European Partnership on Metrology
Call 2022 – Digital Transformation, Health, Integrated European Metrology, Normative and Research Potential

Selected Research Topic number: **SRT-r03**
Version: 1.0

Title: Establishing traceability for medical measuring devices through optical absorbance liquid filters

Abstract

Optical absorption measurement capabilities are ubiquitous to most NMIs. However, there is a capability gap in the manufacture, characterisation and use of liquid optical absorption filters, which leads to a lack of traceability in medical measuring devices. Proposals addressing this SRT should reduce the capability gap in this area and develop traceable measurement capabilities of optical absorbance that use liquid filters. Proposals should also produce guidance aiming at supporting national compliance with EU Directives for control of medical measuring devices.

Keywords

Liquid filters, optical absorbance, medical measuring devices, traceability

Background to the Metrological Challenges

The EU regulation (2017/745) clearly states that all medical measuring devices must be verified and ISO 15189:2012 adds that all medical measuring devices with high impact on results must be calibrated. Many medical measuring devices used in clinical diagnostics (e.g. biochemical analysers and immunological analysers), use optical absorbance as the basic measured quantity.

In classical metrology the equipment that measures optical absorbance is calibrated, verified and inspected using optical neutral glass filters, which are calibrated using high performance spectrophotometers. However, the use of neutral glass filters is not always possible in medical setups. Optical absorbance liquid filters are an alternative solution. However, not all European NMIs have the necessary experience in the manufacturing, characterisation and use of liquid optical absorption filters, even more so in the use of liquid filters to ensure metrological traceability of medical measuring devices. Inadequate knowledge of calibration, verification and inspection methods can jeopardize the accuracy and the precision of the traceability chain, which are required by accredited bodies, healthcare centres, hospitals and medical testing laboratories. It is therefore of upmost importance to reduce the existing capability gap in this area.

Capabilities must be developed that enable the measurement of optical absorbance using existing and new liquid filters produced, which can operate in wide spectral and photometric ranges, at room temperature, and can be used to support the healthcare sector. The capabilities developed should be verified through an interlaboratory comparison of the obtained results and guidelines should be developed and disseminated to promote uptake.

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 of metrology capability in optical absorption using liquid filters and establish national traceability chains for medical measuring devices.

EURAMET MSU,
Phone: +44 20 8943 6666 Email: part.msu@euramet.org
Metpart.eu

The specific objectives are

1. To develop traceable measurement capabilities of optical absorbance of liquid filters for the spectral range from 250 nm to 800 nm, for the photometric range from 0.001 A up to 2 A (≈100 % to 1 % transmittance), at atmospheric pressure, within the temperature interval from 15 °C to 40 °C and with a target expanded uncertainty ranging from 0.005 A to 0.010 A.
2. To carry out an interlaboratory comparison of the optical absorbance liquid filters measurements obtained in Objective 1, and analyse the results.
3. To produce a good practice guide on the manufacture, characterisation and use of optical absorbance liquid filters, which should be shared with EURAMET along with a request for its consideration to be published as a EURAMET guide.
4. To facilitate the take up and long-term operation of the capabilities, technology and measurement infrastructure developed in the project by the measurement supply chain (NMIs/DIs, calibration and testing laboratories), standards developing organisations (e.g. ISO), and end users (e.g. healthcare sector). The approach should be discussed within the consortium and with other EURAMET NMIs/DIs e.g. EURAMET TCs or EMNs, 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 area for which the capabilities will be built (Green Deal, Digital Transformation, Health, Integrated European Metrology, Industry, Normative or Fundamental Metrology) and in which future main call the developed research capabilities are planned to be employed,
- the impact the developed research capabilities 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 expects the average EU Contribution for the selected JRPs in this TP to be 0.5 M€ and has defined an upper limit of 0.9 M€ for this project.

EURAMET also expects the EU Contribution to the external funded beneficiaries to not exceed 20 % of the total EU Contribution across all selected projects in this TP.

Any industrial beneficiaries that will receive significant benefit from the results of the proposed project are expected to be beneficiaries without receiving funding or associated partners.

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 healthcare 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 the Partnership 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.