EMPIR Call 2016 – Energy, Environment, Normative and Research Potential

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

Title: Traceability in medical measurements

Abstract

The safety of patients is paramount and all hospitals and medical device manufacturers have to perform periodic testing and calibration of devices as part of their quality control. However, current metrological tools are insufficient for many such measurements and therefore the traceability of all medical devices has not been established. Further to this, multi-parameter medical devices such as patient simulators need their many parameters to be calibrated simultaneously in a single laboratory under the same environmental conditions. However this is not possible in all European metrological institutes as their calibration laboratories are often separated into different technical areas such as pressure, temperature, flow and electrical quantities or the capability is split between different organisations. Therefore, research is needed in order to establish the measurement parameters, SI traceability and uncertainties for medical devices in use across Europe and to develop single laboratory calibration facilities for multi-parameter medical devices, for those metrological institutes that are currently not able to offer this service.

Keywords

Medical metrology, traceability, medical devices, medical measurement parameters, multi-parameter medical devices, patient simulators

Background to the Metrological Challenges

Currently, the traceability and conformity of medical devices is not consistent across all countries. In Europe, medical devices are tested using several “New Approach Directives” (http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.main), and there are a number of national and international standards used within this field including the IEC60601 series, EN61010 series, ISO 15189, ISO 13485 and ANSI/AAMI SP10 etc.

Medical devices should also be calibrated by accredited laboratories that comply with the requirements of ISO/IEC 17025 (the standard for testing and calibration laboratories) and ISO/IEC 17020 (the standard for inspection bodies). However, in practice, conformity assessment for medical devices is, in most cases, performed by the device manufacturers.

Evidence of incomparable results is frequently found with medical devices that have been calibrated and inappropriate applications have been observed in medical device calibration procedures. For example simple functional checks of switches, buttons, lamps/LEDs, numbers and displays have been considered as a test or calibration, which raises questions over the validity of the calibration certificates for the medical devices.

Further to this, some secondary calibration laboratories that are only accredited in one area (i.e. pressure), will perform calibrations for other parameters that are outside their accredited scope. This is particularly relevant for medical devices such as patient simulators, gas flow analysers and infusion pumps, which are multi-parameter devices. With such multi-parameter medical devices it is important that all their parameters are calibrated simultaneously in a single laboratory that is accredited for all the required parameters.

All this evidence supports the need for an established and consistent technical framework for the traceability of medical measurements across Europe. This framework should establish the measurement parameters, traceability and uncertainties for medical devices in use across Europe and develop single laboratory calibration facilities for multi-parameter medical devices.

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The EMPIR initiative is co-funded by the European Union's Horizon 2020 research and innovation programme and the EMPIR Participating States

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 metrological capacity for the traceability of measurements of medical devices.

The specific objectives are

1. To assess the current situation in terms of the traceability of medical devices across Europe.
2. To determine the most common measurement parameters used in medical devices and calibrators and evaluate their associated traceability and uncertainties.
3. To establish single laboratory, calibration facilities for multi-parameter medical devices such as patient simulators, including the measurement of the parameters such as voltage, resistance, pressure and temperature etc.
4. To develop and validate calibration procedures, including the evaluation of uncertainty, for single laboratory calibration facilities for multi-parameter medical devices.
5. For each participant, to develop an individual strategy for the long-term operation of the capacity 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 competiveness 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 healthcare and medical sectors 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.