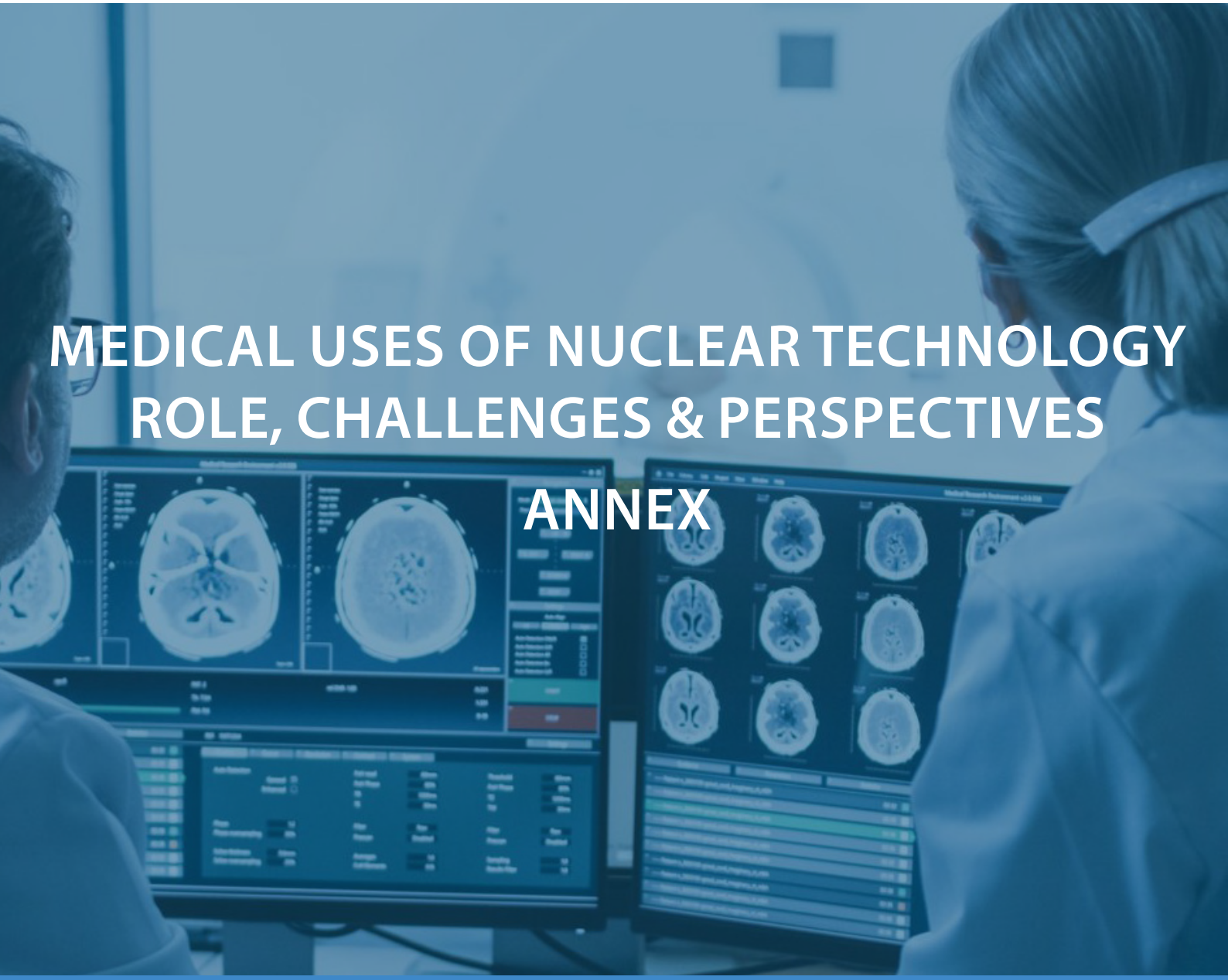
FORATOM
THE VOICE OF THE EUROPEAN NUCLEAR INDUSTRY

NUCLEAR MEDICINE EUROPE
the industry association



MEDICAL USES OF NUCLEAR TECHNOLOGY
ROLE, CHALLENGES & PERSPECTIVES
ANNEX

FACTS

9 Mn

Patients in Europe who benefit from nuclear medicine every year

1.5 Mn

Radiotherapy procedures for cancer therapy in Europe every year

100

Different nuclear medicine procedures approved by health regulators

4 out of 6

Research reactors providing 95% of the world's Mo-99 or Lu-177 production, are based in the EU

June 2021

ACTIVITIES AT EU LEVEL

The EU is involved in the nuclear medicine sector by, for example, monitoring all the latest developments. The nuclear medicine sector collaborates with the EU through a variety of projects, which seek to identify opportunities and challenges for the use and development of ionising radiation and in order to discuss potential solutions to address challenges in areas where the EU can add value. In one of the recent documents on this topic, the Council of the EU highlighted[1] that "nuclear and radiological technologies play an important role outside the nuclear energy sector in vital areas, such as medicine, industry, research and environment, providing numerous benefits to the EU citizens and AWARE OF the significant contribution that nuclear science can make to addressing societal challenges". In addition, it was underlined that "Euratom legislation requires that non-power use of nuclear and radiation technologies is appropriately justified, the radiation protection of the public, patients and staff is adequately optimised and that non-power radioactive waste and spent fuel are safely disposed". The document also mentioned the importance of "ensuring additional radioisotopes production capacity and launching or advancing projects for new production facilities, including research reactors and alternative technologies" as the "production of source materials for the supply chain of medical radioisotopes is important to increase the resilience of the European supply chain and to reduce the dependence on foreign actors".

Nuclear medicine-related programmes conducted at EU level:

- ## European Observatory on the Supply of Medical Radioisotopes

In 2012, the Commission established a European Observatory on the Supply of Medical Radioisotopes, aimed at "bringing together all relevant information to the decision makers in the EU institutions and national governments in order to assist them in defining strategies and policies for their implementation". Since 2012, the European Observatory on the Supply of Medical Radioisotopes has been monitoring the overall supply of medical radioisotopes and, in particular, the coordination of reactor schedules and has made important contributions to avoiding significant shortages of medical radioisotopes in the EU. It is also developing policies to secure the long-term supply of radioisotopes. The Observatory follows the OECD/NEA principles established by the High-Level Group on Medical Radioisotopes (HLG-MR), of which the Commission is a Member, and focuses on the specificities of their implementation in the EU.

The European Observatory has four general strategic objectives:

- To support a secure Mo-99/Tc-99m supply across the EU.
- To ensure that the Mo-99/Tc-99m supply issue is given high political visibility.
- To encourage the creation of a sustainable economic structure of the supply chain.
- To establish periodic reviews of the supply chain and capacities.

The Observatory is composed of members from the Euratom Supply Agency (ESA), the Commission (DG ENER, JRC, RTD, SANCO and ENTR), the European Association of Nuclear Medicine (EANM) and various industry stakeholders most of which are grouped within the Nuclear Medicine Europe.

- ## Euratom Supply Agency

The role of the Euratom Supply Agency (ESA) is to ensure the supply of nuclear source material needed for research reactor fuels and targets for production of medical radioisotopes for research reactors and the production of medical radioisotopes.

[1] https://data.consilium.europa.eu/doc/document/ST-9437-2019-INIT/en/pdf
Council of the European Union (2019, 24 May), Non-power nuclear and radiological technologies and applications-Adoption of Council Conclusions (Item Note 9437/19)

- **HEU to HALEU conversion of targets used for Mo-99 production**

The importance of the conversion of targets used for Mo-99 production from HEU to LEU was highlighted in the Council Conclusions adopted in 2012, which called upon the Commission to identify research needs that might be supported by the Euratom research and training programme. As a result, a research and innovation action grant (EUR 6.35 million) was awarded to the Heracles-CP project 'Towards the conversion of high performance research reactors in Europe', coordinated by the Technical University of Munich and involving five partners. The main objective of the project is to provide support for further investigation of future needs in terms of volume and fuel design requirements in line with relevant data for each EU research reactor type, and to prepare technical requirements for the safety of manufacturing, storage, transport and reprocessing of such research reactor fuel.

- **SAMIRA**

In 2016, the SAMIRA (Strategic Agenda for Medical, Industrial and Research Applications of Nuclear and Radiation Technology) programme, which is being developed by the European Commission's DG Energy, "seeks to identify opportunities and challenges for the use and development of ionising radiation and to discuss potential solutions to address challenges in areas where the EU can add value, alongside actions taken by other stakeholders". SAMIRA goes hand in hand with many EU initiatives, including the Council's call for action in the following priority areas: security of supply of medical radioisotopes, radiation quality and safety in medicine, and innovation and technological development of medical ionising radiation applications. SAMIRA is also closely linked to the Commission's "Europe's Beating Cancer Plan" as it can contribute to the main objectives of the initiative.

In 2019, a dedicated SAMIRA workshop was held in order to investigate the challenges and opportunities in this area. Also, in the same year, the Commission published a study into the non-power applications of nuclear and radiation technology, including an evaluation of demand and supply of medical radioisotopes. The study examined a significant amount of evidence and supports the identification of issues and actions to take and address. These are largely concentrated in the medical field: secure the supply of radioisotopes for Europe, improve radiation protection and safety for European patients and medical staff and facilitate innovation in medical practice.

In 2019, DG Energy issued a tender for a "Co-ordinated approach to the development and supply of radioisotopes in the European Union".

Several factors have been identified that could affect security of supply in the medium to long-term:

- The aging of Europe's research reactors.
- Conversion from Highly Enriched Uranium (HEU) to High-Assay Low Enriched Uranium (HALEU) for reactor fuels and targets for production of medical radioisotopes as part of international efforts.
- Supply chain investment in emerging radioisotopes and production methods as the range of medical radioisotopes being utilised for medical diagnosis and therapy is continually expanding.
- Attention should be paid to other aspects, such as other radioisotopes, supply of non-fissile source materials and production techniques other than those based on research reactors.
- Need to harmonize legislation to facilitate transport and marketization in the EU.

The objective of this Commission study is to fill in the gaps relating to available information on supply chains for the main established and novel radioisotopes that have, or are expected to have, significant uses in Europe. The work should also prepare the ground for long-term European co-operation in this area. The study has to meet the following specific objectives:

- Identify the main radioisotopes currently in use in the EU, and the main radioisotopes expected to be in use by 2030.
- Identify the existing and emerging methods and technologies for production of the radioisotopes and fully describe the main elements of their respective supply chains.
- Identify the main suppliers of source materials and technologies for production of radioisotopes and the facilities which are part of the above supply chains.
- Develop scenarios and concrete options for a sustainable and secure supply of radioisotopes in the EU.

The study held its 4th Steering Group meeting in February 2021 to review the 2nd interim report of the study, which is planned to be completed in May 2021.
In 2019, under the SAMIRA Project, the Finnish Presidency of the European Council organised a workshop on the "Management of spent fuel and radioactive waste arising from non-energy uses of nuclear and radiation technologies[2]".

In addition, the Romanian Presidency of the European Council prepared a brochure on the topic of "Non-power nuclear technologies and applications", which is a collection of good practice examples and ideas from different Member States across the EU and from the Commission's the Joint Research Centre.

SAMIRA Action Plan

In February 2021, the Commission adopted the SAMIRA Action Plan "Strategic Agenda for Medical Ionising Radiation Applications". The Action Plan refers to Europe's Beating Cancer Plan, which aims to ensure that EU citizens have access to high-quality radiological and nuclear technologies in medicine, with the highest safety standards. It defines actions and measures in three key areas:

- Securing the supply of medical radioisotopes.
- Improving radiation quality and safety in medicine.
- Facilitating innovation and the technological development of medical ionising radiation applications.

The Action Plan's main deliverables will be:

Supply of medical radioistotopes

- European Radioisotope Valley Initiative (ERVI)

The Commission intends to start a process towards establishing a European Radioisotope Valley Initiative (ERVI) aiming to maintain Europe's global leadership role in the supply of medical radioisotopes and help accelerate the development and introduction of new radioisotopes and production methods.

- Supply of source materials for radioisotopes production

The Euratom Supply Agency (ESA) will continue to identify potential risks to the security of supply of High Enriched Uranium (HEU)25 and HALEU and strive to secure sufficient supplies, in compliance with international nuclear security and non-proliferation commitments.

- Support long-term sustainability of radioisotopes production in Europe

In addition to the actions above, the Commission intends to undertake a series of complementary actions aiming to support the long-term sustainability of radioisotope production in Europe.

[2] https://ec.europa.eu/energy/sites/ener/files/documents/samira_workshop_memo.pdf

Quality and safety of medical radiation applications

- European Initiative on Quality and Safety of medical applications

The Commission intends to launch a European Initiative on quality and safety aiming to ensure that the main diagnostic and therapeutic applications of ionising radiation in the Member States operate in line with high standards for quality and safety, in the interest of patients.

- Improve workforce availability and education and training

This action will aim to mitigate the gaps between workforce supply and demand and ensure that all categories of staff in radiology, radiotherapy and nuclear medicine receive adequate education, training and continuous professional development in quality and safety.

- Equal access to modern technology and interventions

This action will aim to improve EU patients' access to modern equipment and procedures used in radiology, radiotherapy and nuclear medicine across and within Member States. This action will in particular focus on ensuring that modern safety and radiation dose control features are implemented on new and existing equipment in a timely manner, in line with the highest standards for quality and safety.

Innovation and technological development

- EU research and innovation support

This action will aim to develop and implement a research roadmap for non-power applications of nuclear and radiation technology. The main objective is to develop a strategic plan and identify common actions between the 'Health' cluster of the Horizon Europe and the Euratom Research and Training Programme in the 2021-2025 period.

- Joint HTAs

The Commission's proposal for a Regulation on Health Technology Assessment (HTA) aims to provide a legal framework for strengthened and sustainable EU cooperation on HTA and enable Member States to conduct joint comparative clinical assessments of new medicines, medical devices and diagnostics.

- **SMER-1 & SMER-2**

In 2018-2019, the Commission's Joint Research Centre conducted a research project called SMER-1, which contributed "to a sustainable and resilient supply of medical radioisotopes in the EU and investigating the medical radioisotope reimbursement systems in the EU Member States". After the project's finalisation, the JRC launched a new 12-month project (SMER-2) in 2019, with the objective of providing the Commission with current information on the radionuclide therapy market in the EU.

About us

The European Atomic Forum (FORATOM) is the Brussels-based trade association for the nuclear energy industry in Europe. The membership of FORATOM is made up of 15 national nuclear associations and through these associations, FORATOM represents nearly 3,000 European companies working in the industry and supporting around 1.1 million jobs.

Nuclear Medicine Europe (ex AIPES) is a European Industrial Association working on promotion, awareness and defence of Nuclear Medicine and Molecular Healthcare in Europe. We are active in the field of Imaging and Therapy with Molecular and Radioactive Tracers. The main objective of our association in this field is to ensure the promotion of the economic and/or commercial interests of its Members, in particular, by all means allowing to increase the awareness to the benefits of the products and services they offer

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