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Metrological traceability of the breath alcohol measurements

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Abstract

Breath alcohol measurements are widely used worldwide to detect the presence of alcohol in the human body. For those measurements, different metrological traceability chains are used, both in the international normative documents and at the national level. Different measurement standards used to calibrate breath analysers reproduce different quantities: on the one hand, an «actual» ethanol mass concentration, and, on the other hand, the operationally defined «ethanol mass concentration by Dubowski (or Harger)». This makes the comparability of the breath alcohol measurements questionable. According to various studies, the discrepancy between the operationally defined quantity and the concentration not related to the empirical interphase distribution coefficients, lays within (1-2) %, although there is also an evidence of a larger deviation. It is possible to construct a common metrological traceability chain by using reference gas mixtures in cylinders and dynamic gas mixture generators based on the principles not related to empirical equations, as well as determining more accurately the interphase distribution coefficient and evaluating its uncertainty. SE «Ukrmetrteststandart» possesses internationally recognised calibration and measurement capabilities for measuring ethanol concentration and producing reference materials: calibration gas mixtures of ethanol with nitrogen or air in cylinders and reference aqueous solutions of ethanol that provide metrological traceability for the breath alcohol measurements.

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1. Relevance of the topic

Thousands of people around the world become the victims of car accidents. Many of those accidents are caused by drivers under the influence of alcohol. According to the US National Highway Traffic Safety Administration (NHTSA), in the USA the number of alcohol-impaired-driving fatalities is about 30 people daily and more than 10,000 annually [1]. In the countries of the European Union, the number of victims of drink-driving reaches more than 10 thousand people per year, which is about a quarter of all fatalities in road accidents [2]. In Ukraine, according to the Patrol Police [3], in 2020 driving under the influence of alcohol caused 4,522 traffic accidents in which 103 people were killed and 1,554 injured.

An effective way to prevent accidents and identify their causes is to determine the alcohol content in the human body, in particular by measuring the concentration of ethanol in the exhaled air.

As the price of alcohol measurement results can be high, both figuratively and literally, they should not be doubtful. One of the most important factors of credibility is the metrological traceability of measurement results and the related comparability of results.

2. Metrological traceability and comparability of results

As defined in the International Vocabulary of Metrology (VIM), metrological traceability is a «property

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of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty» [4]. Another concept, which is closely related to metrological traceability, is metrological comparability. In VIM, it is defined as «comparability of measurement results, for quantities of a given kind, that are metrologically traceable to the same reference». Thus, it depends on the traceability chains whether it is relevant to compare the values of alcohol content in exhaled air that were measured with different devices, for example, before and after crossing the border between the countries in which different metrological rules for the breath analysers are established.

3. Calibration standards for the breath analysers

For breath alcohol measurements, the first link of the unbroken chain of calibrations, which is referred to in the metrological traceability definition, is a calibration of the breath analyser using a working measurement standard. Let us consider what working standards are used to calibrate those devices, and where the traceability chains lead further up.

3.1. Calibration gas mixtures

Breath analysers can be calibrated with reference materials: ethanol-in-nitrogen or ethanol-in-air calibration gas mixtures contained in the pressurized cylinders. In general, calibration gas mixtures (CGM) are a special kind of certified reference materials (CRM) as defined in VIM [4] and ISO Guide 30 [5]. CGM are usually prepared in the pressurized cylinders by the gravimetric method according to ISO 6142-1 [6]. The principles of metrological traceability for CGM has been discussed for many years, in particular in the Working Group on Gas Analysis (GAWG) of the Consultative Committee for the Amount of Substance (CCQM) of the International Committee for Weights and Measures (CIPM) and the Technical Committee of the International Organization for Standardization ISO/TC 158 «Gas analysis». Those principles are summarized in the international standard ISO 14167 [7]. According to them, in particular, for metrological traceability of the CGM component mole fractions, it is not sufficient just to provide the traceability of masses of the parent «pure» gases to SI «kilogram» unit, but it is also necessary to verify the composition of the prepared CGM. The mixtures are verified by demonstrating the metrological compatibility (see 2.47 in VIM [4]) of the mole fraction values calculated by the gravimetric preparation procedure and the values determined by comparison with other reference gas mixtures of similar composition. With this regard, only the National Metrology Institutes (NMIs[1]) can provide primary realisation of a mole fraction unit for gas mixture components, and other organisations should establish metrological traceability to NMIs' primary standards.

The scheme of metrological traceability dissemination through calibration gas mixtures according to [7] is shown in Fig. 1.

SE «Ukrmetrteststandart» has been working for many years to ensure metrological traceability in the gas analysis [8]. The metrological traceability chain adopted in Ukraine for gas mixture component content was developed by SE «Ukrmetrteststandart», and it is based on the principles set out in ISO 14167 and the IUPAC Technical Report [9]. The traceability chain is described in detail in the [10].

A simplified traceability chain for the analysers calibrated with the certified reference materials – CGMs, is shown in Fig. 2.

3.2. Dynamic generators of alcohol-air calibration mixtures

Dynamic generators are used to prepare the calibration gas mixtures directly where they are used. Let us consider the main types of generators.

[1] Here, NMI means organisations that have the status of both the National Metrology Institute and the Designated Institute following the definitions adopted by the International Bureau of Weights and Measures (BIPM).

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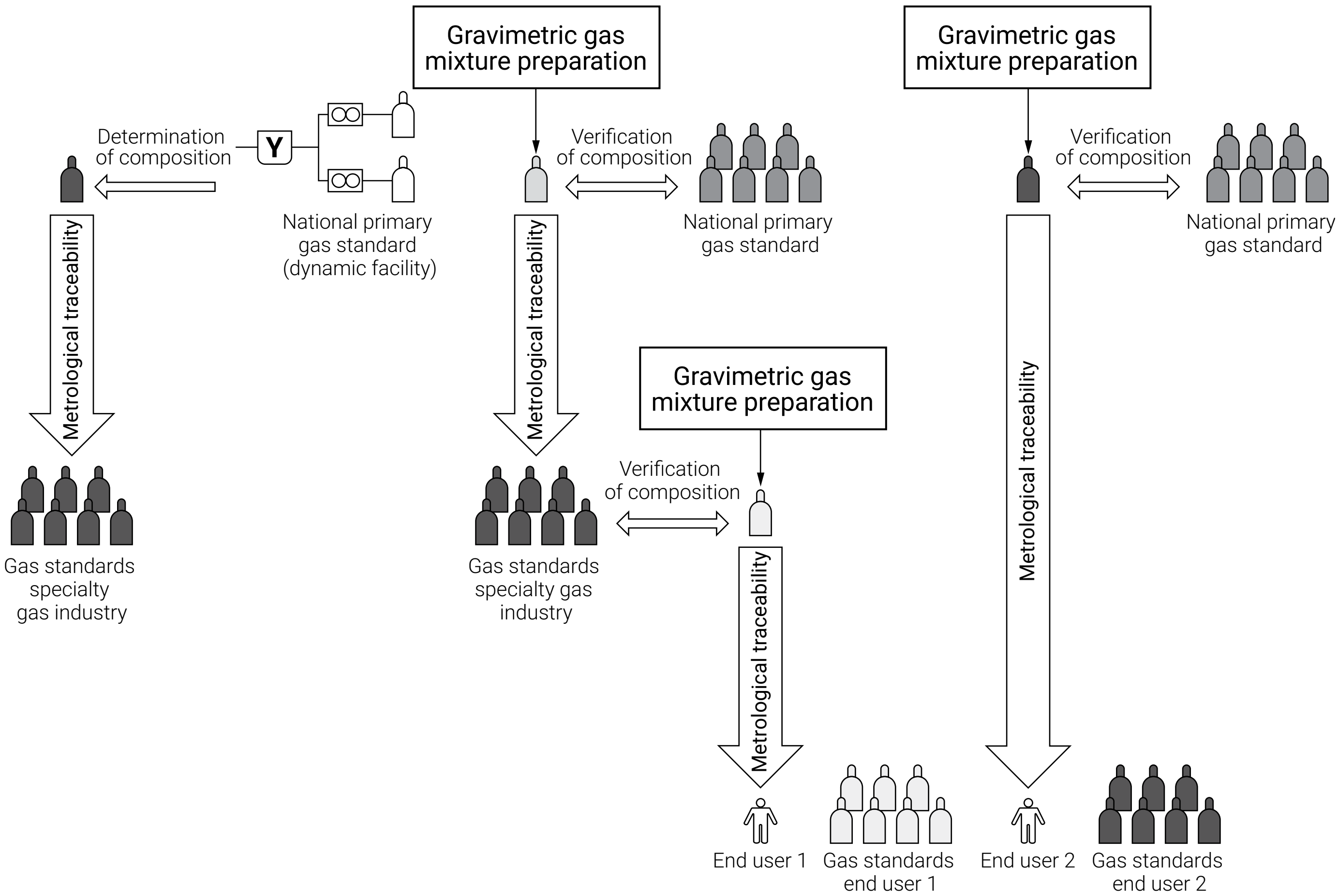

Fig. 1. *Scheme of metrological traceability dissemination through calibration gas mixtures according to ISO 14167* [7]

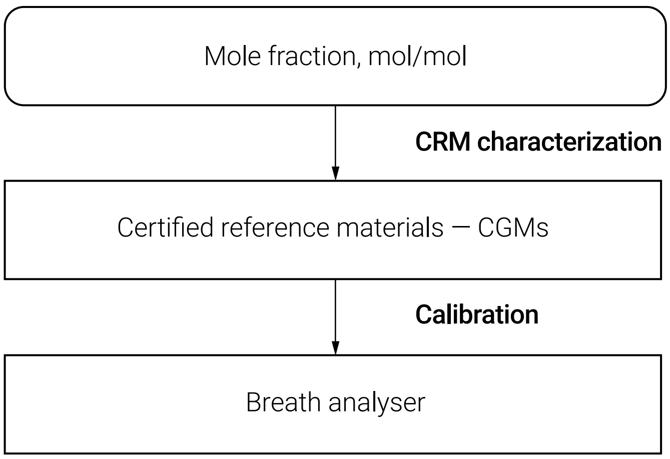

Fig. 2. *Simplified traceability chain for the analysers calibrated with the certified reference materials – CGMs*

3.2.1. Generators based on the ethanol distribution between the liquid and gas phases of an aqueous solution (type A generators)

The most common generators are those based on the law of a solute distribution between liquid and gas phases (Henry's law). In such generators, the air is continuously blown through an aqueous ethanol solution, and the mass concentration of ethanol in the mixture at the generator outlet γ_{air} depends on the mass concentration of ethanol in the solution γ_{H_2O} and the solution temperature t. This dependence is described by Dubowski's formula [11]:

$$\gamma_{air} = 0{,}04145 \cdot 10^{-3} \cdot \gamma_{H_2O} \cdot e^{0{,}06583t}, \qquad (1)$$

where

temperature t is expressed in Celsius degrees.

At the temperature of 34 °C (which is close to the temperature of exhaled air), the formula takes the form:

$$\gamma_{air} = 0{,}38866 \cdot 10^{-3} \cdot \gamma_{H_2O}. \qquad (2)$$

A measurement model described by Dubowski's formula has two input variables: mass concentration

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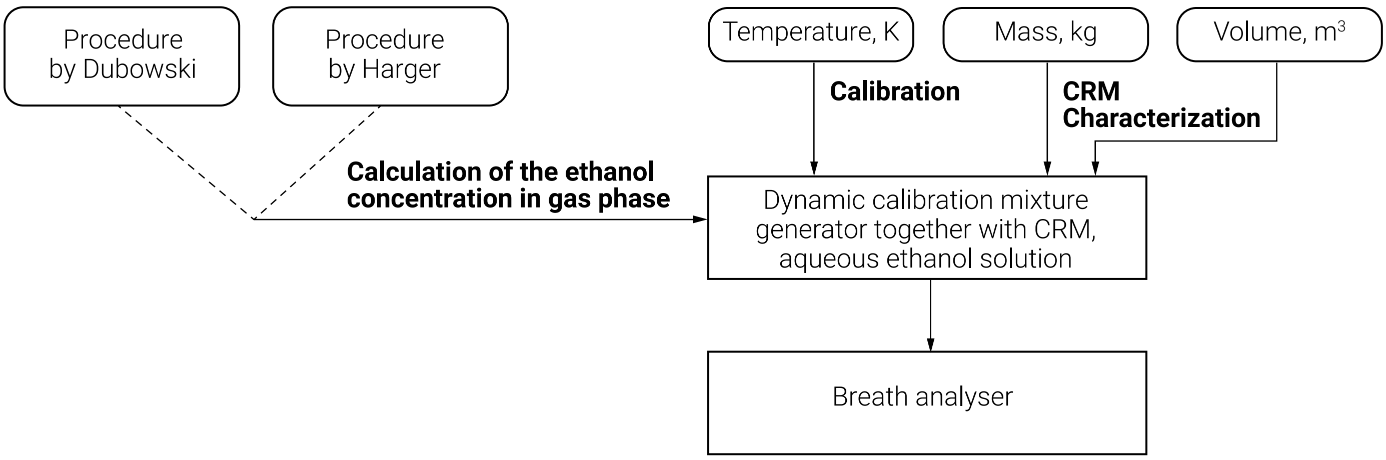

Fig. 3. *Simplified metrological traceability chain for the analysers calibrated with type A generators*

of ethanol in the solution γ_{H_2O}, and temperature t, which should be traceable to the SI units of mass and volume (γ_{H_2O}), and temperature (t), respectively. But that is not the whole story. Let's make a short digression to consider the concept of «operationally defined measurand».

The definition of «operationally defined measurand» (also called «method-defined measurand» or «empirical measurand» [12]) can be found in ISO 17034 [13]: «a measurand that is defined by reference to a documented and widely accepted measurement procedure to which only results obtained by the same procedure can be compared». An approach to the metrological traceability of such quantities has its specific features. In particular, the measured values, under certain conditions, can be considered traceable to SI units, but their comparability is limited by the method specified in their definition [14].

In 2019, the CCQM adopted the document «Report of the CCQM task group on method-defined measurands» [15]. One of the method-defined measurands mentioned in this document is an «ethanol mass concentration in wet air by Dubowski». Then it turns out that analyser calibrated with compressed gas mixtures shows mass concentration values that are not related to any specific method, and the other one, which is calibrated using the above-described generator, shows the values of the «mass concentration by Dubowski», i.e. of the different measurand. Consequently, it is not relevant, at least formally, to compare the readings of the two analysers.

In addition, according to [11], Harger's formula can be used instead of Dubowski's formula, according to which the ethanol partition coefficient between the liquid and gas phases of the solution:

$$K_{a/w} = 0{,}000393,$$

and at 34 °C:

$$\gamma_{air} = 0{,}393 \cdot 10^{-3} \cdot \gamma_{H_2O}. \qquad (3)$$

Thus, similarly to the «mass concentration by Dubowski», we have another operationally defined measurand, «mass concentration by Harger».

It is important to note that for the operationally defined measurands, the uncertainty associated with the method is zero, this follows from the very definition of this type of quantity. This means that the coefficients in equations (1-3) are considered constant numbers, with no uncertainty.

Simplified traceability chains for the analysers calibrated with type A generators are shown in Fig. 3.

3.2.2. Dynamic generators not related to any empirical equations (type B generators)

A description of such a generator can be found in a new version of the OIML R 126 Recommendations just adopted [16]. Its simplified scheme is shown in Fig. 4 (the elements allowing to humidify the mixture, add

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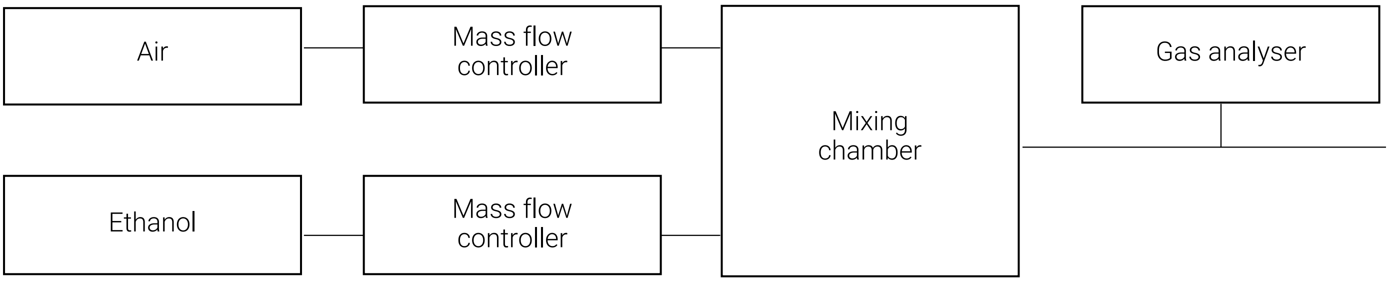

Fig. 4. *Simplified scheme of the type B generator*

carbon dioxide, and reproduce the exhalation profile are not shown).

The gas mixture with the specified ethanol concentration is obtained using ethanol and air mass flow controllers, and the determination of the outlet ethanol concentration is done through an analysis system. Concerning the metrological traceability, the following piece of generator description in [16] is interesting:

«According to the technical solutions adopted, ... the gas analyser that is included can be considered as a means of checking the apparatus or as providing a standard if it is calibrated periodically».

This means that in the former case (gas analyser is a means of checking) the ethanol concentration in the mixture is calculated according to the readings (settings) of the mass flow controllers, and in the latter case (gas analyser provides a standard) the concentration is determined by the readings of the gas analyser. Respectively, there are two different metrological traceability chains: in the former case, the concentration is traceable to the mass and time SI units, in the latter case – to the gas mixture component mole fraction unit, as in the case of calibration gas mixtures in cylinders (see Section 3.1 of this article). Simplified traceability chains for the analysers calibrated with type B generators are shown in Fig. 5.

4. Metrological traceability in the international normative documents on breath analysers

There are several international documents establishing metrological requirements and test methods for the breath analysers: OIML Recommendation R 126 [11] on evidential analysers, its new version [16] and European standards EN 15964 [17] on non-evidential professional test devices, EN 16280 [18] on test devices for the general public, and EN 50436-1 [19] on alcohol interlocks for cars. Let us consider the requirements of those documents

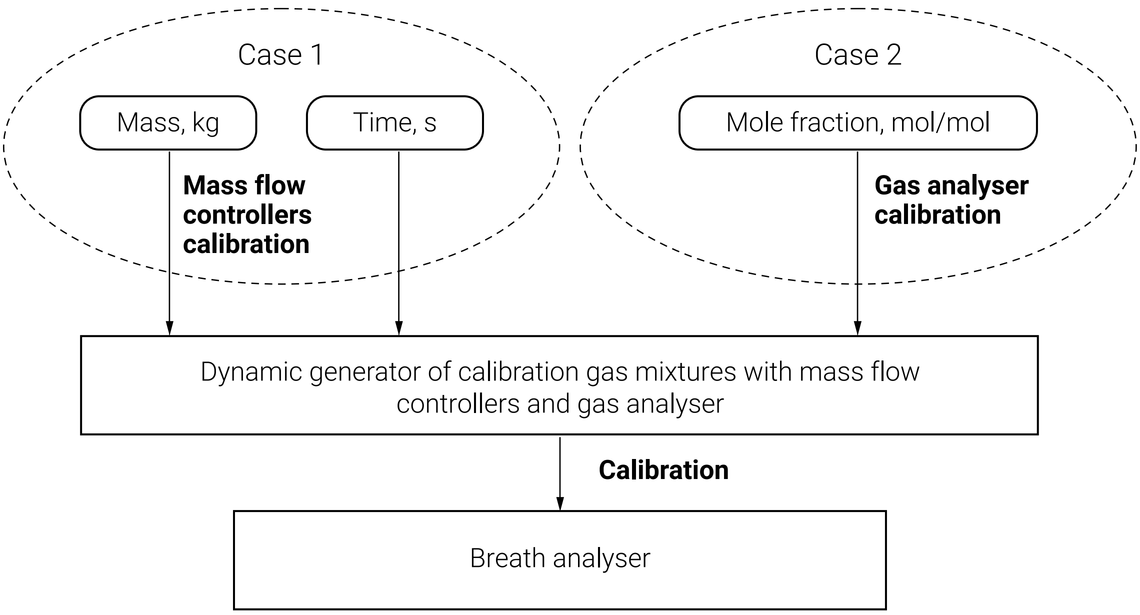

Fig. 5. *Simplified metrological traceability chains for the analysers calibrated with type B generators*

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concerning test (calibration) gases and gas mixture generators, and whether the choice of the calibration means depends on the different metrological traceability chains discussed above.

According to OIML R 126 [11, 16], it is allowed to determine the analyser error characteristics, in particular, for verification, using wet mixtures obtained from dynamic generators, but not «dry» gas mixtures from cylinders. However, it is clear that such «discrimination» of mixtures in cylinders is not due to the traceability chains, but to the fact that the presence of water vapour in the mixture (and probably CO_2) is an important influence factor for the analysers. In other words, there is an issue not of metrological traceability, but of the commutability of reference materials [4, Cl. 5.15]. It should also be noted that according to [16], the mixtures obtained from type A and type B generators are equivalent, although, according to [15], they reproduce different physical quantities: mass concentration (type B) and operationally defined «mass concentration by Dubowski (or Harger)» (type A). The OIML R 126 new version [16] has its own classification of generator types (type 1 and type 2), but they are distinguished not by traceability chains, but by the ability to reproduce the exhalation profile required for some types of tests.

Standard EN 15964 allows the analysers to be adjusted with both dry and wet gas, provided it can be shown on the device that the results from each are equivalent. The concentration of ethanol in the wet mixture should be calculated by Dubowski's formula (it can be assumed that Harger's formula is not mentioned there, because it was not given in the OIML R 126 version of 1998, which was valid at the time of adoption of EN 15964). Thus, there is no thought about different traceability chains or different measurands in this standard too. The same can be said about EN 16280 [18] and EN 50436-1 [19].

5. National rules on metrological traceability for breath analysers

Diverse approaches to providing metrological traceability for breath alcohol measurements are used in different countries. The countries can roughly be divided into three groups: those where the traceability system is based on gas mixtures in cylinders, those where the system is based on aqueous ethanol solutions and dynamic generators of wet mixtures, and those where both mixtures in cylinders and aqueous solutions of ethanol together with generators are used.

The first group includes Portugal, where, according to [20, 21], the entire traceability chain is formed by calibration gas mixtures of ethanol with nitrogen. Those mixtures are manufactured by IPQ, the National Metrology Institute of Portugal, and they are traceable to the primary reference gas mixtures of the National Metrology Institute of the Netherlands.

The countries belonging to the second group, i.e., those where traceability is fully provided through aqueous ethanol solutions and type A generators, are e.g., Germany [22], Romania [23] and Australia [9, 24, 25].

The multilevel traceability chain [9], which is based on the Australian scheme, is shown in Fig. 6. The calibration means («calibrator») in the upper link of the chain is pure ethanol, followed by calibration solutions of different metrological levels. Note that at the lower level of this chain, the calibration solution («working calibrator 4») reproduces a certain ethanol concentration in an aqueous solution, whereas the device calibrated with it gives the result of sample analysis in units of another quantity, the ethanol concentration in air. How does it happen, that one quantity transforms into another? The answer is that the actual calibrator at this level is not an aqueous solution itself, but a type A dynamic gas mixture generator filled with the solution. Since the generator is not shown, there is no temperature at the upper part of the scheme among the quantities and units, providing traceability to which is necessary, while the others (mass – kilogram, volume – litre, wavelength – meter, absorbance – number 1) are present. But it is the temperature that, together with the solution concentration, determines gas mixture composition at the generator outlet. Also, the method by which the ethanol concentration in the solution is converted into the ethanol concentration in the gas mixture («Dubowski's formula») is not stated.

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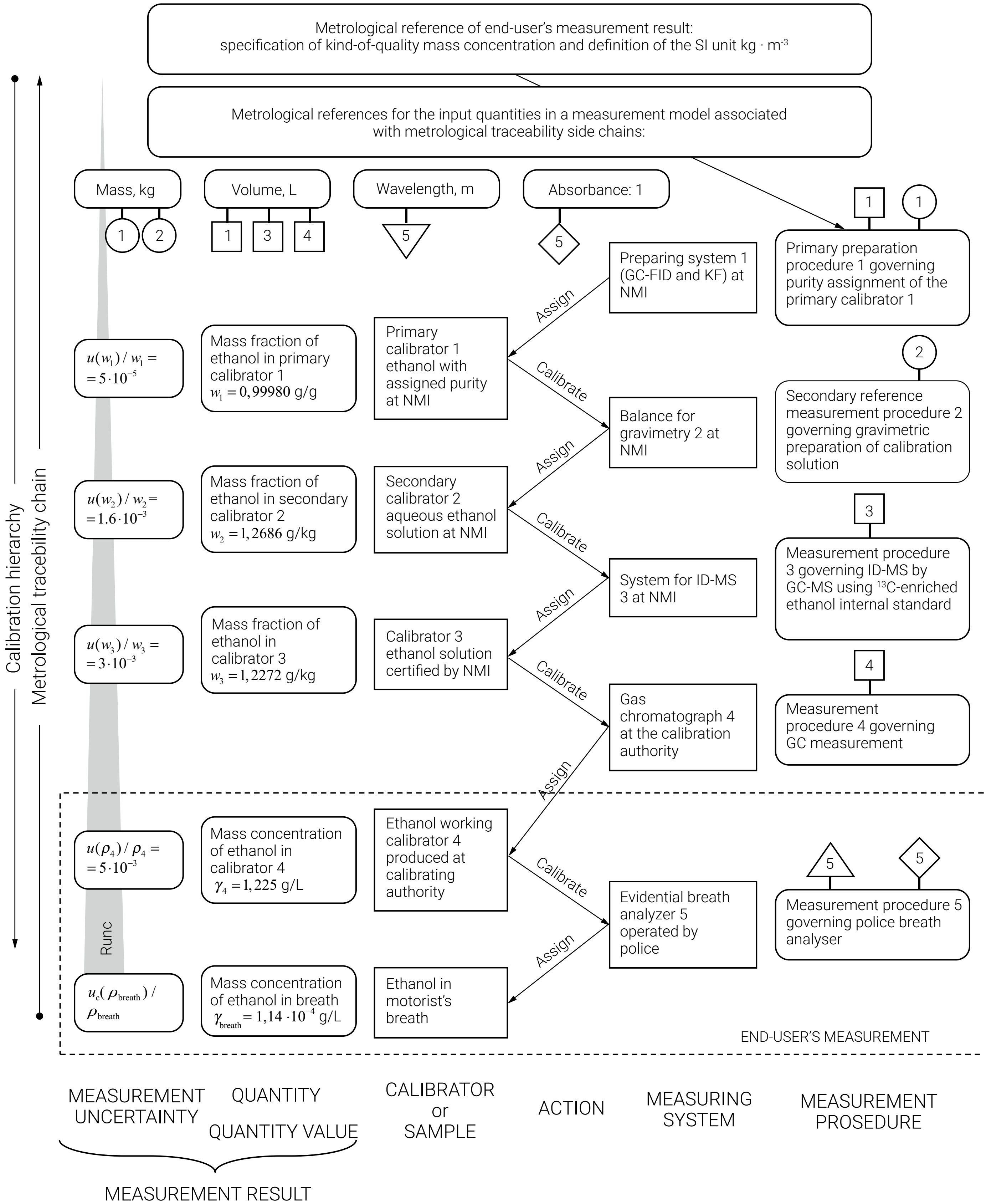

Fig. 6. *Metrological traceability chain for the breath analysers according to* [9]

In this respect, the metrological traceability chain for breath analysers presented in [9] is incomplete.

A representative of the third group of countries is Poland. On the one hand, there is a traceability

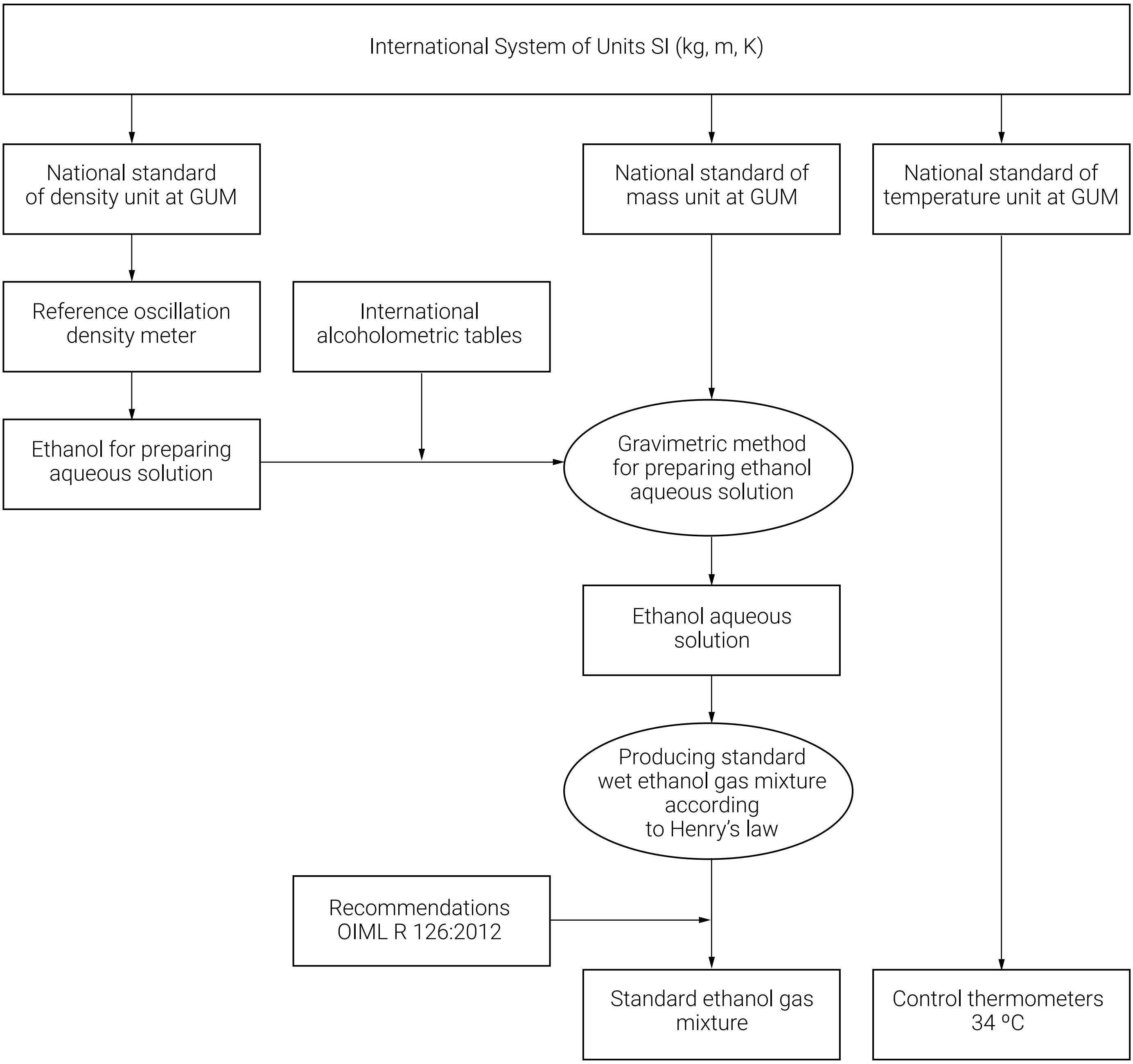

Fig. 7. *The traceability chain, based on dynamic generators and standard ethanol solutions, adopted in Poland* [26]

chain based on dynamic generators and reference ethanol solutions [26], see Fig. 7.

Unlike the Australian scheme, it shows traceability to the temperature measurement standard and refers to the gas mixture preparation method using aqueous ethanol solutions according to Henry's law. Thus, from the traceability chain it clearly follows that the realised quantity, by which the analysers are calibrated, is the operationally defined «ethanol mass concentration in air by Dubowski». One can also note the traceability to the national density standard shown in the scheme. This is because the ethanol content in «pure» alcohol used to prepare reference solutions is determined through its density.

On the other hand, GUM, the National Metrology Institute of Poland, also developed and created reference facilities using dry gas mixtures in pressurised cylinders [27]. As a justification for the development of the dry-gas facilities, it is noted that «the Dubowski formula includes empirically determined factors», but in [27] there are no considerations regarding the comparability of the quantities realised in two different ways.

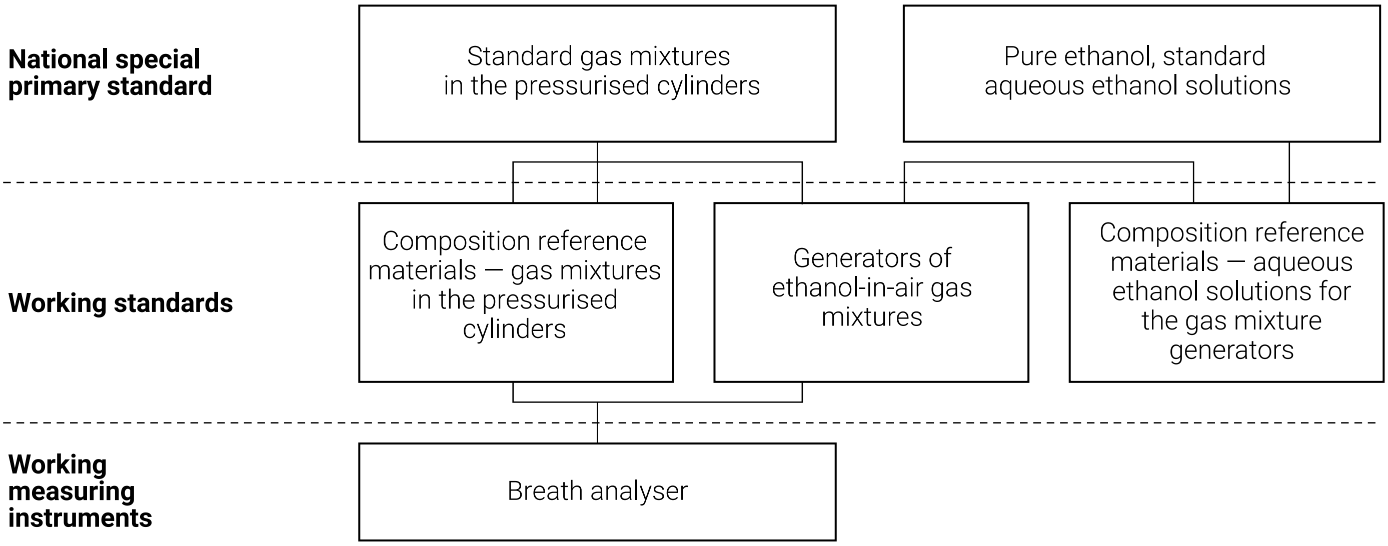

Fig. 8. *Traceability chain based on the «verification chart» for breath analysers adopted in Russia* [28]

Also, the reference standards of both types, gas mixtures in cylinders and type A dynamic generators, are used in Russia, but there they are built into a single hierarchical subordination scheme, «verification chart» [28]. Fig. 8 shows a simplified traceability chain based on this scheme (omitted is its part concerning measuring instruments for ethanol concentration in liquids, as well as a division of the working standards and working measuring instruments into grades and groups of different accuracy).

Fig. 8 shows that the scheme does not make any distinction between the two quantities, ethanol concentration in the gas mixture and the operationally defined «ethanol concentration by Dubowski». Practically, it means that type A generators are filled with reference aqueous ethanol solutions and calibrated with reference gas mixtures in the pressurised cylinders.

In Ukraine, there is no separate verification chart for the breath analysers. These analysers, as well as relevant measurement standards, in particular gas composition reference materials and gas mixture generators, are included in the general verification chart for gas-analysis measuring instruments [29]. Accordingly, they are also covered by the metrological traceability chain for the gas composition measurements, which is described in detail in [10]. So, the documents adopted in Ukraine also do not distinguish between ethanol concentration and «ethanol concentration by Dubowski».

6. Discrepancy between the ethanol concentration in air defined operationally and concentration not related to any specific method

From a practical point of view, it is interesting to estimate how the diversity of the applied traceability chains influences measurement results obtained with the breath analysers.

The easiest problem is to estimate the difference between «ethanol concentration by Dubowski» and «ethanol concentration by Harger». To do this, it suffices to look at the relative difference between the coefficients of equations (2) and (3). It equals 1 %, and this is how much the readings of the instruments calibrated using the two equations would differ. Is it a lot or a little? Compared to the maximum permissible relative error of the evidence analysers according to OIML R 126 [11], which is equal to 5 % (during type approval and initial verification), the difference obtained could be considered negligibly small. On the other hand, OIML R 126 says that the uncertainty of the ethanol concentration in the gas mixtures used for the instrument testing shall be less than or equal to one-third of the maximum permissible error, i.e. 1,7 %, and then the discrepancy between the Dubowski's and Harger's coefficients is now significant.

It is more difficult to estimate the difference between the ethanol concentration calculated

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by empirical formula (2) or (3) and concentration determined by independent methods. In fact, this problem is reduced to the experimental verification of the previously established values of the ethanol interphase distribution coefficient according to Henry's law, which were used in Dubowski's and Harger's equations. Such studies were performed using various methods.

In [30], the pressurized ethanol-in-nitrogen gas mixtures in cylinders and mixtures from a type A dynamic generator were compared using two evidential breath analysers with infrared sensors. Based on the data obtained, it was concluded that the two types of mixtures were completely equivalent in terms of ethanol concentration. As a criterion of an acceptable discrepancy, requirements to the accuracy of the evidential analysers, which are quite strict, were taken.

To complement the study reported in [30], another research was undertaken [31]. Again, pressurized gas mixtures in cylinders and mixtures from a dynamic generator were compared, but that time the ethanol concentration in the mixtures was measured by an independent titration method. The conclusion on the equivalence of the two types of mixtures was confirmed.

PTB, the National Metrology Institute of Germany, has developed a dynamic generator of ethanol-in-air mixtures [32], which can be considered a version of the type B generator described above. The mass concentration of ethanol in the mixture is determined by the mass of the ethanol aqueous solution used to prepare the mixture, the mass of water added to moisten the mixture, the air mass flow rate, and the mixture compressibility factor. The latter is close to unity under normal conditions, and it can be calculated by the virial coefficients of the equation of state. That is, the determination of the ethanol concentration in the mixture is not related to any empirical phase distribution coefficients. The mixtures obtained with this generator were compared with the mixtures from the type A generator. Breath analysers with infrared and electrochemical sensors were used as comparators. In contrast to previous comparative tests [30, 31], the relative difference between the «concentration by Dubowski» and the concentration calculated independently of the empirical equation was quite large, about 5 %. However, the authors of [32] noted that the results of comparisons using breath analysers have significant uncertainty, and it would be appropriate to conduct research using more suitable comparators.

A new device that can be used to compare different methods of the reference ethanol-in-air mixtures preparation is described in [33]. The authors propose to measure ethanol concentration by laser absorption spectroscopy. At present, we have no information on the results of reference mixtures comparison with this method.

7. What to do next with metrological traceability?

The alcohol concentration in the exhaled air is measured daily and at the same time in different countries worldwide. Obviously, for this type of measurement, it would be desirable to establish full traceability to SI units, without involving operationally defined quantities. This could be achieved by using reference gas mixtures in cylinders and mixture generators, based on direct determination of the amount of mixture components («type B generators»). Such generators have been developed at the National Metrological Institutes of Germany, PTB, [32] and Switzerland, METAS [34]. Nevertheless, it is clear that type A generators cannot and should not be abandoned: they are easy to produce and to use, and therefore widely applied at almost all the companies and laboratories, where breath analysers are manufactured, tested, calibrated and verified. To «embed» them into traceability chains with no operationally defined quantities, it is necessary to obtain a more accurate value of the interphase distribution coefficient according to Henry's law and evaluate its uncertainty that could be included in the uncertainty budget of the analyser calibration. An overview of the currently available results of determining the distribution coefficient can be found in [26] and [35].

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Analyte	Matrix	Measurand	Measurement range and range of the CRM certified value	Expanded relative uncertainty (coverage factor)
Ethanol	Nitrogen or air	Mole fraction	(50-500) μmol/mol	0,7 %
Ethanol	Water	Mass fraction	(0,5-5) g/kg	0,9 %

Table 1. *Characteristics of the institute's CMCs in the KCDB database*

8. Calibration and measurement capabilities of SE «Ukrmetrteststandart» concerning metrological traceability of the breath alcohol measurements

SE «Ukrmetrteststandart» performs the functions of the Metrology Institute of Ukraine in the field of the quantity of substance (QM) (which is traditionally called «physico-chemical measurements»). The institute has internationally recognised calibration and measurement capabilities (CMC) for measuring ethanol concentration in both gas mixtures and aqueous solutions and producing appropriate certified reference materials (CRM). The capabilities of the institute are confirmed by the results of the international key comparisons: COOMET.QM-K93 [36] for gas mixtures and SIM. QM-K27 [37] for aqueous ethanol solutions. These CMCs have been entered into the CIPM database (KCDB) [38] under the CIPM Mutual Recognition Agreement (CIPM MRA).

Characteristics of the institute's CMCs in the KCDB database are given in Table 1.

9. Conclusions

1. Different metrological traceability chains are used for the breath alcohol measurements, both in the international normative documents and at the national level.

2. Different means of breath analyser calibration realise a unit of different quantities: the actual ethanol concentration and the operationally defined «ethanol concentration by Dubowski (or Harger)».

3. The use of diverse metrological traceability chains and realisation of different measurands makes questionable the comparability of the breath alcohol measurement results obtained with instruments calibrated in different ways.

4. Common metrological traceability chain can be constructed by using reference gas mixtures in cylinders and dynamic gas mixture generators based on direct determining of the amount of mixture components, as well as by determining more accurately the interphase distribution coefficient according to Henry's law, which is a basis for the most commonly used generators, together with evaluating the uncertainty of this factor, which can be included into the uncertainty budget of the analyser calibration. An accurate determination of the interphase distribution coefficient and evaluation of its uncertainty will be the subject of further studies.

5. The discrepancies found between the operationally defined quantity («concentration by Dubowski») and concentration not related to the empirical interphase distribution coefficients, even in the worst case, do not exceed 5 %. Those discrepancies, as well as the use of different metrological traceability chains, in no way doubt the possibility and feasibility of using breath analysers to check the presence of alcohol in the human body.

6. SE «Ukrmetrteststandart» possesses internationally recognised calibration and measurement capabilities providing metrological traceability for the breath alcohol measurements through the certified reference materials, both calibration gas mixtures of ethanol with nitrogen or air in cylinders, and reference ethanol aqueous solutions.

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