EUT".</td></tr>
<tr><td>France</td><td>11.5.4.10</td><td>The term "G" should be replaced by term "g "</td><td>Accepted.</td></tr>
<tr><td>Poland</td><td>11.4.5.10</td><td>Precondition should include sentence Power is to be "off" for the duration of the test.</td><td>Accepted.</td></tr>
<tr><td>United Kingdom</td><td>11.4.6</td><td>Does not say in 11.4.3.1 which gases are allowed to be used for these tests. We propose dry gases.</td><td>It is indicated that the test concentration is 0.4 mg/L ± 5 %. Gas may be either dry or wet. Reference to 11.4.6 will be added in 11.4.3.1.</td></tr>
<tr><td>Poland</td><td>11.4.6</td><td>"National Authorities may decide to test the influence of other compounds" this statement is already written in 5.10.2.</td><td>Accepted. The last sentence will be deleted.</td></tr>
</table>

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Country	Document clause	Comments	Secretariat's replies
Germany	11.4.5.11	delete "… *in brief*.. in the table: - in the second row: enhance the explanation of Condition of the EUT, e.g: "The EUT shall not be readjusted at any time during the test. If a reset, caused by the indication of a significant fault, requires a readjustment, then it is allowed."	See reply in 11.4.5.1.
Ireland	Annex A	A.2.1 has been extensively modified without consultation. I have no record that mouth alcohol detection was discussed. A.2.1.2 contains details of a test method using test gases as set out in Table 1 of the Annex. The target values of the test gases in some cases differ by only 0.01mg/100ml (e.g. Test gas No.11 0.28mg/L, Test gas No. 12 0.29mg/L) Given that the uncertainty of the test gas is 1/3 MPE (1/3 x 0.02mg/L = 0.007mg/L) there is a significant overlap between the confidence intervals for the test gases. This fact together with the uncertainty of the measurement result means that there is a significant likelihood that test results for adjacent gas concentrations will be identical. We feel that this test procedure is too complex and its aim is not clearly defined. Because of its complexity it could lead to difficulties in a Court of law.	The purpose of this Annex is to give examples of means to be used for alcohol detection in upper respiratory tracks. This annex is informative and other solutions may be applied by National Authorities.
Australia	A.1	Remove the balloon diagram if no longer relevant. Add an explanatory clause and caption if it is still relevant to the document. This diagram has become orphaned. 6CD does not contain the clause from R 126:1998 Annex A.6 that referred to the balloon diagram "...Such a test gas can be obtained by blowing clean air through a balloon flask having a volume equal to 500mL..." In R 126:1998, the test in Annex A.6 referred to the balloon diagram that was originally located in Informative Annex H (Figure H.2).	See reply to Ireland on Annex A. The paragraph in A 6 of OIML R 126:1998 is not necessary considering the rewording in A 1 associated with the figure.
Poland	A.2.1	"First measurement less.." – maybe should be added "value"?	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Austria	A.2.1.2	Table 1; first row "Test gas No (mg/L)" , delete (mg/L); it is only the number of the test gas, not a mass concentration	Accepted.
United Kingdom	A.2.1.2 part b	Change "…gas is…" to "…is gas…"	Accepted.
Australia	Annex B	Simulation curves and theoretical equation in this Annex require references and labels (e.g. Figure B.1). This will increase the credibility of information presented and make the diagrams more relevant to the preceding text.	Accepted.
Kenya	Annex B	Delete "reproducibly" and replace with "reproducible"	Not accepted. The wording is correct in the clean version. This is a problem between the marked-up version and the clean version as indicated in the reply to the first general comment made by Australia.
Australia	B.1.1	The title as well as the underlying statement are not clear.	Noted. No proposal made.
Australia	B.1.1	Fix the label of y-axis in flow rate curve as it is difficult to read Editorial	Accepted. The figure will be improved.
Australia	B.1.2	The x-axis of the graph is either missing one scale interval between 0 s and 1.5 s, or it should begin at 0.5 s. Editorial	Accepted.

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Country	Document clause	Comments	Secretariat's replies
Australia	B.1.2	To increase the credibility of this curve, a reference to the study that it came from is required. If only a portion of a normal breath profile is relevant to the simulation (e.g. between exhalation time 1.5 s and 5 s) then substitute a feint line or a dotted line for other parts of the simulation curve. Shape of curve noted to be unusual by a Type Approval testing authority in Australia. Questions for TC17/SC7: Is it really like the recorded curve above (the conventional forced exhalation curve in B.1.1.)? Why does it have a log shape drop off? Why does it have a final plateau?	Noted. B.1.2 aims to be an example for a simulation and intends to show the decrease of the flowrate over time. The plateau corresponds to the end of the exhalation.
France	B.1.2	The term "**description if the test in 11.4.4.2.c** " should be replaced by term "description if the test in 11.4.4.2.c "	Accepted.
Australia	B.2	Two decimal places not required for scale markings of y-axes for graphs in B.2.1.and B.2.2. Editorial	Accepted.
France	B.2.1	The term "150 ml " should be replaced by term "150 mL"	Accepted.
Australia	B.2.2	"within 99% of the reference value" to be changed to "within 1% of the reference value" OR "to at least 99% of the reference value". Editorial. Need to be careful when using 99% or 1% for defining plateau.	Accepted. See reply to the United States on 2.19. The sentence will be changed accordingly.
Australia	B.2.2	Remove the final close bracket in Appendix B, final line of text before the figure. In the figure itself, "exemple" should be "example". Editorial	Not accepted. The brackets are correctly placed. Accepted.

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Country	Document clause	Comments	Secretariat's replies
Brazil	Annex C	Annex C presents the Dubowski's formula to calculate the mass concentration in the vapor phase. The 1998 edition of R 126 has the same information, making reference to the National Testing Information Service, USA. However, since 1984 the value used in the United States for the partition ratio for concentration of ethanol in headspace to concentration in solution at 34 °C comes from the Harger's work: $K_{a/w}$ = 0,000393 For t = 34 °C, $C_{air} = 0.393 \times 10^{-3} C_{H2O}$ We think it would be better to inform the figure actually used currently in the United States, or alternatively, make reference to the most common values found in the specialized literature, mentioning that each country is free to adopt any of the reported figures.	Accepted. The Harger's method will be added.
United States	Annex C	[Jeff Rost]: Dubowski's Formula This is not the only acceptable method for determining ethanol concentration in air from an aqueous solution. The use of this formula for calculation of mass concentration of ethanol in aqueous solution does not recognize other equally acceptable methods. Method used to perform this calculation should be a responsibility of the national authority. New text under Annex C: Allow for national authority to determine method by which ethanol concentration in aqueous solution is determined (i.e., may use Dubowski, Harger, or other method).	Accepted. See reply to Brazil.

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Country	Document clause	Comments	Secretariat's replies
United States	Annex C	Dubowski's Formula This is not the only acceptable method for determining ethanol concentration in air from an aqueous solution. The use of this formula for calculation of mass concentration of ethanol in aqueous solution does not recognize other equally acceptable methods. Method used to perform this calculation should be a responsibility of the national authority. We are attaching a spread sheet which contains references and equation coefficients for Harger and Dubowski's formula. Annex should contain both methods and the national authority should decide on the method used in that jurisdiction	Accepted. See reply to Brazil.
Austria	Annex D	(1) V 2-200:2007, "International voc……; change to : (1) JCGM 200: 2008 (E/F), "International voc……..	Not accepted. JCGM 200 is not an official document. The official Publications are the OIML, the BIPM and the ISO ones. In an OIML Recommendation, we refer to the OIML Publication.
Poland	Annex D	There are new editions of 11 standards, may be should replaces the older ones e.g. IEC 60068-2-1:2007 should be IEC 60068-2-1:2009; IEC 60068-2-2:2007 should be IEC 60068-2-2:2009 etc. Reference [11] is not mentioned within the Recommendation.	Will be checked before final editing.
Australia	Part.3	Will there be a test report format included with the Final publication? This would assist in clarifying ambiguities with certain tests (e.g. 11.4.4.2.b) and provide guidelines for the validation requirements under 11.3.3.	It is intended to have a part. 3 of course. The objective is to develop it as soon as parts1 and 2 are finalized. It will be a separate publication since the OIML voting rules for the Evaluation Report Format (Test Report Format) are different from those for the approval of parts 1 and 2.