

TOWARDS METROLOGICAL BEST PRACTICES IN RADIATION PROTECTION

Consortium of 22NRM07 GuideRadPROS^{1,2,3}

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Abstract. This paper presents the state of the art and expected impact on metrology, health, standards, and society of the new joint research project – 22NRM07 GuideRadPROS, started in June 2023 and is running for 36 months. The main objective is to provide technical guidance to metrology institutes, standardization bodies, regulators, and manufacturers for a harmonized approach to calibration, testing and measurements using the radiation protection dosimeters for photon radiation. Moreover, manufacturers and standardization bodies will be helped to prepare for the forthcoming change in radiation protection quantities. The results of this research project will facilitate the take up of the technology and measurement infrastructure developed and consequently will ensure the improvement of the measurement supply chain from the manufactures to the end users. New guidelines and new protocols provided by this research in early 2026 will contribute to best metrological practices in radiation measurements in line with technological developments and standardization requirements. This project was selected for funding through the European Partnership on Metrology program of the European Commission and the participating countries. It involves several participants from national metrology institutes and designated institutes and a private company.

Keywords: Dosimetry, ISO 4037, Radiation, Protection.

1 Introduction

Diagnostics and treatments are fundamental pillars of health units' operations, characterized not only by the financial resources allocated to them, but also by scientific excellence and the inherent technological developments, through which reliable and accurate measurements must be a mandatory requirement. In this context and considering the definition of metrological traceability [10] the impact of the measurements on the performance of equipment's and devices as also on the quality of services and patient safety must represent an added challenge throughout the healthcare system. Overall, this dimension is faced as a multidisciplinary task which can mirror a pressing healthcare management issue that involves the knowledge and resources needed to implement good practices.

Ionising radiation is a type of energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometers or less capable of producing ions (directly or indirectly) [1]. It can be in the form of gamma rays or X-rays or particles (neutrons, beta, or alpha rays). Exposure to ionising radiation can result from

the operation of radiation sources and can occur in a variety of contexts. It is therefore important to be aware of its potential effects, whether in public places, at work or in healthcare facilities. Since the health effects of ionising radiation depend on the dose of radiation, the damage caused, and its side effects depend on the type of radiation and the sensitivity of the tissues to which the radiation is applied. In this context, the role of dosimeters in radiation protection is very important.

Dosimeters are medical devices widely applied to measure the effects of ionising radiation in various applications such as environmental dose monitoring, medical applications, emergency response and worker protection, among others, in order to protect against the harmful effects of ionising radiation. To measure the external dose in the work environment, health professionals are one of the largest groups for whom the dose monitoring needs to be implemented. The occupational dosimetry in medical applications is a complex task with largely varying exposure conditions and work practices. To achieve harmonized and consistent estimates of occupational exposure the dosimeters must follow harmonized type testing and calibration protocols.

Reliable and accurate measurements are of great importance to reduce the risk and to improve the confidence of the general public. Calibration [10] and testing [10] of photon dosimeters is performed in the reference fields defined by the standard ISO 4037 [7],[8], which has been recently changed. Together with the proposed changes of operational quantities by International Commission on Radiation Units and Measurements ICRU 95 report [5], this has presented significant challenges for calibration laboratories, but also for manufacturers and all users of dosimeters and ionizing radiation sources, causing a need for new research data and new and improved guidance, calibration and measurement procedures and standards in this field.

Facing the current European regulatory requirements applied to radiation dosimeters [1], metrology [10], as the science of measurement, can bridge the scientific tools by uptake of novel technical procedures in this important field of IR [11], [15]. Within this framework, priorities have been identified and a strategic research agenda for research projects within European Partnership on Metrology- EPM Program has been developed. Under that scope, a new Joint Research Project – 22NRM07-GuideRadPROS was funded. Started in June 2023, the project called by “Harmonisation, update and implementation of standards related to radiation protection dosimeters for photon radiation” [12], involves 17 participants from national and designated institutes (STUK, CEA, CIEMAT, CMI, ENEA, GUM, IMBiH, IPQ, IRB, IST, PTB, SCK-CEN, TENMAK, EEAE, INM, VINS, QST), a private company (Mirion) and a Japanese associated partner (QST). For three years of this joint research project, the consortium believes that its advancements are relevant for industries and related activities.

2 State of the art and progress

Generally, standards are highly relevant documents with a wide application throughout the life cycle of a product/device or measuring instrument. On the one hand, standards play an important role in the development, production and conformity

assessment before the products are putting on the market. On the other hand, and after the products/devices or measuring instruments have been marketed, standards are reference documents used to create procedures applied for the quality assurance of the devices throughout their lifetime.

In that context, the standard series from the International Organization for Standardization ISO 4037 [7], [8], plays an important role to define the requirements for the technical parameters of calibration facilities. As the reference calibration X-ray and gamma-ray radiation fields for radiation protection are defined in that standard, its implementation needs a coordinated effort by the entities and organizations responsible for its implementation. It is also important to highlight the conflicting requirements for the dosimeters given by different standards published by the International Electrotechnical Commission (IEC). Therefore, the future standardization needs must be analyzed to harmonize the standards as well as to implement the new radiation protection quantities suggested by the International Commission on Radiation Units and Measurements ICRU 95 [5]. However, to put it in force, a complete analysis of the type test standards and characterization of existing dosimeters is a requirement in order to analyse what modifications are necessary.

In the last update (2019) of ISO standard 4037 [7], the requirements for parameters of matched and characterized reference fields were based on the uncertainty limits for reference values of operational quantities, among others requirements for the X-ray tube high-voltage, filter thickness and filter purity. These requirements are in need to be reviewed based on the experimental data, as many have been established by calculations or simulations. The review is also needed, as the requirements are difficult to fulfil for many calibration facilities. Additional, spectrometry is required to set up characterised fields. Establishing spectrometry at an X-ray calibration facility requires much expertise due to the special equipment and unfolding procedures. Therefore, it is not possible for all laboratories to fulfil the requirements for matched fields or to set up the required spectrometry for characterized fields. Furthermore, there are two methods proposed by ISO 4037:2019 to calculate conversion coefficients for characterized fields: a) the dosimetric method and b) the spectrometric method. In order to estimate their uncertainty and their consistency, both methods must be reviewed [12].

3 Scientific objectives

The overall goal is to enable traceable measurements of conversion coefficients, and, subsequently, operational radiation protection quantities, for both methods mentioned before, to provide input for the future updates of ISO 4037 standard series, and to harmonize the type testing standards. Thus, the specific objectives of the project are:

- To develop harmonized approach to X-ray spectrometry in concordance with the current ISO standard 4037, evaluate the discrepancies between measured and calculated Half-value layer (HVL) [16] of X-ray spectra and to produce data to update requirements for reference X-ray fields.
- To produce data for ²⁴¹Am reference fields to be included in that standard and evaluate methods to determine X-ray tube high voltage.

- To develop cost effective procedures and guidance for the calibration of dosimeters and determination their response as a function of photon energy.
- To produce guidance on validated procedures for harmonized type testing with valid metrological solutions for situations where requirements in existing standards deviate and standardization gaps exist.
- To assess future standardization needs related to new and upcoming technologies and to produce a guidance document for the implementation of the new operational quantities of ICRU 95 [5].
- To collaborate with ISO and IEC and the users of their dosimetry standards to ensure that project outputs align with their needs.
- To produce guidance for incorporation of this information into currently regulations and recommendations to improved new procedures and policy enforcement.

4 Impact

As GuideRadPros has significant input from a variety of sectors, these results can also be used by healthcare organisations, public authorities, equipment manufacturers, research and development institutes, regulatory bodies and calibration and testing laboratories.

4.1 On Industry and health sectors

The new operational quantities may require changes in the characteristics of the measuring equipment because of their impact on the value of the conversion coefficients from air kerma to operational quantities [9]. These changes will have consequences for all stakeholders, including calibration laboratories, equipment manufacturers, dosimetry services and users of ionizing radiation in industry, research, and medical applications where radiation protection measurements are needed.

The adoption of the spectrometric characterization of radiation beams impacts the traceability of calibration beams to national references and the accuracy of calibrations [12]. The latter can be drastically improved allowing a more precise and comparable characterization of the measuring devices. This, together with the revision of the type tests carried out before the devices are put on the market will impact European regulation [1], [14] applied to this field.

By assess the consequences of the adoption of new proposed operational quantities [5] on radiation protection measurements, the possible transition from the present to the new operational quantities may be carried out in the most harmonious way possible.

These modifications could require adaptations of the devices, either in the data processing algorithms, or in the physical design of the detectors, or both, to remain in compliance with the type test acceptance criteria. Adaptation of these criteria may be necessary in coordination with the regulatory bodies and enforcement policies related with a possible change in the architecture of the legal procedures.

4.2 On Metrology

The implementation and harmonization of the spectrometry measurements ensure reliable validation and calculation of laboratory-specific conversion coefficients [12].

The guidance developed within this research lead to comparable procedures and therefore increase the confidence in metrology and testing.

Spectrometry can provide new research data, which is currently available only to a few metrology institutes, and thus help proliferation of scientific knowledge and research. With spectrometric capabilities improved, institutes can develop new radiation fields for upcoming applications, needed to metrologically support changes in technology and regulation.

The evaluation of the impact of the new proposed ICRU 95 quantities on the photon reference field standards will allow for an informed realization of calibration fields in the metrology institutes and calibration laboratories.

4.3 On Standardization

This work will contribute to the implementation and future updates of ISO 4037 standards series and IEC standards that set requirements for radiation protection dosimeters by providing relevant data, guidance documents and validated limits. Moreover, the implementation of the newly proposed operational quantities of ICRU 95 will have an impact on some of the limits given by ISO 4037-1 for matched and characterized reference fields and on the radiation doses recorded by the dosimeters. This affect the personal doses that are monitored nowadays in compliance with Council Directive 2013/59/Euratom [1] and will influence the dose limits and the future update of this safety standard.

4.4 On Economy and regulation

Stronger confidence in radiation protection dosimetry, both via the promotion of the implementation of the ISO 4037 standard series, and via the assessment of the impact of the new operational quantities defined in ICRU 95 has the clear potential of making radiation protection dosimetry practises even better than at present day. It provides dosimeter producers harmonized and appropriate means for producing competitive products on the global market.

The wide adoption of the ISO 4037 standard worldwide and the related services that can be derived from it, will improve reliability of measurements and the confidence of the European and international public, as well as the safety and security [12]. Furthermore, a reliable tested instrumentation in radiation protection dosimetry, possibly supported by the well-informed technical adoption of the new operational quantities defined in ICRU 95 report, could also lead to a stronger industry with a significant impact on the economy and society.

The adaptation of new operational quantities in regulations and type testing standards help regulatory bodies to implement future updates of Basic Safety Standard and additional national requirements that may follow.

5 Conclusion

Best practices in radiation protection are naturally achieved by the improvement of relevant standards and by wider implementation and harmonization of the type testing standards. For healthcare facilities and metrology institutes, more complete data for

radiation dosimetry, as well as a reduction in calibration uncertainties are both synonymous of a reliable and trustworthy activities. For industry, the harmonization of type tests improves the quality of the products and services, promoting the competitiveness of manufacturers. For regulators, the basic data, and methods for updating the legal dose limits and the Basic Safety Standard 2013/59/Euratom are considered a relevant output from this work. For the community at large - society - more reliable measurements and tests help to increase the comprehensive trust in the competent authorities having legal competence on radiation protection dosimetry. The outcomes of this research could also be reflected on the healthcare facilities running costs. Within the framework of quality improvement in all sectors, namely in the healthcare and related activities, a continuous international collaboration of experts is needed for promoting a comprehensive approach to good measurement practices.

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