Potential European Partnership on Metrology
Call 2021 – Green Deal and Normative

Selected Research Topic number: **SRT-n07**
Version: 1.1

Important information about these documents

This call is being held ahead of any agreement from the Commission that the relevant funding will be available. At present the relevant legislation is still under discussion in both Council and Parliament, and there is no certainty on the detailed arrangements for funding selected projects. The funding of any selected project, and the terms and conditions of participation in the projects, are dependent on completion of the legislative process and the subsequent contractual processes between the European Commission and EURAMET. Proposers submit to this call at their own risk.

Background

Last year, EURAMET submitted a draft proposal to the EC for a further research programme to be established under article 185 of the Treaty on the Functioning of the European Union (TFEU) to follow on from EMRP and EMPIR. This was published by the EC at https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe/candidates-digital-industry-and-space_en

The initiative would be called the European Partnership on Metrology and would aim to create, by 2030, a sustainable and effective system for metrology at European level that ensures Europe has a world-class metrology system that:

- Provides metrology solutions, fundamental metrological reference data and methods, offering fit-for-purpose solutions supporting and stimulating European innovation and responding to societal challenges.
- Supports and enables effective design and implementation of regulation and standards that underpin public policies that address societal challenges.

The Commission commissioned an impact assessment into this proposal and 11 others in similar priority areas, and, based on those findings, published their own proposal for the Partnership, their response to the impact assessment and a draft of the Decision on 23rd February 2021. See:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:89:FIN

https://ec.europa.eu/commission/presscorner/detail/en/ip_21_702

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0035&qid=1614677899327

That draft Decision is currently under discussion in the European Council and the European Parliament.

Under the assumption that the Council and Parliament pass the basic act which would form the legal basis for this research programme, and that the participating countries named in the Draft Decision submit the required commitment letters, EURAMET is publishing these potential Selected Research Topics and draft guidance notes. These documents are not approved by the Commission nor will they lead to a binding decision by EURAMET e.V. for any further negotiation or funding. All published guides and templates are subject to amendment by the EC and EURAMET e.V. as further information becomes known.

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Title: Standardisation for safe implant scanning in MRI

Abstract

Magnetic resonance imaging (MRI) is still a safety hazard for patients with medical implants, i.e. ~10 % of the EU population. Improved standardisation of both implants and MRI scanners is key to overcome this problem and the convenors of international standards board's call for dedicated research. Standardisation of an implant safety concept built on smart implants communicating with the MRI scanner is requested to provide easy and patient specific safety assessments. Improved safety assessments would provide 50 million implant carriers in the EU safer access to a potentially life-saving diagnostic modality and improved diagnostic image quality. Implant and MRI manufacturers will also benefit from faster development and market introduction times of their innovative products.

Keywords

Medical implants; MRI; device safety; compliance testing; smart implants

Background to the Metrological Challenges

Medical implants are a 3 billion € market in the EU, with approximately 50 million citizens carrying one. Due to of comorbidity effects, 60- to 80-year olds have the highest probability of both needing an implant and an MRI. With an aging population, these numbers are likely to further increase and future smart implant technologies for medical and non-medical use are needed. Metallic implants in a patient's body are a safety hazard in MRI, since interaction of the conductive device with the MR scanner's strong electromagnetic fields can result in dangerous tissue heating. Demonstrating compliance with MRI safety, in particular with respect to heating effects, is a challenging process with high product liability risks for implant manufacturers.

ISO/TS 10974 is presently limited to only two MRI field strengths, 1.5 T and 3 T, and only birdcage-type body coils are considered for RF excitation. Advanced radiofrequency (RF) technologies like parallel RF transmission (pTx) are not included, and the important aspect of diagnostic image quality in the presence of implants is not considered. Parallel transmit technology in MRI has been pioneered by European MRI vendors more than a decade ago but still it is only available on research scanners as its use is still not adequately covered in harmonised standards as called for by the IEC 60601-2-33 convenor. Safety margins are adopted to accommodate rare worst cases and are therefore unnecessarily large for most patients, thus wasting image quality. As requested by the co-convenors of ISO/TC 150/SC 6/JWG 2, the joint working group developing ISO/TS 10974, an *in situ* safety assessment combined with image optimization, specific for the given patient with the given implant in the given scanner is needed. The IEC, SC 62B MT40 convenor also calls for the development of suitable test and reference equipment as such equipment does not yet exist. The development of an open-source reference system to investigate implant heating by multi-element RF coils in MRI is needed. Radiofrequency heating of metallic implants is most critical for long leads and electrodes. These are part of active implants, like pacemakers or stimulators, and covered by ISO 10974. MRI safety of passive implants, on the other hand, is historically covered by a series of ASTM standards, most notably ASTM F2182 for RF heating. However, passive implants cover a much broader range and orthopaedic implants in particular tend to be massive chunks of metal with a large heat capacity. Gradient heating effects reach a completely different level here and require much more in-depth coverage that is not currently available in any standards document.

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 metrology research necessary to support standardisation for safety assessments of medical implants and MRI scanners.

The specific objectives are

1. To develop, evaluate and explore the uncertainty of an implant safety concept in MRI comprised of sensor-equipped smart medical implants (e.g. pacemakers or neuro stimulators) and pTx capable MRI scanner to assess and mitigate in situ RF induced implant heating. In addition, to formulate technical specifications for sensor-equipped smart medical implants and a communication interface between such implants and MRI scanner.

2. To develop reference hardware and traceable measurement procedures that allow testing of implants (mainly active ones) under pTx MR conditions. In addition, to develop, design and build a preliminary version of an open-source reference system of a pTx body coil, suitable for offline implant testing by manufacturers or test houses.
3. To develop, standardised measurement procedures for the interaction of bulky metallic implants with RF and alternating magnetic fields in the kHz range. In addition, to provide guidelines and technical specifications for comprehensive *in-vitro* testing of gradient-induced heating of such implants.
4. To contribute to the standards development work of ISO 10974, ASTM F2182 and IEC 60601-2-33 to ensure that the outputs of the project are aligned with the needs of these bodies, communicated quickly to those developing the standards and to those who will use them (MRI manufacturers and test houses), and in a form that can be incorporated into the standards at the earliest opportunity.

The proposed research shall be justified by clear reference to the measurement needs within strategic documents published by the relevant Regulatory body or Standards Developing Organisation or by a letter signed by the convenor of the respective TC/WG. EURAMET encourages proposals that include representatives from industry, regulators and standardisation bodies actively participating in the projects. The proposal must name a “Chief Stakeholder”, not a member of the consortium, but a representative of the user community that will benefit from the proposed work. The “Chief Stakeholder” should write a letter of support explaining how their organisation will make use of the outcomes from the research, be consulted regularly by the consortium during the project to ensure that the planned outcomes are still relevant, and be prepared to report to EURAMET on the benefits they have gained from the project.

Proposers should establish the current state of the art, and explain how their proposed research goes beyond this. In particular, proposers should outline the achievements of the EMRP project HLT06 MRI Safety and EMPIR project 17IND01 MIMAS and how their proposal will build on those.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 0.8 M€, and has defined an upper limit of 1.0 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 30 % of the total EU Contribution across all selected projects in this TP.

Any industrial partners that will receive significant benefit from the results of the proposed project are expected to be unfunded 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,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Transfer knowledge to the medical sector.

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 potential European Partnership on Metrology 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.