



Publishable Summary for 19NET04 MIRA

Support for a European Metrology Network on the medical use of ionising radiation

Overview

Ionising radiation in medicine is an area of rapid technical evolution and new innovations. Therefore, a coordinated action is needed to improve safety and efficacy of patient imaging and treatment, optimise radiation dose delivery and understand its radiobiology to assess the risk of side effects and to optimise therapeutic effects. A high-level coordination of the metrology community is needed to promote and support countries in establishing and adopting adequate standards, sharing their measurement infrastructure and data, and to ensure wider access to high quality metrological facilities. The project will address the absence of high-level coordination of the metrology community by establishing a single hub for stakeholder consultation, a knowledge base of relevant research results, and a strategic research agenda (SRA). Thus, ensuring support for associated training, research and development, as well as accessibility to metrological infrastructure. The project will develop a joint and sustainable European metrology infrastructure for medical use of ionising radiation via a European Metrology Network (EMN).

Need

Among the domains which use ionising radiation, the evolution of Radiation Therapy is the most rapid and important in the past few years. It is clearly demonstrated, with the publication of updated and new International Atomic Energy Agency (IAEA) protocols, that new facilities aimed at improving the efficiency of the treatment and diagnosis lead to increasingly complex patient exposure regimes and these require, in turn, updated and new metrology techniques.

Imaging is commonly joined to the therapy machines and aging population will need more and more invasive cardiac procedures that result in high doses and potentially skin and vascular reactions. Ever more, there is a continuous updating process, new and enhanced diagnostic and radiation therapy tools requiring appropriate measurement techniques and the proliferation of radiation production facilities prove that this situation will prevail in the future. For example, MRI-LINAC machines are arriving on the market, dedicated hadron facilities are becoming less expensive, emerging radiopharmaceuticals and diagnostic procedures are tending to the use of very short radiation pulses. This updating and renewing process must therefore follow the evolution of the techniques as rapidly as possible, which requires a sustainable expert structure to be established that can react within the same time schedule.

Radiobiology represents a key tool for improvements and further developments in radiotherapy, in order to understand the mechanisms behind radiation effects, to lower dangerous induced effects and to improve treatment efficacy, it is essential to have accurate radiobiology data. A closer link and dialogue with stakeholders and academic institutions carrying out clinical trials and studies on radiobiology data needs to be established by the metrology community. Further to this, there are currently large discrepancies between European countries in terms of access to high investment radiotherapy and radiobiology facilities. This is due to the complexity and cost of operating such irradiation facilities, meaning that only the most developed countries are currently able to operate them. Therefore, a network is needed to promote and support countries in sharing their measurement infrastructure and data. Currently there is no single European-wide coordination point for the metrology of medical use of ionising radiation. The IAEA and a limited number of companies offer postal quality control services in radiotherapy. Existing coordination for the medical use of ionising radiation is also very compartmentalised, for example metrology is well represented in standardisation bodies such as ISO and IEC, but not in other expert groups like ESTRO (European Society for Radiotherapy and Oncology) or EURAMED (European Alliance for Medical Radiation Protection Research).

Objectives

The overall aim of this network project is to accelerate the implementation of the future EMN on medical use of ionising radiation. The specific objectives are:

1. To establish regular, constructive dialogue and liaison (e.g. workshops) between the project partners and stakeholders in order to identify the priority areas in terms of research and standardization, in the medical use of ionising radiation. Stakeholders should include (i) manufacturers of medical equipment, (ii) academic experts, (iii) standards development organisations, (iv) national and international bodies on those topics, e.g. radiation oncology, medical physics, pre-clinical research, and (v) medical staff.
2. To develop a Strategic Research Agenda and roadmaps for the medical use of ionising radiation, taking into account the feedback from key stakeholders in Objective 1. This should take into account the evolution of techniques, applicable regulation (e.g. Medical Device Regulation (EU) 2017/745) and existing roadmaps of networks (e.g. MELODI, EURAMED).
3. To define how current European metrological services meet regulatory and stakeholder needs, taking into account the feedback from stakeholders in Objective 1. This should include existing quality assurance mechanisms and networks e.g. European Network of biological and physical-retrospective dosimetry (RENEB) and EURADOS and the development of a web-based platform for stakeholder information. The platform should be developed in a manner that allows it to be maintained by a future EMN.
4. To set up and promote a knowledge-sharing programme for stakeholders, taking into account the feedback from stakeholders in Objective 1, in order to support the dissemination and uptake of results and the safe use of ionising radiation. This will include a range of regularly hosted activities, such as the exchange of researchers between organisations, metrology workshops, stakeholder events and training courses.
5. To develop a plan for a joint and sustainable European metrology research infrastructure for the medical use of ionising radiation via a European Metrology Network. The plan should be completed within 12 months of the start of the project and address how to (i) develop coordination and smart specialization of capabilities (ii), align with existing networks, other EMNs and TC-IR, (iii) promote the development of emerging member states, and (iv) extend the collaboration to third countries.

Results

Establish stakeholder dialogue in order to identify the priority areas (Objective 1)

The stakeholders of the project have been selected and a data base has been created. Their needs in terms of research priorities were identified and collated into the Orientation document provided to EURAMET for the preparation of the EPM call for projects.

Using the defined selection criteria, all partners established the potential stakeholders within relevant communities in each country. Moreover, the partners have initiated liaison with some of the selected stakeholders and informed them about the approach of this project along with the scope of the future EMN.

A constructive dialogue is being initiated with stakeholders who answered the first contact taken by the project, it needs to be extended as part of a future EMN, between all the actors involved in medical applications using ionising radiation, including metrology institutes, relevant stakeholders (such as professional societies and device manufacturers) and end-users. These exchanges will support the continuous update of research and measurement infrastructure needs of the community. It will also be used to build an extensive database which will address the present capabilities and priorities along with the projected ones for the next 5 to 10 years via the development of a plan for a future EMN (Objective 5).

Develop a Strategic Research Agenda and roadmaps for the medical use of ionising radiation (Objective 2)

The project identified 95 potential stakeholders gathered in the stakeholder database including organisation and network). The project selected 54 to get in touch within May and June 21, among them only 26 answered which is not enough for the moment to establish such advisory committee or get a reliable feedback, As it turns that the foreseen general stakeholder meetings were not feasible, it is decided to organize individual meetings before the end of 2023 to keep the selected stakeholders more involved; This process is ongoing. The stakeholder advisory committee, composed of 8 members will be created depending on the answers of the stakeholders. The information collected from the community on the research priorities, at present and for the

next 5 to 10 years, will be used as the basis for the definition of roadmaps and a Strategic Research Agenda of the EMN. Four roadmaps will be provided for each specific topic addressed by the future network, namely radiotherapy (external, brachytherapy), nuclear medicine, imaging (diagnostic, patient positioning, interventional, radionuclide-based) and radiobiology (in the context of medical use of radiation).

Define how current European metrological services meet regulatory and stakeholder needs (Objective 3)

The project will create an appropriate stakeholders' structure (core group, advisory committee) which enables regular interaction of the metrology community with representatives from standardisation bodies (ISO, IEC) and manufacturers in the field of medical devices using ionising radiation sources and of measurement instruments. The achievements of the project in terms of identification of new standards, harmonisation and exploration of the continuous and fast evolution of the techniques will provide appropriate answers to the community, supporting their implementation through this structure. So far, CMI, IFIN-HH and SCK•CEN have identified and analysed other existing or no longer existing web-based platforms, which offer services to stakeholders in other fields identified the requirements for a web-based platform. A list of existing platforms has been created with examples from already existing EURAMET networks, industry, scientific organisations, professional associations, nuclear authorities, scientific journals and public administration. NPL, CEA, ENEA and VSL have also prepared a list of requirements for a web-based platform, which offers easy and targeted access to relevant information to stakeholders. A draft web portal of the platform has been prepared based on the findings from all partners summarised in a report the work will be finalized after the lift of the suspension.

Set up and promote a knowledge-sharing programme for stakeholders (Objective 4)

Existing facilities for the medical use of ionizing radiation and the metrological infrastructure in emerging member states and have been analysed. This was done by selecting three countries (Serbia, Romania and Czech Republic) and by identifying relevant organisations within those countries, which have been contacted. The analysis of the existing capabilities for the three emerging member states has been summarized in a report. A questionnaire has been sent to relevant end users in the selected countries, The analysis of the questionnaire allows identifying potential opportunities for NMI's and DI's in the field of the medical use of ionizing radiation namely for brachytherapy traceability and quality assurance and proficiency testing in radio-diagnostic. The extension of the services will provide researchers a broader access to laboratory infrastructures which currently are accessible only to the most developed countries. It also reported the needs for knowledge transfer tools, which would allow the training of young researchers and workers in the field of ionising radiation use for medical applications. This will be an important activity addressed by the future EMN, intended to ensure sustainable expertise across Europe.

Furthermore, a plan was envisaged for the organisation of technical training sessions, metrology workshops and training courses, it turn from the experience of the MIRA partners that such a face to face meeting would have a very small audience compared to the cost of such an organization, and therefore relevant content of short video post on the website will be defined in agreement with the objectives of the network. For stakeholder event virtual event will be preferred. Part of the sharing information is in progress when looking at the situation in emerging countries where needs have been identified. However, until now no plan have been proposed and it turns that the organization of such training in emerging countries is not feasible. Therefore, other partners than the representatives of emerging countries listed the existing training in their own countries, which is really useful for the progress of the project. The project will also develop a plan for a European metrology research infrastructure for the medical use of ionising radiation via a European Metrology Network.

A plan for a future EMN on medical use of ionising radiation has been proposed for the 2022 EURAMET GA, addressing the organisation of the network, its coordination and governance. A proof of concept for the sustainability of the EMN will be provided based on the commitment by the participants to the network of a dedicated consortium agreement. This however, has not been approved by EURAMET and so the proposal was not presented to the GA. Therefore a new proposal will be made to EURAMET this proposal will account for the recommendation of midterm review. This new proposal, firstly planned during the first mid of 2023 have had to be delayed it is now foreseen at the beginning of 2024

Impact

The partners have given presentations at key conferences and workshops (Serbia XXXI DZZ SCG 2021 in Oct 2021, the National Conference of the Romanian Radiation protection Society SRRp in November 2020, the RaCHy JRP workshop in November 2021, the RAD conference in Montenegro in 2022).

In addition, the project's progress has been presented to the EURAMET TC-IR members during the 2021, 2022, and 2023 annual meetings.

Results from projects dealing with new research topics and new metrology services on dosimetry in medical imaging and radiotherapy were disseminated within EURADOS at annual meetings of the concerned working groups.

Dedicated calibration services have been set for specific needs of end-users, namely in the field of medical imaging and nuclear medicine.

Work on the creation of the external web site has started, the content requirements have been agreed between partners and aspects of the communication material have been produced (e.g, posters, presentations and official stakeholders contact letters).

Impact on the metrology and scientific communities

To fulfil the goal of the future EMN, established in this project, the JNP has started a constructive dialogue with relevant stakeholders in the field of medical use of ionising radiation. This is the first step towards a complete overview of the needs among European countries within metrology, research and medical communities. Over the past year consortium members were involved in the Strategic Research Agenda of the EURADOS and the roadmap of the EURAMET TG Health once the stakeholder feedback will be completed and in the light of the needs identified for the selected emerging countries it will be possible to draw topic specific roadmaps to define the research priorities and help in harmonisation of activities at the European level in medical applications of ionising radiation including radiobiology and radiation protection. The goal is to increase the visibility of Europe through European harmonisation within international organisations such as IAEA, ICRU, ICRP, ISO, IEC.

Impact on industrial and other user communities

The questionnaire developed and sent to the end users in the selected emerging countries is the first step to get impact in the dissemination of the knowledge as well as the harmonization of the quality assurance and proficiency testing for radio-diagnostic and the identification of the gap of traceability for brachytherapy. The final goal being, by establishing an EMN, that all member countries have access to the same data and latest results. In addition, having access to the same calibration methods to ensure improved health care due to a more precise and less error-prone exposure and harmonised and improved reporting within Europe.

Impact on relevant standards

The first analysis of the situation in emerging counties put into evidence the need for the dissemination of existing protocol of quality assurance and traceability challenges across the field of the medical use of ionising radiation based on the liaisons established between acting communities to allow the harmonisation of their procedures. Through the improvement of the traceability of exposures during diagnosis and radiotherapy and radiobiology studies the reproducibility of results, will increase and provide a greater statistical power to study correlations between the doses and biological outcomes. The SRA and roadmaps of the future EMN will be strongly linked with the development of new standards, leading to safer and more efficient use of treatment and imaging techniques.

Since radiobiology investigates the link between physical and biological effects of radiation, more accurate assessment of quality factors, to account for the biological effect of radiation, will contribute towards EURAMET's Strategic Research Agenda for metrology in Europe.

Longer-term economic, social and legal impacts

The EMN will provide the platform for cost-effective evidence-based use of ionising radiation, which in turn will accelerate the translation of novel radiation therapy and radio-diagnostic tools into clinical practice, benefiting patients earlier and therefore improving their quality of life. This is the case for the work initiated by members of the consortium toward organisation like ANSM (Agence Nationale de Sécurité du Médicament et des produits de santé) when wording control procedure for radiotherapy and radio-diagnostic facilities A deeper understanding and enhanced knowledge of the effects of radiation on living organisms, will result not only in improved diagnosis and treatment, but also in understanding beyond the medical sphere on radiation protection in all human activities where one can be exposed to radiation. Improved dosimetry and radiobiology capabilities will also facilitate the study of the stochastic effects from low levels of radiation exposure. Therefore, patient and public will benefit from an increased understanding of the risk factors for radiation induced secondary cancers.

List of publications

Not yet available.

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

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| Project start date and duration: | | 01 June 2020, 48 months |
| Coordinator: Jean-Marc Bordy, CEA EMN website address: n/a | | Tel: +33 169084189 E-mail: jean-marc.bordy@cea.fr |
| Internal Funded Partners: 1. CEA, France 2. CMI, Czech Republic 3. ENEA, Italy 4. IFIN-HH, Romania 5. IRSN, France 6. NPL, United Kingdom 7. SCK•CEN, Belgium 8. VINS, Serbia 9. VSL, Netherlands | External Funded Partners: No | Unfunded Partners: 10. STUK, Finland |