

## WHAT REQUIREMENTS SHOULD EVIDENTIAL BREATH ANALYSERS FULFIL?

Dariusz ZUBA

*Institute of Forensic Research, Cracow*

**ABSTRACT:** In this paper, Polish legal regulations that came into force in 2003 relating to the study of evidential breath analysers have been analysed and compared to recommendations of international organisations that deal with metrology. Furthermore, suggestions for future amendments so that Polish regulations will be consistent with the legislation that is binding in most European countries have been put forward.

**KEY WORDS:** Breath analyser; Alcohol; Legal regulations.

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### INTRODUCTION

In the Act of 26 October 1982 on Upbringing in Sobriety and Counteracting Alcoholism<sup>1</sup>, the separate limits for alcohol content in blood and in expired air for “the state after use of alcohol” and “the intoxication state” were stated. Therefore the analysis of expired air is treated as an independent method of sobriety testing. Because of many advantages of the expired air as the tested material, including the opportunity of measurement performing at the place of event and taking the decision concerning e.g. the withdrawal of the driving licence, such analysis became common over the world and currently it is treated as the priority. The changes in the Polish legislation heads towards the same direction. Article 126 of the Act of 20 June 1997 – the Road Traffic Act<sup>2</sup> states that analysis aimed at establishing alcohol content in the organism should be carried out using electronic appliances measuring concentration of alcohol in exhaled air. This regulation is not applied only in cases where the state of the person being subjected to analysis makes it impossible to use an electronic appliance. The decree of the Minister of Health and Social Welfare of 6 May 1983 concerning conditions and method of carrying out analysis for alcohol content in the organism<sup>3</sup> states that this analysis may encompass

<sup>1</sup> Published in official journal of the Republic of Poland, *Journal of Laws* of 2002, No. 147, item 1231.

<sup>2</sup> Consolidated version, *Journal of Laws* of 2003, No. 58, item 515.

<sup>3</sup> *Journal of Laws* of 1983, No. 25, item 117.

analysis of exhaled air, blood or urine, bearing in mind that where possible analysis of exhaled air should be carried out before other types of analysis for alcohol content in the organism (§ 3.4). Bearing the above in mind, recent changes that have been introduced into Polish legislation concerning the examination of exhaled air analysers have been analysed.

#### THE CURRENT STATE OF THE LAW CONCERNING THE EXAMINATION OF EXHALED AIR ANALYSERS

According to the Measurement Law<sup>4</sup>, that came into force on 1 January, 2003 before introducing a defined appliance into circulation or use, official metrological inspection is carried out in accordance with procedures of assessment of concordance (modules), and in particular by testing the given model – if the test is passed this is confirmed by a decision of official approval of the model, or by first-time certification (for use in Poland) or individual certification. In the case of measuring appliances that are already in use, successful testing results in renewed certification. Measuring devices used in, amongst others, the field of protection of public safety and order, are subject to official (legal) metrological inspection. Evidential breath analysers are also included in this category, in accordance with the decree of the Minister of the Economy, Labour and Social Policy of 20 February 2003, concerning defining of measuring appliances subject to official metrological inspection and also measuring appliances which are certified without official approval of model<sup>5</sup>.

On 3 May 2003, on the basis of Article 9 Point 3 of the Measurement Law, the decree of the Minister of the Economy, Labour and Social Policy of 2 April 2003 came into force concerning metrological requirements that should be fulfilled by breath analysers<sup>6</sup>. In this document, the main emphasis was placed on fundamental features of the appliances, such as how they are marked, the units applied, the size of figures and letters on the screen and whether they are equipped with a mouthpiece. The tests, which the analysers should be subjected to, are defined in clauses 9 and 10. In accordance with them, for an analyser to gain official approval, first-time certification or renewed certification, acceptable margins of error are:

1.  $\pm 0.020$  mg/l for mass concentrations lower than 0.400 mg/l;
2.  $\pm 5\%$  of the measured value for mass concentrations not lower than 0.400 mg/l and not greater than 2.000 mg/l;

<sup>4</sup> *Journal of Laws* of 2001, No. 63, item 636 with subsequent amendments.

<sup>5</sup> *Journal of Laws* of 2003, No. 41, item 351.

<sup>6</sup> *Journal of Laws* of 2003, No. 67, item 626.

3.  $\pm 20\%$  of the measured value for mass concentrations greater than 2.000 mg/l.

However, for renewed certification of analysers that have not previously been repaired:

1.  $\pm 0.032$  mg/l for mass concentrations lower than 0.400 mg/l;
2.  $\pm 8\%$  of the measured value for mass concentrations not lower than 0.400mg/l and not greater than 2.000 mg/l;
3.  $\pm 30\%$  of the measured value for mass concentrations greater than 2.000 mg/l.

The repeatability of analyser indications should be such that experimental standard deviation calculated for a measuring series consisting of 20 measurements in the case of official approval of a model and 10 measurements in the case of first-time certification was less than:

1. 0.007 mg/l for mass concentrations less than 0.400 mg/l;
2. 1.75% of the measured value for mass concentrations not smaller than 0.400 mg/l and not greater than 2.000 mg/l;
3. 6% of the measured value for mass concentrations greater than 2.000 mg/l.

The decree of the Minister of the Economy, Labour and Social Policy concerning metrological requirements that should be fulfilled by breath analysers is thus very general – legal metrological inspection in the case of official approval of a model and first-time certification is limited to defining the repeatability of analyser indications and acceptable margins of error, whilst in the case of renewed certification, it consists only in defining acceptable margins of error. Furthermore, it was not defined which standard(s) should be used for the measurements, nor number of measurements which should be carried out during metrological inspection. Thus, one measurement would be sufficient to carry out a renewed certification! In the decree, the period of validity of official approval of the model and certification documents was not defined, and examinations carried out in accordance with the decree do not allow us to define conditions and technical conditions of proper use of breath analysers. Thus, it can be stated that the content of the decree does not correspond to Article 9 points 2 and 3 of the Measurement Law, which states that the minister for economic affairs will define, by means of a decree, a detailed procedure for carrying out official metrological inspection. It should take into account procedures for assessment of concordance (modules) for defined models of measuring appliances before their introduction into circulation or use and the method of documenting approval of a model, period of validity of decision of approval of a model and also principles for issuing limited decisions of approval of a model: a shorter period of validity, number of measuring appliances or technical conditions of their use. It should also define conditions and procedure for retracting a decision of approval of

a model, and also the metrological requirements which should be fulfilled by measuring instruments that are subject to official metrological inspection, taking into account types of documents of this inspection, and also conditions of proper application and technical conditions of their use.

#### COMPARING POLISH METROLOGICAL REGULATIONS WITH RECOMMENDATIONS OF INTERNATIONAL ORGANISATIONS

The metrological regulations legally binding in most of the European countries are based on the R126 "Evidential breath analysers", issued in 1998 by the International Organisation of Legal Metrology (OIML), and prepared by specialists in the field of alcohol study. This document admitted the possibility of modification of examinations recommended by the national legislation and it was the Institute of Forensic Research that concluded that the decree should take into account the fact that Polish legal regulations concerning acceptable levels of alcohol in exhaled air differ from regulations that are legally binding in most European countries. In the Act of 26 October 1982 on Upbringing in Sobriety and Counteracting Alcoholism, two thresholds of sobriety were defined, of which the lower, corresponding to a "state after using alcohol" amounts to 0.1mg of alcohol in 1 litre of exhaled air, whilst in most European countries there is only one threshold of sobriety, corresponding to a concentration of alcohol of 0.25 mg/l. For this reason, legal metrological inspection in Poland should be concentrated on lower concentrations of alcohol than recommended by OIML, and the influence of various factors on the result of analysis should be studied with use of a standard of mass concentration of alcohol equal to 0.1 mg/l. One should be aware that a concentration of alcohol in exhaled air above this value may have serious consequences and that is why one should strive to carry out metrological inspections that ensure reliability of analyser indications as low as this concentration of alcohol.

The draft version of the decree, concerning metrological requirements that should be fulfilled by breath testers, dated 21 January 2003, that was conveyed for consultation to, amongst others, the Institute of Forensic Research, was also based on the OIML document. For some reasons or another its final version differs fundamentally from the first draft.

The crucial disadvantage of the decree is a lack of testing with men in real conditions. A breath tester is a measuring appliance serving to measure ethyl alcohol content in air exhaled by persons and it is difficult to imagine official approval of such an appliance without carrying out experiments in real-life conditions. Evidential breath analysers are the only measuring appliances from the list of devices contained in the decree of the Minister of the

Economy, Labour and Social Policy of 20 February 2003, which serve to study persons and require their active participation in the measuring process. For this reason, examinations of analysers should be broader than that of other apparatus on this list, e.g. gas meters, water meters or measuring flasks or cylinders.

Because the studies with performed with persons were neglected, in the decree checking whether the analyser can detect so-called mouth-alcohol was abandoned, although such studies are recommended by the OIML document (point 5 of document R126). Taking of a substance containing alcohol (e.g. a medication or mouthwash) just before measuring is a frequent line of defence by persons accused of driving a mechanical vehicle under the influence of alcohol. A lack of studies defining how an analyser reacts to the presence of so-called mouth-alcohol, carried out with the participation of probationers, may be the basis for discrediting results of sobriety tests.

The next drawback of the decree is giving the same requirements for all types of the exhaled air analysers, despite they differ both in the analytical method applied to determining alcohol concentration and in the conditions of their application. In Poland three classes of the breath analysers are used by the police: working on the basis of spectrophotometric measuring in infra-red, designated mainly for stationary use (e.g. Alcometr A 2.0, Alcomat, Alcotest 7110); working on the basis of electrode oxidation of alcohol, mainly designated for use in external conditions (e.g. Alcotest 7410, Alco-Sensor IV); and equipped with a semi-conductor detector (e.g. Alert J4X).

Portable (“mobile”) analysers, working on the basis of electrochemical oxidation, are appliances with a simpler construction, often with weaker electronics; they are designed for work in external conditions (“the field”), and thus they function over large ranges of temperature and humidity of air, which is why it is difficult to imagine that measurements taken by them have the same level of error as “stationary” analysers, working on the basis of infrared measurements. In the OIML bulletin it was stated [4] that for this type of appliance, acceptable error should not be greater than 10%. Furthermore, none of the portable (“mobile”) analysers available on the Polish market is capable of detecting so-called mouth-alcohol in a proper way.

The most appropriate solution would be to introduce two or three classes of breath analysers, analogous to weight classes, for which there would be varying metrological requirements.

Analysers working on the basis of spectrophotometric measurement would be placed in Class 1, analysers working on the basis of electrode oxidation of alcohol in Class 2. Class 3 could encompass devices applied for screening purposes, giving a qualitative or semi-quantitative result (e.g. semi-conductor analysers or those carrying out measurements in a passive way). A positive result of analysis by this type of appliance would, however, have

to be directly confirmed each time by a class 1 or class 2 appliance. Differences in classes of appliances were also perceived in order no. 16 of the head of the Polish national police force of 4 April 1996 concerning the carrying out of analysis by policemen of alcohol content in exhaled air, modified by order nr 3/97 of 10 February 1997, where it was put forward that in the case where a subject has been involved in an accident in which persons have been killed or wounded, or there is justified suspicion that a crime has been committed by the subject or there has been a significant divergence between the first and second measurement, a positive result of analysis by a portable appliance working on the principle of electrochemical oxidation should be verified by analysis by a stationary appliance working on the basis of infrared measurement or by a blood test. Also under OIML, guiding principles have been elaborated concerning assessment of portable analysers applied in external circumstances (“Test procedures and test report format for the evaluation of portable breath testers used in open air – Annexes to R 126”).

There is no doubt that uncertainty in measurement would vary when applying various classes of appliances [2], but the degree (of uncertainty) for particular classes could be assessed on the basis of correctly carried out examinations, aimed at approving analyser models. The magnitude of error that is made when measuring alcohol in exhaled air has great significance for correct interpretation of the result. Studies carried out in accordance with the guiding principles of the decree allow us to define acceptable margins of error and repeatability. However, these measurements relate to laboratory studies carried out with use of gas standards (mixtures of alcohol vapours with other gases, e.g. air or nitrogen). On their basis it is not possible to define the error which is made when studying persons in changeable external conditions (temperature, humidity/moisture). Thus these studies do not allow us to define measurement uncertainty in the sense of norm ISO 17025<sup>7</sup>, where in point 5.4.6.2 it is put forward that “(...) a laboratory should at least try to identify all components of uncertainty and carry out a rational assessment and also ensure that the method of presenting results does not give an erroneous impression relative to uncertainty”, and in point 5.4.6.3: “When assessing uncertainty of error, all components of uncertainty should be taken into account that are significant in a given situation, taking into account appropriate methods of analysis”. Data gained from the literature of the subject [3] indicate that the error resulting from unstable work of the analyser – and thus (the error) which would be assessed in examinations carried out in accordance with guiding principles of the decree – constitutes not more than 10–20% of the total error committed when measuring by analyser in real conditions. Dubowski and Essary showed [1] that measure-

<sup>7</sup> European norm ISO/IEC 17025:2000 General requirements for the Competencies of Testing and Calibration Laboratories.

ment with application of the same gas standard in external conditions causes an approximately threefold increase in the value of error in relation to measurements carried out in laboratory conditions, if a portable analyser is used. The main source of measurement uncertainty when using analysers is the so-called biological factor – the variability of volume and duration of exhalation, changes in intensity of exhalation or differences in temperature of air exhaled by a person. Bearing the above in mind, it can be stated that experiments with use of gas standards do not allow a rational assessment of all components of uncertainty and may give an erroneous impression as to its value (e.g., that in accordance with § 10 of the decree, repeatability for mass concentrations of alcohol smaller than 0.400 mg/l is 0.007 mg/l). In order to carry out an assessment of the real value of measurement uncertainty, examinations aimed at approving a model of analyser must also encompass experiments with participation of probationers.

A breath tester is a measuring appliance serving to measure ethyl alcohol content in air exhaled by persons and it is difficult to imagine official approval of such an appliance without carrying out experiments in real-life conditions. Evidential breath analysers are the only measuring appliances from the list of devices contained in the decree of the Minister of the Economy, Labour and Social Policy of 20 February 2003, which serve to study persons and require their active participation in the measuring process. For this reason, examinations of analysers should be broader than that of other apparatus on this list, e.g. gas meters, water meters or measuring flasks or cylinders.

#### RECOMMENDED EXAMINATIONS OF EVIDENTIAL BREATH ANALYSERS

Examinations aimed at approving a given model (type of breath analyser used for the determination of alcohol concentration in exhaled air for forensic purposes) should thus encompass the following modules:

1. checking whether the analyser detects so-called mouth-alcohol; these studies must be carried out with the participation of probationers;
2. Assessment of accuracy of measurements, in other words checking whether the analyser is not continually overestimating or underestimating results; the examinations consists in comparing averages from series of measurements with real (declared) mass concentrations of alcohol;
3. Assessment of the precision, i.e. repeatability, of the measurements, carried out both with use of gas standards and participation of probationers;

4. Defining the working range of the analyser by ascertaining the limits of detection and the limits of determination in relation to alcohol and the range of linearity of analyser indications;
5. Comparing results of indications of the tested appliance with results gained using approved models of analysers;
6. Assessment of changes of indications by the analyser caused by:
  - a) the influence of the following chemical substances: acetone, acetaldehyde, methanol, iso-propanol, carbon monoxide, toluene, diethyl ether, which may be present in air exhaled by persons,
  - b) the influence of masking substances, such as tobacco smoke or car exhaust fumes,
  - c) a change in temperature and relative humidity of the surroundings and also atmospheric pressure,
  - d) the method of passing the sample into the analyser taking into account various volumes of breath, various durations of breath and the variability in passing samples of exhaled air (variable intensity of exhalation) into the analyser,
  - e) the influence of hyperventilation (i.e. taking 2–3 deep breaths before carrying out measurement) and hypoventilation of lungs (i.e. holding breath for 1–2 seconds before measurement),
  - f) drift expressed as the difference between averages from measurement series carried out after the passage of a defined time,
  - g) the effect of memory, i.e. the difference between results of two measurements carried out using a standard of defined mass concentration of ethanol, between which a measurement with use of a standard with appropriately higher mass concentration of ethanol was carried out,
  - h) a short-term lowering in voltage of power supply, the influence of spurious currents and disturbances in supply, electrostatic discharges and magnetic and electromagnetic field,
  - i) accidental vibrations, the influence of humid air, the influence of conditions of storage deviating from the norm and jolts during transportation – by carrying out a so-called durability test.

Examinations defined in Point 6 should be carried out using a standard with a mass concentration of alcohol of 0.1 mg/l.

It is also very important for the evidential breath analyser to print – besides the result of alcohol concentration – identification data of the analyser, date and time of measurement, duration and volume of exhalation, bearing in mind that for the result to be credible, the minimum duration of exhalation should be 3 seconds, and volume of exhalation: 1.5 litres. This is due to the fact that analysis of exhaled air in humans for alcohol content should be performed on air from air sacs, since only the concentration of alcohol in this



part of the lungs is proportional to its concentration in blood and that is why it can be a measure (indicator) of the state of sobriety. Acceptance of lower values of volume and duration of exhalation might result in the fact that the measurement taken by the analyser would record the concentration of alcohol in the so-called anatomical dead space; this concentration does not define in a proper way, the exposure of the organism to the action of alcohol. Measurement of alcohol concentration in exhaled air should be carried out either in a continuous way, or it should be carried out at the end phase of the exhalation.

Performing a measurement using a breath analyser should not be possible, if the value of the electric signal, after zeroing of the reading, corresponds to alcohol content equal to or greater than 0.005 mg/l, if during automatic monitoring of correct functioning an irregularity of functioning has been detected or if the analyser has been damaged, the device for automatic calibration and regulation has broken down, the result of automatic checking of correctness of readings is negative, or if in a battery-powered analyser there has been a drop in voltage below a value specified by the producer.

Primary certification and renewed certification should encompass at least an assessment of accuracy and precision of measurements carried out (by the analyser) on several standards with a broad range of mass concentrations of alcohol (from 0.05 or 0.1 mg/l to at least 1.5 mg/l). Certification of breath analysers should be carried out at least every 6 months.

Apart from strictly metrological requirements, in the decree – in accordance with Article 9 Point 3 of the Measurement Law – there should also be detailed notes concerning conditions of appropriate application and technical conditions of use of the analyser. An important issue is, for example, to define requirements which should be fulfilled by mouthpieces used with evidential breath analysers. Mouthpieces for these types of analysers should have a one-way valve, which enables a flow of gas in only one direction (preventing drawing in of air by the studied person). It should be visible from the outside, e.g. by its characteristic colouring (making it possible to check whether this valve has been removed). Furthermore, mouthpieces should contain a “trap”, making it impossible for saliva to get through to the measuring device. Carrying out a comprehensive approval examination for each analyser model would mean that much valuable information could be passed on to later users.

The decree of the Minister of the Economy, Labour and Social Policy concerning metrological requirements which should be fulfilled by breath analysers rules out the use by Polish police of devices that are applied routinely in many countries for screening purposes. These are measuring appliances of simple design, giving semi-quantitative (approximate) results, often sampling exhaled air in a passive way (the studied person does not have to blow into the analyser – it is sufficient to position the analyser near the

subject's mouth). Their advantage is the possibility of testing a significantly greater number of drivers in a given period of time, since a measurement using a "passive" analyser can be carried out in the space of several seconds, without the driver having to leave their vehicle, whereas a "traditional" measurement by an analyser carried out in accordance with standard procedure takes 10–20 minutes. Taking into account the high percentage of drivers driving after use of alcohol, estimated in Poland at about 15%, the use of screening analysers could contribute to more effective selection of this group of people, and thus lead to an increase in safety on the roads. As mentioned above, a positive result gained using this type of analyser should be confirmed by an analyser that works on the basis of infrared spectrophotometry or by blood test. The possibility of applying them was excluded by the decree due to the fact that uniform criteria were defined for all analysers in respect of repeatability of results and acceptable errors, and also the requirement of possessing single-use replaceable mouthpieces.

Breath analysers that would be used solely for screening purposes (proposed class 3 appliances) should be examined mainly from the point of view of fulfilling requirements concerning their sensitivity (checking the detection limits), ability to detect "positive" and "negative" samples and the influence of various factors on the value of the signal.

#### SUMMARY

The objective of the modifications in the legislation concerning the testing of the expired air analysers was unification of the Polish law with regulations of the European Union. Unfortunately, in the content of the decree of the Minister of the Economy, Labour and Social Policy defining requirements that should be fulfilled by evidential breath analysers a lot of studies that are of important for correct interpretation of results was neglected. Taking into consideration the great importance of the expired air analysis in sobriety testing of the traffic participants, the hope may be expressed that in a short time the decree will be amended and the criticisms presented in this work will be taken into account, thanks to which results of measurements of alcohol concentration in exhaled air will become more reliable.

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