

Title: Supporting regulation in Europe by developing appropriate type testing requirements for radiation protection dosimeters for a common market

Abstract

Council Directive 2013/59/Euratom, the Basic Safety Standards, is presently enforced in the European Union member states. However, there exists a huge variability in legal dosimetry requirements and criteria for individual monitoring services across European countries, including differences in type testing, traceability, verification but also in approval criteria and required quality assurance standards. Additionally, for some measurement tasks no compliant dosimeters are available at all. Support is needed to improve regulation by adopting harmonised type testing requirements and providing guidance for their application. This will lead to a more coherent common European market and help manufacturers to develop compliant instruments.

Keywords

Type test, Radiation Protection, Dosimeters, Council Directive 2013/59/Euratom, Euratom, Basic Safety Standards, BSS

Background to the Metrological Challenges

Council Directive 2013/59/Euratom of 5 December 2013 [1], the Basic Safety Standards (BSS), is presently enforced in the European Union member states. Its equivalent document IAEA General Safety Requirements (GSR) part 3 is also followed by member states that benefit from the IAEA's technical cooperation programmes. Both documents emphasise that individual monitoring of workers (and workplaces) should be performed by approved dosimetry services. However, significant variability in legal dosimetry requirements exists across European countries, including differences in type testing, traceability, and verification. The requirements for dosimetry services (individual monitoring services (IMS)) also vary greatly within Europe, encompassing different approval criteria and quality assurance standards.

Specific metrological expertise related to dosimeter calibration and testing is critical to support European legislation and operators in addressing the challenges related to quality assurance for radiation exposure situations [2, 3]. Based on results from the Metrology Partnership project 22NRM07 GuideRadPROS, technical requirements for personal and workplace dosimeters differ across the European Union and internationally, with standards set by IEC and ISO, CENELEC and CEN, and national regulation. These requirements are not enforced in every country, and in some cases, only partial testing is performed. Additionally, the software requirements in legal metrology, as stated in the Guide 7.2 of WELMEC which are crucial for measuring instruments with software components (i.e. all modern dosimeters) are not consistently applied.

As pointed out in EURAMET's open consultations in 2023 and 2024, the existence of deviating requirements in different countries is a barrier to the implementation of a single European market. They reduce the market size for dosimeter manufacturers which leads to limited availability of dosimeters in countries with stricter requirements. Additionally, in some of these countries, no dosimeters are available at all for some measurement tasks, e.g. for low energy X-ray fields. Unnecessarily stringent requirements in the relevant standards, which may get adopted by developing countries, make dosimeters more expensive and so fit for purpose requirements will remove unnecessary costs, supporting the UN sustainable development goal 10 to reduce inequalities.

Some of the (national) requirements are based on general considerations for measuring devices used for legally relevant measurements. These requirements are somehow an overregulation and place heavy demands on dosimeters, with limited benefits compared to the uncontrollable influence of the wearer of the dosimeter. The risk mitigated by some requirements is sometimes lower than the risk of wrong results due to uncertainties introduced by the behaviour of the monitored person.

Harmonised requirements and harmonised dose monitoring procedures across Europe are essential to ensure compliance with the dose limits set by the Basic Safety Standards as also pointed out in the EMN for Radiation Protection in their orientation statement on the Call 2025 [2,3]. The use of widely different monitoring systems, coupled with incompatible national dose registers, pose challenges for dose transfer when workers move between countries. Addressing these issues is essential for ensuring effective radiation protection for workers across borders and compliance with radiation protection regulations.

International Commission on Radiation Units and Measurements (ICRU) proposed new operational quantities within Report 95. If these proposed quantities are adopted as legal quantities, they will require metrological support. To disseminate the quantities or measure in unknown radiation fields, secondary standards are needed, as pointed out by CENELEC CLC/TC 45B and in the IAEA technical meeting in 11/2024. A first step to overcome this situation is the development of a spectrometer for measuring the electron component of the radiation fields. This is not an established procedure in current reference fields as presently calibrations are performed under charge particle equilibrium. For the new operational quantities according the ICRU proposal, the determination of the electron contribution in workplace fields is needed for compliant dose determination as charged particle equilibrium is not assumed.

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 proposal shall focus on metrology research necessary to support regulation in radiation protection dosimetry.

The specific objectives are

1. To collect and analyse metrological needs for legal dosimetry with passive and active dosimeters for individual and workplace monitoring across European countries identifying gaps, differences and similarities to inform future harmonisation efforts. In addition, to collect and analyse stakeholder needs for legal dosimetry and individual monitoring, identifying needs for digitalisation towards national dose registry considering the new generation of dosimeters and approval processes for online real-time dosimetry.
2. Based on the needs collected in Objective 1, to derive a common set of minimum requirements and validated test methods for passive and active dosimeters used in legal dosimetry, individual and workplace monitoring.
3. To develop a prototype spectrometer for the assessment of the electron component in photon reference fields. Using this prototype, to gather experimental data for workplace dosimetry under ICRU 95 operational quantities which do not assume charged particle equilibrium unlike the current operational quantities.
4. To develop fit-for-purpose procedures and guidance on common regulatory practices for individual and workplace monitoring of staff in different settings (medical use and industry applications) of ionizing radiation, which can be used, if applicable, to substantiate and revise current legislation.
5. To support the implementation of Council Directive 2013/59/Euratom, the Basic Safety Standards, and facilitate the take up of the technology, methods and measurement infrastructure developed in the project by national regulatory authorities and international organisations (IAEA) or European organisations (Heads of the European Radiological Protection Competent Authorities (HERCA)), the measurement supply chain, standards developing organisations (CEN/CENELEC, ISO, IEC), European Metrology Network (EMN) for Radiation Protection, and end users (dosimeter manufacturers).

The proposed research shall respond to documented requirements related to specific regulations and legislation or explore the background and feasibility of expected possible future regulation. To enhance the impact of the research, the involvement of the appropriate user community such as regulatory authorities, conformity assessment bodies, standardisation bodies, and industry, is strongly recommended. Where

relevant, proposals are encouraged to build on, or seek collaboration with, existing projects and develop synergies with other relevant European, national or regional initiatives and funding programmes. In particular, links are encouraged with (i) the projects funded under earlier relevant topics of the Horizon Europe programme; or (ii) other relevant European Partnerships.

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 Metrology Partnership project 22NRM07 GuideRadPROS and how their proposal will build on those.

Proposers should note that the programme funds the activity of researchers to develop the capability, not the required infrastructure and capital equipment, which must be provided from other sources.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.0 M€ and has defined an upper limit of 1.3 M€ for this proposal.

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 proposal's 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,
- Facilitate improved industrial capability, or improved quality of life for European citizens in terms of personal health, protection of the environment and the climate, or energy security,
- Transfer knowledge to the radiation protection sector and regulatory authorities.

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 Metrology 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.

Timescale

The project should be of up to 3 years duration.

Additional information

The links provided in this section are only correct at the time of publication up until the end of the Call year.

The references below were provided by PRT submitters; proposers should therefore establish the relevance of any references.

- [1] COUNCIL DIRECTIVE 2013/59/EURATOM
<https://eur-lex.europa.eu/eli/dir/2013/59/oj/eng>
- [2] EMN Radiation Protection Strategic Research Agenda
<https://www.euramet.org/research-innovation/metrology-partnership/strategic-research-and-innovation-agendas>
- [3] EMN Radiation Protection Call 2025 Orientation Paper
<https://www.metpart.eu/applicants-2025/regulation-call-2025-s1.html>

These references have been provided by EURAMET.

- [4] *001 CLC TC 45B Implementation of new quantities in radiation protection.*
<https://www.metpart.eu/go/need01>