EMPIR Call 2018 – Health, SI Broader Scope, Normative and Research Potential

Selected Research Topic number: **SRT-n09**
Version: 1.0

Title: Primary standards and traceable measurement methods for X-ray emitting electronic brachytherapy devices

Abstract

In the past decade, electronic brachytherapy (eBT) has emerged as an attractive radiotherapeutic treatment modality. The full utilisation of this modality has yet to be achieved and is unlikely to be whilst each system relies on specific and individual calibration tools, procedures and quality assurance systems. In almost all cases these systems are not directly traceable to SI and rely on indirect methods requiring uncertainties larger than those deemed clinically acceptable.

This SRT is intended to deliver a harmonised, simplified and traceable dosimetry for eBT so that these systems can achieve their full clinical potential.

Keywords

Electronic brachytherapy (eBT), Intra-Operative Radiotherapy (IORT), X-ray, absorbed dose to water, standardisation.

Background to the Metrological Challenges

In the past decade eBT, comprising Intra-Operative Radiotherapy (IORT) with miniature X-ray sources, has emerged as an attractive modality for the treatment of skin lesions, intraoperative partial breast irradiation and applications in intracavitary and interstitial sites. eBT is considered a cost-effective treatment application, has an inherent portability, and since no radioactive sources need to be handled, the effort for radiation protection, transportation and safety are reduced. However, with increased freedom comes increased risk of misuse by those unfamiliar with radiation. Harmonised and simplified dosimetric procedures would improve the safety of use.

Due to the range of eBT and IORT equipment available, there is currently just one single dosimetry system available which is directly traceable to SI and so the dose values are only valid within a specific system. This makes it difficult to adopt a clinically established treatment plan from one system to another and to verify dosimetry independently, contrary to the core requirement of clinical medical physics that dosimetry should be subject to independent and traceable verification.

In addition, lower uncertainties in the calibration and dosimetry of treatment with kV X-rays are required. In total, a typical uncertainty of ±10 – 15 % for IORT procedures are reported. This is much more than the general acceptable levels of accuracy in radiation therapy.

It is necessary to provide metrological input and pre-normative research to simplify and harmonise the dosimetric procedures by establishing primary standards for the absorbed dose rate to water, suitable transfer chambers and corresponding easy and robust procedures for the dissemination of the dosimetric quantity. In addition, detectors and measuring devices for the determination of 3D dose distributions in water, should be established to facilitate quality assurance measurements and investigations of commercial Treatment Planning Systems.

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.

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The JRP shall focus on the provision of metrological input and pre-normative research to harmonise and simplify dosimetric procedures by establishing primary standards specific for eBT for the absorbed dose rate to water as well as suitable transfer instruments and procedures for the dissemination to end users

The specific objectives are

1. To establish primary standards for the absorbed dose rate to water for eBT devices at 1 cm depth of water for internal radiation therapy. To evaluate currently used transfer instruments and corresponding measurement procedures and establish simple and robust tools for dissemination of the absorbed dose rate to water to clinical practice.
2. To establish and validate a dosimetric methodology for superficial eBT aligned with or comparable to the recommendations for superficial (skin) external radiation therapy given in IAEA TRS 398 or DIN 6809-4.
3. To characterise detectors and measuring instruments suitable for the determination of 3D dose-distributions in water by eBT devices. To develop a standardised traceable calibration process for these detectors, allowing a reduction of the uncertainties in dose, dose distribution and dose-effect-relation to a level recommended in IAEA Human Health Reports No 31.
4. To provide traceable dosimetry for eBT systems such as INTRABEAM, XOFT or ESTEYA for which no dosimetry system currently exists and to make them available for the end user community
5. To contribute to the development of standards work of the technical committee IEC TC 62 and others where appropriate to ensure that the outputs of the project are aligned with their needs, communicated quickly to those developing the standards and to those who will use them, 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 MetrExRT HLT09 and how their proposal will build on it.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 0.6 M€, and has defined an upper limit of 0.8 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 Standards Developing Organisations, Organisations of clinical End-users and suppliers.

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.