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Internal Funded Partners: 1. IMBiH, Bosnia and Herzegovina 2. GUM, Poland 3. IRB, Croatia 4. IST, Portugal 5. PTB, Germany 6. SCK•CEN, Belgium 7. SMU, Slovakia 8. TAEK, Turkey 9. VINS, Serbia	External Funded Partners: 10. EEAE, Greece 11. INM, Moldova, Republic of 12. NSC-IM, Ukraine 13. USC, Spain	Unfunded Partners:
RMG1: INM, Republic of Moldova (Employing organisation); PTB, Germany (Guestworking organisation) – *terminated due to COVID-19* RMG2: VINS, Serbia (Employing organisation); PTB, Germany (Guestworking organisation) RMG3: IMBiH, Bosnia and Herzegovina (Employing organisation); IST, Portugal (Guestworking organisation)		

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1 Overview

Traceable dosimetry measurements are necessary for meeting the legal requirements of the EU Council Directive 2013/59/EURATOM. This project aimed to develop procedures for calibrating radiation protection dosimeters in various types of radiation protection beams, with a measurement uncertainty of ≤ 5 % (k=2). This was accomplished through further research on operational quantities for external radiation exposure and the development of secondary standards for eye lens dosimetry. In addition, all participating NMIs have prepared individual strategies for radiation protection metrology which were reviewed within the EURAMET community, in order to ensure a coordinated and optimised approach.

2 Need

Controlling the level of exposure to ionizing radiation for patients and individuals working in science, medicine or industry has been widely recognized as the most urgent need. Therefore, there was a demand for new and improved calibration services for operational radiation protection quantities, to ensure that the services provided fulfil the requirements of regulatory authorities.

The International Commission on Radiation Units and Measurements (ICRU) has defined four operational dose quantities for use in radiation measurements for external exposure that can assess the protection quantities. The operational quantities related to area monitoring are: ambient dose equivalent H*(10) and directional dose equivalent H'(0.07, Ω), and in terms of individual monitoring, the quantities are defined as: personal dose equivalent $H_p(10)$ for control of effective dose and personal dose equivalent $H_p(0.07)$ for control of skin dose. For the special case of controlling the dose to the lens of the eye the directional dose equivalent, H´(3,Ω), and personal dose equivalent $H_p(3)$ have been defined. Since protection quantities cannot be measured directly, operational quantities are used for monitoring external exposures instead.

Both theoretical and practical training courses were required to extend the capabilities of participating NMIs on calibrating radiation protection equipment at a secondary level, in order to ensure the stakeholders needs for traceable measurements of radiation protection quantities can be met. In addition, the obligations to legal metrology and the dissemination of the standards obtained, should lead to improved radiation protection.

3 Objectives

The overall aim of this project was to improve the capabilities of participating NMIs from emerging countries so that operational radiation protection quantities are traceable to the SI. The specific objectives of the project were:

1. To develop traceable measurement capabilities for operational radiation protection quantities, including the full characterisation of a measurement setup conversion procedure from air kerma (K_{air} kinetic energy released per unit mass) to ($H_p(0.07)$, $H_p(3)$, H_p (10), $H'(0.07)$, $H'(3)$, $H^*(10)$ operational quantities with an uncertainty of 5 % (k=2) or less. The applicable photon energy range and dose rate range are 5 keV to 7 MeV and 0.05 µSv/h to 100 Sv/h respectively.
2. To validate the developed measurement capabilities for operational radiation protection quantities, to ensure that within an applicable energy range, from 5 keV to 7 MeV and dose rates, 0.05 µSv/h to 100 Sv/h, the accuracy of the dose measurement under well-defined calibration conditions has to be at least 5 % (k=2), by organising and undertaking a intercomparison in dosimetry, including activities related to travelling standards, technical protocols, logistical provisions, and the evaluation of intercomparison results.
3. To develop and submit draft CMCs for the traceable calibration of dosimeters, thus proving the international equivalence of their measurement standards and the calibration and certificates that they issue.
4. For each partner, to develop an individual strategy for the long-term operation of the capacity developed, including possible regulatory support, research collaborations, quality control, the quality management system and accreditation. They should also develop a strategy for offering calibration services from the established facilities to their own country and neighbouring countries. The individual strategies should be discussed within the consortium and with other EURAMET

NMIs/DIs, to ensure that a coordinated and optimised approach to the development of traceability in this field is developed for Europe as a whole.

4 Results

4.1 To develop traceable measurement capabilities for operational radiation protection quantities

Measurement capabilities and a unified code of practice were set up for the measurement and secondary realisation of the operational radiation protection quantities. This enabled harmonisation in the field, so the services provided are now comparable across Europe.

Harmonised and traceable calibration is a basic requirement for mutual recognition of calibration results. The recognised traceability of calibration results will also provide an important contribution to consumer protection.

To ensure a unified code of practice, a theoretical training course ″Metrology and Calibration in Radiation Protection″ was organised in September 2018 at IST where all participating laboratories were familiarised with the common code of practice in accordance with ISO 4037:2019 and other relevant standards. A supplementary “hands-on” training course on the practical aspects of calibrations was held in March-April 2019 at PTB laboratories covering topics such as: half value layer measurements for ISO 4037 validation of a matched field, charged particle equilibrium, homogeneity of phantom irradiation, etc. This training course opened new research possibilities that were conducted through Research Mobility Grants (RMGs) in the laboratories of PTB and IST. Two RMGs were performed during the lifetime of the project.

In RMG2, ″Research in area and environmental dosimetry″, a researcher from VINS moved to PTB to investigate the type test requirements and methods valid for area workplace and environmental dosemeters. The results of this research was communicated to IEC, ISO, national committees and project partners. In RMG3, Researcher in personal and ambient dose equivalent dosimetry″, a researcher from IMBIH performed research and analysis of the requirements of the new standard ISO 4037-1 at IST. Special attention was paid to the personal dose equivalent $H_p(10)$ and the ambient dose equivalent $H^*(10)$.

The lessons learned from the training actions have been shared with EURADOS and the new European Metrology Network for Radiation Protection to optimise their future training actions. One of the partners gave a talk on ISO 4037 in the CCRI webinar. This webinar will become content of the IAEA training material and was included in an IAEA SSDL Newsletter 74 in 2021.

The inclusion of emerging EURAMET member countries such as Bosnia and Herzegovina, Croatia, Greece, Moldova, Poland, Serbia, Slovakia, Turkey and a non EURAMET country, such as Ukraine, in the research and development of methods for calibrations of radiation protection dosimeters was necessary to bridge the existing gap between countries with different levels of services and to harmonise dosimetry calibration procedures across Europe.

The knowledge and expertise shared within the consortium, as well as combined facilities and resources, strengthened the collaboration between European NMI/DIs and increased their competitiveness by narrowing the capability gap. Many of the less experienced partners are now involved in very important new projects, e.g 19NET03 supportBSS ″Support for a European Metrology Network on reliable radiation protection regulation″, as well as in the new ENM for radiation protection.

Additionally, a methodology for the design of an $H_p(3)$ secondary standard ionization chamber was developed in the project, with a focus on measurements at the radiology and nuclear medicine departments.

Three different prototypes of the $H_p(3)$ secondary standard ionization chamber were built and tested in laboratory conditions and two were tested also in work place fields. The advantage of a $H_p(3)$ secondary standard is that such ionization chamber will be calibrated in one reference beam quality and then used for all other energies, therefore no spectrometric measurements will be necessary. Since its design fulfils the ISO 4037-2 requirements for a secondary standard in respect to the energy dependence of the response, conversion coefficients from air kerma will also not be needed, as the measurement provides directly the $H_p(3)$ dose value. By using these new transfer instrument in laboratory, X-ray units can be calibrated in terms of $H_p(3)$ and these used for the calibration of eye lens dosimeters. For measurements in unknown radiation fields at workplaces in radiology and nuclear medicine departments, this new secondary standard chamber represents an easier and direct measurement method.

The development of the $H_p(3)$ chamber addressed and closed the gap of missing secondary standards for the

operational quantities ($H_p(0.07)$, $H'(0.07)$, $H_p(3)$, $H'(3)$, $H_p(10)$, $H^*(10)$).

Calibration measurements with an uncertainty better than 5 % (k=2) were achieved and the results were validated through an intercomparison carried out in the project. The objective was fully achieved.

4.2 To validate the developed measurement capabilities for operational radiation protection quantities within an applicable energy range

An extensive intercomparison exercise was organised, so the partners were able to compare and validate their measurement capabilities for the operational quantities identified, with the target uncertainty of 5% (k=2). The comparison included 5 radiation qualities: i) N-40 (mandatory), ii) N-100 (mandatory), iii) N-200 (additional), iv) S-Cs (mandatory), and v) S-Co (additional). In order to minimise the influence of dose rate, it was agreed for each laboratory to select a dose rate within the range between 0.5 mSv/h and 10 mSv/h (the recommended value was 6 mSv/h). The comparison was delayed due to the COVID-19 pandemic; however, the work was completed and Draft B report written before the end of the project.

One project partner was not able to participate in the official comparison, because of their status (not an NMI/DI and missing approval from their NMI). Due to technical problems, three laboratories didn't complete the measurements in all planned radiation qualities. Four values of dose rate were outside of the agreed range, but the comparison results for all of the measurements were acceptable. The target uncertainty was achieved by most laboratories in the comparison. Exceptions are the following: NSC IM for X-ray radiation qualities, TENMAK-NÜKEN for N-40, HMI/IRB-SSDL for S-Cs and S-Co, SMU for S-Co. In most cases the reason for higher uncertainty was calibration coefficient of the reference chamber, and the solution would be to reduce the traceability chain or to calibrate the chamber in a primary laboratory, which can provide lower uncertainty.

All the reported results are consistent within the reported uncertainties. During the comparison, a new version of ISO 4037 was published, so some laboratories realised radiation qualities according to ISO4037-1:1996, and some laboratories according to ISO 4037-1:2019. The transfer chamber stability was evaluated by performing repeated measurements in VINS, and the uncertainty due to the stability was added to the uncertainty of the Degrees of Equivalence.

Based on the new concept for CMC entries, a validation for the most challenging measurement condition, in this case lowest possible photon energy, is sufficient to cover the whole possible parameter range (from 5 keV to 7 MeV). Additionally, the used primary standard or method must be validated. This was fulfilled by the intercomparison in the selected measurement conditions.

4.3 To develop and submit draft CMCs for the traceable calibration of dosimeters

In November 2021, an online workshop on ″Approval process for CMCs″ was organised and held by EEAE to all project partners. A workshop was organised, and a procedure written to explain the approval process for CMCs to the consortium. The laboratories gained more information on three fundamental elements, required to the approval of CMCs such as: i) participation in reviewed and approved scientific comparisons, ii) operation of an appropriate and approved quality management system; iii) international peer-review (regional and inter-regional) of claimed calibration and measurement capabilities. This will lead to the approval of the institutes' CMCs, who will be able to request the BIPM to publish those CMCs in their database, after the end of the project. IRB created a procedure for submitting new or revised CMCs under the CIPM MRA framework. In this document, general features and requirements of CMCs are presented, as well as the procedure for submitting one. CMC requirements include measurement comparison, quality management system and review from regulatory bodies. Each of these requirements are briefly overlaid, starting with the measurement comparisons and ending with the acceptance and publishing in the KCDB (BIPM key comparison database, International Bureau of Weights and Measures). In the end, some specific notes are given about the CMCs regarding Ionizing Radiation. Notes and recommendations are given by the CCRI (Consultative Committee for Ionizing Radiation). This document is a short overview of the documented guides available on the BIPM website.

Currently, several CMCs are in various stages of the publication process. In June 2020, project partner VINS published 18 CMC lines in the KCDB - 16 of which are in the field of radiation protection.

Besides the knowledge gained on the approval process for CMC submission, the successful participation in an intercomparison and the development of harmonised calibration procedures and quality management systems, enabled the participating laboratories to fulfil the requirements for submitting draft CMCs for traceable calibration of dosimeters.

New or improved CMC claims in radiation protection operational quantities will be submitted to the BIPM by IMBiH, GUM, IRB, IST, SCK-CEN,SMU, TAEK, VINS, EEAE, INM, NSC-IM and IJS after the end of the project,

leading to greater confidence in each institute's capabilities and reduced calibration uncertainties for their customers.

4.4 Development of an individual strategy for the long-term operation of the capacity developed

The individual strategies, for the long-term operation of the developed capacities, will lead to the provision of calibration services from the established facilities and this will ensure the sustainability of the activities undertaken. The partners with less developed laboratories increased their research activities and established standards, methods and uncertainty budgets for the calibration of radiation protection dosimeters at an acceptable international level. The general structure of the strategy document was adopted by the project partners and individual national strategies have been developed.

The individual strategies describing present and future capacity development for traceable measurements of operational radiation protection quantities and calibration of radiation protection dosimeters in radiation protection have been developed by IMBIH, GUM, IRB, SMU, TAEK, VINS, EEAE, INM and NSC-IM. The institutions have adopted the general structure / minimum topics of individual radiation protection strategy documents.

Following the short- and long-term tasks described from strategy plans the following directions are highlighted:

- Implement DOSETRACE results, mainly through intercomparison results, or other project outcomes
- QMS (compliance with ISO 17025, EURAMET peer review)
- Update of measurement capabilities and calibration procedures through adoption of 4037:2019, improvement or repair of equipment and expand calibration fields
- Promote calibration to stakeholders
- Publish CMCs

The majority of the above highlighted tasks were boosted by DOSEtrace. Laboratories are urged to adopt the results and improve their capacities and status.

5 Impact

Five presentations have been given at European and International conferences, such as the CROLAB international conference on laboratories competencies, held on October 2018, in Croatia. Also, 2 posters on the research capabilities of radiation protection dosimeters have been presented at relevant events (such as the 3rd International Conference on Dosimetry and its Application, held in May 2019, in Portugal). In addition, the partners have presented the project results to 4 key standardization bodies that are involved in the ionizing radiation field: EURAMET TC-IR, EURADOS, ISO TC/85 and IEC SC/45B. The project has successfully organized 3 workshops for various target audiences. Simulations of the secondary standard for eye lens dosimetry were demonstrated during the training course on *Metrology and Calibration in Radiation Protection*, in September 2018. In addition, the project partners have implemented three main approaches of the Monte Carlo simulations in order to design prototypes for a $H_p(3)$ standard ionization chamber. Three prototypes of $H_p(3)$ standard ionization chamber were constructed and tested in laboratory and workplace fields. This work is beneficial for calibration laboratories and will have a clear impact on industry. As such, the progress on the design of the prototypes was presented at each technical meeting, as well as, on the annual EURAMET Technical Committee meetings for ionizing radiation.

A supplementary "hands-on" training course on the practical aspects of calibrations was held in March-April 2019, opened new research possibilities that were conducted through Research Mobility Grants (RMGs) in the laboratories of PTB and IST. Two RMGs were performed during the lifetime of the project. One studied the type test requirements and methods valid for area workplace and environmental dosimeters and another studied the requirements of the new standard ISO 4037-1 with special attention to personal dose equivalent $H_p(10)$. Both RMGs' results are of importance for the international standardization in ISO and IEC. Also, the project website was updated regularly with progress overviews and highlights.

As a result of the work, 3 papers were prepared for submission to open-access peer-reviewed journals. One paper on the influence of photon spectra and long-term stability on calibration of field-class dosimeters, other on the interlaboratory comparison, and a third on the harmonisation of IEC type testing requirements and test methods for active area dosimeters in environmental monitoring.

Impact on industrial and other user communities

The knowledge transfer amongst the participating calibration laboratories, created impact by enabling greater confidence in the measurements of radiation protection quantities, through an improved accuracy of national reference standards for operational radiation protection quantities with an uncertainty of 5 % (k=2) or less. Partners are able to use the calibration techniques validated in the project, as well as, the measurement uncertainty which is a vital parameter in assessing the operation and quality of a measuring instrument, to provide traceable measurements. Therefore, the calibration laboratories have an increased capability (calibration, measurement, training, consultancy, etc.) and the metrology services provided are now more widely available, which will benefit the end-users.

Furthermore, the research on the secondary standard for eye lens dosimetry will provide industry with more information on the design of the standard ionization chamber based on measurements in standard laboratory radiation fields and in workplace radiation fields such as the ones found in radiology departments at hospitals. The uptake of the new measurement capabilities developed by the partners in this project is expected after the end of the project, after CMCs are published. Early uptake will also be important for the accredited laboratories and manufacturers of radiation protection devices as it will enable them to confidently demonstrate the performance of their products which will ensure that they remain internationally competitive. In addition, the project will contribute to improving the quality of the information available on the performance of different types of dosimeters. This information will be valuable for the manufacturers of these devices, in light of the improvements to the dosimeters characteristics thus ensuring their clients requirements are met.

IMBIH and TAEK started providing services for the calibration of radiation protection dosimeters using techniques developed in this project. TAEK completed the quality management system and was subject to an external audit. IMBiH also prepared a quality management system and will have this peer reviewed after the end of the project. Both partners made important improvement in terms of developing capacities and providing calibration services to end-users such as: industry, clinical centres, radiation protection centres, regulators, etc.

In order to ensure that the calibration capabilities are harmonized and recognized by external bodies and at the same level as in developed European countries, information on the performance of radiation protection devices will be included in a calibration certificate from a laboratory accredited in compliance with EN ISO/IEC 17025 [9] or in a certificate with a CIPM MRA logo representing published CMCs. As a result, the end users of these services will benefit most from the improved performance characteristics in light of increased quality of life due to better dose assessment in the workplace.

Impact on the metrology and scientific communities

The project improved collaborations between European NMIs which will decrease the gap between emerging NMIs and more experienced NMIs. To ensure the sustainability of the project's results, most of these countries developed long term strategies for the operation of the developed capacities and they drafted a report on their long-term strategy for radiation protection dosimetry that responds to future challenges, for presentation to the metrology community.

The knowledge transfer between more experienced NMIs and emerging NMIs on developing and validating radiation protection operational quantities was beneficial for the metrological community on the whole. In particular, it had impact on laboratories that have either not established or needed to improve their traceability chain for radiation protection operational quantities.

Impact on relevant standards

This project has contributed towards the implementation of EU Council Directive 2013/59/EURATOM, by developing procedures for measuring and assessing human exposure and radioactive contamination of the environment as well as establishing methods for the regular calibration of measuring equipment. The project's outputs will directly influence the following international standards: ISO 29661, ISO 4037, ICRU51 and could help to revise CMCs according to the latest version of ICRU90. Research on the secondary standard for eye lens dosimetry, in both dosimetry laboratories and clinical environments, will provide new input to relevant standards (e.g. ISO 15382), on the correction factors for the discrepancies between laboratories and clinical environments. The research activities within both RMG will have impact on ISO 4037 and on the IEC type test standards for area and environmental dosemeters.

Longer-term economic, social and environmental impacts

The results of the project will have an indirect impact on environmental safety as environmental radiation monitoring measurements will be traceable and more reliable, and the road transport and import/export of radioactive materials at border crossings will be safer. The results of the project will also improve safety and

the radiation protection of the general population via more reliable and traceable radiation/contamination measurements of the environment (soil, water, air).

Lower measurement uncertainty and unified calibration procedures will improve the performance of radiation protection monitoring equipment. This will result in a better quality of life for the general public and workers.

By improving radiation protection calibration services among the project partners' countries, this project will provide adequate dissemination of radiation protection operational quantities. Moreover, calibration laboratories will be able to introduce new/improved calibration services and in doing so, will meet industry's need for higher accuracy calibration services across Europe. Thus, making calibrations more efficient, economical and readily available.