

Title: Metrology for next-generation safety standards and equipment in Magnetic Resonance Imaging

Abstract

State-of-the-art metrology for Magnetic Resonance Imaging (MRI) is lacking consistency for established applications and does not exist for emerging MRI technologies like higher magnetic fields (≥ 3 T) or multi-channel transmission. This leads to an inability to demonstrate compliance with the EN/IEC standard governing patient safety.

Metrological research is required to develop validated measurements, and to assess the risks to human health. The proposed JRP should liaise with standards organisations and stakeholders in the medical industry, to ensure the developed metrics are widely applicable and useful, and that they are suitable to underpin safety regulations for patients and staff exposed to MRI.

Conformity with the Work Programme

This Call for JRPs conforms to the EMRP Outline 2008, section on “Grand Challenges” related to Health, on pages 8 and 10.

Keywords

MRI, medical implants, mathematical modelling, ageing society, cardiovascular diseases, cancer, quantitative imaging, Physical Agents Directive, patient safety, physiological quantities

Background to the Metrological Challenges

After X-ray MRI is the most commonly used medical imaging modality for diagnosis and monitoring of neurologic, oncologic, cardiovascular, or musculoskeletal diseases. Being non-invasive and non-ionising, and is an indispensable method of creating three-dimensional images with good spatial resolution.

In 2004 an EC directive (2004/40/EC) was published addressing the safety of staff exposed to electromagnetic fields, including those from MRI scanners. The directive was hotly debated following claims that it was based on non-metrological, and controversial input data. This threatened the reputation of EU legislation for MRI, and demonstrated the vulnerability of medical tools to regulatory decisions. Specific risks due to static magnetic fields exist in interventional MRI when medical professionals move within or close to the bore of an MRI scanner. The induced currents densities in their bodies can easily exceed regulatory limits and must be assessed to identify possible safety measures.

MRI patient safety is regulated by the international standard EN/IEC 60601-2-33. Recent progress in mathematical modelling has demonstrated inconsistency in the global and local SAR requirements, and research is required to resolve this. The current numerical simulations of SAR spatial distribution inside the human body cannot be validated, therefore scanner manufacturers do not base any safety limits upon SAR. This hampers the uptake of innovative RF concepts of higher field strengths and multiple RF transmitters. These offer reduced patient RF dose, and potential improvements in MR image quality, hence earlier and more reliable diagnoses for the patients, but they cannot reach clinics until the local SAR problem is resolved. The current state of the art is a set of basic restrictions in induced E field and SAR dose, but no limits are specified for time-varying phenomena below 1 Hz, additionally there are no validated methods for calibrated measurements of RF electric fields in the range 64 MHz – 300 MHz.

Currently, patients carrying a medical implant are excluded from MRI scanning due to fears about safety hazards including magnetic forces and torques, device malfunctioning, or excessive heating due to RF focussing. This leaves about 10 % of the European population without access to a potentially life-saving diagnosis. A standardised approach is required to assess the risks of the many available devices, and to ascertain if “MRI safe modes” can be standardised for scanning implanted patients. The current state-of-the-art for MRI scanning medical implanted patients is described in two standards but both of these have limitations:

- ASTM F2182-11 "Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging"
- ISO/DTS 10974 "Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device" (to be published June 12)

Scientific and Technological 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 JRP-Protocol.

The JRP should address the metrology required to underpin new safety requirements for Magnetic Resonance Imaging (MRI) scanners by combining traceable electromagnetic-field measurements and mathematical modelling. Recommendations shall be made to the relevant bodies for standardisation and regulation. The interaction with stakeholders from standardisation and regulation bodies is key for this SRT.

The specific objectives are:

1. To develop theoretical models for deducing radio-frequency (RF) electromagnetic fields in the range 64 MHz to 300 MHz inside the human body from a limited number of measurements outside the body and thereby derive the *locally* deposited RF power (specific absorption rate, SAR) averaged over 10 g of tissue. Validate the theoretical model by traceable measurements and validated uncertainty budget in phantoms and preferably in-vivo.
2. To evaluate the risk to humans (both patients and operators) from moving through strong magnetic fields (100 mT to 7 T).
3. To develop an approach, suitable for subsequent use in documentary standards, for assessing local SAR hazards due to new approaches in MRI, which may include ultrahigh field strength (> 7 T), and parallel and multichannel transmission.
4. To evaluate the effects of MRI on passive medical implants and to develop a set of standard MRI settings (including magnetic field strength, RF exposure, switching rates, etc) suitable for scanning patients with implants.

These objectives will require large-scale approaches that are beyond the capabilities of single National Metrology Institutes and Designated Institutes, and it is expected that multidisciplinary teams will be required. To enhance the impact of the research, the involvement of the appropriate user community such as medical practitioners and industry is strongly recommended.

Proposers should establish the current state of the art, and explain how their proposed project goes beyond this.

The total eligible cost of any proposal received for this SRT is expected to be around the 2.7 M€ guideline for proposals in this call.

Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the “end user” community. This may be through the inclusion of unfunded JRP partners or collaborators, or by including links to industrial/policy advisory committees, standards committees or other bodies. Evidence of support from the “end user” community (e.g. letters of support) is encouraged.

You should detail other impacts of your proposed JRP as detailed in the document “Guide 4: Writing a Joint Research Project”

You should detail how your JRP results are going to:

- Feed into the development of urgent documentary standards through appropriate standards bodies. Standards include:

- IEC/EN 60601-2-33 "Medical electrical equipment –Particular requirements for the safety of magnetic resonance equipment for medical diagnosis"
- 2004/40/EC Physical Agents Directive, regulatory decisions update
- ASTM F2182-11 "Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging"
- ISO/DTS 10974 "Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device" (to be published June 12)
- Propose reference measurement procedures and validated model(s) to relevant standards, legal and regulatory bodies,
- Work towards reuniting divergent EU and US regulations
- Transfer knowledge to the medical sector.

You should also detail how your approach to realising the objectives will further the aim of the EMRP to develop a coherent approach at the European level in the field of metrology. 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 Member States and countries associated with the Seventh Framework Programme whose metrology programmes are at an early stage of development to be increased
- outside researchers & research organisations other than NMIs and DIs to be involved in the work

Time-scale

The project should be of up to 3 years duration.