EMPIR Call 2015 – Health, SI, Normative and Research Potential

Selected Research Topic number: **SRT-h19**
Version: 1.0

Title: Metrology for accuracy of clinical dose delivery in hadron therapy

Abstract
Radiotherapy using proton and ion beams is one of the fastest growing cancer treatment strategies worldwide allowing delivery of lethal doses of radiation to tumours with potentially unprecedented accuracy and significant sparing of surrounding healthy tissues. The rapid development of dedicated hadron therapy centres (18 currently in operation in EU, doubled since 2010) and the fast advances of related technologies promise to extend the treatment's application and efficacy. However, this also results in new challenges and metrological needs. Protocols, guidelines and characterisation tools are urgently needed to support clinical implementation, trial design, optimisation of hadron therapy full potentials and increase patient safety.

Keywords
Radiotherapy, Hadron therapy, Dosimetry, Radiation protection, Neutrons, Biological Effectiveness, Phantoms.

Background to the Metrological Challenges

In Europe 18 hadron therapy centres are in operation, 6 are under construction and a further 10 are planned due to the establishment of commercial products and development of new technologies. This will lead to an expected number of proton and carbon ion therapy patients in the EU of the order of over 30,000 patients per year. While tools and an established metrology for assessment of the dose delivered to patients exist for conventional X-ray dosimetry standards, present standards and protocols for protons and ions do not adequately reflect the new technologies. This affects treatment outcome, jeopardises the advantage of particle treatments and poses challenging obstacles to the further development of associated technologies and establishment of clinical trials. In order to improve the status of hadron therapy and benefit from its full therapeutic potential, it is necessary to improve all the steps of the metrological chain from the primary standards, to the knowledge of dose deposition at micro- and nano-scale, to verification of the dose in and around the tumor and to link to the biological response. This will require characterisation of primary and secondary standards for the new modalities, improved knowledge and measurement accuracy of key parameters for clinically beams, tools and methods for assessment of primary and secondary radiation dose and good practice guidelines.

Reference dosimetry and assessment procedures for characterising particle beams in existing hadron therapy centres are mainly based on local expertise. While the potential of calorimeters as primary instruments for proton and ion beam dosimetry has been investigated in previous projects, no operational primary standards exist. Their characterisation has so far been restricted to a limited range of specific reference conditions (broad, passive or scattered beams) and has not addressed the increasingly complex radiation fields that are nowadays applied such as e.g. in intensity modulated proton therapy.

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 in hadron therapy by cooperatively addressing all the steps of clinical dose delivery.

EURAMET MSU, Hampton Road, Teddington, Middlesex, TW11 0LW, UK
Phone: +44 20 8943 6666 Email: msu@npl.co.uk
msu.euramet.org

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The specific objectives are

1. To develop tools and methodology for beam characterisation and modelling. This should include characterisation of non-uniform, pulsed and scanned beams with nanodosimetric characteristics, beam stability and delivery modalities. Innovative technological approaches should be investigated as a simpler, lower cost and more accurate means of range verification.
2. To develop dosimetry techniques for complex beam delivery. Investigations into water and tissue equivalent materials, detector development, validation and comparison combined with advanced Monte Carlo modelling should be used to evaluate and reduce the uncertainty. This should include primary and secondary radiation.
3. To develop tools and methodology to verify the accuracy of clinical and secondary dose delivery. This should include end-to-end assessments of delivery accuracy, which take into consideration pre-treatment imaging, treatment planning and radiation transport modelling. It should require development of anthropomorphic and 4D phantoms (including specific sites and paediatric) to assess the distribution of dose and the dose-mean lineal energy in the nanometre region as a measure related to radiation quality. It should include metrology for the assessment of secondary radiation doses at patient level for risk estimation.
4. To design protocols and guidelines for quality control and inter-centre comparisons. Updating the existing guidelines with appropriate tolerances for the new modalities should be performed after reviewing local quality assurance procedures. Audit procedures for inter-centre verification, neutron determination and guidelines for biological verification should also be addressed.
5. To facilitate the take up of the technology and measurement infrastructure developed by the project by healthcare professionals and instrumentation manufacturers.

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, medical (academic) hospitals and industry is strongly recommended, both prior to and during methodology development.

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

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.8 M€, and has defined an upper limit of 2.1 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 35 % of the total EU Contribution to the project. Any deviation from this must be justified.

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 healthcare sector.

You should detail other impacts of your proposed JRP as specified in the document “Guide 4: Writing a 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.