



THE EANM POLICY BULLETIN

SHAPING THE FUTURE OF NUCLEAR MEDICINE IN EUROPE TOGETHER

Welcome to the EANM Policy Bulletin!

This newsletter provides you with an overview of policy updates related to nuclear medicine, hand-picked by the EANM just for you. Read below about:

- **Cooperation & Community Involvement**
- **Publications & Positioning**
- **Policy Initiatives & Political Developments**
- **Events**
- **Statement**

Should you wish to bring any questions, feedback or inquiries forward, please contact the EANM via [e-mail](#).

Enjoy reading!

COOPERATION & COMMUNITY INVOLVEMENT

Launch of the CLAUD-IT Project

Since September 1st, 2024, the EANM has been a key partner in **the new EU4Health project**, organised in collaboration with [the European Institute for Biomedical Imaging Research \(EIBIR\)](#) and 11 clinical partners from across Europe. **The CLAUD-IT project aims to implement clinical audits in Europe** through a practical and multidisciplinary approach.

Over the next 36 months, the consortium will work to achieve the project's vision, assisting Member States in implementing clinical audits, a critical requirement of [the Basic Safety Standards Directive](#). This initiative will enhance the quality and safety of healthcare for patients across Europe. The project will develop a comprehensive clinical audit guidance and toolbox for nuclear medicine, with a staged implementation approach. Clinical audits will be carried out in hospitals across 9 EU Member States by local multidisciplinary teams, under external guidance.

The project officially launched with a two-day kickoff meeting on September 12-13, 2024, at the University of Barcelona, Spain. Stay tuned for updates!



CLAUD-IT WEBSITE

RLT Academy: A Successful Conclusion of the Project

The Erasmus+ Radioligand Therapy (RLT) Academy, led by KU Leuven and involving 14 organisations from 9 EU countries, was successfully **completed on July 31, 2024**.

This project was kindly supported by the European Commission (ERASMUS+) and has been the EU's **first project to offer specialised training and resources specifically designed for RLT healthcare providers and trainees across Europe and beyond**.

Over the last two years, the consortium has worked on bridging the knowledge gap in RLTs and on facilitating their integration into standard cancer care protocols. The journey began with a comprehensive analysis of the [current training landscape on RLTs](#), pinpointing key educational deficiencies and evaluating the training needs of the target audience.

The EANM wants to thank again everyone who contributed to this joint effort. We are also pleased to report that the [RLT Academy online learning platform](#), which was launched on April 4, 2024, has been a huge success. After the end of the project, the online learning platform will remain accessible to all!

If you would like to learn more, make sure to read the [RLT Academy Policy Recommendations](#).



MARLIN Project: Introducing Best Practice Consensus Guidelines

Over the past two years, the MARLIN consortium has gathered and analysed information on the implementation of [Council Directive 2013/59/Euratom](#), focusing on the requirements for reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine, as well as interventional and diagnostic radiology. This effort has resulted in the development of best-practice consensus guidelines.

As a member of the Advisory Board for this 24-month initiative - in collaboration with EIBIR, ESTRO, and EFOMP - the EANM ensured that the perspectives of the Nuclear Medicine Community were integrated into the development of the Practice-Specific Guidelines and Recommendations.

On September 5 and 6, 2024, the EANM participated in the MARLIN workshop in Brussels, where the progress and outcomes of the project were discussed. This event centred on the project's work, focusing on the creation of guidelines and recommendations to enhance incident reporting and learning in radiotherapy, interventional cardiology, nuclear medicine, and radiology.



[MARLIN PROJECT WEBSITE](#)

PUBLICATIONS

Joint Research Center Report: Research and Innovation for Sustainable Medical Radionuclide Supply in the EU

Building on the momentum from the European Commission's Karlsruhe workshop in November 2023, which focused on 'Research and Innovation for Sustainable Medical Radionuclide Supply in the EU', **the Joint Research Center has recently published a new report.**

The report highlights the **research and innovation required to ensure the continuous availability and advancement of medical radionuclide production, a crucial element for the future of nuclear medicine within the EU.** Its objectives are twofold: to assess the current state of radiopharmaceutical production and to spark discussions around emerging infrastructures and innovative methodologies that could reshape nuclear medicine.

As an outcome of the workshop, the report seeks to initiate the **development of an action plan aimed at overcoming obstacles to efficient radionuclide production and distribution.** This plan would help accelerate the transition from research and development to clinical application, strengthening the EU's leadership in this vital healthcare sector.

The report presents several key recommendations, including:

1. Establish dedicated funding for nuclear medicine that supports alternative, more localised production methods for radioisotopes, alongside large centralised production, considering the isotopes' half-life.
2. Strive for EU autonomy in maintaining a continuous, stable, and uninterrupted supply of medical radionuclides, especially considering the growing demand for certain radionuclides, such as alpha emitters.
3. Develop a mechanism to better coordinate current and future EU/Member State initiatives on both supply security and research & innovation, ideally supported by a strong, stable European initiative on radioisotopes.
4. Harmonise the requirements for clinical trials with radiopharmaceuticals across EU Member States, including standardised timelines for approval.
5. Address regulatory issues related to radiation protection, including harmonising guidelines for hospitalisation length following routine radiopharmaceutical treatments.

FULL REPORT

Euratom Supply Agency: 2023 Annual Report

As part of the ESA Annual Report, Michael Hübel, the new Director-General of the Euratom Supply Agency, provides an insightful overview of EU developments in the supply of medical radioisotopes.

The report highlights the significant progress made by the European Commission over the past year in implementing [the SAMIRA Action Plan](#), detailing various European projects focused on the non-power applications of nuclear technology, as well as ongoing studies and research in Europe.

For more information on the conversion of high-performance research reactors, [PRISMAP](#), [TOURR](#), and [SECURE](#), we encourage you to review [the full report](#).

POLICY DEVELOPMENTS

Revision of the European Pharmaceutical Legislation: Ensuring a Flexible Regulatory Framework for Radiopharmaceuticals

In the context of [the revision of the EU Pharmaceutical Legislation](#), the EANM regrets that its proposed recommendations were not included in the European Parliament's final position. **THE EANM is concerned that the current regulatory framework for radiopharmaceuticals is inadequate, potentially preventing Europe from leading future advancements in the field.** As a result, modern radiopharmaceuticals will continue to face challenges within the existing regulatory system.

With the focus now shifting to the Council of the EU, the EANM urges policymakers to reconsider the development of radiopharmaceuticals. [The EANM Policy & Regulatory Affairs Council](#) is actively working with representatives from EU Member States in these crucial negotiations, which could have a lasting impact on Nuclear Medicine.

The EANM is advocating for:

- Recognition of the unique characteristics of radiopharmaceuticals through updated definitions.
- Harmonisation of regulatory perspectives and requirements for the preparation of radiopharmaceuticals.
- Acknowledgment of the special status of in-house production.

[FIND OUT MORE](#)

EVENTS

Workshop on Basic Safety Standards Provisions

On October 3 and 4, 2024, the EANM will participate in a project workshop in Luxembourg focused on the review and analysis of the transposition and implementation of the Basic Safety Standards provisions concerning the Radiation Protection Expert (RPE), Radiation Protection Officer (RPO), and Medical Physics Expert (MPE) in EU Member States.

During this two-day event, the final analysis, key findings, and preliminary recommendations will be presented. Stay tuned for updates!

Register for the EANM'24 Congress!

Each year, the EANM Annual Congress features plenary lectures, free paper sessions, symposia, and debates on the latest advancements in nuclear medicine, drawing over 7,000 participants from around the globe.

This year, the EANM Congress will take place in Hamburg on October 19-23, 2024. In this setting, the EANM aims to highlight the progress of [the SAMIRA Action Plan](#) to address the preparation of radiopharmaceuticals and related regulatory challenges in both daily clinical practice and research.

Save the Date! Join us **on October 22, 2024, for two EU Policy Symposia:**

1. Bridging the Basic Safety Standards – Navigating Legal Complexity in Member States
2. Empowering Tomorrow – The Strategic Role of the Nuclear Medicine Community in EU Projects & Tenders on Workforce

We look forward to seeing you there!

[EANM'24 PROGRAMME](#)

STATEMENT



"The EANM is thrilled to celebrate the successful completion of several EU-funded projects and tenders, which have produced remarkable advancements in nuclear medicine. As we embark on new initiatives, we are excited about their potential to further drive innovation in the field. We sincerely thank the European Commission for their ongoing support and express our deepest appreciation to the volunteers whose dedication has been instrumental in making these projects a reality."

Michel Koole
EANM Scientific Liaison Officer



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