European Commission

Research and Innovation for Sustainable Medical Radionuclide Supply in the European Union

Workshop report with conclusions and recommendations

Eloirdi, R., Kirchsteiger, C., Marabeau, G.

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Contact information
Name: Rachel Eloirdi
Address: European Commission, D-76125 Karlsruhe
Email: rachel.eloirdi@ec.europa.eu

EU Science Hub
https://joint-research-centre.ec.europa.eu

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Contents

Abstract

Building on the momentum of the European Commission's stakeholder consultation workshops on nuclear medical applications initiated in 2023, this third and latest workshop in a series convened on 22 November 2023 at the Joint Research Centre (JRC) in Karlsruhe and delved into the critical domain of *"Research and Innovation for Sustainable Medical Radionuclide Supply in the EU."*

While the first workshop, organised on 27 April 2023 at JRC Ispra, discussed the trajectory of "*radiotheranostic cancer treatments from research benches to clinical reality"* and emphasized the challenges from clinical translation gaps to workforce training, the second workshop was organised with the European Nuclear Education Network (ENEN) the 24 October 2023 at JRC Petten, on "*nuclear competences and skills needed for medical applications of nuclear science"*.

This third workshop at JRC Karlsruhe, with the hybrid participation of 100 participants from 15 Member States as well as Switzerland, UK and US, linked the two previous workshops. It focused on the research and innovation needs in order to ensure the sustained availability and innovation in the production of medical radionuclides, a cornerstone for the future of nuclear medicine within the EU.

The discussions at the workshop in JRC Karlsruhe were enriched by the presence of key stakeholders covering the entire spectrum from academia, industry, research communities to health experts and policymakers, all united in their quest to bolster the EU as a nucleus of medical radionuclide research and supply. Objectives were not only to survey the current landscape of radiopharmaceutical production but also to ignite dialogue on emerging infrastructures and innovative methodologies that could redefine the paradigm of nuclear medicine. Through collaborative deliberation, the workshop aimed at initiating the development of an action plan that would – by addressing the impediments to efficient production and distribution of radionuclides – accelerate the transition from R&D to clinical application and fortify the EU's leadership in this vital healthcare sector.

The main recommendations are the following:

- Strive for EU autonomy for a continuous, stable and uninterrupted supply of medical radionuclides in a way that takes into account an increasing demand for several radionuclides including alpha-emitters.
- Consider dedicated funds for nuclear medicine with alternative, more domestic production methods for radioisotopes, in addition to large centralized production, to take into account the half-life of isotopes.
- Revisit the business model of medical radioisotopes needs to ensure a sufficient return of investment to fund irradiation capacities and their operating costs. In addition, European funds beyond EURATOM need to become accessible for nuclear medical applications as they significantly contribute to the European health system.
- Find a mechanism to better coordinate existing and forthcoming EU/MS initiatives on both security of supply and research & innovation, ideally underpinned by a future single, strong and stable European backbone initiative on radioisotopes. Explore the possibility of funding for such a European partnership beyond EURATOM.
- Accordingly, streamline role of Commission services, with horizontal services more effectively linking e.g. innovative research at JRC with EU/MS policy programs.
- Harmonise in a graded approach the requirements for clinical trials with radiopharmaceuticals at EU Member States level, including timelines for approval.
- Address regulatory issues concerning radiation protection, including harmonisation of guidelines for hospitalisation length after routine radiopharmaceutical treatments.
- To make nuclear medical applications truly accessible across the EU, in addition to a secure supply and an adequate and harmonised regulatory framework, improve the availability of workforce in the field with a high level of competence.
- Regarding innovative approaches, it could be recommended to consider acceleration of delivery process by the use of drones and facilitate related regulatory aspect.

All presentations as well as the results of the online survey are collected in the public link

https://circabc.europa.eu/ui/group/0e8b2985-afd8-485c-8db1-e1cba61eccd3/library/d99e2036-47f4-4d00-8ab2-9a2c6e54253f

"Welcome" by Ulla Engelmann, Director for Nuclear Safety and Security, JRC (European Commission)

"Introduction" by Bernard Magenhann, Deputy Director General, JRC (European Commission)

Acknowledgements

The workshop (see Annex 1 for agenda) was organised by the Radionuclides for Health and Innovation Unit of the Joint Research Centre (JRC) in Karlsruhe, Germany, in collaboration with colleagues from JRC, the Euratom Supply Agency (ESA), DG ENER, DG RTD and OECD/NEA along with the support of European stakeholders from the research community (SCK-CEN, MYRRHA, CERN, CIEMAT, POLATOM, Commissariat à l'Energie Atomique – CEA), medical associations (European Association of Nuclear Medicine – EANM, European Medicines Agency – EMA), as well as industry (NRG/PALLAS, SHINE, Orano, PanTera), see Annex 2 for list of organisations.

The authors would like to thank the speakers, listed in Annex 3, for their valuable contributions which provided the basis for fruitful discussions among all workshop participants (see Annex 4) during the event and for their valuable cooperation in preparing the event.

Also many thanks to the co-organiser* and chairs of the sessions who also contributed to the Review of this report

Remigiusz Baranczyk* (DG ENER), Willem Janssens (JRC), Margarida Goulart (JRC), Domenico Rossetti di Valdalbero (DG RTD), Uwe Holzwarth (JRC), Bernard Ponsard (SCK-CEN), Nicholas Sherman (OECD/NEA), Georgi Simeonov (DG ENER), Joge Tanarro Colodron (JRC), Alice Seibert (JRC).

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"Group picture" Wokshop on Research and Innovation for Sustainable Medical Radionuclide Supply in the EU, 22 November 2024 at JRC Karlsruhe

Introduction

In the ever-evolving landscape of nuclear medicine, the European Union continues to play a pivotal role, not only as a major global supplier of medical radionuclides but also as a beacon of innovation, producing 60% of the world's imaging radionuclides and a wealth of innovative nuclear medical applications, e.g. Targeted Alpha Therapy (TAT) at JRC Karlsruhe on the basis of its "clinical grade" ^{225}Actinium.

This third workshop in a series of stakeholder consultation workshops on the use of radionuclides for medical applications, held on 22 November 2023 at JRC Karlsruhe, aimed at addressing the pressing need for new radionuclides and production methods, especially for therapeutic radionuclides in high demand and the related research and innovation needs.

It built upon the foundation set by previous discussions, furthering the mission to integrate cutting-edge research and innovation in sustainable radionuclide supply for the improvement of patient care across Europe. The series of workshops, initiated by the Joint Research Centre of the European Commission, serves as a nexus for stakeholders from academia, industry, policy makers and health experts to dissect the multifaceted challenges and barriers faced in the translation of nuclear research into clinical practice.

Mirroring the objectives set forth during the High-Level Nuclear Roundtable chaired by EU Commissioner Mariya Gabriel on 13 February 2023, the workshop sought to align the EURATOM programme's goals with EU-wide health initiatives, such as the EU's Beating Cancer Plan and the SAMIRA Action Plan. Emphasis was on fostering innovation and technical solutions, nurturing specialised staff across medical, nuclear, and scientific domains, and ensuring equitable access to state-of-the-art diagnostic and treatment technologies for European patients.

Participants engaged in a critical dialogue to identify challenges that constrain the efficiency of current production methods and impede the emergence of alternative and innovative pathways for medical radionuclides.

The goal was to develop practical recommendations in order to reinforce the EU's long-term leadership in this critical healthcare sector, ensuring secure supply chains for relevant radionuclides and accelerate the transition from innovative nuclear medical applications research to clinical trials and, ultimately, to patient access.

Summary of Presentations

Ulla Engelmann, Director - DG JRC.G - European Commission, and **Bernard Magenhann, Deputy Director General - DG JRC – European Commission**, welcomed the participants and introduced the background and objective of the workshop.

Next, in the name of the Spanish Presidency of the Council of the EU, **José Manuel Perez, Deputy Director General – CIEMAT – Spanish Ministry for Science and Innovation**, highlighted the importance of the topic of the workshop. Isotopes, both conventional ones and non-conventional ones for advanced or experimental medical treatments, are in high demand for both medical diagnosis and treatment. The global situation makes it mandatory for Europe to analyse and reconsider all corresponding supply chains. What is essential to succeed ultimately in EU-wide high availability of high precision, personalised medicine in that field is a strengthened coordination between research & innovation and policy, including better alignment of EU tools and coordination services.

Session 1 – Landscape and challenges for medical radionuclide supply and research in the EU

- **Racing against time: The radiopharmaceutical supply chain (Paola Erba, European Association of Nuclear Medicine (EANM))**

The EU's access to medical radionuclides and their respective radiopharmaceuticals for diagnosis and treatment continues to be a high priority for clinicians and researchers. Despite improvements since the severe supply crisis in 2008-2010 of Mo-99 and its decay product, Tc-99m, there is agreement among experts from isotope producers and users on the urgent need for a long-term EU strategy to prevent a critical shortage of research and production capacities that includes establishing the necessary infrastructure for preparing and applying related nuclear medical treatments. Only on such an EU-wide basis, sufficient stimulation for much needed policy changes and investments would emerge.

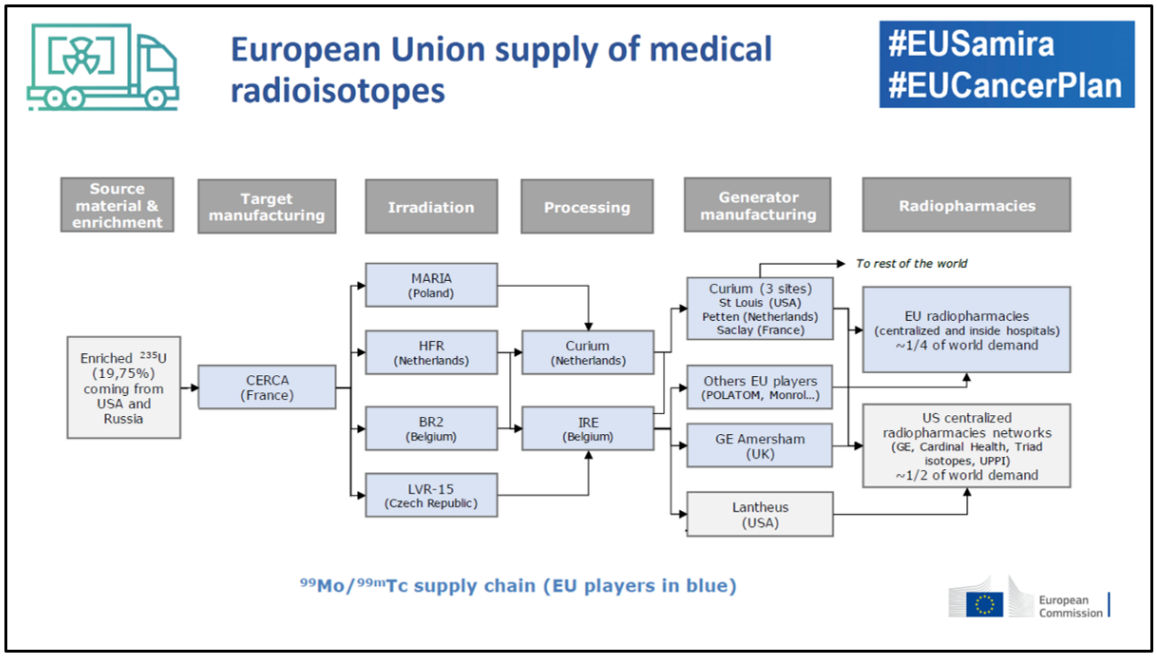
A common future framework would aim at a robust supply chain that goes from the producer to the patients, including supply of starting materials and processing materials. – But there is more than production and large-scale preparation: Most of the time, the problem in the supply chain lies with distribution, pointing to the need for both large-scale preparation (with distribution) and small-scale preparation (without distribution). Other factors for consideration are the short time spans between generation of medical radioisotopes and their application and the necessary precision of nuclear medical treatments, requiring both technological and regulatory flexibility (e.g. regarding rules for transport of medical isotopes).

In future, the nuclear medical ecosystem needs to consist of a community of multidisciplinary teams centred on the patient. In this regard, it is important to have reliable production of radioisotopes, because not every centre will have the expertise to monitor the production of radioisotopes and will not have all the specific requirements that big universities or academic centres have. If you want to make nuclear medicine accessible, you need to make sure you have the workforce and the competences as well as a secure supply of radioisotopes.

- **Commission action on medical isotopes – The SAMIRA action plan (Michael Huebel, European Commission – DG ENER (replacing Jan Panek))**

The "Strategic Agenda for Medical Ionising Radiation Applications" (SAMIRA) is the EU's first comprehensive plan for action to support a safe, high quality and reliable use of radiological and nuclear technology in healthcare. It defines EU actions in three priority areas: securing supply of medical radioisotopes, improving radiation quality and safety in medicine and facilitating innovation in medical ionising radiation applications.

Europe is a world leader in the supply of medical radioisotopes but not fully self-sufficient in supply of stable isotopes and High-Assay Low-Enriched Uranium (HALEU) where it depends on Russian and US supplies. One of SAMIRA's goals is to ensure long-term European security of supply of medical radioisotopes with a sufficiently diversified supply chains. To achieve this, there is need to continue production from research reactors, to support accelerator-based production and to ensure investments from industry.



For this purpose, the Commission has started a process towards establishing a "European Radioisotope Valley Initiative" (ERVI) to develop domestic production of source materials and reduce EU reliance on foreign suppliers, to improve supply security and sustainability of industrial scale production, and to support research on innovative production technologies. The process started in 2022, followed in 2023 by stakeholder engagement activities, a High-Level Workshop on Security of Supply of Isotopes in Brussels and the launching of a feasibility study by the contractor. Projects currently analysed for prioritisation are, among other, a European HALEU facility, stable isotopes facility, irradiation facility, medium-size accelerator network, demand/supply monitoring toolset and European coordination of supply. Implementation is foreseen after 2025 together with a legal basis and a dedicated budget.

For a long time, Europe had sufficient capacity to maintain a competitive edge in this area. However, ageing reactors and many new developments in the field are jeopardizing this competitive edge. For example, the US is making significant investments into development of new nuclear technologies and production facilities. For the future, what is important is to build a system that will foster private investment in this area. Interaction between the health system and supply is likely to remain based on a mix of public and private funds.

Coordination among initiatives needs to improve, e.g. via creation of a single and stable European initiative on radioisotopes. As minimum, this would have the task of maintaining an overview.

- **Monitoring of irradiation capacities and supply of medical radionuclides (Bernard Ponsard, European Observatory on the Supply of Medical Radionuclides)**

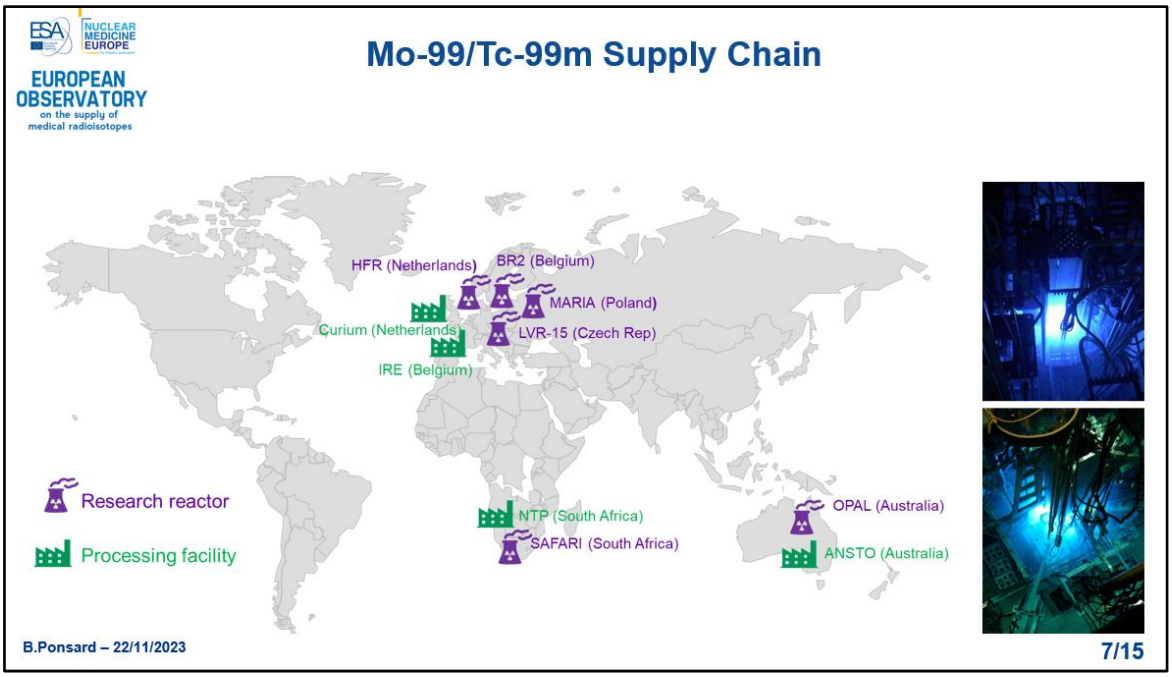
In 2012, the European Commission and stakeholders created the "European Observatory on the Supply of Medical Radioisotopes" in response to several unexpected radioisotope supply shortages in research reactors. The Observatory follows the OECD/NEA principles established by the High-Level Group on Medical Radioisotopes (HLG-MR) with a focus on European specificities.

The Observatory has the following objectives: (1) to support secure and sustainable medical radioisotope supply across the EU taking into account the worldwide need and supply; (2) to ensure that the medical radioisotope supply issue is given high political visibility in international and national institutions, organisations and bodies; (3) to identify any event or trend likely to impact the medical radioisotope supply, including logistics,

and call relevant parties to take appropriate countermeasures; (4) to promptly disseminate through agreed communication channels the enquired information regarding any possible supply disruptions or other supply related issues; (5) to establish periodic reviews of the medical radioisotope supply chain and capacities with all stakeholders across the EU, taking into account the worldwide need and supply, and to forecast future needs; (6) to build a foresight overview of the supply and demand of medical radioisotopes at EU level; (7) to acquire the latest information on the development and implementation of new and alternative methods and technolo-gies of medical radioisotope production.

It is co-chaired by the Euratom Supply Agency (ESA) and Nuclear Medicine Europe (NMEU), an industry associa-tion, with participation from Commission services (DGs ENER, JRC, RTD, SANTE, GROW), the European Medicines Agency (EMA), EU Member States, OECD/NEA, IAEA and the European Association of Nuclear Medicine (EANM).

The Observatory's main scope is to monitor the Mo-99 supply chain via the scheduling of production reactors on a short, medium and long-term basis as well as the related infrastructure development including transport and regulatory issues.



The NMEU Security of Supply Working Group checks every week the demand and the available irradiation capacity from six reactors and four processors in Europe, South Africa and Australia, and coordinates the operating periods of the research reactors to secure the Mo-99 supply chain. 2023 supply challenges concerned a delay in return to service of the MARIA reactor in Poland and two delays in the restart of the HFR in the Netherlands.

Regarding the question if we still need large centralized production of radioisotopes, it was felt important to think also about alternative, more domestic production ways given the half-life of isotopes.

➢ Ongoing initiatives to secure supply of medicines in the EU and to prevent shortages of medicinal products (Maria Alcaraz, European Medicines Agency (EMA))

The overall objective of the European Medicines Agency (EMA) is to improve the availability of medicines in the EU as part of the Commission efforts to improve Europe's strategic autonomy at all levels.

EMA's work is integrated in a large number of global and European initiatives, EU policy actions and international partnerships to ensure that regulatory authorities are working together to prevent shortages and to limit their impact whenever they occur. This applies to both normal circumstances and to crisis situations.

Regarding EU actions in relation to security of supply of medicines, not least as an effect of the COVID crisis, there is a clear trend to moving more and more towards prevention and EU-wide coordination. A recent example is the 10/2023 Commission Communication COM(2023) 672 on medicine shortages in the EU. It addresses immediate and short term actions, such as the EU Joint Procurement for the next winter for antibiotics and treatment for respiratory viruses, as well as more structural measures, such as the development of a common strategic approach to medicine stockpiling to prevent and mitigate shortages.

In conclusion, the EMA continues managing shortages of centrally authorized medicinal products and critical shortages of nationally authorized medicinal products outside public health emergencies/major events under preparedness activities. The European Commission proposals for the revision of the general EU pharmaceutical legislation tackle the complexities of shortages. Security of supply and shortage prevention and management are a key focus.

A number of activities foreseen in the reform of the EU pharmaceutical sector are already under development and there is a clear shift from a reactive (management) approach to a proactive (prevention) approach to address shortages.

In the ongoing classification of the EU list of critical medicines by the EMA, radiopharmaceuticals are included. Once the development of the first draft of the EU list is finalised, there will be additional work to issue recommendations to prevent or manage shortages for these medicines, including of course radiopharmaceuticals.

In addition to putting together a list of critical medicines, the forthcoming new regulation foresees a number of additional requirements, not only for shortage prevention plans but also for aspects of the wider ecosystems, such as early communication on shortages so that we can prepare for such contingencies well ahead.

Session 2 – The industrial and innovative nuclear infrastructure landscape for medical radionuclide research and production

➢ The present and future reactor landscape in the Netherlands for the production of medical radionuclides (Ronald Schramm, NRG, The Netherlands)

In 1955, the Dutch reactor centre was established in Petten with the HFR reactor and the objective to acquire and disseminate knowledge for the country's peaceful use of nuclear energy (already recognising that HFR could also be used for medical isotopes).

In general, the reactors built in Europe in the 1950s/60s were built in a time when nuclear was seen as a promising technology and governments therefore put significant budget and effort into it. Over the last 70 years, nuclear medicine has greatly benefited from the existing nuclear infrastructure. For the future, however, we need a different model due to the significantly changed perception by society and policy.

Getting ready for the next 70 years means in our case to construct the PALLAS reactor for medical isotopes production and research. PALLAS will take over the role of the HFR (operational since 1961) when being in full operation (scheduled for ~2030).

The actual building time for PALLAS is shorter than for HFR but the overall development time longer as a significant effort needs to be put nowadays into stakeholder management, creation of awareness and overcoming lack of (political) willingness. PALLAS is designed for 25 MWth and is planned to operate on 300 full power days per year, and produce more and at a higher availability than the HFR. The Dutch government provided to NRG a loan for the reactor construction that has to be paid back via the revenues that NRG will acquire with operating the reactor (state aid procedure with the European Commission still pending). Regarding the future role of PALLAS, the facility will be a reactor/processing plant in between target producers and hospitals/pharma in the supply chain.

In addition to PALLAS, NRG has constructed a new physical lab, FIELD-LAB, with hot cells (providing e.g. no carrier added Lu-177, Pb-212) specifically for nuclear medical innovation (opened on 12/2023). Background for this project are strong requests from hospitals in the Netherlands to have materials available that are required in clinical trials, which are not on the market.

In summary, what we need for future production facilities in Europe is a system of income and revenue for these facilities coming from nuclear medicine, which directly goes back to investing in the facilities so that they can operate in a cost-effective and sustainable manner. – What we need on a European scale is a solid backbone of irradiation capabilities together with dedicated funds for nuclear medicine to ensure both security of supply for today and research & innovation for the future.

➢ The BR2 reactor and the future MYRRHA facility – The role of Belgium for medical radionuclide production (Hamid Abderrahim, SCK-CEN, Belgium)

Although, in a global context, we are in a rather comfortable situation in Europe concerning radioisotopes, the infrastructure is unfortunately ageing and we therefore have to think about security of supply.

In 1994, a strike at the NRU reactor in Ontario, Canada, made 80% of Mo-99 supply disappear from the world. This was an alarm signal for Europe. Belgium and the Netherlands were producing some amounts of the isotope, but this was far from sufficient to fulfil Europe's demand. – In response, SCK-CEN increased Mo-99 production. At the same time, Belgium tried an alternative route and initiated the ADONIS project (Accelerator-Driven Operated New Isotope System), i.e. keeping the same targets, only modifying the irradiation systems. ADONIS was a small-scale project, yet it never succeeded. Therefore, when speaking about innovative production systems, one should be aware that it takes time, even for rather small projects and we should consider this for future planning.

Currently, Belgium and SCK-CEN are investing heavily in the radioisotope sector and working on a centralized radiochemistry facility, which will start operating in 2024. Among others, it will deal with the production of Lu-177 and Ac-225. The BR2 reactor is Belgium's current workhorse for production of radioisotopes and can produce any isotope in large quantities for established treatments and in small quantities for research programs. However, BR2 will stop operation in 2036. MYRRHA, an accelerator driven system will be the successor of BR2 and is planned to be operational by 2036. SCK-CEN is also investing in medical imaging, cancer treatment isotopes, and other medical applications.

In summary, Belgium has been, is and will remain a major player in the production of nuclear medical radioisotopes and their processing thanks to its rather unique large infrastructure and technical and scientific expertise.

On a European level and in a changing geopolitical environment, in addition to preserving the available irradiation infrastructure for medical radioisotopes, it seems important to encourage at both EU and MS levels promising new initiatives for increasing security of supply of therapeutic and theranostic radioisotopes. – However, the business model of medical radioisotopes needs to be revisited to ensure a sufficient return of investment to fund irradiation capacities and their operating costs. In addition, European funds beyond EURATOM need to become accessible for nuclear medical applications as they significantly contribute to the European health system.

➢ The Jules Horowitz reactor in the French landscape of medical radionuclides (Marion Libessart, JHR, France)

The Jules Horowitz Reactor (JHR) is a Material Testing Reactor currently under construction at CEA's Cadarache research centre in France. It was recommended by the "European Strategy Forum on Research Infrastructures" (ESFRI) as a replacement for the EU's existing materials testing reactors, which were all built in the 1960s.

Apart from its important role to support future deployment of power reactors for the French nuclear fleet via dedicated research on fuel and material characteristics, JHR will also be devoted to medical isotopes production.

Its current business model is based on a ratio between irradiation time dedicated to experiments and irradiation time dedicated to radioisotopes production of 80% and 20%, respectively.

Regarding radioisotopes production, JHR is committed to irradiate 25-50% of the annual European Mo-99 targets. In addition, due to its high thermal neutron flux, the JHR can produce a wide range of radioisotopes, such as Lu-177, depending on the demand.

JHR is only an irradiation facility but intends to support also R&D on processing development and progress. JHR is also open to cooperating in future with the processing industry which could develop facilities nearby.

In July 2023, the French state decided to pursue the investments in the project with a view to finalising the reactor by 2032. Taking into account the first phase of operation, the budget for JHR is ~5 bn EUR.

➢ Industrial infrastructure for the production of medical radionuclides (Harrie Buurlage, SHINE Medical, USA)

SHINE is an American-based nuclear technology company that started 15 years ago. Main goal is to become in future a major nuclear fusion company.

SHINE's enrichment program consists of commercial production of highly enriched Yb-176 for high flux system use (besides SHINE, the other source is Russia), scale up of enriched Yb-176 in the coming years to facilitate lower flux systems, development and instalment of Gd enrichments (3 stable isotopes) and

exploration of market needs for other isotopes. – Regarding "fusion-based fission", SHINE aims at creating the world's largest production facilities (locations planned in the USA and in the Netherlands). Capabilities would include Mo99, I-131, Xe-133, Lu-177, and other neutron-based isotopes. SHINE prepares to enter the European market. SHINE's enrichment program could contribute to reducing dependency on Russia and fusion driven fission is a cost effective alternative/addition to reactor-based production of Mo-99 and I-131.

The development of this technology in the USA is due to the fact that until recently every important medical isotope had to be imported from Europe, South Africa and Australia. Ten years ago, the US government decided that the country needs to have a domestic supply and developed initiatives to start the production of Mo-99. The US Department of Energy's philosophy was that "we do everything until private companies are able to take over".

Session 3 – Research and development in Europe on medical radionuclides

The session shared by Domenico Rossetti di Valdalbero from DG RTD, gave an overview on research and innovation projects linked to indirect actions[1], direct actions[2] and those lead by private companies associated to national organisations.

1 Indirect Actions

➢ PRISMAP, towards a sustainable European medical radionuclides programme (Thierry Stora, CERN, Switzerland)

Regarding **Indirect Actions**, the PRISMAP and SECURE projects were presented by their respective project leaders, Thierry Stora from CERN and Renata Mikołajczak from POLATOM.

The EU-funded project **PRISMAP** focuses on the sustainable development of medical radionuclides in Europe. The project aims at providing access to major infrastructures such as nuclear reactors and high-power cyclotrons for researchers across Europe. Projects come from several European countries and cover a wide range of fields related to use of radionuclides for new medical applications. The supply chain involves physical separation facilities in Switzerland and Belgium, with a focus on harmonizing data and radiological protection. PRISMAP has been successful with preclinical proof-of-concept data and patent applications, and the consortium's ambition is to ensure long-term sustainability.

➢ Strengthening the European chain of supply for next-generation medical radionuclides (Renata Mikołajczak, Polatom, Poland)

Next, Renata Mikolajczak presented the **SECURE** project, a 36-month project funded by the EURATOM Research and Training Programme with a budget of EUR 3.6 million. The project aims at ensuring the sustainability of medical isotopes production and safe application in Europe by focusing on the development of irradiation targets and production routes for existing and new isotopes in nuclear therapy and diagnostics. The SECURE consortium, consisting of 18 partners from 10 countries, seeks to remove critical barriers in the production of selected alpha and beta emitting isotopes and develop guidance for exploring the full clinical potential of alpha and beta particle therapy. The project also focuses on the safety and effectiveness of new treatment options based on alpha-particle emitters. The ultimate ambition is to identify and efficiently use the current resources for new radionuclides, particularly for alpha emitters, to create new opportunities for society, healthcare, and economics.

Both SECURE and PRISMAP focus on the development and sustainability of medical radionuclides in Europe, their focus is different, but with complementarity:

While SECURE focuses on overcoming production barriers and ensuring the safe application of specific isotopes, PRISMAP focuses on access, sustainability and standards for a broader range of medical radionuclides. SECURE's emphasis on developing new treatment options complements PRISMAP's focus on providing access to new radionuclides and purity grades for medical research. Both projects share the common goal of improving the availability of medical radionuclides for healthcare applications in Europe.

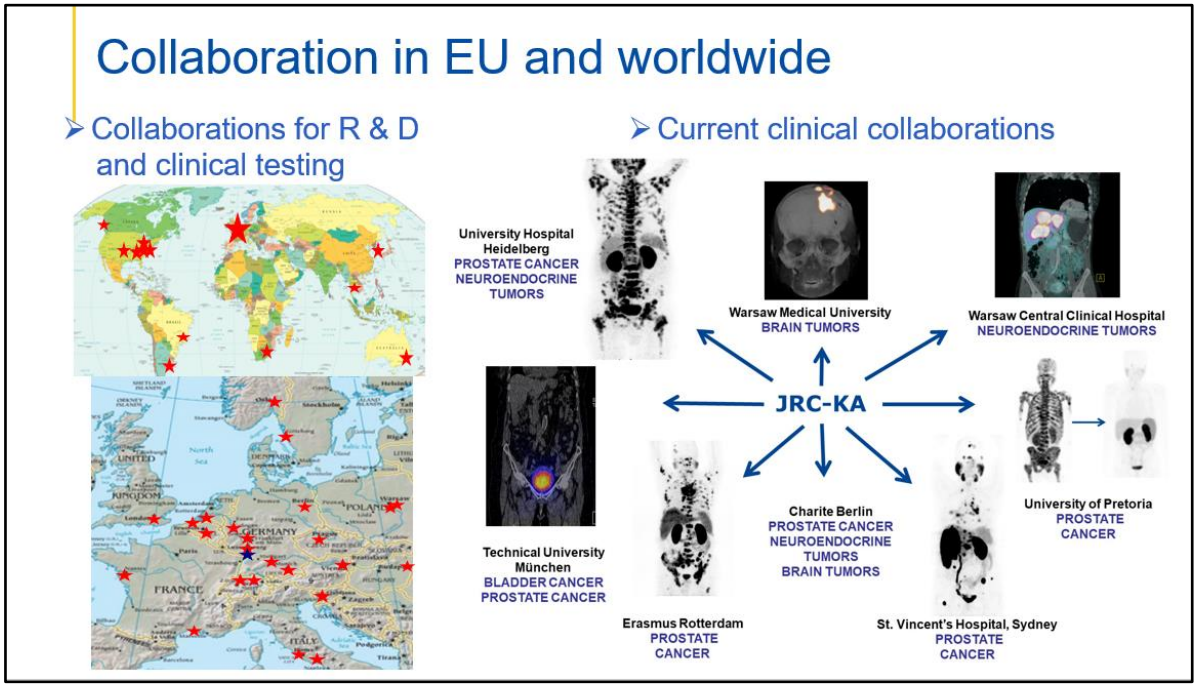
[1] I.e. actions funded under the EU's Horizon Europe program for project consortia from different countreies
[2] I.e. actions funded from the Commission budget and executed directly by Commission services (here the JRC)

2 Direct Actions

➢ Highlights from JRC research on medical radionuclides (Alfred Morgenster, JRC Karlsruhe, Germany)

Alfred Morgenstern from JRC presented innovative research and development of medical radionuclides at **JRC Karlsruhe**, focusing on **Targeted Alpha Therapy (TAT)** of cancer. At JRC Karlsruhe, groundbreaking research over the past 30 years has led to significant advancements in the field of medical radionuclides, particularly development and application of TAT for cancer treatment. The research initially focused on the potential of alpha emitters, such as Ac-225 and Bi-213, which are highly effective at destroying cancer cells due to their potent alpha radiation that causes irreparable DNA damage. JRC's notable contribution includes the development of Ac-PSMA617, which has been instrumental in TAT, particularly for prostate cancer therapy.

JRC activities encompass securing the supply of Ac-225 through radiochemical extraction from Th-229 and innovative accelerator production methods, developing standardized protocols for radiopharmaceuticals, as well as conducting preclinical and clinical tests. The center has also built international collaborations, providing training and organizing symposia. A highlight is the compassionate use of 225Ac-PSMA617, which has shown promising results in patients with metastatic castration-resistant prostate cancer (mCRPC), including a high percentage of PSA decline and improved quality of life.



source: Alfred Morgenstern.

3 Actions by Private Companies

➢ R&D on Radium-226 for Actinium-225 production (Sven van den Berghe, PanTera, Belgium)

Sven van den Berghe from **PanTera** presented R&D efforts on Radium-226 for Actinium-225 production, emphasizing the emergence of targeted radiotheranostics as a new pillar in cancer treatment. The recent integration of targeted radiotheranostics into cancer treatment has provided a new avenue for battling the disease by combining targeted radiation therapy with diagnostic imaging. Among the various isotopes used in this field, Actinium-225 (Ac-225) has emerged as a particularly promising candidate due to its powerful alpha emissions that cause lethal DNA damage to cancer cells while minimizing harm to healthy tissues. Actinium-225 is recognized as a promising isotope for targeted alpha therapy, offering high-energy deposition density and known chemistry similar to 177Lu, with promising results in patients. Despite its potential, the demand for Ac-225 currently surpasses the supply, which is about 2.5 curies per year worldwide, restricting the progress of clinical trials. Addressing future supply and demand challenges, small suppliers have begun emerging, with each contributing approximately 1-3 curies annually. The demand for Ac-225 is expected to spike as clinical trials progress, necessitating reliable and Good Manufacturing Practice (GMP) compliant sources. Moreover, scalability and multi-sourcing will be key differentiators in the early supply stages. For commercial supply, meeting the needs of potentially hundreds of thousands of patients will require a substantial increase in Ac-225 production. The anticipated surge in demand will necessitate a global capacity of about 500-800 curies annually to support major projects under development. PanTera has opted for the gamma route to produce Ac-225, leveraging Belgium's significant Radium resources, due to its safety and output potential compared to the proton route. The partnership with TerraPower aims to secure a stable supply of Ac-225 for both the US and Europe. The unique quantity of pure Radium currently available presents an opportunity to meet demand, with the potential to scale up production significantly in the future.

The presentation emphasized the promising potential of Actinium-225 for cancer treatment, the complexities of production methods, and the need for reliable, scalable, and sustainable supply to meet increasing demand.

➢ Novel alpha- and Auger-emitting radionuclides for medical applications (Bertrand Morel, Orano, France)

Bertrand Morel from **Orano** presented work on novel alpha- and Auger-emitting radionuclides for medical applications, highlighting Orano's expertise in the nuclear fuel cycle and its subsidiary, Orano Med, which is involved in the development of innovative cancer therapies. Alpha therapies offer strong potential in the fight against cancer, with higher cytotoxicity and reduced irradiation of healthy tissues compared to beta therapies. Orano Med focuses on targeted alpha therapy using lead-212 (212Pb) and lead-212-conjugated drugs for different types of cancer, with ongoing clinical trials and strategic collaborations worldwide. The presentation also emphasized the potential of alpha therapies in cancer treatment, large-scale reliable production capabilities of lead-212, and the unique industrial platform being deployed by Orano Med. Ongoing clinical trials and collaborations worldwide demonstrate the potential for 212Pb-conjugated drugs to target various types of cancer. Orano's ongoing development of a purification process for radium-226 and the potential for recycling long-lived elements for medical applications indicate the company's focus on extending its portfolio and addressing future demand. Also the use of Auger emitters in radiopharmaceuticals is a long-term project worth investigating, with 97Ru identified as a good candidate for therapy.

The presentation emphasized the potential of targeted alpha therapy using 212-Pb-conjugated drugs, Orano Med's global industrial platform, and the company's focus on addressing future demand and exploring innovative radiopharmaceuticals using Auger emitters. As the market for radiopharmaceuticals continues to grow, Orano Med's efforts indicate a commitment to advancing cancer treatment through nuclear medicine.

Summary Breakout rooms / Survey on line

- ### Breakout room 1 – Enhancing Collaboration between Research and Industry for Sustainable Medical Radionuclide Supply in the EU

The importance of forging synergies between researchers and the industry was emphasized as a driver for innovation in the sustainable supply of medical radionuclides in the EU. The group identified the need for respect and acknowledgment of the distinct roles of academia and industry: Academia as the source of innovation and industry as the implementer. A key point raised was the necessity of improved coordination between European Commission services, as the current segmentation leads to a piecemeal approach that could hinder progress. The participants pointed out the challenges researchers face in accessing radionuclides, with a call for a more stable, long-term solution akin to the US Department of Energy's model. The group also tackled the complexities and costs associated with ADR[3] transport regulations for radiopharmaceuticals in Europe, advocating for EU funds beyond EURATOM to be made accessible for the advancement of nuclear medicine applications.

- ### Breakout room 2 – Enhancing Coordination and Communication among Stakeholders at National, European, and Global Levels for Facilitating a Secure Radioisotope Supply Chain

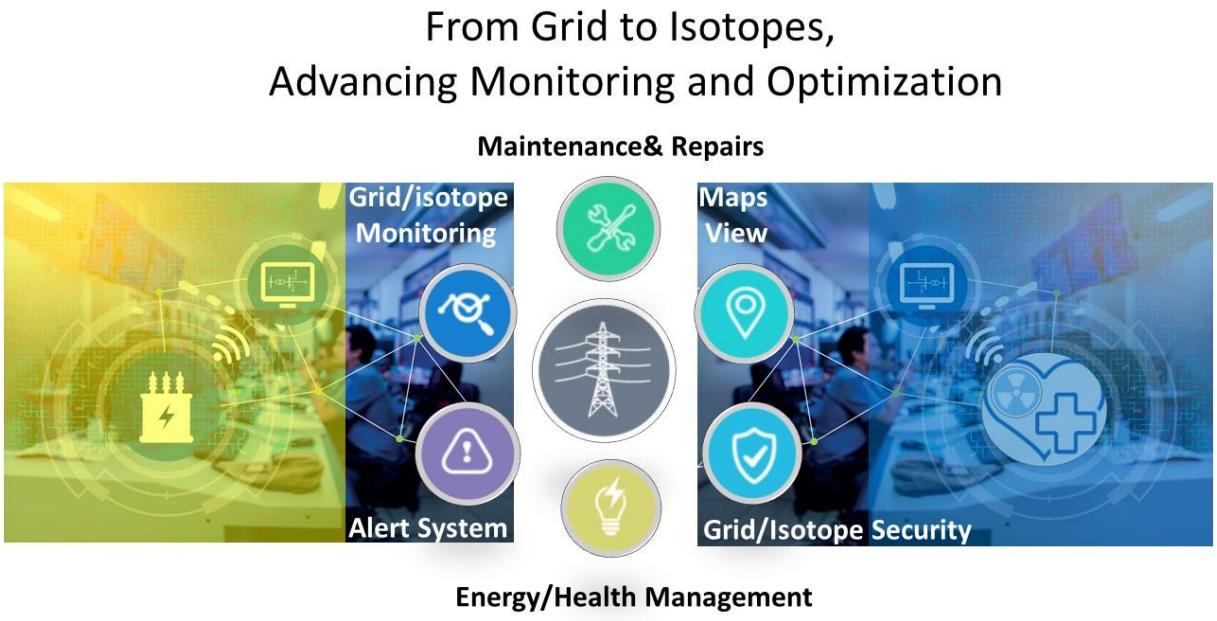
The dialogue revolved around the crucial need for enhanced coordination and communication among stakeholders at the national, European and global levels to secure the radioisotope supply chain. The group reflected on the advancements made in short-term crisis communication within Europe over the last decade, citing the improved coordination during events like Brexit and the response to the Russian aggression in Ukraine. Despite these improvements, there was a consensus that strategic and long-term cooperation was lacking and that involvement from a broader range of authorities is required. Participants recognized the need for improved communication not only between different levels of government but also within organizations. The discussion highlighted the absence of understanding among medical professionals and authorities about radiopharmaceuticals, the disconnect between health and nuclear sectors, and the insufficient recognition of waste management and transportation issues.

Source: Rachel Eloirdi

[3] ADR refers to the European Agreement Concerning the International Carriage of Dangerous Goods by Road

- Breakout room 3 – Future Monitoring of Supply and Demand of Medical Radioisotopes

Participants explored the current state and future prospects of monitoring the supply and demand of medical radioisotopes, with a primary focus on Mo-99/Tc-99m. They noted that monitoring began in earnest following the major supply crisis of 2008-2010 and acknowledged ongoing concerns such as confidentiality and the involvement of private and public stakeholders. The variability of radioisotope use across countries and the need for data to inform policies, such as reimbursement rates, were discussed. The group considered the potential for third-party data collection and the possibility of adopting the EU electricity production reporting model for radioisotope usage. They also examined the challenges newcomers face in entering the Mo-99/Tc-99m market and emphasized that while there is no one-size-fits-all solution, understanding the demand side is crucial for shaping investment plan and government policies.



Source: Rachel Eloirdi

- Survey on line

Feedback from the online survey revealed concerns regarding the regulatory framework for medical radionuclides across Europe. Respondents called for improvements in the harmonization and standardization of regulations, pointing out that despite Europe's success in producing radionuclides, it struggled with regulatory coherence. The survey touched upon the implications of the Medical Device Regulation (MDR) and the disparities in how European directives are implemented at the national level. Participants discussed the potential benefits of research and innovation in medical radionuclides for patients, such as biological targeting and single-injection therapies. The survey highlighted Ac-225, Lu-177, and At-211 as radionuclides of significant interest. The complexity of harmonizing access to radiopharmaceuticals was emphasized, pointing out that harmonization efforts could unintentionally lead to adopting the most stringent regulations. The survey underscored the need for clear regulatory objectives, careful coalition building, and recognition of legitimate policy concerns from various sectors.

Conclusions and recommendations

This workshop at JRC Karlsruhe, with the physical and online participation of about 100 participants from 15 Member States as well as Switzerland, UK and US, focused on the research and innovation needs in order to ensure the sustained availability and innovation in the production of medical radionuclides, a cornerstone for the future of nuclear medicine in the EU.

Objectives were not only to survey the current landscape of radiopharmaceutical production but also to ignite dialogue on emerging infrastructures and innovative methodologies that could redefine the paradigm of nuclear medicine.

The workshop aimed at initiating the development of a set of practical recommendations that would ultimately accelerate the transition from R&D to clinical application and establish an EU leadership in this vital healthcare sector.

The main recommendations are the following:

- Strive for EU autonomy for a continuous, stable and uninterrupted supply of medical radionuclides in a way that takes into account an increasing demand for several radionuclides including alpha-emitters.
- Consider dedicated funds for nuclear medicine with alternative, more domestic production methods for radioisotopes, in addition to large centralized production, to take into account the half-life of isotopes.
- Revisit the business model of medical radioisotopes needs to ensure a sufficient return of investment to fund irradiation capacities and their operating costs. In addition, European funds beyond EURATOM need to become accessible for nuclear medical applications as they significantly contribute to the European health system.
- Find a mechanism to better coordinate existing and forthcoming EU/MS initiatives on both security of supply and research & innovation, ideally underpinned by a future single, strong and stable European backbone initiative on radioisotopes. Explore the possibility of funding for such a European partnership beyond EURATOM.
- Accordingly, streamline role of Commission services, with horizontal services more effectively linking e.g. innovative research at JRC with EU/MS policy programs.
- Harmonise in a graded approach the requirements for clinical trials with radiopharmaceuticals at EU Member States level, including timelines for approval.
- Address regulatory issues concerning radiation protection, including harmonisation of guidelines for hospitalisation length after routine radiopharmaceutical treatments.
- To make nuclear medical applications truly accessible across the EU, in addition to a secure supply and an adequate and harmonised regulatory framework, improve the availability of workforce in the field with a high level of competence.
- Regarding innovative approaches, it could be recommended to consider acceleration of delivery process by the use of drones and facilitate related regulatory aspect.

References

Eloirdi R., Kirchsteiger C., Marabeau G., ***Research and Innovation for Sustainable Medical Radionuclides Supply in the European Union***, Workshop report and conclusions, Publications Office of the European Union, Luxembourg, 2024, https://data.europa.eu/doi/10.2760/01088, JRC137214.

All presentations as well as the results of the online survey are collected in the public link, https://circabc.europa.eu/ui/group/0e8b2985-afd8-485c-8db1-e1cba61eccd3/library/d99e2036-47f4-4d00-8ab2-9a2c6e54253f

Goulart, M., Holzwarth, U., Marabeau, G. and Lauwers, G., **Competences for medical applications of nuclear science**, Publications Office of the European Union, Luxembourg, 2024, https://data.europa.eu/doi/10.2760/90025, JRC137512

Goulart M., Holzwarth U., ***Translating radiotheranostic cancer research into clinical practice in Europe***, Workshop report and conclusions, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/92392, JRC134480.

Proceedings of the High Level Workshop on Security of Supply of Medical Radioisotopes, 27 April 2023, Brussels, NucAdvisor, https://energy.ec.europa.eu/events/high-level-workshop-security-supply-medical-radioisotopes-2023-04-27_en

Annexes

Annex 1. Workshop Agenda

09:30-10:00 Welcome remarks

Ulla Engelmann (Dir JRC.G, European Commission)
Bernard Magenhann (Deputy Director General JRC, European Commission)
Jose Manuel Perez (Deputy Director General, CIEMAT, Spanish Ministry for Science and Innovation)

10:00-11:15 Session 1 – Landscape and challenges for medical radionuclide supply and research in the EU

Chair: Remigiusz Barańczyk (Euratom Supply Agency - ESA)

10:00–10:15	Racing against time: the radiopharmaceutical supply chain (Paola Erba, European Association of Nuclear Medicine - EANM)
10:15–10:30	Commission action on medical isotopes – the SAMIRA Action Plan (Michael Huebel, DG ENER, European Commission)
10:30–10:45	Monitoring of irradiation capacities and supply of medical radionuclides (Bernard Ponsard, EU Observatory on the Supply of Medical Radionuclides)
10:45–11:00	Ongoing initiatives to secure supply of medicines in the EU and to prevent shortages of medicinal products (Maria Alcaraz, European Medicines Agency - EMA)

11:45-13:00 Session 2 – The industrial and innovative nuclear infrastructure landscape for medical radionuclide research and production

Chair: Willem Janssens (DG JRC, European Commission)

11:45–12:00	The present and future reactor landscape in the Netherlands for the production of medical radionuclides (Ronald Schram, NRG/PALLAS)
12:00–12:15	The BR2 reactor and the future MYRRHA facility – The role of Belgium for medical radionuclide production (Hamid Abderrahim, MYRRHA, SCK-CEN)
12:15–12:30	The Jules Horowitz Reactor in the French landscape of medical radionuclides (Marion Libessart, CEA)
12:30-12:45	Industrial infrastructure for the production of medical radionuclides (Harrie Buurlage, SHINE Medical)

14:00-15:30 Session 3 – Research and development in Europe on medical radionuclides

Chair: Domenico Rossetti di Valdalbero (DG RTD, European Commission)

14:00-14:15 PRISMAP, towards a sustainable European medical radionuclides programme (Thierry Stora, CERN)

14:15-14:30 Strengthening the European chain of supply for next-generation medical radionuclides (Renata Mikołajczak, Polatom)

14:30-14:45 Highlights from JRC research on medical radionuclides (Alfred Morgenstern, DG JRC, European Commission)

14:45-15:00 R&D on Radium-226 for Actinium-225 production (Sven van den Berghe, PanTera)

15:00-15:15 Novel alpha- and Auger-emitting radionuclides for medical applications (Bertrand Morel, Orano)

16:00-17:30 Break-out rooms / Survey on line / Discussion – Synergies to keep the EU at the forefront of R&I to secure radionuclide supply

Chair: Rachel Eloirdi (DG JRC, European Commission)

- Breakout room 1, "Enhancing Collaboration between Research and Industry for Sustainable Medical Radionuclide Supply in the EU" (chaired by DG JRC & Nuclear Medicine Europe - NMEU)
- Breakout room 2, "Enhancing Coordination and Communication among Stakeholders at National, European, and Global Levels for Facilitating a Secure Radioisotope Supply Chain" (chaired by DG ENER & OECD/NEA)
- Breakout room 3, "Future monitoring of supply and demand of medical radioisotopes" (Chaired by ESA / DG JRC)
- Survey on line (chaired by DG JRC)

17:30-17:45 Wrap-up and closing remarks

Alberto Fernandez Fernandez (Director Nuclear Applications, Belgian Ministry of Economy & Energy)
Bernard Magenhann (DDG DG JRC, European Commission)

Annex 2. List of Organisations

CIEMAT:	Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas (Spain)
EANM:	European Association of Nuclear Medicine
EMA:	European Medicines Agency
ENER:	Directorate-General for Energy – European Commission
ESA:	Euratom Supply Agency
GROW:	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs – European Commission
JHR:	Jules Horowitz Reactor
JRC:	Directorate-General Joint Research Centre – European Commission
NMEU:	Nuclear Medicine Europe
NRG:	Nuclear Research and Consultancy Group
OECD/NEA:	Organisation for Economic Cooperation and Development / Nuclear Energy Agency
Orano:	French nuclear fuel cycle company (activities in uranium mining, conversion-enrichment, spent fuel recycling, nuclear logistics, dismantling, and nuclear cycle engineering)
PanTera:	Joint venture to produce actinium-225 launched by IBA (Ion Beam Applications) and SCK-CEN
Polatom:	Polish National Centre for Nuclear Research Radioisotope Centre POLATOM
RTD:	Directorate-General for Research and Innovation, European Commission
SCK-CEN:	Belgian Nuclear Research Centre
SHINE:	SHINE technologies (private corporation planning to build a facility to produce radioisotopes for medical applications using particle accelerator technology)

Annex 3. List of speakers and chairs

Last Name	First Name	Organisation	Country
ALCARAZ TOMAS	Maria Jesus	EMA	The Netherlands
AÏT ABDERRAHIM	Hamid	MYRRHA	Belgium
BARAŃCZYK	Remigiusz	Euratom Supply Agency – ESA	Luxembourg
BUURLAGE	Harm	SHINE Europe B.V.	The Netherlands
ELOIRDI	Rachel	EUROPEAN COMMISSION, DG JRC	Germany
ENGELMANN	Ulla	EUROPEAN COMMISSION, DG JRC	Germany
FERNANDEZ FERNANDEZ	Alberto	FPS Economy, SMEs and Energy	Belgium
HOLZWARTH	Uwe	EUROPEAN COMMISSION, DG JRC	Italy
JANSSENS	Willem	EUROPEAN COMMISSION, DG JRC	Italy
LIBESSART	Marion	CEA	France
MAGENHANN	Bernard	EUROPEAN COMMISSION, DG JRC, DDG	Belgium
MIKOLAJCZAK	Renata	POLATOM	Poland
MOREL	Bertrand	ORANO	France
MORGENSTERN	Alfred	EUROPEAN COMMISSION, DG JRC	Germany
HUEBEL	Michael	EUROPEAN COMMISSION, DG ENER	Luxembourg
PEREZ	José Manuel	CIEMAT, DDG	Spain
ROSSETTI DI VALDALBERO	Domenico	EUROPEAN COMMISSION, DG RTD	Belgium
SCHRAM	Ronald	NRG/PALLAS	The Netherlands
SEIBERT	Alice	EUROPEAN COMMISSION, DG JRC	Germany
SHERMAN	Nicholas	OECD – Nuclear Energy Agency	France
SIMEONOV	Georgi	EUROPEAN COMMISSION, DG ENER	Luxembourg
STORA	Thierry	CERN	Switzerland
TANARRO COLODRON	Jorge	EUROPEAN COMMISSION, DG JRC	The Netherlands
VAN DEN BERGHE	Sven	PanTera	Belgium

Annex 4. List of participants in presence

Last Name	First Name	Organisation	Country
BACHORCZYK-NAGY	Renata	EUROPEAN COMMISSION, DG RTD	Belgium
BAKO	Ildiko	EUROPEAN COMMISSION, DG ENER	Luxembourg
BAUMEISTER	Bruno	Technical University München, FRM-II	Germany
BONNET	Jean	INSTITUT DES RADIOELEMENTS	Belgium
BROWN	Roy	Curium	United States
CHERUBINI	Nadia	ENEA	Italy
CICCARELLO	Stefano	Euratom Supply Agency – ESA	Luxembourg
CIRILLO	Roberta	ENEN	Belgium
DE MARTINI	Amélie	EANM	Austria
DE LANGHE	Pascal	SCK CEN	Belgium
DODARO	Alessandro	ENEA	Italy
DOGARU	Delia Alexandra	EUROPEAN COMMISSION, DG JRC	Belgium
ERBA	Paola	EANM	Austria
ERIS	Aysin	Full Life Technologies	Belgium
HELMKE	Lutz	Eckert & Ziegler Radiopharma GmbH	Germany
HEYNISCH	Thomas	EUROPEAN COMMISSION, DG GROW	Belgium
HOJNY	Arkadiusz	Ministère de la Santé/Direction de la santé/DPM	Luxembourg
HUTANU	Vladimir	FRM II, TU München	Germany
JACKSON	Niina	EUROPEAN COMMISSION, DG ENER	Luxembourg
KELLERBAUER	Alban	EUROPEAN COMMISSION, DG JRC	Germany
KIRCHSTEIGER	Christian	EUROPEAN COMMISSION, DG JRC	Germany
KOLLEGGER	Erich	Institute for Radioelements	Belgium
KRÓLICKI	Leszek	Medical University of Warsaw	Poland
KUBIAK	Arlena	Ministry of Climate and Environment	Poland
KUNIKOWSKA	Jolanta	Medical University of Warsaw	Poland
MARABEAU	Gwladys	EUROPEAN COMMISSION, DG JRC	Belgium
MILOT	Guillaume	Services de la Première ministre, Comité Technique Euratom (CTE)	France
MORENO BERMUDEZ	Josue Manuel	ITM Medical Isotopes GmbH	Germany
PEL	Ellen	Council of Europe, European Directorate for the Quality of Medicines & HealthCare	France
PONSARD	Bernard	SCK CEN / BR2 REACTOR	Belgium
ROSSETTO	Daniel	ARTBIO	Switzerland
TODDE	Sergio	University of Milano-Bicocca	Italy
URBONAITĖ	Martyna	Research Council of Lithuania	Lithuania
VAN DE MAELE	Hans	World Infinity Services	Belgium
VAN DE VOORDE	Michiel	SCK CEN	Belgium
VAN PUT	Philippe	Full-Life Technology Europe	Belgium
VITOVA	Tonya Oleg	Karlsruhe Institute of Technology (KIT)	Germany
Von BREMEN	Konrade	NMEU	Switzerland
WAGNER	Christine	Orano Support	France

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