European Partnership on Metrology
Call 2022 – Digital Transformation, Health, Integrated European Metrology, Normative and Research Potential

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

Title: Traceability in Medical X-ray Imaging dosimetry

Abstract

Around 660 million diagnostic and interventional X-ray imaging examinations is performed each year in Europe which corresponds to about 1.1 examination per person. The traceability and quantification of patient's exposure in X-ray imaging depends strongly on appropriate calibration of dosimetry equipment. Currently, the calibration procedures on relevant IEC standards and international dosimetry code of practice do not fully consider the recent technical developments of dosimeters and clinical X-ray devices. This proposal aims at the critical assessment of conditions applied in calibrations compared to those used in patient x-ray imaging and study the vibration of response for different types of dosimetry instruments in clinical fields.

Keywords

Traceability, calibration, radiology, standardisation, Code of Practice, semiconductor detectors, radiation quality, dosimetry, ionising radiation.

Background to the Metrological Challenges

The development of technology in medical X-ray imaging is rapid and the necessary standardisation of dosimetry procedures often lag the rate of technology development. The exposure parameters, such as the X-ray tube voltage and filtration, needs to be adjusted to achieve a variety of energy spectra (radiation quality) to have an impact on the image quality and radiation exposure of the patient. At present, these radiation qualities do not cover the clinical range and thus, the traceability chain is broken.

The IAEA has recognised the need to review current calibration practices and in 2021 launched a new Coordinated Research Project to evaluate the needs for the update of the TRS-457. In addition, strict requirements have been defined for reference-class dosimeters in radiation therapy and for dose area product meters. Also, the IEC 61674 standard has defined the performance characteristics of dosimeters with ionisation chambers and/or semiconductor detectors as used in clinical X-ray diagnostic imaging however, no specific requirements has been provided for reference-class dosimeters to provide traceability for hospitals.

Furthermore, the recent development in dosimetry technology has had an impact on the selection of dosimetry equipment used in hospitals. The use of semiconductors as detectors in X-ray multimeters (XMMs) offers a wide range of applications. This type of equipment in addition to radiation dose measured in terms of air kerma, provides further quantities and parameters such as X-ray tube voltage, half-value layer, total filtration, tube loading, and irradiation time etc. However, there is no agreed performance requirements, limits of variation or calibration guidance for dosimetry equipment used for these measurements. The IEC 61676 has provided requirements only for X-ray tube voltage measurement instruments, but calibration methods is not yet defined, and calibration services is not widely available. The definition of reference-class dosimeters for X-ray imaging can help categorize different levels of dosimeters, as well as provide support for dosimetry laboratories in their selection of appropriate standards for metrology and improve procedures to ensure traceability of such measurements.

The medical use of radiation is typically well justified, but due to the potential damage, the radiation doses, measured with dosimeters, still needs evaluation, optimisation and calibration in order to achieve consistent, comparable, and traceable measurement results. Also, improvements to the calibration procedure can help XMMS manufacturers to better position their productions on the international market and integrate their products as a part of dosimetry chain in an accurate but cost-efficient way and provide a benefit to high number of patients through a reliable quality assurance of X-ray imaging.

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 in calibration and measurement procedures to ensure traceability and accurate dosimetry in medical X-ray imaging.

The specific objectives are

1. To review a representative range of radiation fields relevant in medical imaging and, based on the outcome, to propose an update of reference X-ray qualities. This provides input to the future revisions of IEC 61267 and IAEA TRS-457.
2. To investigate the performance of at least 5 different commercially available X-ray dosimeters in at least 3 NMIs and 3 clinics calibration and clinical conditions. Based on the results, updated limits of variation of the response are proposed to define specific requirements for reference- and field-class dosimeters. This provides input to the future revisions of IEC 61674 and IAEA TRS-457.
3. To define a harmonised calibration procedure for X-ray multimeters, i.e. specific dosimeters which are clinically widely used to measure all relevant quantities and parameters considered in quality assurance of X-ray systems (such as radiation dose and skin exposure), but also taking into account peak voltage (kVp), tube current (mAs), radiation spectrum, etc., and thus, to enable an unbroken traceability chain for measurements of relevant clinical parameters. This provides input to the future revisions of IEC 61676 and IAEA TRS-457.
4. To establish and validate updated calibration and comparison procedures for radiation fields as identified in objective 1, applied to different classes of dosimeters as identified in objective 2.
5. To collaborate with the technical committees IEC, TC62 SC62C WG 3, IAEA, and the users of the standards they develop to ensure that the outputs of the project are aligned with their needs, including the provision of a report on a report on updated reference X-ray qualities and a calibration procedure for X-ray dosimeters and recommendations for incorporation of this information into future 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 EMPIR project 19NET04 MIRA 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 1.2 M€ for this project.

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

Any industrial beneficiaries that will receive significant benefit from the results of the proposed project are expected to be beneficiaries without receiving funding or associated 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 Joint Research Projects (JRPs)”

You should also detail how your approach to realising the objectives will further the aim of the Partnership 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.