



CIML and TC 17/SC 7 comments on CD 7

Comments on:

Revision of OIML R 126: Breath alcohol analyzers

Country	Document clause		Comments	Secretariat's replies
Australia	General comment		<p>Australia notes that requirements for initial verification and subsequent verification, which were present in the original version of OIML R 126 has been removed from later drafts.</p> <p>Australia is of the view that the previous (i.e. original) requirements for subsequent verification and reverification of evidential breath analysers could be reintroduced as the test requirements for initial and subsequent verification.</p> <p>Consequently initial verification and subsequent verification would be confined to the verification of accuracy. Further, the previous (i.e. original) requirements for initial verification such as accuracy, repeatability, effect of volume delivered, effect of the duration of exhalation and effect of the duration of the plateau be reinstated for conformity to type testing. Conformity to type testing can be carried out based on random sampling – (a) sampling procedures for inspection based on attributes or (b) sampling procedures for inspection by variables for percent nonconforming.</p>	
Austria	General comment		<p>For an evidential test 2 measurements must be carried out. Austria is of the opinion that this rule should be added in Part 1 chapter 5, metrological requirements.</p> <p>Austria suggests to make also additional tests with test gases with different pressures (back pressure), there should also be some test procedure 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.</p>	

Country	Document clause	Comments	Secretariat's replies
Germany	General comment	<p>Within the 7th Committee Draft, changes were made which were not discussed in this form at the last meeting of the TC.</p> <p>Despite having serious concerns we will still vote yes, on the condition that the work for a further revision of OIML R 126 will be immediately started after the approval of the revised document.</p> <p>The two topics we are most concerned about are:</p> <ul style="list-style-type: none"> – The reducing of the software validation procedure down to a level which was meant to be applied for mass-produced instruments like water meters. Since the measurement results of breath alcohol analyzers may be relevant for prosecution of a person and have to be evidential in legal actions, we insist that they should be treated with an appropriate security level. As National Authorities we should bear in mind that our main task is consumer protection and the insurance of a reliable and trustworthy measurements. The proposed examination level A is intended by D 31 for everyday products, but for instruments which require higher protection level due to their scope of application, e.g. breath alcohol analyzers, the extended examination level B must be applied, if not generally then at least as an option, depending on existing national regulations. Otherwise we are convinced that R 126 will be of limited use both for manufacturers and Certification Bodies. – The implementation of another partition ratio into the Annex C was never mentioned or discussed before. We feel that this Recommendation should try to explain the physical laws which apply for partition ratios rather than trying to illustrate the differences in legislation of various countries. To present two different partition ratios without any further explanations may lead to some misinterpretations. To avoid any ambiguity, we should clearly state the purpose and the field of application of the shown partition ratios. Additionally, we are missing any information about uncertainties of the partition ratios, which have to be recognized necessarily when calculating the uncertainty budget for the test gases. As long as no uncertainty values for these partition ratios are to be found in the literature, this problem can be handled by defining a conventional value with a formal zero-uncertainty. But this convention has been published in an official form, and we consider the R 126 just adequate for it. 	

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Japan	General comment		<p>In Japan, a quantitative alcohol measurement using an indirect sampling method with a gas bag is mandatory in the law controlling alcohol abuse.</p> <p>This method has been well established in Japan and reliability as well as robustness is very high.</p> <p>We therefore request to add a word "directly-sampled" into "Scope" as shown below in order that our method is excluded from the scope clearly.</p> <p>If this requirement is taken into consideration, we will basically support future revisions of R126.</p>	

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The Netherlands	General comment		<p>No adequate response from the OIML secretariat TC 17/SC 7 was given to the objections from side of The Netherlands, although during August 2010, on request by Mrs. Régine Gaucher extensive input was given to support the comments from The Netherlands.</p> <p>Moreover no rationale has been given by the secretariat to its response: <i>“this will not solve the problem”</i> In response to the underneath comments of NL: <i>“To solve this problem NL has proposed in an earlier stages (and Germany had a similar proposal) to introduce accuracy classes”</i>. which was meant to create an acceptable solution.</p>													
			<p>Comments given on the 6CD OIML R127, which all still apply.</p> <p>1. MPE's are not suitable for The Netherlands.</p> <table><tr><td>Stage</td><td>Current NL legislation</td><td>OIML</td></tr><tr><td>type-evaluation</td><td>0,01 mg/l</td><td>0,02 mg/l or 5%</td></tr><tr><td>initial verification</td><td>0,02 mg/l or 4%</td><td>0,02 mg/l or 5%</td></tr><tr><td>periodical re-verification</td><td>0,025 mg/l or 5%</td><td>0,03 mg/l or 7,5%</td></tr></table>	Stage	Current NL legislation	OIML	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%	
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	<p>2. An even larger problem is caused by the MPE for interfering substances:</p> <table><tr><td>Current NL legislation</td><td>OIML</td></tr><tr><td>0,01 mg/l</td><td>0,1 mg/l</td></tr></table> <p>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.</p> <p>To solve this problem NL has proposed in an earlier stages (and Germany had a similar proposal) to introduce accuracy classes.</p> <p>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.</p>	Current NL legislation	OIML	0,01 mg/l	0,1 mg/l											
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United Kingdom	General comment		The UK comment refers mainly to the use of alcohol plateau detection as the definitive means of detecting alveolar alcohol. Annex A referred to by SC7 covers mouth alcohol detection. The comment about limiting the technology is correct BUT there appears to be allowance for all testing using type 1 testing and not type 2 (see also comment 11.4.3.3 below), so this is a simplification of the Recommendation not an attempt to make it more robust. <u>We seek a statement that if a national body accepts Type 1 testing and another requires Type 2 testing these are not compatible or equivalent.</u>	
United Kingdom	General comment		It is normal in standardisation documentation, and similar to give special definitions in the terminology section of the Document, where these will not be generally understood, even if these are from another document. Expecting the reader to search the bibliography in Annex D without reference is unhelpful. Annex D is not in the main body of the document.	
Japan	1	Scope	This Recommendation applies to quantitative breath alcohol analyzers that render a measurement result of alcohol concentration in directly-sampled exhaled human breath for the purpose of establishing compliance with national policy for fighting against alcohol abuse.	
Norway	1	Scope	First passage “... for the purpose of establishing compliance with national policy for fighting against alcohol abuse.” Should be deleted.	
Norway	1	Scope	New ball point “Measuring exhaled breath temperature”. Supplement.	
Norway	2.3	Mobile breath alcohol analyzer	“.... applications (e.g. in vehicles, vessels, airplanes, helicopters etc).” Supplement.	
United States	2.7	Dead anatomical volume	Definition was confusing New text The respiratory volume from the conducting areas of the respiratory system, such as the mouth and trachea, where inspired air participates very little in gas exchange	
Norway	2.15	Drift	Change “ <i>indication</i> ” to “ <i>indications</i> ”. Editorial.	Editorial comment taken into account
Norway	2.19	Plateau of alcohol	“The plateau is defined as the part of an exhalation when the alcohol....” Supplement.	

Country	Document clause		Comments	Secretariat's replies
United States	2.19	Plateau of alcohol	<p>The 'stable plateau' referred to does not correspond to the human alcohol profile, which does not normally exhibit a true plateau, but shows a slight slope. The profiles shown in Annex B are artificial profiles of the type produced by the 'test rig' and have a stable plateau. There is a good reason that the test plateau should be an actual plateau, so it would be helpful if this difference were discussed.</p> <p>This is definition of the plateau of the profile of the gas used for testing purposes only and is not representative of alveolar air.</p> <p>Suggest plateau of alcohol (testing).</p> <p>Remove text - (representative of the alveolar air)</p>	
United States	3	Description of the instrument	<p>The "analysis" of the sample is analogous to the "determination" of the result and is more correctly completed during the second stage of the analysis. The third stage refers entirely to the presentation, recording, and storage of the result.</p> <p>Remove word "determination" from third bullet.</p>	Editorial comment taken into account
United States	3.1	Sampling	<p>Grammatical correction.</p> <p>Remove the comma contained in the last sentence of the paragraph</p>	Editorial comment taken into account
Germany	3.1	Sampling	Add: A <u>disposable</u> mouthpiece...	Editorial comment taken into account
Norway	3.3	Determination, presentation and storage of the result	<p><i>"The final result of the determined ethanol concentration shall be displayed. Additionally this and the results of any sub samples may be printed...."</i></p> <p>Supplement.</p>	
The Netherlands	5.2	Maximum permissible errors	See Netherlands's comment "general comment "	
Austria	5.3	Scale interval	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.	
Poland	5.3 (and 6.5.1.3)	Scale interval	We propose to use "not greater than" instead of "at least", which could be understood as "value of the scale interval is greater than 0,01 mg/L". According to p 6.1.1 <i>"In measuring mode, the minimum breath alcohol analyzer display shall be to indicate at least two digits"</i>	

Country	Document clause		Comments	Secretariat's replies
United States	5.3	Scale interval	Clarify the last sentence of the section by including an example. This section correlates to section 6.1 and presentation of the result. Thus, the example of "rounding down the result" needs to be included, such as 0.427 mg/L being rounded down to 0.42 mg/L (see section 6.1.1)	Editorial comment taken into account
Austria	5.5.2.1	short-term driftat 0,40 mg/L shall be less than 0,01 mg/L in 4 hours. We can nor 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 0,051 mg/L in 4 hours."	
Austria	5.5.2.2	Long-term driftat 0,40 mg/L shall be less than 0,02 mg/L in two months. We can nor 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 time of 2 years (with an additional check every 6 months by the manufacturer) , and the instruments must 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."	
Norway	5.8.1	Physical influence factors	See Table – b Any demands for stationary instruments?	
Czech Republic	5.8.1	Physical influence factors	Remove "-10 °C" to "-5 °C" Motivation : at –10 °C condensation problems influe ncing accuracy of the measurement, at present no manufacturer can guarantee this equipment. If the alcohol detector would not have heated mouthpiece, then there will be too much influence of condensation at the temperature –10°C. Note : At the moment in The Czech Republic there is no measuring device with heated mouthpiece.	
United Kingdom	5.8.1 (j)	Physical influence factors Total fraction by volume of hydrocarbons in the environment	The UK cannot accept the response given to our original comment. This means that where methane is employed for the tests the analyser may pass and where another hydrocarbon is used (e.g. propane) the instrument may fail the similar test. This does not provide uniform test results.	

Country	Document clause		Comments	Secretariat's replies
Austria	5.8.2	Conditions of exhalation	<p>We can not accept the given values. We prefer the values:</p> <p>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.</p> <p>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.</p>	
Poland	5.8.2	Conditions of exhalation	<p>We propose to use the same unit of measurement for flowrate in both points, eg. 0,20 L/s and 0,10 L/s or 12 L/min and 6 L/min</p>	Editorial comment taken into account
Norway	5.8.2	Conditions of exhalation	<p>Ball points Flow rates should be given by the same units of measurements.</p>	Editorial comment taken into account
United Kingdom	5.8.2	Conditions of exhalation	<p>There are a number of separate requirements that must be fulfilled, but 5 seconds is too long for people with small FVC. We are not convinced that this covers "most human behaviour" as is stated. It needs to cover all people that deliver a valid breath sample – normal or not.</p>	
United States	5.8.2	Conditions of exhalation	<p>The total time that a subject takes to blow into an instrument is a function of the flow resistance of that instrument and therefore a function of the instrument design.</p> <p>An instrument with a low flow resistance will allow a subject to blow at a high flow rate. Some subjects will therefore reach the 1.2 L capacity in less than 5 seconds.</p> <p>For example 0.5 L/s flow rate and minimum volume of 1.2 L=2.4seconds.</p> <p>Suggested Text Exhalation time: greater than or equal to 2 s</p>	
Germany	5.10.2	physiological influence quantities	<p>Question to the last sentence: Does this imply that national regulations may also change the limit value for allowed influence or the nominal values of the already listed gases?</p>	

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The Netherlands	5.10.2	physiological influence quantities	See Netherlands's comment "general comment "	
United Kingdom	5.10.2	physiological influence quantities	The lowering of the number of interferent species is a retrograde step. The requirements in CD7 are now less stringent than any other earlier version of the Recommendation. The UK supports the Ireland proposal for 5.10.2	
United States	5.11	Durability	Editorial : Should be ...National Authorities. This clause only allows the device to remain in-service during entire verification period where most devices can provide an alert when device is not suitably adjusted regardless of period of time in-use Include allowance for device to be designed such that either the device maintains metrology stability for period as long as verification period, or provides indication that device is no longer suitably adjusted.	Editorial comment taken into account
Norway	5.11	Durability	"Stability" should be defined. What is "good enough"?	
Austria	6	Technical requirements	Breath alcohol analysers must have a device to detect or to avoid sucking.. Austria suggests to include a new requirement to avoid or to detect sucking instead of blowing. (see original R126, edition 1998) – see general comments.	
Austria	6.1.1	Displayof 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	
United States	6.1.1	Display	Requirement for display illumination. Delete"if the characters are not illuminated, the display shall have an illumination device." Readability of the result secondary to illumination is not a metrological characteristic. Most police stations are lighted and most police have flashlights in the field. This requirement should be removed.	

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Germany	6.2	Protection against fraud	clarification needed at the third bullet point: please define in technical terms the meaning of the phrase: the risk of calculated influence of... shall be minimized .	
United States	6.2	Protection against fraud	...and; whereas possibilities.... Add ...“and the possibilities....”	Editorial comment taken into account
Norway	6.3.3	Continuity of the exhalation	“...flow of exhaled air is interrupted or changed to no longer fulfilling predefined limits between the beginning....” Supplement	
Austria	6.3.4	Alcohol in the upper respiratory tract	We prefer an additional note “ To avoid influences by alcohol in the upper respiratory tract it is appropriated to wait 15 Minutes before starting the next measurement”	
Germany	6.4	Software	According to the minutes, the proposal for software of Sam Just/ BIML shall be included, so add: <i>The severity level applicable to the software embedded to breath alcohol analyzer is the raised severity level (level II) as defined in OIML D 31:2008 (see OIML D 31:2008 chapter 8).</i>	
Germany	6.4.1	Software identification (D 31:2008; 5.1.1 [7])	Add to the 5. sentence: The checksum algorithm shall be a normalized algorithm. Depending on the actual configuration of the analyzer, the CRC16, MD5, SHA-1 and SHA-2 algorithms <i>could be</i> are acceptable solutions for this calculation.	
Austria	6.5.1	Printing device	We are missing additional requirements on the printing device as in the former CD	
Austria	6.5.1	Printing device	A requirement how long the printout is readable is missing. Austria suggest: Printouts shall remain readable for 12 month.	
Norway	6.5.1.1	Printing device	New ball point “Information to identify the test/sample”. Supplement.	
Germany	6.5.2	Storage of data	Add to 5.2.3: The software <i>that displays or further processes the measurement values and accompanying data</i> shall check the time of measurement, authenticity, and...	

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United States	6.5.2.1	Storage of data	<p>Why should the memory contain any more information than that required on the printout used in court?</p> <p>This is new text not discussed in previous TC meetings.</p> <p>This should not be included in this draft.</p> <p>6.5.2.1 Second paragraph: "The measurement value stored shall be accompanied by all relevant information that is necessary for future legally relevant use"</p>	
United States	6.5.2.3	Storage of data	<p>Keys are only one method of securing data and only part of the means may be inside the breath analyzer.</p> <p>Suggested Text: Confidential keys Software means employed for protecting data shall be kept secret and secured in the breath alcohol analyzer. Means shall be provided whereby these keys software means can only be utilized, input or read only if a seal is broken.</p>	
United States	6.5.3.1	Storage of data	<p>See US comment 6.5.2.1</p> <p>6.5.3.1 Second sentence: "When the final value results from a calculation, all data that are necessary for the calculation must be automatically stored with the final result"</p>	
Norway	8.2	Additional instructions	<p>Third passage <i>"The sampling system of the breath alcohol analyzer, including the mouth piece,..."</i> Editorial.</p>	Editorial comment taken into account
United States	11.1	Units submitted to the type test	<p>Grammatical error 5th paragraph "...and as a result <u>and</u> it has..." Delete second instance of <u>and</u>.</p>	Editorial comment taken into account
Norway	11.1	Units submitted to the type test	<p>Fifth passage <i>"...a specific test and as a result it has to be....."</i> Deletion.</p>	Editorial comment taken into account
United States	11.2 g)	Documentation	<p>What is the "panel layout"? Suggest: operator input panel layout</p>	
Norway	11.3.2	Testing of instrumentation	<p><i>"Test of instrument."</i> Editorial.</p>	Editorial comment taken into account

Country	Document clause		Comments	Secretariat's replies
Austria	11.3.3	Software validation procedure	Software identification: Change Examination level A to level B, level A can not be accepted – see CD 6	
Austria	11.3.3	Software validation procedure	Fraud protection: Change Examination level A to level B, level A can not be accepted	
Austria	11.3.3	Software validation procedure	Storage of data: Change Examination level A to level B, level A can not be accepted – see CD 6	
Germany	11.3.3	Software validation procedure (D 31:2008; 6.3 [7])	<p>We feel that the decrease of the examination level is not appropriate, because some issues can be checked more effectively and more comprehensively by code inspection than by random functional testings.</p> <p>We consider the higher examination level as more than appropriate since the results of the breath alcohol analyzer will be used in court and the measuring results will be the basis for prosecution of a person. The D 31 suggests the normal examination level A for “everyday” instruments like water meters, but for instruments which require higher protection level due to their scope of application, the extended examination level B should apply. So, at least we would like to add the following sentence below the column:</p> <p><u>National regulations may require increased examination levels and validation procedures.</u></p> <p>We strongly suggest a further discussion of the topic with experts in software from the NMIs</p>	Editorial comment taken into account
Poland	11.3.3	Software validation procedure	<p>the table, row “Fraud protection”</p> <p>Should be “AD+VFTM” instead of “AD+VTFM”.</p>	Editorial comment taken into account
United States	11.3.3	Software validation procedure	<p>Typo – VTFM – should be VFTM</p> <p>Good to see that Secretariat has dropped examination level B –.</p>	Editorial comment taken into account
United States	11.4.2 & B.1 & B.2	Breath profile	<p>Breath profile shown in Annex B.1.1 is described as “through a breath alcohol analyzer” and describes Annex B.2 as providing “generally accepted breath profiles”</p> <p>This text should be modified to indicate that this profile is obtained from the flow sensor of a particular design of BAA. Because of variation in design of flow passages in different BAA and variation of flow sensors (accuracy, repeatability, associated circuits, A/D's etc) this profile cannot be held as a generic (“generally accepted”) profile that may be achieved by all other types of BAA.</p>	
Poland	11.4.3	Test sample delivery apparatus	Should be “ <i>k</i> = 2” instead of “ <i>k</i> = 2” in accordance with ISO 31-0, the symbols for quantities are printed in italic.	Editorial comment taken into account

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Norway	11.4.3.1	Characteristic reference values of the test gas	Change " <i>injected</i> " to " <i>fed</i> ". Editorial.	
Poland	11.4.3.1	Characteristic reference values of the test gas	We propose to use "volume fraction", term used in the rest of the text of the Recommendation instead of "volumetric fraction"	Editorial comment taken into account
United States	11.4.3.1	Characteristic reference values of the test gas	6 th bullet: The carrier gas should contain CO ₂ only in the case that the EBA is capable of 'seeing' CO ₂ . Otherwise, the carrier gas need not contain CO ₂ .	
Germany	11.4.3.3	Type of testing apparatus	<i>change</i> : Type 1: the apparatus delivers constant test gases with constant volume mass concentrations of alcohol For the uncertainty determination, see comment to Annex C	Editorial comment taken into account
Poland	11.4.3.3	Type of testing apparatus	We propose to use "mass concentrations of alcohol" or "concentrations of alcohol" instead "volume concentrations of alcohol »	Editorial comment taken into account
United Kingdom	11.4.3.3	Type of testing apparatus	This section now states (following the UK proposal) that both types of test apparatus are needed ; BUT the wording of the tests now means that only type 1 testing apparatus may be used in practice. This refers to 11.4.2 that is a generic clause that refers to INFORMATIVE Annexes B and C only. Most of the tests in 11.4.4.1 allow either Type 1 or Type 2 to be used. SC7 comments to this state that in 11.4.4.2.d, 2 "a Type 2 shall be used" but the amended text of 7CD states "a Type 1 test apparatus". <u>This is incorrect and contradicts the comment on this by SC7, as there is a test for plateau here.</u> Therefore there is now NO REQUIREMENT to use a Type 2 testing apparatus in the normative document.	
United States	11.4.3.3	Type of testing apparatus	Type 2 description Should be bulleted like the Type 1 line	Editorial comment taken into account
Poland	11.4.4.2	Influence factors of the conditions of injection	We propose to use term "Exhalation" for point titles and "injection" for test parameters, as in point a).	

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United States	11.4.4.2	Influence factors of the conditions of injection	This text, which is used throughout this section, seems to contradict the sentence in 11.4.3.3 Type Testing apparatus: For complete test program, both types are needed" First paragraph last bullet point: "variation of the alcohol concentration as a function of time" Paragraph a): "variation of the alcohol concentration as a function of time: no variation (type1 testing apparatus) or plateau duration of the plateau equal to 3 s (type 2 testing apparatus)."	
Norway	11.4.4.2 a.	Influence factors of the conditions of injection	Fourth ball point " <i>...no variation or duration of the plateau....</i> " Deletion.	Editorial comment taken into account
United States	11.4.4.2 a)	Influence factors of the conditions of injection	new or plateau duration of the plateau Remove "of the plateau"	Editorial comment taken into account
United States	11.4.4.2 c)	Influence factors of the conditions of injection	Incomplete text? The text in this paragraph is incomplete and confusing. The text used in B.1.2 Simulation curve of forced exhalation (top of page 72) is more complete.	
United States	11.4.4.2 c)	Influence factors of the conditions of injection	Second test – second bullet Make two sentences and change 'exhalation' to 'injection'. "during 1.5s. Between 1.5s and 5s of exhalation injection.	Editorial comment taken into account
United States	11.4.4.2 d)	Influence factors of the conditions of injection	Change test apparatus from type 1 to type 2. The test is for duration of plateau, but calls for type 1 apparatus. Type 1 apparatus delivers 'constant test gases with constant volume concentrations of alcohol'. Type 2 apparatus should be called for instead.	
United States	11.4.4.2 e)	Influence factors of the conditions of injection	Reference should be to 11.4.3.1 instead of 11.4.1	Editorial comment taken into account
Poland	11.4.4.7	Random vibration	" <i>Preliminary test: Before the vibrations, the MPE shall be determined.</i> " – MPE are stated in 5.2? Maybe compliance with?	
Poland	11.4.4.11	Voltage variation of a road vehicle battery	Delete ..."in brief".... In the first column, second row of the table, should be "Condition of the EUT" instead of "Stabilization".	Editorial comment taken into account

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Poland	11.4.4.12	AC mains frequency variations	Delete ... "in brief" We propose to maintain the order of tests according to table in 5.8.1 or to change the order in this table (letters from "g" to "i", tests from 11.4.4.10 to 11.4.4.12).	Editorial comment taken into account
United Kingdom	11.4.4.13	Total fraction by volume of hydrocarbons in the environment	See UK comment to 5.8.1.j	
Poland	11.4.4.14	Influence of the volume fraction of CO ₂	We propose to use the same terms in table in p. 5.8.1 and in the title of this test: either "mass concentration" or "volume fraction" of CO ₂	
Poland	11.4.5	Disturbance tests	We propose to maintain the order of tests according to table in 5.10.1.2 or to change the order in this table (letters from "a" to "c", tests from 11.4.5.9 to 11.4.5.11). Within p.11.4.5, in tests: 11.4.5.3, 11.4.5.10 11.4.5.12 the number of measurement performed during/after disturbance is clearly stated. What about the number of measurements during/after other tests?	
Australia	11.4.5.8	Electrical transient conduction for external batteries of a vehicle	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.	Editorial comment taken into account
Poland	A 2.1.2	Test procedure	Note <i>"The mass concentration of the first test gas is equal to the mass concentration of the legal value minus 0.3 mg/L"</i> According to tables 1, 2 and 3 it seems it should be "0.03 mg/L" instead of "0.3 mg/L"	
Poland	A 2.1.2	Test procedure	Within the text of other parts of the Recommendation, "greater than" is used instead of "more" and "smaller than" is used instead of "less". We propose to use the same terms.	Editorial comment taken into account
Poland	A.2.1.2	Test procedure	Part c) Should be "injection to" instead of "breath of".	Editorial comment taken into account

Country	Document clause		Comments	Secretariat's replies
United States	Annex B	General information and breath profile	<p>See US comment 11.4.2</p> <p>Figure B.1.2 Simulation curve of forced exhalation (Description of the test in 11.4.4.2 c)</p> <p>The test and the flow profile defined are arbitrary. What is testing to this profile trying to achieve?</p> <p>Many instruments are designed to ensure that the subject provides a steady, continuous breath flow through the instrument until the instrument has determined that the sample is suitable for analysis. This flow profile would be rejected by most designs because of the large variation in flow in a short length of time.</p>	
Poland	B.2	Measurement of the alcohol concentration during exhalation /determination of the alcohol plateau	<p>Figures</p> <p>The layout of each figure is different. Is it on purpose or could be made one way?</p>	
Poland	B.2.1	Theoretical curves of the alcohol concentration as a function of time obtained from a human exhalation	<p>formula, figures</p> <p>We propose to use “% of the expected concentration” or “% of the reference value” instead of “alcohol concentration (expressed in %)”.</p>	
Australia	B.2.2	Simulation curves of the alcohol concentration as a function of time	<p>Editorial. Remove the final close bracket in Appendix B, final line of text before the figure.</p>	Editorial comment taken into account

Country	Document clause		Comments	Secretariat's replies
Germany	Annex C	Reference principle for the implementation of the tests (Informative)	<p>See also general comment.</p> <p>The explanation regarding the partition ratios (Dubowski as well as Harger) is difficult to understand and doesn't explain the circumstance that partition ratios only apply at dynamic equilibrium. For a better understanding of the topic, the sketches for the examples of gas generators from page 34 to 36 of the R 126:1998 should be reinserted. We feel that explaining the partition ratio without linking it to practical use doesn't make much sense. It will also help and give much advice to persons who are new to the subject.</p> <p>It should be made clear that the Dubowski formula is the basic formula for OIML R 126, with the partition ratio as a conventional value, which has the formal uncertainty of zero.</p> <p>It may be open for National Authorities to choose other formulae such as Harger's.</p>	Editorial comment partially taken into account
Poland	Annex C	Reference principle for the implementation of the tests (Informative)	CH ₂ O, C _{air} , t – in accordance with ISO 31-0, the symbols for quantities are printed in italic.	Editorial comment taken into account
United States	Annex C	Reference principle for the implementation of the tests (Informative)	<p>The formula given for Harger's Ka/w is incorrect.</p> <p>It should be: $Ka/w = 0.000393 \text{ at } 34^{\circ}\text{C}$ for $t = 34^{\circ}\text{C}$, $C_{\text{air}} = 0.393 \times 10^{-3} C_{\text{water}}$</p>	Editorial comment taken into account
United States	Annex D	Reference principle for the implementation of the tests (Informative)	<p>Incomplete information.</p> <p>The section needs to include references for other annexes, principally support for use of general flowrate profiles, alcohol profiles, and alcohol partition values for Harger and Dubowski.</p>	