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on a Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)

SAMIRA: Strategic Agenda for Medical Ionising Radiation Applications

An Action Plan for security of radioisotope supply, quality and safety, and technological development and innovation

1. INTRODUCTION

Nuclear and radiation science and technologies play an important role and provide a wide range of benefits to EU citizens in many areas beyond the production of nuclear energy, in particular in relation to human health. These technologies are indispensable in the fight against cancer and contribute significantly to all stages of cancer patients' care, including early detection, diagnosis, treatment and palliative care[1]. This is why this Action Plan is closely linked, and intended as a contribution, to the main objectives of the Commission's "Europe's Beating Cancer Plan" initiative[2]. The activities included in the SAMIRA Action Plan serve one common objective: to ensure that EU citizens have access to high quality radiological and nuclear technologies in medicine, at the highest safety standards.

Several EU policies influence these technologies, notably Energy policy activities on radiation protection and the supply of radioactive material, but also EU policies in the areas of Health and Research. The Council has consistently supported EU actions on the supply of radioisotopes and on non-power applications. Most recently, in June 2019, the Council adopted conclusions that specifically call upon the Commission to deliver an Action Plan in this respect[3].

This Action Plan responds to the Council's call for action in the priority areas of securing the supply of medical radioisotopes, improving radiation quality and safety in medicine and facilitating innovation and the technological development of medical ionising radiation applications. It further builds upon the preparatory activities carried out by the Commission over the past three years[4].

Notwithstanding their focus on cancer, the actions included in this Plan are expected to have a positive impact on the uses of ionising radiation in medicine and human health

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1 WHO list of priority medical devices for cancer management, World Health Organisation, 2017

2 https://ec.europa.eu/health/non_communicable_diseases/cancer_en

3 Council Conclusions on non-power nuclear and radiological technologies and applications, 9437/19 https://data.consilium.europa.eu/doc/document/ST-9437-2019-INIT/en/pdf

4 https://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/radiation-medical-use

more generally, including in the management of other non-communicable and infectious diseases[5].

2. SUPPLY OF MEDICAL RADIOISOTOPES

2.1. Why is it important?

Medical radioisotopes play a vital role in diagnosing cancer, cardiac conditions and other diseases, and are increasingly used for cancer treatments. Over 10,000 hospitals worldwide use radioisotopes in about 100 different nuclear medicine procedures totalling almost 49 million medical procedures each year. In the EU alone, more than 1500 nuclear medicine centres deliver about 10 million procedures to patients each year[6].

Nuclear medicine is an important tool for cancer management, contributing to early cancer diagnoses and prognostic assessments aimed at helping doctors to make critical decisions and tailor the treatment to the patient's needs. Depending on the national practices, up to 65% of nuclear medicine procedures are performed in oncology, potentially translating to more than 6 million procedures in Europe alone. The therapeutic use of medical radioisotopes in cancer therapy is increasingly expanding, with a forecasted considerable growth of the market for novel therapeutic radiopharmaceuticals by 2030[7].

Europe, with its unique supply network, innovative technology developments and strong clinical research commitment, plays a central role in the nuclear medicine domain. The EU is the leading supplier of medical radioisotopes to the world market, with a market share of more than 60% for some of the most widely used radioisotopes[8]. Some of the most important recent pharmaceutical and clinical developments in nuclear medicine cancer treatment originated in the EU.

Currently the main source of radioisotopes are research reactors, with several other technologies that use cyclotrons or linear accelerators in use or under development. The different radioisotopes and production technologies rely on highly specialised complex supply chains, which often extend across countries and continents and involve 24/7 "just-in-time" delivery.

2.2. What issues do we face?

There is a need to secure the supply of medical radioisotopes in the medium to long term, in order to maintain EU patients' access to vital medical procedures and support the development of new treatments to help in the fight against cancer. A strategic approach in this area will need to address issues relating to supplies of

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[5] These technologies contribute directly to nine of the Sustainable Development Goals set out in the UN 2030 Agenda for Sustainable Development, https://www.iaea.org/about/overview/sustainable-development-goals

[6] SMeR study on sustainable and resilient supply of medical radioisotopes in the EU (JRC/BRU/2017/A.7/0001/0C)

[7] MEDraysintell Nuclear Medicine Edition 2019, http://medraysintell.com/

[8] Namely, Molybdenum-99 (Mo-99) and its daughter product Technetium-99m (Tc-99m), used in 80% of all nuclear medicine diagnostic procedures worldwide

source materials and the replacement of ageing production infrastructures, and support the long-term sustainability and public acceptance of these technologies.

All available and potential methods of producing radioisotopes involve supply chains that need source materials that are not readily available in the EU. In particular, the production of some of the most widely used medical radioisotopes requires High-Assay Low Enriched Uranium (HALEU)[9], which is currently delivered from limited stocks available in the US or from Russia. Moreover, the production of traditional and novel medical radioisotopes through non-fission methods requires other source materials that are often in limited supply from sources outside the EU[10].

The EU research reactors currently used for producing medical radioisotopes are on average 40 years old and experiencing ageing issues. Besides the need for regular planned maintenance, they are prone to unplanned shutdowns, which cause production interruptions and potentially serious radioisotope shortages. Many of these reactors are approaching the end of their lifetime and will need to undergo major refurbishments, or be replaced with new reactors or by other production facilities by 2030. This will require significant investment but also creates an opportunity for efficiency and sustainability gains through technological innovation in the radioisotopes supply chain.

Production of radioisotopes for medical applications implies the generation of radioactive waste and spent fuel. Therefore, it is paramount to consider the full life cycle, by ensuring the safe and responsible management of radioactive waste resulting from medical applications. While the Euratom legal framework[11] includes requirements contributing to this purpose, further action is needed to ensure its proper implementation at Member States' level.

2.3. What have we done so far?

The critical importance of the security of supply of medical radioisotopes was illustrated in 2009-2010, following a severe supply crisis that resulted in the cancellation or delay of important diagnostic tests for many patients and exposed the fragility of the current production chain. This prompted the adoption, in 2010, of a Commission Communication[12], followed by Council Conclusions[13], which analysed the situation and proposed a set of principles and actions to ensure the sustainable production of radioisotopes in the EU.

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[9] Uranium enriched to just below 20% uranium-235 (usually 19.75% enrichment)

[10] E.g. Russia is the sole supplier of source material for production of Lutetium-177 for cancer therapy

[11] In particular, but not exclusively, Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste

[12] COM(2010)423 - Communication from the Commission to the European Parliament and the Council on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine

[13] Towards the Secure Supply of Radioisotopes for Medical Use in the EU, 3053rd Employment, Social Policy Health and Consumer affairs Council meeting, 6 December 2010

In response to the Council Conclusions, the European Commission and industry stakeholders[14] jointly established, in 2012, a European Observatory on the Supply of Medical Radioisotopes, with the aim of supporting the continuity of supply of medical radioisotopes. The Observatory proved to be a successful mechanism for achieving the objectives set by the Council, in particular with respect to coordinating production and supply activities of the various players and avoiding major shortages, including during the Covid-19 crisis. Nevertheless, there are still challenges related to the supply of radioisotopes in the medium to long term and to the development of novel radioisotopes and production methods, which go beyond the Observatory's mandate.

The EU radioisotopes supply situation was assessed in a 2018 Commission study[15], which examined a significant amount of evidence and identified issues and potential remedial actions. In February 2019, the Commission organised a dedicated workshop to investigate the challenges and opportunities in this area. In 2019, the Commission also published a study on Member States' good practices and differences in the use of diagnostic radioisotopes and the impact of health systems' reimbursement mechanisms[16]. The study concluded that there is space to improve the flexibility and transparency of the supply chain and the reimbursement of diagnostic radioisotopes.

The EU has already provided significant financial support for projects contributing to the security of supply of medical radioisotopes. Euratom funds have been made available for developing Low Enriched Uranium (LEU)[17] fuels[18] and as support for new research reactor projects[19]. The European Regional Development Fund, as well as the European Investment Bank, have also supported projects for the supply of radioisotopes in Member States[20,21].

2.4. What do we want to achieve? General objectives

The Commission is committed to securing the supply of medical radioisotopes in the European Union, in order to ensure that European patients reap their full benefits in battling cancer and other diseases. Notwithstanding the achievements of the past decade in stabilising the EU's radioisotopes supply, there is significant scope for further action to secure and develop the radioisotope supply for the coming decades. This Action Plan aims to support the domestic supply of source materials, reduce the

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[14] Mainly through the industry association of nuclear medicine (NM-EU), http://nuclearmedicineeurope.eu

[15] European study on medical, industrial and research applications of nuclear and radiation technology, February 2019 ('SAMIRA study'), ISBN 978-92-79-99659-7

[16] JRC SMeR study, referenced above

[17] Uranium enriched to below 20% uranium-235

[18] EUR 20.45 million granted in 2015-2020 for HERACLES-CP, LEU-FOREvER and EU-Qualify projects

[19] Euratom is supporting the Jules Horowitz Reactor in France and will hold 6% of the access rights for the total amounting of about EUR 38 million. The MYRRHA project in Belgium was supported with about EUR 36 million in Euratom cross-cutting research grants.

[20] https://www.world-nuclear-news.org/Articles/NRG-receives-funding-for-nuclear-medicine-R-D-cent

[21] https://itm-radiopharma.com/news/press-releases, 2/11/2020

EU's dependence on foreign suppliers, and enable and accelerate the development of new radioisotope production methods. It further seeks to improve the long-term sustainability and resilience of radioisotope supply chains through strengthening the EU monitoring of radioisotopes supply, enhancing the safety of research reactors in the long term, and supporting the safe and responsible management of radioactive waste resulting from medical applications.

2.5. How will we achieve it? Main Action Plan proposals

2.5.1. European Radioisotope Valley Initiative (ERVI)

Specific goals and objectives

The European 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. The intention is that ERVI will boost the sector and help set the priorities for the future by securing long-term commitments and resources for investment in radioisotope research and production infrastructures. The initiative should bring together the key stakeholders playing a role in the development of nuclear imaging and therapy compounds.

ERVI should become a European centre of excellence based on collaborations and partnerships. On one hand, it should be a breeding ground for the development of new or improved nuclear medicine techniques and technologies by establishing interdisciplinary collaborations between various research groups. On the other, it should be a platform for industrial-scale producers of medical radioisotopes and source materials, aiming to support a secure, resilient and sustainable supply.

Subject to discussion and the agreement of all actors, ERVI could have the following specific objectives:

- to facilitate access to the source materials needed to produce medical radioisotopes, through both fission and other production methods, aiming at developing domestic production to reduce the EU reliance on foreign suppliers;

- to improve the efficiency and further optimise industrial-scale production of radioisotopes, aiming at supply security, flexibility, resilience and sustainability;

- to develop new production methods through networking actors and promoting advanced research on innovative techniques and technologies of production.

Main deliverables and timelines:

Action	Deliverables	Indicative time-table	Funding and lead DG
European Radioisotope Valley Initiative (ERVI)	Engagement with stakeholders and potential partners	2021	EU general budget **DG ENER**, ESA, SANTE
	Develop scenarios and feasibility studies	2022	EU general budget **DG ENER**, JRC, RTD
	Preparation of legal framework (if needed)	2023	EU general budget **DG ENER**
	Official launch	2024	EU general budget **DG ENER**, SANTE, RTD, JRC, ESA

Engagement with stakeholders and potential partners

To start a process towards the objectives set out above, the Commission services will bring together the relevant actors to discuss the need, feasibility and the design of ERVI. The main potential partners will be identified among institutional, industrial and research stakeholders, by consulting the European Observatory on the Supply of Medical Radioisotopes and the relevant Member States and expert groups in the nuclear[22], health[23] and research[24] areas. The Commission services intend to create a stakeholder group – a combination of academic centres, state-of-art research laboratories, best-practice production infrastructures and leading healthcare institutions – in order to take forward the initiative.

A dedicated workshop with representatives of Member States, stakeholders and patients will kick off a public consultation on the process towards a common set of ERVI objectives.

Develop scenarios and feasibility studies

The results of the public consultation will be analysed and summarized together with the stakeholder group. For the most important identified objectives, scenarios and potential measures will be developed and examined for feasibility. Co-funding sources and R&D partners will be identified.

Preparation of the legal framework

Based on the preparatory work, agreed interest in committing resources and their form, the Commission services will consider working towards a legal framework for

[22] The Council Working Party on Atomic Questions, the ESA Advisory Committee, etc.

[23] DG SANTE will provide links with national and regional stakeholders for identification of public health priorities and on assessment of diagnostic and therapeutic needs, through existing mechanisms, such as SGPP. Other SANTE groups and activities, e.g. on information systems, data collection and monitoring, etc., will be involved, where necessary.

[24] For example, the Euratom Scientific and Technical Committee (STC)

the initiative encompassing all prior agreed objectives. The most appropriate set-up will be discussed and agreed with the partners.

Establishment of the mandate and operational arrangements

The mandate and operational arrangements of the initiative will be developed in detail, with the help of an advisory board consisting of leading institutional, industrial and research partners, as well as EC and Member State representatives. Stakeholders from the Energy, Health and Research areas will be involved, in order to facilitate the policy- and decision-making process with respect to research and technology priorities.

Official launch

The intention is to launch the initiative at a dedicated high-level public event, aiming at mid-2024.

2.5.2. Supply of source materials for radioisotopes production

Specific goals and objectives:

The Euratom Supply Agency (ESA) will continue to identify the potential risks to the security of supply of High Enriched Uranium (HEU)[25] and HALEU and to strive to secure sufficient supplies, in compliance with international nuclear security and non-proliferation commitments. To this end, ESA will closely cooperate with the Member States concerned and the US Department of Energy (DoE) under the umbrella of the 2014 Memorandum of Understanding (MoU) on the exchange of HEU. It will further strategically examine feasible long-term supply alternatives with a view to achieving either self-sufficiency (domestic production) or strong guarantees of a reliable supply of HALEU. This action will further seek to diversify the EU supply of non-fissile source materials for the production of medical radioisotopes, with the ultimate objective of reducing dependence on external suppliers.

Main deliverables and timelines:

Action	Deliverables	Indicative time-table	Funding and lead DG
Supply of source materials for radioisotopes production	Support short- to medium-term supply of HEU	2021-2030	EU general budget **ESA**
	Explore option for European production of HALEU	2021-2025	EU general budget **ESA, ENER**
	EU support for domestic supply of source materials	2025-2030	Horizon Europe **DG ENER, DG RTD**

[25] Uranium enriched to more than 20% uranium-235

Support short- to medium-term supply of HEU

ESA will hold annual review meetings with the US and the Member States concerned to monitor progress and to allow for the effective implementation of the 2014 MoU between US DoE/NNSA and ESA concerning the exchange of HEU needed for European research reactors and radioisotope production facilities. Amounts of HEU supplied by US and estimated future needs will be reviewed on an annual basis.

The future review of the applicability of the MoU, required after five years in force, will be discussed at the next meeting[26]. This could lead to a revision of the MoU.

Explore options for European production of HALEU

ESA will follow-up on its report on Securing the European Supply of 19.75% enriched Uranium Fuel[27]and examine the option of building a European capacity for the production of metallic HALEU. To this end, ESA will reinstate its dedicated Working Group with the Member States concerned, international partners and the European industry representatives, with the aim to assess the political and industrial willingness, agree on the strategic objectives and identify cooperation pathways for the future supply of HALEU.

Based on the results of the Working Group, an industrial roundtable for EU and international stakeholders will be organised, in order to define concrete cooperation actions along the lines agreed among the EU stakeholders. In parallel, options for Euratom research in support of a future domestic HALEU supply, as identified by the Working Group, will be examined.

EU support for domestic supply of source materials

As a first step, the European Commission – through a contractor – is collecting information with respect to the supply chains of the main medical radioisotopes already in use or in an advanced stage of clinical development. In the next stage, the project will develop scenarios and technology options for a sustainable and secure supply of medical radioisotopes in the EU.

Based on the above work, the Commission, in cooperation with the emerging ERVI stakeholders, intends to define the need for EU-funded research and other forms of support needed to develop and roll out a domestic supply of source materials for the production of medical radioisotopes. Horizon Europe's Health and Industry clusters should play a key role in supporting research needs in this area, in close cooperation with the relevant Euratom research actions.

[26] Scheduled to take place before the end of 2020.

[27] https://ec.europa.eu/euratom/docs/ESA_HALEU_report_2019.pdf

2.5.3. Support long-term sustainability of radioisotopes production in Europe

Specific goals and objectives:

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. The first objective will be to ensure a continuous monitoring of the supply of the full range of medical radioisotopes, taking into account the evolution of the supply chain, including new alternative production methods and technologies and novel medical radioisotopes. The actions in this area will further seek to deliver on the Council's call for EU research support on topics related to improved fuels for the production of medical radioisotopes and optimised use of European research reactors. The Commission services intend to support the safe long-term operation of European research reactors through the implementation of periodic safety reviews and follow-up on initiatives to improve ageing management and to develop safety reference levels for European research reactors. Finally, the intention is to support the emergence of appropriate conditions – including political commitments and societal acceptance, as well as technical and legal solutions – for sharing of storage and disposal solutions between Member States[28], and improve reporting at EU and Member State level on radioactive waste from non-power applications.

Main deliverables and timelines:

Action	Deliverables	Indicative time-table	Funding and lead DG
Support long-term sustainability of radioisotopes production in Europe	EU monitoring of supply of medical radioisotopes	2022-2030	EU general budget **ESA**
	Support research reactors conversion to HALEU	Ongoing	Euratom research programme **DG RTD**
	Roadmap for optimised use of research reactors	2023	Euratom research programme **DG RTD**
	Ensure safe long-term operation of research reactors	2023	EU general budget **DG ENER**
	Ensure safe and responsible management of waste resulting from medical applications	2023	EU general budget **DG ENER**

<u>EU monitoring of supply of medical radioisotopes</u>

In cooperation with the Observatory members and the emerging ERVI stakeholders, a revision of the Observatory's mandate and structure will be initiated, in order to provide regular monitoring and long-term forecasts for a broad spectrum of radioisotopes and production methods. Subject to stakeholders' endorsement of the revised mandate and appropriate resource allocation, the Observatory should systematically review the supply situation and produce reports and long-term

[28] As recognised by the Council, decisions for such sharing are under the competence of the Member States.

forecasts, in order to provide greater certainty for investment in the supply chain. The evolution of the Observatory should take into account the possible development of ERVI, and aim to feed it with the data required for strategic foresight, policy development and strategy shaping.

The lessons learnt from the Covid-19 crisis, in particular with respect to engaging with institutional stakeholders from the areas of health and border controls, will also be taken into account.

Support research reactors conversion to HALEU

In order to ensure a sustained production of medical radioisotopes in line with international nuclear security and non-proliferation objectives[29], the Commission is supporting the conversion of High Performance Research Reactors (HPRRs) to LEU[30,31] through the Euratom research programme. Euratom is contributing to the development of high-density LEU fuels through different phases, including the establishment of scientific basis[31,32] and generic fuel qualification[33].

Roadmap for optimised use of research reactors

In addition, a Euratom action is underway[34] to develop a roadmap for the optimised use of research reactors in Europe, in particular, in the area of radioisotopes.

Ensure safe long-term operation of research reactors

Based on the ENSREG progress reports[35], the Commission services intend to follow up with Member States on the recommendation of the 1st topical peer review under the Nuclear Safety Directive with respect to ageing management of research reactors[36]. They will further support exchanges between national authorities, technical support organisations and licensees with respect to the management of safety-related issues that could affect the safe long-term operation of research reactors and, through ENSREG, follow on the WENRA plan to develop and issue Safety Reference Levels for Research Reactors[37].

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29 The Hague Nuclear Security Summit 2014, https://2009-2017.state.gov/documents/organization/237002.pdf

30 Europe's HPRRs initiative HERACLES https://www.heracles-consortium.eu/index.php

31 HERCALES-CP project, running from 2015 to 2020, https://cordis.europa.eu/project/id/661935

32 LEU-FOREvER running from 2017 to 2021, https://cordis.europa.eu/project/id/754378

33 EU-QUALIFY project running from 2020 to 2024, https://cordis.europa.eu/project/id/945009

34 TOURR project, running from 2020 to 2023, https://cordis.europa.eu/project/id/945269

35 ENSREG – the European Safety Regulators Group – peer review report on the implementation of the national action plans, due in December 2021, update foreseen for May 2024

36 "*Systematic and comprehensive Overall Ageing Management Programmes are implemented for research reactors, in accordance with the graded approach to risk, the applicable national requirements, international safety standards and best practices.*"

37 Section 9.7. 'Main results regarding Research Reactors', ENSREG 1st Topical Peer Review Report, "Ageing Management", October 2018

Ensure safe and responsible management of waste resulting from medical applications

Based on the ENSREG position[38] on best practices in national management systems for radioactive waste generated from non-power use of nuclear and radiation technology, the Commission services will follow up by engaging relevant stakeholders (administrations, regulators, agencies, waste producers) in a roundtable to further discuss best approaches and identify common practices to set standards under the relevant European legal requirements. The intention is that the third report from the Commission to the European Parliament and the Council on the implementation of Council Directive 2011/70/Euratom will specifically address the results of the previous action, e.g. with respect to inventories of radioactive waste from non-power use of nuclear and radiation technology. In parallel, a recommendation on radioactive waste classification schemes – including its view on specificities of radioactive waste from non-power use of nuclear and radiation technology – could be developed, providing the Member States with a tool to report inventories in a consistent manner.

3. QUALITY AND SAFETY OF MEDICAL RADIATION APPLICATIONS

3.1. Why is it important?

A variety of nuclear and radiation technologies play a key role in the fight against cancer. Mammography, computed tomography and other forms of radiological imaging are indispensable technologies for all stages of cancer management. Radiotherapy is among the most effective, efficient and widely used cancer treatments available to patients and physicians. Nuclear medicine is routinely used for cancer diagnosis and follow-up, and increasingly available for cancer treatment.

Notwithstanding the benefits that medical ionising radiation technologies bring to patients, the significant increase in the radiation exposure of the European population caused by the growing use of these technologies is a matter of concern. Medicine is now responsible for up to half of the total and more than 90% of the man-made radiation exposure of the EU citizens[39].

The Euratom Treaty defines a key EU competence for health and safety with respect to ionising radiation, and the Union has established an ambitious legal framework for protecting patients, volunteers in medical research and medical staff from ionising radiation[40]. This framework is a key driver for the quality and safety of medical applications of ionising radiation in Member States, and in everyday medical practice.

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[38] ENSREG work programme 2021-2023

[39] Calculated from EU-specific data for medical exposures and data about the total radiation exposure of the population around the world. Radiation Protection 180: Medical Radiation Exposure of the European Population, European Commission, 2015. Radiation Effects and Sources, United Nations Environment Programme, 2016

[40] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (BSS Directive)

This section of the plan sets out a series of actions to advance the quality and safety of medical procedures involving ionising radiation, with the aim of bringing tangible benefits to patients by ensuring that these procedures are used strictly in line with clinical needs. These actions provide an important contribution to the Europe's Beating Cancer Plan objectives of ensuring sustainable cancer prevention, supporting the early detection of cancer and ensuring access to high standards of diagnosis and treatment.

3.2. What issues do we face?

Developments in several areas of European policy have a direct influence on the quality and safety aspects of medical applications – for instance, recent revisions of the legal frameworks for radiation protection and for medical devices[41] are expected to bring significant benefits to EU patients and medical staff in coming years.

Notwithstanding these developments, there are a number of areas where action could be undertaken to further advance the quality and safety of these applications. The implementation of the Euratom BSS Directive has proven to be particularly challenging in areas requiring changes in the organisation and resource allocation in healthcare, such as clinical audit, appropriate use of imaging and availability of medical physicists[42]. In addition, the introduction of new technologies, including decision support and AI systems, calls for a greater involvement of equipment manufacturers in ensuring the quality and safety of its clinical use.

The different medical uses of ionising radiation pose specific challenges with respect to radiation protection and safety, some of which are described below:

- With about 500 million procedures carried out in the EU annually, radiological imaging is by far the most widespread form of medical application of ionising radiation. Computed tomography (CT) alone is responsible for less than 10% of the total number of radiological imaging procedures in Europe, but for more than 60% of the radiation dose. At the same time, 20 to 40% of the CT studies may not be clinically justified[43] and the use of CT can be significantly improved through better justification and optimisation. According to the industry[44], excessive ageing of the CT equipment installed in Member States makes it impossible to realise the full benefits of recent advances in dose reduction technologies. The use of interventional radiology poses challenges also from an occupational protection perspective.

- With 1.5 million treatments in Europe annually, radiotherapy is an indispensable part of modern cancer treatment. Huge discrepancies exist among Member States in terms of access to modern equipment and availability of qualified staff to

[41] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, fully applicable from May 2021, https://ec.europa.eu/health/md_newregulations/overview

[42] http://www.eurosafeimaging.org/bss-transposition

[43] Several surveys in Luxembourg, Northern Ireland and Sweden

[44] COCIR, European Trade Association of the medical imaging, radiotherapy, health ICT and electromedical industries (http://www.cocir.org)

operate it safely and effectively[45]. While high-income European countries are generally well served with radiotherapy resources, other Member States face important shortages, especially of modern machines capable of delivering high-precision treatments. Additionally, there is a disparity between the skills and workload of personnel across Member States, while equipment is becoming increasingly complex. Radiotherapy accidents are very rare but have the potential to cause severe harm to patients, should they occur[46].

- Nuclear medicine has been predominantly used for diagnostic purposes, which traditionally involved the handling of small amounts of short-lived radioisotopes by specialised departments. The increasing availability of radionuclide cancer therapies, combined with the lack of trained staff and proper facilities in some Member States, poses specific challenges with respect to ensuring quality and safety of treatments. Furthermore, there is an urgent need to include specific safety and efficacy data in clinical trials and drug authorisations, as well as to develop patient dosimetry and treatment planning procedures and introduce them in clinical practice. Issues relating to the hospital release of nuclear medicine patients and the management of hospital waste also exist.

Medical applications of ionising radiation are constantly evolving in a complex regulatory environment. For instance, medical radiation equipment is subject to the EU medical devices and the Euratom radiation protection legislations, both setting requirements for installation and acceptance testing, reporting of adverse events, etc. Furthermore, radiopharmaceuticals are regulated under the EU pharmaceutical and radiation protection regimes, with important implications for clinical trials, drug authorisations and routine clinical use. There is scope to improve coordination in implementing the different regulatory frameworks.

The significant growth and technological innovation in medical uses of ionising radiation require a proportional growth in available human resources, and appropriate education and training for all categories of staff. This concerns, in particular, support staff with key responsibilities for quality and safety, such as medical physicists, radiographers, radiotherapy technologists and radiopharmacists.

3.3. What have we done so far?

Euratom legislation on radiation protection in medicine was first adopted in the 1980s, followed in 1997 by new legislation which considerably expanded and strengthened the rules in this area[47]. The legal system aims to ensure that medical ionising radiation procedures are used only when appropriate and with the minimum clinically needed radiation dose. It also includes requirements with respect to staff, procedures and equipment in use, and mandates a number of quality and safety tools, with particular attention to applications involving high radiation doses and/or childhood exposures to ionising radiation. The 2013 revision of the Euratom Basic

[45] Radiotherapy equipment and departments in European countries: Final results from the ESTRO-HERO survey. Radiotherapy and Oncology 112 (2014)

[46] Epinal and Toulouse accidents in France, US cases, resulting in mass media attention (Le Figaro, NYT, etc.)

[47] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom

Safety Standards (BSS) Directive brought important changes to radiation protection in medicine, in particular with respect to the recording of radiation doses, the role of medical physicists, risk assessment and accident learning systems.

In 2010, the Commission issued a Communication[48], which identified the challenges facing radiation protection in medicine and proposed actions to address them. As a result, besides its legislative action, the Commission has launched numerous studies and support activities to help collect evidence, identify good practices and provide guidance to Member States and stakeholders[49]. Other relevant EU work has been carried out through the European Commission Initiative on Breast Cancer (ECIBC), which provides European guidelines, good practice recommendations and training resources[50].

In 2015, the Council issued conclusions on "Justification of medical imaging involving exposure to ionising radiation", calling upon Member States to improve the use of referral guidelines and clinical audit and stressing the importance of raising awareness, education and training, and defining the responsibilities of healthcare professionals. The 2019 Council conclusions on non-power applications further call upon the Commission to "*improve radiation protection and safety for European patients and medical staff, in accordance with the objectives set out in the Directive 2013/59/Euratom*".

Medical radiation dose concerns have led to important international initiatives, notably the Bonn Call for Action issued in 2012 by the International Atomic Energy Agency and the World Health Organization[51]. European radiation protection authorities[52], industry and professional societies[53] have launched several cooperation initiatives on quality and safety of medical applications of ionising radiation.

3.4. What do we want to achieve? General objectives

The Commission is committed to ensuring that citizens receive the best possible protection from the carcinogenic effects of ionising radiation, while fully benefiting from the advantages it offers in battling cancer and other diseases. Notwithstanding recent developments in the European regulatory framework, there remains significant room for improvement of the quality and safety of medical radiation applications.

This Action Plan aims to support the implementation of high standards for quality and safety of medical radiation applications into Member States' health systems. It aims to establish improved EU coordination in this area and guide the complementary use of EU Energy, Health and Research programmes and

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48 COM(2010)423

49 https://ec.europa.eu/energy/topics/nuclear-energy/radiation-protection/scientific-seminars-and-publications/radiation-protection-publications_en

50 https://healthcare-quality.jrc.ec.europa.eu/

51 https://www.iaea.org/resources/rpop/resources/bonn-call-for-action-platform

52 HERCA – Heads of the European Radiological Protection Competent Authorities, www.herca.org

53 For example, European Society of Radiology's EuroSafe Imaging campaign, http://www.eurosafeimaging.org

instruments. It further seeks to reduce inequalities within and between Member States through improved workforce availability, radiation safety culture, education and training, and equal access to modern medical ionising radiation technology.

3.5. How will we achieve it? Main Action Plan proposals

3.5.1. European Initiative on Quality and Safety of medical applications

Specific goals and objectives:

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 Member States operate in line with high standards for quality and safety, in the interest of patients.

The Initiative will provide a common European platform to support the implementation and integration of European requirements for radiation protection and other quality and safety standards into the Member States' health systems. It will, in particular, develop high-quality evidence, clinical guidelines, medical devices standards and practical tools, and support their implementation in clinical practice across Europe. The actions in this area will further support the carrying out of clinical audits, as well as the identification and sharing of good practices in radiology, radiotherapy and nuclear medicine.

The Commission intends to implement a coordinated and collaborative approach to deliver complementarity of activities between different EU instruments and programmes. The Euratom BSS Directive provides the Union with a strong mandate for quality and safety in the medical uses of ionising radiation. The enforcement of the legal requirements in Member States will be complemented by coordination and support measures in the Energy, Health and Research EU policy areas, as follows:

- The Energy area will continue to provide an up-to-date legal basis under Euratom, as well as monitor and enforce the implementation of Euratom legal requirements in Member States. It will further provide implementation support through commissioning relevant reports and guidance, and through engaging with Member States authorities, European professional and industry stakeholders and international organisations.

- The Health area will provide a link to the national authorities and stakeholders involved in the definition of public health priorities, and support relevant actions under the EU4Health programme[54]. In particular, support under the Health portfolio will cover the areas of clinical audit, education and training of medical professionals, coordinated implementation of the EU radiation protection, medical devices and pharmaceutical policies, and sharing of best practices in radiology, radiotherapy and nuclear medicine.

- The Research and Innovation area will focus on generating evidence and knowledge, developing evidence-based guidance and tools, and supporting

[54] Proposal for a Regulation of the European Parliament and of the Council on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme"), COM/2020/405 final

education and training of medical professionals and quality and safety attestation and certification. The support for these actions under the Horizon Europe Health cluster and the Cancer Mission, the Euratom Research and Training Programme, and the new JRC Knowledge Centre on Cancer[55], will help develop sustainable mechanisms for providing evidence-based knowledge for policy, while upholding independence from commercial, private and national interests.

Main deliverables and timelines:

Action	Deliverables	Indicative time-table	Funding and lead DG
European Initiative on quality and safety of medical applications	Build up EU governance for quality and safety	2021	EU general budget **DG ENER, DG SANTE**
	EU support action on quality and safety	2022	EU4Health **DG ENER, DG SANTE**, RTD, JRC
	Co-ordinated implementation of EU legislation and policies	2023	EU general budget **DG ENER**, SANTE
	Share good practices	2024	EU general budget **DG SANTE**, ENER, JRC

Build up EU governance for quality and safety of medical ionising radiation applications

In order to achieve the coordination and complementarity required in this area, the Commission services intend to create a specific group with Member States representatives from both the health and the radiation protection authorities, and will also liaise with patients, professional, researcher and industry stakeholders. The group will advise on the direction and the content of the Initiative, draw conclusions from relevant activities and projects, and support the implementation of project results in Member States. The Commission services intend to seek input from the Steering Group on Health Promotion and Disease Prevention (SGPP)[56] with regard to the membership and the mandate of the group and, where appropriate, present and discuss the results of its work with the SGPP.

EU support action on quality and safety in medical radiation applications

This action will primarily consist of generating high quality evidence and developing evidence-based guidance and practical tools needed to improve the quality and safety of medical ionising radiation applications. It will build upon Euratom actions on implementation of legislation[57] and research[58] , and will be further supported under

[55] To be launched by the end of 2020, EC Knowledge Centres – https://ec.europa.eu/jrc/en/knowledge

[56] https://ec.europa.eu/health/non_communicable_diseases/steeringgroup_promotionprevention_en

[57] QuADRANT project, http://www.eurosafeimaging.org/clinical-audit/quadrant

[58] MEDIRAD project, https://cordis.europa.eu/project/id/755523 ,

the Horizon Europe Health cluster, the EU4Health, and other relevant EU programmes. The first task would be to explore synergies and to define areas and mechanisms for cooperation between policy areas and programmes[59]. For instance, depending on the needs and feedback from Member States, Commission services and stakeholders, the JRC work on guidelines and training could expand into further medical applications of radiation[60].

This action will further support the implementation of clinical audits[61] into national health systems, in order to bring its full benefits to patients. The clinical audit action will, in particular, seek to improve justification of radiological imaging in line with the 2015 Council conclusions on this topic[62].

Coordinated implementation of European legislation and policies

This action will aim to coordinate the implementation of the Euratom requirements for radiation protection in medicine with the relevant elements of EU Health legislation and policy, including on medical devices, radiopharmaceuticals and electronic health records. In terms of medical equipment, it would be useful to explore common acceptance and performance testing procedures, standards with technical solutions in support of safety and performance requirements of the EU legislation on medical devices[63], as well as harmonize reporting of adverse events between the EU and Euratom legislation. In the radiopharmaceuticals area, activities should focus on improving the safety and efficacy of new therapies, in particular with respect to integrating patient-specific dosimetry and treatment planning into clinical trials and marketing authorization. Finally, the EU action of standardisation of electronic health records should consider appropriate ways of integrating information on patient radiation dose[64].

Moreover, actions should be foreseen to improve the cooperation between national regulators for radiation protection in medicine and those responsible for radiopharmaceuticals and medical devices, for example in the Medical Devices Coordination Group's (MDCG) expert group on New Technologies[65]. Appropriate mechanisms for regular exchanges between the appropriate EU Member States groups should be devised. This may include the creation of ad-hoc joint working parties, where necessary.

SINFONIA project, https://cordis.europa.eu/project/id/945196
HARMONIC project, https://cordis.europa.eu/project/id/847707

59 EURAMED rocc-n-roll project, https://cordis.europa.eu/project/id/899995

60 For example, through the new Knowledge Centre on Cancer

61 Clinical audit is mandated under the BSS Directive

62 Council conclusions on the Justification of medical imaging involving exposure to ionising radiation, adopted by the Council at its 3433rd meeting held on 3 December 2015

63 Harmonised European standards in support of the EU legislation on medical devices are developed by the European standardisation organisations CEN and CENELEC on a specific request by the Commission.

64 Through the eHealth Network, https://ec.europa.eu/health/ehealth/policy/network_en, and the European Electronic Health Record exchange format, https://ec.europa.eu/digital-single-market/en/exchange-electronic-health-records-across-eu

65 https://ec.europa.eu/health/md_dialogue/mdcg_working_groups_en#seven

Share good practice in quality and radiation safety of medical applications

This action will ensure that good practices in quality and safety of medical radiation applications are shared among Member States through the Commission Public Health Best Practice Portal[66]. The process of identification, validation and selection of priority practices for support under the EU4Health programme will follow the established procedures, and involve the SGPP as well as the new Member State Group, as proposed above.

3.5.2. Improve workforce availability and education and training

Specific goals and objectives:

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. This will be achieved by providing quality workforce information and forecasts, developing EU training curricula and accreditation schemes, and continuing EU support for students, researchers and professionals in radiology, radiotherapy and nuclear medicine. The activities in this area will support, in particular, networking and cooperation between the different concerned health professionals and medical disciplines. They should further take into account the needs associated with ageing populations in most EU Member States and the rapid innovation and technological development that has taken place in the medical sector.

Main deliverables and timelines:

Action	Deliverables	Indicative time-table	Funding and lead DG
Improve workforce availability, education and training	Support for researchers and professionals	2021	HE-MSCA **DG EAC**, ENER, SANTE
	EU monitoring on workforce availability, education and training	2022	EU4Health, HE **DG SANTE**, ENER, RTD
	EU training curricula and certification schemes in quality and safety	2024	EU4Health, HE **DG SANTE**, JRC, EAC

Monitor the staffing and education and training levels across the EU

The Commission intends to put particular emphasis on monitoring the national implementation of the BSS Directive requirements with respect to the availability, training and recognition of medical physics experts and other medical staff with key responsibilities for quality and radiation safety. The Commission intends to further use EU4Health to gather and publish up-to-date data with respect to staffing, education and training of key radiology, radiotherapy and nuclear medicine

[66] https://webgate.ec.europa.eu/dyna/bp-portal/

professionals in Member States. A graded approach will be used, prioritising higher-dose diagnostic and treatment procedures, such as radiotherapy, interventional radiology and computed tomography, as well as professionals involved in reporting and learning from adverse events.

EU training curricula and certification schemes

This action will aim to establish standardised European training curricula for the various categories of staff with responsibilities for quality and safety of medical radiation applications. It will further provide support for existing, or explore the creation of new, EU certification schemes for quality and safety in radiotherapy, radiology and nuclear medicine. The specific activities will build upon the previous task and involve European professional and scientific societies and other stakeholders in the areas of radiotherapy, radiology and nuclear medicine. Support will be provided through the EU4Health programme, in line with its defined objectives, as well as through the existing programmes and initiatives in the Research[67] and the Education[68] domains.

Support EU researchers and professionals

The Commission intends to continue to support students, researchers and healthcare professionals in radiology, radiotherapy and nuclear medicine through the established EU programmes in the Education and Training area. The actions in this area will build, in particular, upon existing Marie Skłodowska-Curie Actions (MSCA)[69] in the area of cancer prevention, prediction, detection, diagnosis and treatment[70]. The Commission proposal for the Euratom Programme 2021-2025 provides for synergies with Horizon Europe in this area by making MSCA fellowships available to researchers in radiation protection. Further mechanisms and programmes, such as the European Institute of Innovation and Technology (EIT) and the Knowledge and Innovation Communities (KICs), the Erasmus+ programme and the European University alliances, could be used depending on the particular needs and interest from Member States and stakeholders.

3.5.3. Equal access to modern technology and interventions

Specific goals and objectives:

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 timely manner, in line with the highest standards for quality and safety. It will further aim to improve the evidence base and transparency with respect to efficacy and safety of equipment and procedures in radiology, radiotherapy and nuclear

[67] Horizon Europe, Knowledge Centre for Cancer

[68] For example, through the Marie Skłodowska-Curie Actions (MSCA)

[69] For example, the DevelopMed project in precision oncology, and the adaptive particle therapy RAPTOR project

[70] Since 2014, the MSCA have funded 533 excellence research projects in the field of cancer, representing around 3000 researchers.

medicine through support for targeted research actions and clinical trials. Finally, the Commission intends to support the inclusion of key medical ionising radiation technologies in national cancer plans and explore with Member States opportunities for the development of specific plans for equipment replacement at national and EU level.

Main deliverables and timelines:

Action	Deliverables	Indicative time-table	Funding and lead DG
Equal access to modern technology and interventions	Improve the implementation of Council Directive 2013/59Euratom's requirements for medical equipment	2021	EU general budget **DG ENER**
	Improve evidence for clinical efficacy of novel cancer interventions involving ionising radiation	2022-2030	Horizon Europe **DG RTD**, SANTE
	Cover modern radiation technology in national cancer plans	2022	EU4Health **DG SANTE**, ENER, JRC

Improve the implementation of Council Directive 2013/59Euratom's requirements for medical equipment

The Commission intends to put particular emphasis on the national implementation of the BSS Directive requirements with respect to medical radiological equipment. The implementation monitoring will specifically follow the introduction in Member States of systems, devices and features for controlling, recording and reporting patients' radiation doses.

Improve evidence for clinical efficacy and effectiveness of novel cancer interventions

The Commission intends to use available instruments and initiatives under the EU4Health and the Horizon Europe programmes to gather and maintain up-to-date evidence on the efficacy, effectiveness and safety of novel cancer interventions involving ionising radiation, e.g. photon, hadron therapy and/or targeted alpha therapy (TAP). The actions in this area will focus on conducting multi-centre clinical trials to validate novel interventions to treat and care for patients living with cancer. They will further seek to improve access to clinical trial data (e.g. through a common European database), with the aim of creating a good evidence base and allowing Member States to make informed decisions about the introduction of new treatments into clinical practice.

National cancer plans and equipment replacement plans

This action will support the inclusion of key cancer diagnosis and treatment technologies involving ionising radiation into national cancer plans. Current evidence suggests that 40% of high-income countries do not address radiotherapy in their national cancer or non-communicable disease plans[71]. Continuous EU monitoring of national cancer plans[72] will aim to ensure that their updates take into account the best available evidence with respect to the value of radiation technology in cancer care.

A recent Joint Action on cancer care (CanCon) demonstrated the need for "enhancing the value of cancer care" through better use of healthcare interventions. Follow-up EU actions in this area should take into account the results of SAMIRA activities and extend to radiological imaging and radiotherapy equipment. Mechanisms for exchanging information between Member States and coordinating national plans and actions for introducing new technologies or major replacements and upgrades of equipment should be considered.

4. INNOVATION AND TECHNOLOGICAL DEVELOPMENT

4.1. Why is it important?

Modern radiation-based imaging and therapy are constantly progressing, leading to new and improved approaches to diagnosing and treating cancer and other major diseases. This rapid technological innovation is, on one hand, supported by significant private investment in research and development[73] and, on the other, has to respond to the needs of publicly funded health systems (in the EU). Issues of public interest, such as quality and safety of medical applications and supply of radioisotopes, are not always commercially attractive and will need public support, including at EU level.

The variety and scale of nuclear and radiation technologies used for healthcare purposes in the EU is staggering – from world-leading research reactors and high-energy particle accelerators, to everyday clinical uses of x-ray machines, smaller accelerators and radioactive substances in tens of thousands of European hospitals. Cancer interventions increasingly rely on novel radiation technology, such as image-guided radiotherapy, proton therapy, targeted radionuclide therapy and hybrid imaging, in order to advance precision and personalised treatments. The rapidly developing medical radiation technologies are becoming more complex and increasingly rely on automation, computerised decision support and AI systems.

In economic terms, the global market for medical equipment utilising ionising radiation is estimated to be about EUR 28 billion, with Europe accounting for about 30% of the market[74]. A number of major European companies and thousands of

[71] Radiotherapy: seizing the opportunity in cancer care, November 2018, https://www.estro.org

[72] Under the on-going Joint Action iPAAC and similar future actions

[73] Up to 8% of sales volume, https://www.cocir.org/our-industry.html

[74] European study on medical, industrial and research applications of nuclear and radiation technology, February 2019, ISBN 978-92-79-99659-7

small and medium-sized European enterprises operate in this market. The medical radiological equipment market employs over 60,000 workers in Europe and supports about 700,000 jobs in healthcare.

In its Conclusions on *Non-power nuclear and radiological technologies and applications* of 2019, the Council invited the Commission to support research on topics related to non-power applications of nuclear and radiological technologies, such as medical applications of ionising radiation, improved fuels for the production of medical radioisotopes and optimised use of European research reactors. The Council stressed the importance of delivering a research roadmap for medical applications in a timely manner.

4.2. What issues do we face?

The wide variety of radiation technologies and applications in healthcare calls for an in-depth analysis of the associated issues and identification of the research needs, in consultation with national authorities, professional organisations, industry, researchers and other key stakeholders. Furthermore, the identification of key needs and actions for European research into the medical applications of ionising radiation should cover the full spectrum of diagnostic and therapeutic applications of various technologies including x-rays, particle accelerators, radioisotopes and research reactors.

In addition to the specific challenges posed by the medical applications of ionising radiation, wider issues should be considered, such as the inequalities between EU Member States in accessing research and technological development infrastructures and programmes. Improving technology transfer from concept to application through better cooperation between the research community and the industry would also decrease the time required to put products on the market and improve access to innovative treatments across all Member States. The Commission's support for addressing these challenges will maximise the overall impact of the EU research and innovation programmes.

4.3. What have we done so far?

The Commission has supported research to improve the understanding of the effects of ionising radiation, including in medical applications, as well as for development of new viable technologies through the Euratom Research and Training Programme 2014-2020 and the Horizon 2020.

Euratom has also reinforced in recent years the research actions developing the knowledge base on risks from low dose of radiation[75], leading to improvements in the medical practices using ionising radiation. Most recently, the 2019-2020 Euratom call for proposals[76] resulted in research actions on the health effects of ionising radiation from diagnostic and therapeutic procedures, and in a support action on medical applications of ionising radiation, building upon the SAMIRA preparatory work.

[75] CONCERT European Joint Programme in radiation protection research https://cordis.europa.eu/project/id/662287

[76] Launched on the basis of Euratom Work Programme 2019-2020, COM(2018) 8412 final

The Commission proposal for the Euratom Research and Training Programme 2021-2025 aims to further develop fundamental research in human health effects of ionising radiation\ and identifies medical applications of ionising radiation as a priority area for cooperation with the Horizon Europe's Health cluster.

4.4. What do we want to achieve? General objectives

A coordinated European approach to research and innovation in medical applications of ionising radiation will aim to support a stable and resilient supply of medical **radioisotopes, guarantee the quality and safety of applications and facilitate** innovation in medical radiation therapies and imaging. This action will, in particular, seek to build synergies between the 'Health' cluster of Horizon Europe and the Euratom Research and Training Programme. Furthermore, it will seek opportunities for carrying out joint Health Technology Assessments (HTA) of novel and emerging radiation technologies.

4.5. How will we achieve it? Main Action Plan proposals

4.5.1. EU research and innovation support

Specific goals and objectives:

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. In particular, pharmacological and clinical research into novel radioisotope therapies and diagnostic tests will complement actions proposed in section 2 with regard to the production of radioisotopes. This action should further facilitate the access of European researchers and industry to top-class accelerator research and test infrastructures.

Main deliverables and timelines:

Action	Deliverables	Indicative time-table	Funding and lead DG
EU research and innovation support	Research roadmap for medical applications of ionising radiation technologies	2023	Horizon Europe **DG RTD** (Euratom)
	Roadmap implementation through specific actions funded under HE Health and Euratom Work Programmes	2024	Horizon Europe **DG RTD** (Euratom + Health)
	Results from research on the health effects of medical ionising radiation	2022-2026	Euratom programme **DG RTD**

Research roadmap for medical applications of ionising radiation technologies

The Euratom funded project[77] aims to develop a roadmap for coordinated European research and innovation in medical applications of ionising radiation, based on extensive stakeholder consultation and building on existing and planned research activities in the field. The roadmap will provide an integrated framework for future calls for proposals in this area, leading to synergies between the Horizon Europe Health cluster and the Euratom Programme. It will benefit from inputs and the active involvement of European stakeholders from the clinical, industrial, regulatory, and scientific fields, and provide guidance to stakeholders and the Commission on the steps needed in the coming years for the development of research activities and knowledge in this area.

Research roadmap implementation

The roadmap's recommendations will be considered by the Commission services for inclusion, after 2023, in the Euratom and Horizon Europe work programmes. The corresponding calls for proposals will support research and innovation into medical applications of ionising radiation in priority areas identified by the work programmes. The implementation of the roadmap should follow the proposals made in previous sections of this Action Plan

Research on the health effects of medical ionising radiation

The activities foreseen under this section will also benefit from research in the health effects of ionising radiation, as foreseen under the Euratom Programme 2021-2025. Euratom will continue supporting fundamental research in this area[78] and further focus efforts on research into the health effects of the medical applications of ionising radiation, taking into account existing research agendas[79].

4.5.2. Joint HTAs

Action	Deliverables	Indicative time-table	Funding and lead DG
Joint HTA	Develop joint HTAs	2025	EU4Health **DG SANTE**

The Commission's proposal for a Regulation on Health Technology Assessment[80] (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. The proposed Regulation would provide for joint assessments of all new cancer medicines that have obtained a central market authorisation at EU level, as well as of medical devices in higher risk classes (as per the EU Medical Device Regulations). Other health technologies, procedures and interventions in the field of cancer could also be assessed jointly, if there is common interest among Member States. New

[77] EURAMED rocc-n-roll project https://cordis.europa.eu/project/id/899995

[78] Based on the roadmap prepared by the CONCERT, project https://www.concert-h2020.eu/

[79] Developed by the EURAMED and the EURADOS platforms

[80] https://ec.europa.eu/health/technology_assessment/eu_cooperation_en

technologies for radiological imaging and radiotherapy, as well as nuclear medicine cancer drugs, would be good candidates for a joint HTA under this framework, expected to be implemented after 2024.

5. CONCLUSION

This Action Plan is closely linked to the Europe's Beating Cancer Plan and defines several ways in which nuclear and ionising radiation technology can contribute to achieving its objectives. The proposed Commission initiative on quality and safety will support the Cancer Plan's objective of ensuring sustainable cancer prevention in the EU, reducing the risk of undesirable effects of the medical use of radiation for citizens and health professionals, while contributing to early cancer detection, diagnosis and treatment. The EU support for a stable and resilient supply of radioisotopes will further help secure EU citizens' access to high-standard cancer diagnosis and treatment. The Action Plan also paves the way for a coordinated EU support for research and innovation into medical radiation applications that will benefit cancer patients. The ultimate goal is to facilitate a response to European citizens' aspirations for equitable, affordable and sustainable cancer prevention, early detection and care, and to help ensure quality of life to cancer patients.

The proposed actions and initiatives are based on the existing EU/Euratom legislative framework and instruments, and take into account recently approved initiatives in various policy areas. The plan has been jointly developed by several Commission services, and its successful implementation will rely on complementary actions and use of instruments and programmes in the areas of Energy, Health and Research and Innovation. The Commission staff invites all stakeholders to actively contribute to the activities that will follow.

The relevant Commission services will monitor the implementation of the Plan and will review it by 2025 to assess whether the action taken is sufficient to achieve its objectives or whether adjustments and/or additional action is necessary.