European Commission

Third European High Level Nuclear Roundtable on Medical Applications

Research Infrastructures and Competences

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Contents

Abstract

A European High-Level Nuclear Roundtable was convened on 13 February 2023 with stakeholders from Member States, the industry, the research community and associations involved with medical applications of nuclear science.

Building on the fruitful discussion from the previous two editions held in May 2021 and March 2022, this third Roundtable offered another opportunity to bring together relevant communities and propose concrete actions to advance research and innovation in this field.

More specifically, the objective was to explore the main challenges faced by medical applications of nuclear technology particularly focusing on two critical areas, research infrastructures and nuclear competences, and to identify the roadblocks preventing technological advances in radionuclide procedures from reaching European patients.

This publication summarises the proceedings of the third European High-Level Nuclear Roundtable on medical applications, presenting the speakers' interventions and the main outcomes of the discussion, as well as follow-up initiatives.

Acknowledgements

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This Roundtable was made possible thanks to the initiative of Commissioner Mariya Gabriel and her Cabinet, especially Carlos Morais, thanks also to Bernard Magenhann, Deputy Director General at the JRC who intervened in the opening remarks and moderated the discussion and to Margarida Goulart, Head of the Euratom Coordination Unit at the JRC who supported the Roundtable process since the early phase.

We thank all the speakers and their respective teams for their valuable interventions which ensured a successful discussion during the Roundtable:

- Ms Katarina Nordqvist, as the Representative of the Swedish Presidency of the EU Council and Head of Section at the Ministry of Education and Research for her opening words;
- Mr Tomáš Ehler, Deputy Minister at the Czech Ministry of Industry and Trade, Mr Mike Lamont, Director for Accelerators and Technology at CERN, Mr Philippe Knoche, CEO of Orano and Ms Agnieszka Kaźmierczak, Director General of ESA (the Euratom Supply Agency) for their insights on the research infrastructures for medical radionuclides production and innovation as well as the associated issues of security of supply.
- Mr Cyril Piquemal, Deputy Permanent Representative of France to the EU, Ms. Csilla Pesznyák, President of ENEN, Ms. Jessica Johnson, Communication and Advocacy Director at nucleareurope and Ms. Paola Erba, President-Elect of EANM for their views on the needs for nuclear competences in the medical fields dealing with nuclear technologies.

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1 Introduction

On Monday 13 February 2023, European Commissioner Mariya Gabriel, in charge of Innovation, Research, Culture, Education and Youth, chaired the Third High-Level Nuclear Roundtable on Medical Applications and Research Infrastructures. This Roundtable built on the two previous editions organised on 12 May 2021 and 15 March 2022. It took place online via videoconference and gathered around 70 participants.

The Roundtable was attended by high-level speakers representing EU Member States, research organisations, industries and associations dealing with medical applications of nuclear science and nuclear competences.

As announced in the conclusions of the previous meeting, this third edition put the focus on medical applications of nuclear technologies with the aim to point out and discuss the main challenges to making technological advances in radionuclides procedures accessible to European patients. For that purpose, the two following critical aspects were addressed:

1) Enabling a sustainable and efficient network of nuclear infrastructures for research and support to the security of supply of medical radionuclides;

2) Ensuring a strong workforce of nuclear experts and related competences in areas critical for all phases of the use of medical radionuclides.

This discussion is complementary to and supports other important EU initiatives in the field, such as: the SAMIRA Action Plan, the European Observatory on the Supply of Medical Radionuclides, the EU Beating Cancer Plan and the Mission on Cancer.

Commissioner Mariya Gabriel opened the Roundtable followed by the JRC's Deputy Director General, Bernard Magenhann and the representative of the Swedish Presidency of the EU Council. The High-Level Roundtable was divided into two panel discussions on Research infrastructures (1st panel) and Nuclear competences (2nd panel).

During the concluding segment of the Roundtable, Commissioner Gabriel announced a follow up initiative consisting of a series of workshops, to be organised in the coming 12 months. The first workshop, scheduled for the 27 April 2023 in Ispra, will focus on the topic of "*Translating radiotheranostic cancer research into clinical practice in Europe*" and aim to foster concrete actions in research and innovation to bridge the gap between research and clinical uses of radionuclides.

2 Opening remarks

2.1 Research and Innovation for the medical applications of nuclear technologies (Mariya Gabriel, European Commissioner for Innovation, Research, Culture, Education and Youth)

Medical applications of nuclear science: a key sector

In the area of health, the medical uses of nuclear technology are extremely impactful for society as a whole. In fact, radiological and nuclear technologies have a crucial place in modern healthcare. Medical radionuclides are essential for the diagnosis but also increasingly for the treatment of cancer and other cardio-vascular and neurological diseases. More recently they have also been involved in complementing the diagnosis of COVID-19 pneumonia.

In the EU, each year we perform around 500 million medical procedures using ionising radiation and among them, around 10 million imaging procedures using radionuclides. Around 50% of cancer patients benefit from radiotherapy treatment.

The therapeutic uses of nuclear medicine are constantly expanding and expected to continue growing in the years to come. However, the use of medical radionuclides faces challenges that need to be addressed to effectively transfer the knowledge emerging from research to clinical use, for the benefit of patients.

Two areas are critical to ensure the availability and accessibility of medical radionuclides to patients. Research and infrastructures are essential to develop and sustain a reliable supply chain for production while appropriate competences are needed for all phases of the use of medical radionuclides.

Supply of medical radionuclides in the EU

The EU is the world's leading supplier of medical radionuclides, responsible for the production of 60% of the world market of imaging radionuclides. A relevant part of these radionuclides is obtained from research reactors, some of them ageing, leading to a potentially fragile supply chain for clinical users. Additionally, highly demanded therapy radionuclides still require more R&D to explore the potential of new radioisotopes and their production routes.

To tackle the challenges on the supply of medical radionuclides, we have to support alternative and innovative methods of production for the current medical radionuclides by enabling research collaborations between relevant research facilities and partnerships across the line of the different actors involved in bringing the technologies to the patients.

Nuclear competences for medical uses

Preserving the EU's leading role in nuclear medical applications also depends on having the relevant competences, covering all phases from source materials and nuclear infrastructures to the management of waste. Maintaining a highly skilled and adequately trained workforce is therefore paramount.

The Euratom Research and Training programme already contributes to this objective with a component dedicated to training and research on the safe use and reliable supply of medical radionuclides. The dialogue between all stakeholders has to be further strengthened to identify and understand the critical challenges ahead.

A number of initiatives are already setting important frameworks at EU level like the EU Beating Cancer Plan, the Mission on Cancer and the SAMIRA action plan.

Complementarities have to be identified to maximise the impact of research and innovation in delivering the different objectives. In this spirit, better synergies have to be encouraged between European programmes on health and the Euratom R&T programme as well as with national and regional programmes.

2.2 JRC contribution to advance medical applications of nuclear science (Bernard Magenhann, Deputy Director General, Joint Research Centre)

Medical applications are among the key priorities set out in the JRC Nuclear Strategy, with the goal to identify new possible uses of radioisotopes, support new production methods and contribute to the safety, security and sustainability of the full process, from production to clinical use and waste management.

This commitment is illustrated by the JRC direct actions under the Euratom R&T programme, but also through the JRC participation in research activities undertaken by multi-partner consortia managed by the DG Research and Innovation.

Research infrastructures and security of supply

The JRC owns a unique set of nuclear research infrastructures, including two accelerators (MONNET and GELINA), contributing to the investigation of alternative routes for radioisotope production. One noticeable impact of the JRC in this field is the successful pioneering of the therapeutic use of an alpha-emitter labelled drug for treatment of prostate cancer. This promising new Targeted Alpha Therapy (TAT) is expected to play a key role in the treatment of metastatic cancer in the future.

In addition, the JRC has completed two studies, the SMER reports (Studies on the supply of medical radioisotopes in the EU during 2019 and 2021), that provide greater insight on the sustainability and resilience of the EU market of medical radioisotopes for both diagnostic and therapeutic radionuclides.

The JRC is also a pro-bono participant in two important consortia funded by the Euratom programme in the latest round of calls for indirect actions: the project SECURE that aims to make a major contribution to the sustainability of medical isotope production and the project OFFERR that aims to establish an operational scheme facilitating access for R&D experts to key nuclear science infrastructures.

Moreover, the JRC also participates in the European Observatory on the supply of Medical Radioisotopes, has active collaborations with international organisations such as the IAEA and provides support to partner DGs.

Nuclear competences

Achieving technological advances also requires a skilled workforce as competences in the nuclear sector are becoming scarcer. This is a challenge that is also faced by the JRC, owing to an aging staff and the difficulty to attract new talents.

The JRC already contributes to this effort by offering training and knowledge transfer on medical applications to EU Member States and worldwide, through a number of activities. For instance, training is provided to hospital staff in South Africa on the safe handling and disposal of alpha emitters in clinical settings.

In addition, as part of its strategy to enhance dissemination of scientific knowledge, to bridge the gap between research and industry and to provide training and capacity building, the JRC opens its nuclear facilities to researchers and students of the EU Member States through its Open Access programme.

The European Human Resources Observatory for the Nuclear Sector (EHRO-N) managed by the JRC can also help by supporting the development of methodologies to assist Member States in performing their own national nuclear workforce assessment and identify the needs in critical areas.

It is indeed necessary to gain a greater insight into the EU supply and demand of human resources for the nuclear sector, in particular for the medical field using nuclear technologies.

2.3 Beating cancer: a priority of the Swedish Presidency of the EU Council (Katarina Nordqvist, Head of Section at the Ministry of Education and Research)

This discussion reflects the importance of the subject of medical applications of nuclear science, and in particular two essential components that come into play, infrastructures and skills, to ensure medical uses of nuclear technology benefit all patients, especially those with cancer.

A secure supply of radionuclides, as well as a competent workforce in the area of nuclear medicine, are important for clinical use, but also for research and innovation which endeavour to find and develop new diagnostics and therapeutics combating cancer.

Swedish Presidency priority

During the Swedish presidency, one of the top priorities is cancer. Two weeks ago, Sweden therefore hosted a conference on cancer in Stockholm. The focus was equal cancer care for all and the implementation of the EU Beating Cancer Plan. The event gathered important stakeholders leading to fruitful discussions about prevention, early detection and the conditions for data-driven cancer care.

From this Roundtable discussion, we should thrive to connect more the Euratom programme with other EU programmes such as the EU Beating Cancer Plan, the Mission on Cancer and other parts of the Horizon Europe programme, in order to build synergies.

3 Innovation and Research infrastructures for the supply of medical radionuclides

3.1 Challenges for the supply of medical radionuclides (Tomáš Ehler, Deputy Minister at Ministry of Industry and Trade of the Czech Republic)

After the supply failures of medical isotopes in the European Union last year, the debate has been accelerated at the European Nuclear Energy Forum in November in Prague and this roundtable is the right opportunity to express the needs and discuss current problems. This topic also needs to be addressed in the Council soon.

Production capacity

The lack of production capacities and instability of fuel and material supplies constitute serious risks and a European roadmap for future steps is necessary. A direction is needed to decide whether to build new research reactors in the European Union and through which means. This will be essential to ensure European self-sufficiency in the production of alpha emitters, considering a significant increase in their importance in therapy is expected. Therefore, appropriate support for the infrastructures and the technological development of production is needed.

Stakeholders' coordination

The information stream is fragmented, as evidenced by the preparation for this roundtable, where coordination was necessary among the Ministry of Industry and Trade, the nuclear regulator, the Ministry of Health and their partners in hospitals, and the Ministry of Education, Youth and Sport, the Czech Technical University, the Academy of Sciences and the Research Centre CEZ which operates the research reactor LVR-15. There is no coordinated approach and we have to establish structures at the national level. I welcome the ongoing work under the SAMIRA Action Plan, the European Observatory on the Supply of Medical Radioisotopes, and the EU Beating Cancer Plan and Cancer Mission. Coordination between those initiatives should be encouraged and I am glad that we will host the next Observatory plenary meeting in March at the Ministry.

European production infrastructures

From the point of view of diversification and stability, we need to orient the debate around the complementarity of the Pallas reactor with new research reactors in Central Europe as these will be needed after LVR-15 in the Czech Republic and MARIA in Poland reach the end of their operation time. We need Pallas, as no other solution is in sight and current capacities are ageing. EU funding should be distributed equally and coordination under the SAMIRA action plan and other European activities related to the production of radioisotopes is needed. If new infrastructures are subsidized, we need to know if the operator is state owned or private and whether we have a European solution as these infrastructures will generate profit and added value, which should be addressed.

Financing

The reality is that research infrastructures are currently underfinanced, both in the operational and in investment areas. The relevant investment subsidy in the Czech Republic, Operational Programme Johannes Amos Comenius, will end in 2029. We need to find consensus in time, nationally and at the EU level, on how to secure investments in new infrastructures and for the modernisation of current infrastructures.

Stability of supply

Besides the debate on new infrastructures, we need an approach for the stability of the supply of materials. I welcome the involvement of the Euratom Supply Agency, which is crucial to ensure the sufficiency of storage stock. The Agency set up a Working Group where considerations about the commercial viability of current capacities have been expressed and a report produced. It is unclear whether a consensus could be found on the building of an enrichment plant in the EU. We still need stability and ESA should in any case be responsible for ensuring there are sufficient storage stocks of material. Another less preferable solution would consist in maintaining the status quo and remaining dependent on external factors.

Research and Development

Regarding the security of fuel supply for European research reactors, I can underline the contribution made by the project LEU-FOREvER under the previous financial instrument Euratom-Horizon 2020. However, there is a

need for a new call in order to continue research towards the development of the first sample. Ideally, a European fuel supplier should be created and an alternative to IRT-4M fuel should be developed, as a way to guarantee independence.

Competences

Finally, we need experts and the required competences in all phases of the use of medical radionuclides as we already face a deficit today as regards to qualified medical doctors, radiopharmacists, physicists and non-physicians, all professions in short supply. Support schemes for students, researchers, and EU strategies for promotion of jobs in this sector are needed as well as international cooperation with third countries, and international training schemes.

3.2 Fostering collaboration between research organisations (Mike Lamont, Director for Accelerators and Technology at CERN)

Effective exploitation in the medical radionuclide domain has long been limited by the difficult access to radionuclides that are not yet commercially available.

PRISMAP project (Horizon 2020)

In order to support ongoing research across Europe and beyond and to give the medical community improved access to novel radionuclides, the PRISMAP consortium federates academic and research institutions from across Europe to form a powerful network to help drive the active translation of emerging radionuclides into medical diagnosis and treatment. Key aims include:

— A sustainable source of high purity novel radionuclides for medical research targeting the development of a new generation of radiopharmaceuticals.

— A single entry point for the pioneering research community using standardised access procedures.

Research infrastructures in PRISMAP

The consortium includes isotope production infrastructures. These have a wide variety of different mandates and well-established expertise in the operation of their facilities (research reactors, medium and high-energy accelerators, JRC, isotope mass separation and radiochemical laboratories).

Some members also have associated biomedical facilities that offer pre-clinical or clinical research, with testing capabilities in close proximity to production experience and the handling of non-conventional radionuclides.

Production of innovative radionuclides

The reality is that radionuclides products have a short lifespan. Development towards the upscaling of the production of these novel radionuclides will be explored in the form of innovative production technology, new purification methods, new data and proof-of-concept investigations to facilitate the development of new treatments from test bench to patient care. We also have to take into account the relatively short product lifecycle of around a decade for diagnostic, therapeutic and indeed “theranostic” treatments, notably targeted therapies, and the intense phases of qualification and the establishment of production pathways in a competitive market.

Added value of large research consortia

PRISMAP has been active for a year and a half, and has demonstrated to be an important collaboration with clear added value demonstrating that there is a lot to be gained from effective collective work. In fact, the efforts of PRISMAP should be framed in relation to the long-standing work of the consortium members, their many collaborations and involvement in other projects and platforms. The project adds value via integration and dissemination, bringing together different experts in a wide range of scientific fields connected to nuclear technology such as accelerators, reactors, radiochemistry, dosimetry, detectors, numerical tools and information architecture, to negotiate the considerable challenges of optimizing the potential of candidate radionuclides.

CERN as a research infrastructure

Besides its flagship accelerator - the Large Hadron Collider, CERN has an extensive accelerator complex which serves a wide variety of physics communities. Among its facilities is the ISOLDE (Isotope Separator On Line Device) Radioactive Ion Beam Facility. ISOLDE provides radioactive ion beams to a community of nuclear physicists. It is the oldest and first dedicated isotope mass separation facility in Europe.

MEDICIS takes advantage of the 1.4 GeV proton beam delivered by ISOLDE to irradiate targets. Non-conventional radionuclides of interest are then extracted from the targets by mass separation and go to support the research and development in nuclear medicine. Irradiated target materials are also received from external stakeholders to undergo mass separation at MEDICIS. Once separated, and in some cases purified, the resulting radionuclides are delivered to external partners for medical research.

CERN's strengths as a research infrastructure are well proven and it is a nexus for international collaboration, innovation, knowledge creation and dissemination. It has a strong desire to leverage its capabilities for societal benefit, has a wide-ranging medical application portfolio, as reflected in its coordination of PRISMAP, the reach of which goes well beyond CERN's activities in the radionuclide domain.

Strength of research collaboration and integration

PRISMAP is already proving its worth in integrating the strengths of a network of research infrastructures nd reinforcing links to medical communities.

The institutes involved are working together to negotiate complex landscape to sustain the pathway from innovative radionuclides to – in a few rewarding cases – production and supply.

Integration takes time and requires a long-term commitment; support will be required to reach the appropriate level of integration and maintain it for the evolving needs of the community to help it contribute to unlocking the potential of this fast-evolving research area.

3.3 Production capacity challenges: the industry's perspective (Philippe Knoche, CEO of Orano)

Orano is a big company which purpose is to master nuclear material transformation for energy and health purposes. We look very positively at initiatives such as SAMIRA or the EU Beating cancer plan and we stand ready to contribute as well. There is a need for a resilient health system as theranostic and self-diagnostic procedures are gaining more importance and these new procedures should be backed by a stable and reliable supply chain.

Source material dependencies

When looking at material supply data, a worrying trend emerges. A great share of the material used for the production of medical radionuclides is sourced from Russia, comprising from 80% to up to 100% of the raw material supplied for some radioisotopes, especially heavy stable isotopes. Dozens of millions of patients are thus dependent on Russia. This has been identified by a study of the JRC on the sustainability of supply chains (SMER 1 and 2) and should form the basis for further work. The USA and Canada have already taken some initiatives to break away for this dependency and we should follow these examples in order to ensure a more stable and diversified supply.

Industrial capacities at Orano

Orano is fully committed to providing solutions in order to secure the supply of materials for the production of radioisotopes. The production of stable isotopes has been developed at Orano based on in-house capabilities in conversion and isotope separation. These stable isotopes will afterwards be irradiated for nuclear medicine and Orano aims to develop a new stable isotope manufacturing purification facility, which will be commissioned soon with first deliveries in early 2024. In addition, Orano Med, the Orano's subsidiary focusing on nuclear medicine, is developing several radioligand therapies based on lead-212, an alpha emitter.

HALEU production for research reactors

The reasoning we have for the production of stable isotopes, taking into account current dependencies, is the same that could be applied for the development of a production capacity of HALEU for research reactors,

which are used to irradiate the stable isotopes. Our main supply of HALEU comes from Russia and the USA, the latter having already allocated budget to build its own production capacity. In Europe, we have the potential in terms of expertise, research and industrial capacities to produce it as well. However, there is currently a lack of coordination and cooperation at EU level.

For instance, at Orano, we own a facility able to produce Alpha emitters with the potential to be used in cancer treatments, however the medical trials are taking place in the US due to authorization constraints with medical and radioprotection authorities. There is clearly a need to work better with medical authorities and possibly to apply new approaches like during the COVID pandemic. ORANO wishes to be able to duplicate the knowledge available at his facility in the USA and transfer it to Europe.

Political support for a strategy at EU level

In order to ensure the success of these projects, we need to receive political support leading to clear decisions able to steer the way forward. It is crucial to anticipate the potential future shortages and to facilitate investments with the objective of giving the EU a strategic autonomy in that field. Existing EU funding programmes are essential to guarantee the development of an innovation capacity in the field of nuclear medicine. However, more can be done. The review of the Multi-Financial Framework next summer will be a key opportunity to reallocate some budgets for strategic topics such as the ones discussed today. Synergies between Euratom programme and other existing funding programmes could also be reinforced.

3.4 Ensuring a stable supply of source materials (Agnieszka Kaźmierczak, Director General of the Euratom Supply Agency)

The Euratom Supply Agency's main strategic objective is the security of supply of nuclear materials for power and non-power uses. From the Agency's perspective there are two factors that are essential for the European production of medical radioisotopes.

Availability of HALEU as source material and fuel

One of the conditions that must be met relates to the availability of the nuclear material for production of targets and as fuel for research reactors. Despite progress made around alternative production methods, we have to acknowledge that irradiation will remain the core process for production of medical radioisotopes.

High-assay low-enriched (19.75%) uranium (HALEU) is not produced in the EU and is currently imported from the USA and Russia. However uncertainties related to the availability of both sources after 2035, pose a high risk for the supply of this critical material, which could endanger patients.

Therefore, the EU urgently needs to define its ambitions to ensure an appropriate level of independence on the provision of HALEU able to match its strong global position in the field of medical radioisotope production.

The Euratom Supply Agency's working group dedicated to the issue recently identified options for achieving different levels of security of HALEU supply for the EU, ranging from continuing current purchases from Russia and the USA, to autonomy through a European production. Depending on the option selected, a set of actions, commitments and/or financing will be necessary from the EU, Member States, industries and end users. The European production of HALEU could possibly take the form of a demonstration project of common interest, implemented for instance under a Public-Private Partnership (PPP).

Monitoring system for medical radioisotopes

Another critical success factor will be the development of a system of regular monitoring and long-term forecasts able to feed the decision makers and stakeholders with the data needed for policy development, strategy shaping as well as decisions on investments in the supply chain.

We have the experience available within the Euratom Supply Agency, but we need to build on this model and the interest of the many actors. Such a monitoring system will require involvement and cooperation of a large variety of actors, as shown by the experience of the European Observatory on the Supply of Medical Radioisotopes, which engages in discussion with representatives of the EU, international organisations and the industry. However, the new monitoring system needs to cover a broader spectrum of radioisotopes than the common Mo-99 and new production methods. The ensuing challenge is to define its scope, means and methods, which will be discussed under the European Radioisotope Valley Initiative process (ERVI – under SAMIRA) and hopefully lead to the development of a feasibility study and subsequent deployment. We

therefore welcome the launch of the ERVI as it is the right platform to move forward on these two critical success factors for the supply of medical radioisotopes.

4 Competences for the medical use of nuclear technologies

4.1 Nuclear skills for European strategic autonomy (Cyril Piquemal, Deputy Permanent Representative of France to the EU)

The Russia's war of aggression against Ukraine has reaffirmed more than ever the need to strengthen the European Union's strategic independence in the nuclear sector. This is for example particularly the case for the operation of research reactors producing radioisotopes for cancer treatments, which are 25% dependent on Russia for enriched uranium, or for the production of certain radioisotopes, such as Lutetium 177 used for radiotherapy treatments, where the EU's dependency to Russia is 100%.

Maintaining nuclear skills in the EU

The European Union is already facing a significant risk of losing expertise and skills in the nuclear field due to an ageing workforce (age group between 45 and 65) and difficulties to renew this highly qualified staff while the nuclear field struggles with attracting the young generation.

It is thus strategically essential to promote nuclear skills at the European level in order to:

— Maintain a high level of knowledge and expertise on the entire life-cycle of the nuclear installations,
— Ensure independent nuclear activities in key areas, such as nuclear medical applications,
— Continue contributing to the EU's global influence as an international reference for nuclear safety and radiation protection.

A strategy for skills at national level

At national level, the French government has raised the topic at the highest political level and initiated a reflection on maintaining the necessary nuclear skills and expertise to guarantee France's energy security of supply, maintain a cutting-edge industrial base in our territories, support the energy transition, and develop the attractiveness of the nuclear industry. In this respect, a University of Nuclear Professions was created and a commitment to develop employment and skills in the nuclear industry has been made.

Initiatives supporting nuclear competences at EU level

The European Union has also already undertaken important steps to strengthen European nuclear expertise, as enshrined in the Euratom Treaty. In 2008, the Council of the European Union sought to support those efforts by adopting Council Conclusions on "The Need for Skills in the Nuclear Sector". Since then, a number of actions and initiatives have been taken forward by the European Commission, such as the establishment of a European Human Resources Observatory for the nuclear sector (EHRO-N), projects under the Euratom Research and Training Program, actions led by the Joint Research Centre or in the framework of European joint partnerships such as EURAD, EUROfusion or Pianoforte. Member States and stakeholders, including the European Nuclear Education Network (ENEN), have also undertaken important work on this issue, contributing to raise awareness on this topic.

Report of the French Presidency

In 2022, the French Presidency of the EU Council decided to give a new impetus to the work initiated at EU level. This has led to a Presidency Report advocating "For a European Dynamic in Nuclear Skills".

The report identifies three main opportunities for action to set up a European skills dynamic in the nuclear field:

— Ensuring sustainable management of human resources,
— Increasing the attractiveness and visibility of the sector among young people,
— Preserving and better coordinating the network of research infrastructures.

Among the recommendations from the report, it is advocated to produce an inventory of the situation as well as to carry out a regular update of data on human resources' needs in order to come up with a long-term knowledge and skills management strategy to be implemented at EU level. Such a strategy should take into account our needs for all nuclear applications, and in particular for the nuclear medicine sector. This should be undertaken in the context of the SAMIRA initiative's objectives.

Encouraging synergies amongst European initiatives

Furthermore, the European Union should take advantage of the European Year of skills to further promote this issue and go forward in supporting Member States' action, in particular by relying on existing European tools such as European universities or platforms for centres of vocational excellence. The establishment of a European academy to strengthen training in the nuclear field could also be considered, based on the model of the "European Battery Academy", launched by the Commission in early 2022. It would also act in synergy with the "Net-Zero Industry Academies" proposed by the Commission in the communication "a Green Deal Industrial Plan for the net zero age".

It is essential to continue discussions on this topic, to promote the dialogue between all relevant stakeholders, and at all levels, on the needs identified, the existing initiatives and solutions and on the synergies that could be implemented at EU level and between Member States.

4.2 High quality education and training to foster necessary competences (Csilla Pesznyak, President of the European Nuclear Education Network - ENEN)

ENEN is an international non-profit association with 20 years of experience in the area of nuclear education and training. Its main goal is to attract new nuclear talents, preserve and further develop expertise via education and training schemes and propose cross-cultural and cross-disciplinary activities supporting safe, competitive and sustainable use of nuclear technologies. ENEN gathers 85 members from 25 countries, among which 17 EU Member States, which make up a network composed of universities, research centres, companies or TSOs and international institutions, through MoU.

Activities in Education and Training

ENEN has taken part in a number of projects funded by European programmes such as Horizon 2020, Horizon Europe and the Euratom Research and Training programme. Overall, ENEN fields of expertise cover a broad range of topics including nuclear energy, engineering, technology, safety, safeguards, radiation protection, medical physics, nuclear chemistry and radioactive waste management.

As an important stakeholder in the area of nuclear education and training, ENEN has also organised competitions aimed at secondary school students as well as PhD event awards gathering over a hundred of young graduates. ENEN has an EMSNE (European Master of Science in Nuclear Engineering) certification, which has received a quality label and already been delivered to over 100 laureates. The association also regularly organises nuclear summer schools in nuclear energy, medical physics, radiation protection and radioactive waste management, attended by more than 150 Bachelor students to date.

Competences for medical applications of nuclear science

Nuclear and medical Education and Training are indispensable for the safe use of nuclear isotopes and ionizing radiation in nuclear therapy and diagnostics. A number of areas like nuclear engineering, radioactive waste management, radio chemistry, radiation protection, medical physics and research reactors should be covered by education and training schemes. Indeed, they represent fields where competences are especially critical for the safe use of medical applications of nuclear science. In addition, we might also consider training medical physics experts the same way we train radiation protection experts in healthcare.

High-quality and non-proprietary education and training are essential for all sustainable nuclear power and non-power programs, like the medical applications. Efficient education and training schemes require universities, training organizations, industry, regulators, and governments in some countries, to commit to work together in the long term in order to ensure the quality and quantity of the workforce.

Tackling challenges and anticipating further needs require a strategic top-down approach aimed at strengthening academic (MSc and PhD) and vocational Education and Training programmes for nuclear professions while facilitating multidisciplinary or cross-disciplinary fertilisation.

European funded projects

Finally, the sustainability of education and training schemes is facilitated by EU funded projects like ENEN2plus which is a continuation of the very successful ENEN+ project. The ENEN2plus will endeavour between 2022 and 2026 to analyse the needs for human resources in the nuclear sector, inform and attract new talents, enhance nuclear competences with continuous education and training programs, develop sustainable vocational training programs and network and establish a successful mobility scheme for nuclear talents, which will be the largest to date. This project is based on an international consortium involving all

relevant stakeholders in the field, which is an essential requirement for its success. This highlights in particular the importance of establishing dynamic networks between the varying stakeholders.

4.3 Recognition of nuclear's added value to prevent skill shortages (Jessica Johnson, Communication and Advocacy Director at nucleareurope)

Skills shortages are not just limited to the nuclear medicine sector as a broad range of activities across the sector face a growing risk of losing essential competences. It would therefore be worth envisaging ambitious all-encompassing actions to encourage for starters more young people among secondary schools students into STEM subjects.

Emphasise the nuclear sector's added value

Greater recognition and support for nuclear technologies at European Union level would help demonstrate that there is a future for nuclear in Europe and thus inspire more people to consider working in the sector. In particular, this would also support the introduction of more nuclear disciplines among students' curricula. For example, in the Netherlands, the fact that the government gives greater recognition to, and support for, nuclear technologies, has helped to attract more young people into the sector.

From a nuclear medicine perspective, actions could also include sponsoring initiatives that bring a greater validation to nuclear medicine among other treatment platforms, especially in the oncology sphere.

Synergies between EU programmes

Concerning EU funding in this area, we welcome the fact that since 2021 the Euratom Research and Training programme includes support for Marie Skłodowska-Curie Actions (MSCA) in nuclear research and training. We believe that it would be beneficial to widen the scope of the MSCA for Euratom researchers beyond Postdoctoral Fellowships in order to enable nuclear researchers to have access to other types of MSCA funding, including Doctoral networks and staff exchanges.

Synergies between Euratom Research and Training programme and other EU funded programmes should be enabled, ensuring access to cross sectorial innovation projects and missions, as well as vibrant education, training and mobility opportunities for scientists and engineers. Furthermore, a more long-term approach should be applied to funding programmes as this will maximise their potential benefits and potentially ensure greater coordination and less overlap or duplication of efforts.

4.4 Critical nuclear competences required for the medical fields (Paola Erba, President-Elect of the European Association of Nuclear Medicine - EANM)

Nuclear medicine is a medical specialisation that involves the administration of radioactive substances (radiopharmaceuticals) for the diagnosis and treatment of diseases in patients of every age groups. With already 100 different nuclear medicine procedures approved by regulators, every year, more than 10 million patients in Europe benefit from nuclear medicine in the diagnosis and treatment of many diseases, including – but not limited to - cancer.

Multidisciplinary approach for the quality and safety of nuclear medicine procedures

In order to bring nuclear medicine to the patients, while ensuring the safe and correct implementation of radioactivity-based procedures, it is essential to rely on an adequately sized and well-trained workforce.

Nuclear medicine is in itself a multi-disciplinary medical specialisation that requires a broad level of in-depth knowledge in various fields such as pathophysiology, radiobiology, radiochemistry, radiopharmacy, radiation protection, imaging technology or automated procedures, along with a team of specialists involved in the optimal delivery of nuclear medicine services to patients. These procedures also have to be performed under the supervision of the nuclear medicine physicians like medical physics experts, radiopharmacists/radiochemists, technologists or nurses.

Shortages of qualified nuclear medicine professionals in Europe

The unprecedented growth of the nuclear medicine specialty over the last decades has exacerbated already existing shortages of nuclear medicine professionals in some parts of Europe.

The nuclear medicine community is therefore pleased that the SAMIRA Action Plan includes actions to improve both workforce availability and education and training aiming to mitigate the gaps between workforce supply and demand. This is crucial to ensure that all categories of staff involved in nuclear medicine receive adequate education, training and continuous professional development in quality and safety issues.

Innovation in nuclear medicine prompting continuous learning

Innovation in nuclear medicine has changed the way procedures are performed and patients are treated. The continued progress in hybrid imaging techniques and breakthroughs in radionuclide therapies have prompted a critical appraisal of the current training curriculum and practices.

For example, the introduction of artificial intelligence (AI) has significantly impacted technological development. However, there is still a gap of knowledge on the real added value of the clinical applications of AI. Other niche fields which tend to be neglected like radiobiology and radiochemistry are nevertheless crucial for the discipline development and need to be fully embedded into the training curriculum. Likewise, the growing interest for theranostic applications of nuclear medicine, combining both diagnosis and therapy, also needs to be factored in training curriculum and practices.

With the growing innovation in the specialty, lifelong learning to deliver state of the art care is becoming increasingly important. As such, EANM has developed the European School of Multimodality Imaging & Therapy (ESMIT) as a response to huge changes in the educational needs of the nuclear medicine community and the rising demand for greater multimodality content, and training courses on therapeutic applications.

In addition, securing the right facilities and networks for sharing knowledge and best practices as well as to define standards to be applied throughout Europe and beyond is essential. Preventing hurdles for innovation, developing bridges between the industry, the academia and the clinical practice and recognizing the importance of research aspects of the nuclear medicine professional´s path are all essential elements to guide investments and to ensure the sustainability from research to clinical applications.

For instance, the EU Network of Comprehensive Care Centres aims to map and share the different capabilities and expertise available across the Union and build the foundation to regularly identify gaps and needs to be addressed at national and regional level across the Union.

The EANM has also launched an Accreditation initiative through EANM Forschungs GmbH (EARL) which aims to advance quantitative imaging harmonisation as standards and certification of equipment is the first step to assure quality procedures and reliable scientific data during clinical trials. It´s only through setting standards that we can achieve a real network for training and science through Theranostic Centres.

Standardized curricula and training programs for nuclear medicine professionals across Europe

There is a huge heterogeneity amongst training pathways available for physicians practising nuclear medicine in Europe, ranging from a three-month rotation as part of radiology speciality training to 4 to 5 years under nuclear medicine specialist training, leading to significant differences in scope of practices and competences among nuclear medicine physicians.

Given the latest developments in nuclear medicine, it is crucial that the duration and scope of the initial training allows to cover the full scope of what needs to be delivered. Due to the complexity of the discipline, of which hybrid imaging is only a component, the recognition of nuclear medicine as a fully independent medicine specialty, requiring an independent training program, is of high importance. This is in fact highlighted within the Europe's Beating Cancer Plan and stated by the European Union of Medical Specialists (EUMS) training requirements.

Consequently, there is a need to define and harmonise the recommended basic minimum training requirements for nuclear medicine as an independent medical speciality. This should be based on the model of the EUMS specialisation-based recommendations for nuclear medicine, whose competences and procedures have already been endorsed by the nuclear medicine community.

Given the multidisciplinary aspect of nuclear medicine, high levels of training for the professionals directly involved in the delivery of such procedures are not enough. In fact, the recent technological and radiopharmaceutical developments have created the need for changes also in the training programmes of all the other professional disciplines involved directly or indirectly in patients' care, including the referring

physicians involved in multi-disciplinary and multi-professional teams working for proper patients' management

Therefore, initiatives such as the Erasmus-Plus Radioligand Academy and INTERACT-EUROPE aiming to develop inter-speciality networks and programs based on relevant needs assessment to foster a patient-centric (as opposed to a discipline-centric) approach to quality care should be encouraged.

Ultimately, providing high quality care to patients no matter where they live is what matters the most to nuclear medicine professionals, and to keep-up with innovation pace, all the above aspects of education and training are of the utmost importance.

5 Main outcomes and next steps (Mariya Gabriel, European Commissioner for Innovation, Research, Culture, Education and Youth)

This discussion gave greater insight on the two important challenges surrounding medical applications of nuclear technology. The Roundtable also offered a platform to exchange ideas from a broad range of parties including EU Member States, Research Organisations, Associations and Industry on how to steer future efforts in the right direction.

Main takeaway messages

The first panel addressed the roadblocks met by nuclear research infrastructures which are otherwise vital to ensure a sustainable and efficient supply of the medical radioisotopes needed to diagnose and treat patients:

— There is consensus around the fact that security of supply of medical radionuclides is a highly critical issue and learning from the experience of past shortages, there is an urgency to prevent any shortfall of production capacities and to address the current and foreseen threats to fuel and source materials.

— The Euratom Research and Training programme, along with the monitoring role of the Euratom Supply Agency and large research consortia, bringing together key stakeholders and production infrastructures, have an undeniable role to play. We need to find strategic alignment with the industry as well to deliver realistic solutions.

— In the end, strong political support to EU funding instruments, which act as catalysers, is needed as well as more synergies between programmes and better alignment of our medium-term research and innovation strategies to the needs identified in the medical applications of nuclear technology. Bridging the gap between research and industry and bringing EU Member States on board will be vital to ensure the necessary investments in an efficient network of research infrastructures enabling innovation in medical radionuclides.

The second panel highlighted key issues related to necessary nuclear competences for the medical sector:

— The availability of a highly skilled workforce trained to handle nuclear technologies for medical uses is essential to ensure the safe and quality access of patients to medical radionuclides. A broad range of medical activities are involved in the use of nuclear technologies making necessary to map out the areas where competences are critically needed.

— Ensuring availability of highly trained professionals however implies a dialogue between academia, industry, public authorities, and other stakeholders, in order to work together at building solid educational and training programmes, starting with attracting the young generations into science subjects.

— Similarly to the issue of research infrastructures, synergies need to be enhanced across programmes dedicated to higher education to support nuclear competences, as illustrated by the integration of Marie Skłodowska-Curie Actions within the Euratom programme. Important Euratom funded projects like ENEN2plus which strive to connect all relevant stakeholders and enhance nuclear skills also have to be highlighted.

Conclusions and next steps

The EU must keep its role as leading innovator in nuclear medical applications. However, it is clear that more actions are needed to bridge the gaps so that the benefits of research reach all patients.

The Euratom programme actions will continue addressing challenges with the support of different stakeholders, nuclear and non-nuclear. We need nevertheless to strengthen our research and training programme, and its synergies with other EU funded schemes, as well as to complement the efforts already undertaken by the SAMIRA Action Plan, the EU Beating Cancer Plan, and the Cancer Mission.

This discussion has invited a reflection on the basic pillars of a strategic agenda exploring future Education, Research and Innovation actions to effectively bridge the gap between infrastructures, development and use of innovative nuclear technologies applied to the medical field.

A series of workshops will therefore be organised in the coming 12 months, bringing together the academia, leading clinicians in different fields of expertise, patient interest groups, the nuclear industry and policy makers. This will aim to foster concrete actions in research and innovation to bridge the gap between

research and clinical uses of radionuclides. The first workshop will be taking place in Ispra on April 27th, on the topic of "Translating radiotheranostic cancer research into clinical practice in Europe".

We must stand together and not let up on our efforts to achieve our common goal: beating cancer through the maximum impact from our research programmes.

List of abbreviations and definitions

AI	Artificial Intelligence
CERN	The European Organisation for Nuclear Research (Conseil Européen pour la Recherche Nucléaire)
DG	European Commission's Directorate General
DG ENER	Directorate General for Energy
DG R&I	Directorate General for Research and Innovation
DG SANTE	Directorate General for Health
EANM	European Association for Nuclear Medicine
EARL	EANM Research GmbH, an initiative to promote multicentre nuclear medicine and research.
EHRO-N	European Human Resources Observatory for the Nuclear Sector
EMSNE	European Master of Science in Nuclear Engineering (certification)
ENEN	European Nuclear Education Network
ENEN+	Attract, Retain and Develop New Nuclear Talents Beyond Academic Curricula (project funded by Euratom R&T 2014-2020)
ENEN2Plus	Building European Nuclear Competence through Continuous Advanced and Structured Education and Training Actions (project funded by Euratom R&T 2021-2025)
ERASMUS +	EU programme to support Education, Training, Youth and Sport in Europe
ERVI	European Radioisotopes Valley Initiative (under SAMIRA Action Plan)
ESA	Euratom Supply Agency
ESMIT	European School of Multimodality Imaging & Therapy (EANM initiative)
EU	European Union
EURAD	European Joint Programme on Radioactive Waste Management (co-funded by Euratom R&T programme 2021-2025)
EURATOM	European Atomic Energy Community
EURATOM R&T	The European Atomic Energy Community programme for Research and Training
EUROfusion	European Joint Programme for the Development of Fusion Energy (co-funded by Euratom R&T programme 2021-2025)
GELINA	JRC's Neutron Time-of-Flight Facility (located in Geel)
HALEU	High-Assay Low-Enriched Uranium (19,75%)
HORIZON 2020	EU's Research and Innovation funding programme for 2014-2020

HORIZON Europe	EU's Research and Innovation funding programme for 2021-2027
INTERACT-EUROPE	Inter-Specialty Cancer Training programme across Europe (co-funded by EU4health programme 2021-2027)
ISOLDE	Isotope Separator On Line Device (Radioactive Ion Beam Facility at CERN)
JRC	Joint Research Centre
LEU FOREvER	Low Enriched Uranium Fuels for Research Reactors (project funded by Euratom R&T 2014-2020)
LVR-15	Research reactor in Czech Republic
MARIA	Research reactor in Poland
MEDICIS	CERN's facility producing novel radioisotopes for medical research
MONNET	JRC's Tandem accelerator based fast neutron source (located in Geel)
MSCA	Marie Skłodowska-Curie Actions (EU programme for doctoral education and postdoctoral training)
nucleareurope	Trade Association representing the European Nuclear Energy Industry
OFFERR	European Platform For Accessing Nuclear R&D Facilities (project funded by Euratom R&T 2021-2025)
ORANO Med's	Subsidiary entity of Orano seeking to develop new generation targeted therapies against cancer
PIANOFORTE	European Partnership on radiation protection (co-funded by Euratom R&T programme 2021-2025)
PRISMAP	The European medical isotope programme: Production of high purity isotopes by mass separation (project funded by Horizon 2020)
Radioligand Academy	Radioligand Therapy Academy, Pan-european consortium funded by Erasmus +
R&D	Research and Development
SAMIRA	Strategic Agenda for Medical Ionising Radiation Applications
SECURE	Strengthening the European Chain of Supply for Next Generation Medical Radionuclides (project funded by Euratom R&T 2021-2025)
SMER	Studies on Sustainable and Resilient Supply of Medical Radioisotopes in the EU
STEM	Science, Technology, Engineering and Mathematics
TAT	Targeted Alpha Therapy

Annexes

Annex 1. JRC's work on medical applications of nuclear science

JRC's activities supporting security of supply of medical radionuclides

- **JRC's infrastructures** contribute to the investigation of new radioisotope production paths:
  - GELINA (Neutron Time-of-Flight facility) and MONNET (Tandem accelerator-based fast neutron) for production of medical radionuclides presently in use or foreseen for future applications (incl. Ac-225).
  - PAMEC facility: preparation and characterization of targets and samples. Includes laboratory on targeted alpha therapy activity for production of short-lived alpha-emitting radioisotopes.
  - FMR facility: fuel preparation and characterization contributing to preparation of targets for radioisotopes production such as Ac-225.
- **Targeted Alpha Therapy (TAT)**: JRC Karlsruhe successfully first characterized an alpha emitter labelled drug for treatment of prostate cancer. JRC collaborates with clinical centres in the EU and worldwide to develop the therapeutic use of alpha-emitters in oncology (actinium-225 and bismuth-213) that has the potential to play a key role in the treatment of metastatic cancer in the future.
- **Project RadioMed**: conducts market studies on radiopharmaceuticals for diagnosis and treatment and explore new production paths for emerging and established radionuclides.
- **SMER reports** Sustainable and Resilient Supply of Medical Radionuclides): completion of two studies in 2016 and 2019 to gain greater insight on EU market, present and future needs for medical radionuclides
- JRC participates in the **European Observatory on the Supply of Medical Radioisotopes**
- JRC provides **support to policy DGs**:
  - DG ENER on the **SAMIRA** (Strategic Agenda for Medical Ionising Radiation Applications) initiative;
  - DG SANTE and DG RTD by operating the European Commission **Knowledge Centre on Cancer** to foster a coordinated European Commission approach to tackling cancer and supporting the Mission on Cancer and the Europe's Beating Cancer Plan.
- **International collaboration:** Practical Arrangement with **IAEA** since 2017 for collaboration in research on nuclear science applications, including medical applications.

JRC's activities related to nuclear competences for medical applications

JRC provides training and knowledge transfer contributing to enhance and reinforce nuclear competences related to medical applications through various activities:

- **Project TAT:** Transferring and disseminating knowledge on cancer research and building capacities by providing trainings to hospital staff on safe handling, detection, quantification ad disposal of alpha emitters in clinical settings.
  - Collaboration with **South Africa** on knowledge transfer, education and training since 2017. **International Symposium on TAT** co-organised by JRC and University of Pretoria (South Africa)
  - **JRC-IAEA** collaboration on "Production & Quality control of Ac-225 radiopharmaceuticals" project involving knowledge transfer, training and guidelines for standardised protocols.
  - **JRC-IPEN Brazil project:** Provides training on radioisotopes, radiopharmaceuticals and radiation technology for health care applications at JRC Karlsruhe.

— **JRC Open Access programme:** JRC offers access to its nuclear facilities to EU Member States and countries associated to the Euratom Research Programme. **EUFRAT** program offers support to production studies for medical radionuclides at GELINA and MONNET, while **ActUsLab** allows access to PAMEC and FMR facilities to investigate actinide and nuclear materials.

— **European Human Resources Observatory for the Nuclear Energy Sector (EHRO-N):** managed by the JRC and set up in 2009, it supports the development of methodologies and best practices for performing national nuclear workforce assessments.

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