Publishable Summary for 22NRM01 TraMeXI
Traceability in medical X-ray imaging dosimetry

Overview

X-ray imaging is an important technique used in medicine however it's use forms the largest component of exposure to artificial ionizing radiation. Consistent quantification of a patient's exposure to radiation with calibrated dosimetry equipment is essential to comply with Council Directive and ensure patient safety. Currently, the procedures used by calibration laboratories, based on relevant standards and international protocols, do not fully consider the recent technical developments in X-ray imaging. This project will perform a critical assessment of conditions applied in calibrations and study the performance of different dosimeters. Updated measurement and calibration procedures will be proposed for inclusion into standards and protocols.

Need

The medical use of radiation is well justified but due to the potential detriment to patients, the radiation doses must be optimized with regards to image quality as required in the Council Directive (2013/59/Euratom). To achieve consistent, comparable, and traceable measurement results, the dosimeters must be calibrated, measurement methods must be harmonized, and uncertainties must be estimated. According to IAEA TRS-457 a measurement uncertainty of 7 % with 95 % confidence level is considered appropriate in X-ray imaging dosimetry.

X-ray systems provide the option of adjusting their energy spectra so that image quality and patient dose can be optimized. Reference radiation qualities are used for calibrations (IEC 61267), however, currently these qualities do not cover the entire clinical range and thus, the traceability chain cannot be fully achieved.

Performance of dosimeters play an essential role in achieving the accuracy required in X-ray imaging practices. Requirements are defined based on limits of variation for the effects of influence quantities in IEC 61674. Currently it does not allow a clear distinction between reference and field-class dosimeters, nor take sufficiently into account the characteristics of the dosimeters that exist on the market today.

Semiconductor-based X-ray multimeters (XMMs) have become the most common dosimeters in use at hospitals. The response of a semiconductor detector has a pronounced energy dependence, but the manufacturers have created algorithmic corrections to overcome this challenge. However, in this case, it can be challenging to confirm the uncertainties and traceability of the measurements. In addition to radiation dose, these multimeters offer the possibility of measuring further quality control parameters. However, there are no agreed performance requirements or calibration guidance for these measurements.

In addition, there are no agreed or validated calibration or measurement procedures for these dosimeters. Thus, there is a need to establish basic metrological support for the new technology already being adopted in clinics.

Objectives

The overall objective of the project is to harmonize and standardize calibration and measurement procedures to ensure traceability and accurate dosimetry in medical X-ray imaging.

1. To review a representative range of X-ray radiation fields relevant in medical imaging and, based on the outcome, to propose an update of reference radiation qualities. This provides input to the future revisions of IEC 61267 and IAEA TRS-457.

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METROLOGY PARTNERSHIP EURAMET

2. To investigate the performance of at least 8 different commercially available X-ray dosimeter types in at least 3 NMIs/DIs and 3 clinics using calibration and clinical exposure conditions. Based on the results, updated requirements for reference- and field-class dosimeters will be proposed to enable measurements with a targeted uncertainty of 7 % (k=2). 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 (XMMs), 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 validate established and updated calibration procedures and related uncertainties identified in objective 3 for radiation fields as identified in objective 1, applied to different classes of dosimeters as identified in objective 2 by an international comparison.
5. To collaborate with the technical committees of international organizations, 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 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.

Progress beyond the state of the art and results

Updated reference radiation qualities

This project will go beyond the state of the art by performing a comprehensive analysis of clinically used radiation qualities. Their energy distribution will be analysed to find a representative set of reference radiation qualities for calibration purpose. Based on this, an update of the list of radiation qualities described in IEC 61267 will be recommended to be further implemented in the IAEA TRS-457.

Requirements for dosimetry equipment

This project will carry out an analysis of commercially available dosimeters and their performance characteristics. This will progress the state of the art by enabling the requirements for reference and field-class dosimeters to be defined. The newly defined reference-class dosimeter could be used at clinics to provide traceability. Based on this, a recommendation will be provided to IEC 61674 and to IAEA TRS-457 for including the classification of dosimeters based on their performance.

Calibration and measurement procedures for X-ray multimeters

The clinical relevance of quantities measured with XMMs will be assessed, and calibration procedures and traceability chain will be established for the most important quantities. Calibration procedures will be adapted for use in clinics, to allow performance checks of XMMs in clinical beams, and to estimate the impact of the differences between clinical beams and reference beams applied for instrument calibration. The obtained data will be used to recommend updates for IEC standards and IAEA TRS-457 for air kerma and practical peak voltage measurement devices, and to propose inclusion of additional quantities measured by the XMMs in IEC standards.

Validated calibration services

A comparison exercise will be organized to validate the newly developed radiation qualities and calibration procedures for XMMs. In addition, the response of field instruments in well-defined but slightly variable conditions at different calibration laboratories will be studied which will result in realistic data on actual variation of calibration coefficients provided to customers.

Outcomes and impact

Outcomes for industrial and other user communities

The updated reference radiation qualities and calibration procedures developed in the project will enable calibration laboratories to improve their calibration services. These improved calibration services will support medical physicists and technical services performing dosimetry measurements by providing more useful calibration data for the end-user. The knowledge of dosimeter response over the clinically relevant range of radiation qualities and defined limits of variation will provide confidence for clinical measurements in varying

conditions. This will also allow better understanding of the uncertainties involved. The guidance on measurement procedures recommended in the project will help performing consistent and comparable measurements. All these results together will enable the end-user to improve the accuracy of clinical X-ray dosimetry.

The data on dosimeter performance and harmonized and standardized procedures developed in the project will be referred by European and national regulators (such as STUK). This will enable regulators to have greater confidence in the calibration of dosimetry equipment and measurements for the implementation of legal requirements.

The developed and improved calibration procedures will enable XMMs manufacturers to test their devices and provide comparable specifications in their manuals. This will improve the position of their products on the international market and integrate their products as a part of the dosimetry chain in an accurate and cost-efficient way.

Different stakeholder groups, such as X-ray system manufacturers as well as medical physicists and technicians performing quality control measurements, are interested in the quality control related parameters of X-ray systems which can now be measured with the XMMs non-invasively. The developed calibration procedures for XMMs will enable these end-users to achieve traceable results for those quality control related parameters which do not currently have available standardized calibration services. The measurement reliability of these parameters will be improved when harmonized calibration procedures are established.

Outcomes for the metrology and scientific communities

The project will publish recommended new reference radiation qualities (RRQs), a spectrum catalogue for RRQs and reference radiation qualities currently described in IEC 61267 on its website. These new reference radiation qualities can be established by other calibration laboratories to better cover the clinical needs. In addition, the spectrum catalogue can be used to compare spectra in different laboratories and estimate radiation quality related uncertainties.

The definition of reference-class dosimeters for X-ray imaging will help dosimetry laboratories to categorize different levels of dosimeters and support their selection of appropriate metrological standards. In addition, this will support those who intend to perform measurements with improved accuracy. The study of the response of semiconductor-based detectors will consider the growing use of such instruments in clinical routine by providing improved procedures to ensure the traceability of such measurements. Ideally, the number of calibration points can be decreased which will reduce the workload of calibration laboratories and simplify the clinical measurement procedures.

In addition to updated calibration procedures for the radiation dose measured in terms of air kerma, the results will open new opportunities for dosimetry laboratories to offer calibration services for other quantities and parameters measured by XMMs. Traceable calibration of this equipment will provide additional confidence for quality control of clinical X-ray systems.

The project will carry out four international comparisons to validate the new proposed radiation qualities and the procedures to measure other parameters provided by the current dosimeters, the results of which will be published in the key comparison database (KCDB). This will allow the participating national metrology institutes (NMIs) or designated institutes (DIs) to amend their calibration and measurement capabilities (CMCs) and NMI's from all over the world to set up similar comparisons.

The planned (EMPIR JNP 19NET04 MIRA) and established European Metrology Networks (Radiation Protection) will also provide valuable support for the dialogue between different stakeholders.

Outcomes for relevant standards

The research results provide relevant data for the updates of existing IEC standards such as IEC 61267, IEC 61674, IEC 61676, IEC 62220-1 and International Code of Practice IAEA TRS-457 and their future extensions. Close cooperation with those standardization organizations is emphasized to achieve international impact. The standards are used by different stakeholders especially by the companies.

The experimental and theoretical investigation on the characteristics of radiation qualities will allow the assessment of relevant radiation qualities that represent clinical conditions. As a result, it will be possible to identify reference radiation qualities that should be included in the IEC 61267, in the IAEA TRS-457 and used for calibrations. The IEC 61674 and IAEA TRS-457 defines the performance requirements for dosimeters and

there are several IEC standards which define requirements for X-ray imaging devices (e.g., IEC 62220-1) They refer to the radiation qualities of IEC 61267 to specify limits of variation for dosimeters and X-ray imaging devices. The assessment of current requirements for dosimeters, existing performance data and the needs in clinical practice will be performed. As a result, all information will be compiled to provide a recommendation towards an update of IEC 61674.

Furthermore, after the evaluation of existing calibration and clinical measurement procedures for XMMs for air kerma and other measurement quantities and parameters (practical peak voltage, tube voltage, half-value layer etc.), updated procedures will be prepared and tested on a sample of XMMs. A method for traceable chain of calibration in terms of practical peak voltage and tube voltage will be investigated and proposed to IEC 61676 and IAEA TRS-457. In addition, new standards or update of existing standards are proposed to cover the other measurement quantities and parameters which are currently not covered by any standards.

Longer-term economic, social and environmental impacts

The calibration procedures developed in the project will provide European countries with a well-consolidated methodology for accurate calibration and verification of X-ray imaging dosimeters. Considering the specific focus on XMM technology and large number of XMMs in clinical use, this will have a significant scientific impact in medical X-ray dosimetry. The European metrology community will profit from this project, by acquiring improved knowledge in the field of X-ray dosimeter calibration, by increasing its influence when responding to an expanding demand related to the appropriate measurement of patient exposure and strengthened collaboration with industry.

The research will have a direct impact on the accuracy, consistency, and comparability of clinical X-ray dosimetry measurements. The proposed procedures will provide the best outcome at all levels to enable a traceability chain and harmonized calibration procedures for dosimeters worldwide. The improved procedures will increase the European influence on the global market. Finally, this will provide a benefit to a large number of patients through a reliable quality assurance of X-ray imaging.

List of publications

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This list is also available here: https://www.euramet.org/repository/research-publications-repository-link/

Project start date and duration:		June 2023, 36 months
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Chief Stakeholder Organisation: IEC TC 62, SC62C WG3		Chief Stakeholder Contact: Wesley Culberson
Internal Beneficiaries: 1. STUK, Finland 2. CMI, Czechia 3. ENEA, Italy 4. IMBiH, Bosnia and Herzegovina 5. IST, Portugal 6. PTB, Germany 7. TENMAK, Turkey 8. VSL, The Netherlands	External Beneficiaries: 9. EEAE, Greece 10. HUS, Finland 11. INM, Moldova 12. OPBG, Italy 13. SKBS, Germany 14. VINS, Serbia	Unfunded Beneficiaries: -