

## **Title: Certified forensic alcohol reference materials**

### **Abstract**

The European status report on road safety of the WHO Regional Office for Europe has identified the need for better enforcement of drinking/driving legislation in a number of European countries. Data obtained from breath analysers need to be reliable, and hence calibration of these instruments against suitable references is important. In some countries there is therefore a need to build up long term capacities for the production and certification of alcohol reference materials suitable for the calibration of evidential breath alcohol analysers as defined by the Organization of Legal Metrology's (OIML) recommendation R126 including assessment of the reference material homogeneity, stability, and uncertainty. The ethanol concentrations addressed should be suitable to meet regional legal limits for alcohol control in traffic.

### **Keywords**

Ethanol reference materials, breath alcohol, blood alcohol, breathalyser, drink driving regulation

### **Background to the Metrological Challenges**

In the WHO European Region, road crashes result annually in 120 000 deaths, 2.4 million injuries and a great economic burden, which may be up to 3% of a country's gross domestic product (European status report on road safety, WHO Regional Office for Europe, Copenhagen, 2009). The European Commission has estimated that about one quarter of road traffic deaths are due to alcohol, at a cost of 40 billion euros per annum (Drinking and Driving in Europe, An Eurocare report to the European Union, Brussels 2003). In addition there is a significant variation across Europe regarding the number of traffic victims, with the Nordic countries having far lower death rates than the Baltic countries and those of southern Europe. The European status report on road safety therefore stated that, among other measures, better legislation and enforcement of alcohol control for road users is needed in several countries. In particular, the report recommends that unrestricted powers to breath test for alcohol, using breathalysers of equivalent and agreed standard, should be implemented throughout Europe.

The regular calibration of such evidential breathalysers requires relatively large volumes of certified ethanol in water reference materials of high metrological quality, which meet the recommendation of OIML [1] and the relevant ISO Guide series (Guides 30-35) for the production and certification of reference materials. National drink driving legislation varies from country to country, hence it is necessary that European countries are able to produce their own traceable certified ethanol in water reference materials tailored for their regional/national needs. However, the metrological quality (homogeneity, stability, uncertainty, traceability) of the materials developed at different NMIs should be comparable in so far as they should meet the requirements of OIML recommendation R126 for Evidential Breath Analyzers. Such materials would also be suitable for the validation of analytical methods for the quantification of blood ethanol. The methods used in preparing these materials should ideally also be transferrable to other liquid mixtures.

OIML recommendation R126 [1] requires breathalysers to be calibrated using a gas sample of defined volume, temperature and relative humidity. Generally, wet bath simulators containing aqueous solutions with an accurately defined (certified) mass concentration of ethanol are used to deliver such gas samples similar to human breath with regard to temperature and relative humidity and containing the desired ethanol mass concentration.

In 2010/2011, the equivalence of certified ethanol in water reference materials available worldwide were compared within a CCQM key intercomparison (CCQM-K79). In total 27 reference materials from 9 NMIs from Africa, Australia, South and North America and Europe covering a concentration range of 0.1 ng/g to 330 ng/g ethanol in water were included in the study. Volumes were typically in the range 5 ml to 50 mL, only one material had a volume larger than 1 L. However, such materials with low volumes and concentration are not

suitable for breathalyser calibration which need litre range volumes and concentrations in the µg/g range. New or improved capabilities are therefore required within some countries to meet the requirements for production of sufficient quantities of the ethanol in water reference materials with appropriate concentrations that are suitable for the calibration of evidential breath analysers to underpin road safety legislation in those countries.

## Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The JRP shall focus on the development and/or improvement of metrological capacity in the preparation and certification of alcohol in water reference materials for forensic breath analysis.

The specific objectives are

1. To develop traceable production capabilities for ethanol in water reference materials at NMIs and DIs seeking to establish research capacity in this field. The range of materials should be suitable for the calibration of evidential breath alcohol analysers (breathalysers) as defined by OIML recommendation R126 and also for the quality assurance of analytical methods for blood alcohol testing. Target values and measurement ranges to be covered should address legal limits of regional/national drink driving legislation.
2. To develop and implement agreed, common techniques to certify forensic alcohol reference materials following an appropriate quality system according to ISO Guides 30 to 35. The certified values should be traceable to the SI and include appropriate assessment of homogeneity, short and long term stability and uncertainties the measurement capabilities and reference materials developed should be at a metrological level suitable for participation in CCQM intercomparisons and CMC entries into the BIPM key comparison database. This may involve improvements to existing techniques for those NMI's/DI's that have some basic capability in the field.
3. To undertake a EURAMET TC-MC intercomparison to evaluate the quality and metrological integrity of the reference materials produced and associated measurement and certification techniques.
4. For each emerging NMI and DI, to develop an individual strategy for the long-term operation and development of their measurement and production capacities developed, including regulatory support, research collaborations, quality schemes and accreditation. They should also develop a strategy for offering calibration services from the established facilities to their own country and neighbouring countries. The individual strategies should be discussed within the consortium and with other EURAMET NMIs/DIs, to ensure that a coordinated and optimised approach to the development of traceability in this field is developed for Europe as a whole.

Joint Research Proposals submitted against this SRT should identify

- the particular metrology needs of stakeholders in the region,
- the research capabilities that should be developed (as clear technical objectives),
- the impact this will have on the industrial competitiveness and societal needs of the region,
- how the research capability will be sustained and further developed after the project ends.

The development of the research potential should be to a level that would enable participation in other TPs.

Proposers should note that the programme funds the activity of researchers to develop the capability, not the required infrastructure and capital equipment, which must be provided from other sources.

EURAMET has defined an upper limit of 500 k€ for the EU Contribution to any project in this TP, and a minimum of 100 k€.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 10 % of the total EU Contribution to the project.

## Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the “end user” community, describing how the project partners will engage with relevant communities during the project to facilitate

knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the “end user” community (e.g. letters of support) is also encouraged.

You should detail how your JRP results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Provide a lasting improvement in the European metrological capability and infrastructure beyond the lifetime of the project,
- Facilitate improved industrial capability or improved quality of life for European citizens in terms of personal health or protection of the environment,
- Transfer knowledge to the breath alcohol analysis and law enforcement sector and the metrology community.

You should detail other impacts of your proposed JRP as specified in the document “Guide 4: Writing Joint Research Projects (JRPs)”

You should also detail how your approach to realising the objectives will further the aim of EMPIR to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased
- organisations other than NMIs and DIs to be involved in the work

## **Time-scale**

The project should be of up to 3 years duration.

## **Additional information**

The references were provided by PRT submitters; proposers should therefore establish the relevance of any references.

- [1] OIML R 126:2012 - Evidential breath analyzers, Organisation Internationale de Métrologie Légale (OIML).