EUROPEAN JOINT PROGRAMME FOR THE INTEGRATION OF RADIATION PROTECTION RESEARCH
CONCERT

This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No 662287.

EJP-CONCERT

European Joint Programme for the Integration of Radiation Protection Research

H2020 – 662287

D3.7 Second joint roadmap for radiation protection research*

**Draft* for review by CONCERT, the radiation protection research platforms and stakeholders

Lead Authors: Nathalie Impens[1], Sisko Salomaa[2]

Affiliations: [1]SCK CEN, [2]UEF, STUK

With contributions from:

MELODI co-authors	**Simon Bouffler, Balazs Madas, Laurence Roy, Sisko Salomaa, Nathalie Impens**
ALLIANCE co-authors	**Rodolphe Gilbin, Hildegarde Vandenhove, Almudena Real, Nick Beresford, Nele Horemans, Jordi Vives I Battle**
NERIS co-authors	**Thierry Schneider, Wolfgang Raskob, Johan Camps**
EURADOS co-authors	**To be confirmed**
EURAMED co-authors	**Klaus Bacher, John Damilakis, Guy Frija, Christoph Hoeschen, Graciano Paulo**
SHARE co-authors	**Tanja Perko, Catrinel Turcanu, Susan Molyneux-Hodgson, Nadja Zeleznik, Meritxell Martell Lamolla**
Other members of the CONCERT WP2-WP3 working group	• **Laure Sabatier, input to infrastructure and resources texts** • **Vere Smyth, Andrea Ottolenghi, input to E&T and implementation texts** • **Roger Harrison, Filip Vanhavere, Werner Ruehm, María Antonia López, Benjamin Zorko, contributions to general parts**

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a) The information and views set out in this report are those of the author(s). The European Commission may not be held responsible for the use that may be made of the information contained therein.

b) The current version of the joint roadmap is the work of the joint roadmap working group consisting of the above mentioned authors and co-authors. Due to COVID-19, activities regarding the joint roadmap commenting slowed down. For example there was no physical CONCERT Management Board, the IRPA meeting where the JRM would have been presented has not yet taken place, and the collection of comments was slow and cumbersome. Not all platforms were able to provide a ranking of the Game Changers yet. As there are a lot of comments and rankings to be taken into account the revision process will take a few months after the end of CONCERT.

Work package / Task	WP3	T3.3
Deliverable nature:	Report (Draft)	
Dissemination level: **(Confidentiality)**	Public	
Contractual delivery date:	31 December 2019 (M55)	
Actual delivery date:	M60 (revised)	
Version:	2	
Total number of pages:	57 + annexes	
Keywords:	Joint Roadmap, radiation protection, low dose risk, radioecology, nuclear and radiological emergency preparedness and response, dosimetry, medical radiation	
Approved by the coordinator:	M60	
Submitted to EC by the coordinator:	M60	

Abstract

This Joint Roadmap for radiation protection research is established under WP3 of the H2020 CONCERT European Joint Programme by a working group including representatives of the six radiation protection research platforms and specific CONCERT Programme Owners and Programme Managers.

Within Europe, many organisations and associations have important experience in radiation protection research. To face effectively future challenges and make efficient use of resources (at both national and European levels), we believe that a common and shared vision for radiation protection research is required – the Joint Roadmap provides this vision.

Future challenges can be addressed and answered if we have a clear path forward both in terms of a common programme (R&D and implementation) and required capacities (maintaining and building future workforce and infrastructure) clearly set out in the Joint Roadmap, presented within this deliverable. Additionally, we need to develop the structure and governance to manage a European radiation protection R&D programme, which is another expected outcome from CONCERT.

This Joint Roadmap defines priority areas and strategic objectives for mutual cooperation and provides a vision and role for a European radiation protection research programme to 2030 and beyond.

The Joint Roadmap presents a view of the research challenges in the context of existing and potential exposure scenarios, relevant from societal and radiation protection points of view. Within these research challenges, the joint roadmap presents '*game changers*', defined as research issues that, when successfully resolved, have the potential to impact substantially and strengthen the system and/or practice of radiation protection for man and/or the environment through 1) significantly improving the evidence base, 2) developing principles and recommendations, 3) developing standards based on the recommendations and 4) improving practice.

Within the first half of 2020, this Joint Roadmap, and the associated game changers were sent for consultation to the research communities, end users, decision makers and other stakeholders for evaluation and further evolution of priorities.

Due to COVID19 pandemic a final consultation round within the time frame of CONCERT and approval by the CONCERT consortium to produce a final version of the joint roadmap (JRM) with strengthened priority setting could not be realised. But CONCERT do not see any reason for any stumbling blocks that the JRM will be basis of future R&D, resource and financial support planning since a next version of the JRM to be prepared in the near future (2020) will be taken up by the MANEES and future project in radiation protection in Horizon Europe. Within the course of 2020 the joint roadmap will also be presented within and beyond Europe, aiming to build cooperation and collaboration between research communities on a global scale. The joint roadmap is a living document that will need to be updated on a regular basis, considering advances and developments that affect the research needs.

The implementation and timescale of the joint roadmap will depend on the availability of human, infrastructural and financial resources in the Member States, on the EU level and progress with wider global integration. The availability of a coordinated funding mechanism would benefit the implementation of the roadmap and realisation of its goals. A long-term commitment by Europe of this sort would allow for the implementation and realisation of this ambitious radiation protection research roadmap shaped by societal challenges.

CONTENT

1. Foreword

Since the HLEG report[1] about ten years ago, a remarkable reorganisation of the European radiation protection research landscape has taken place. The report on European Low Dose Risk Research subsequently led to the establishment of the MELODI platform, an association of European institutes committed to low dose risk research and openly sharing their vision and Strategic Research Agenda with the multidisciplinary scientific community. The mode of operation turned out to be very successful and several other research platforms in radiation protection were set up soon thereafter, addressing research on radioecology (ALLIANCE), nuclear and radiological emergency preparedness and response (NERIS) and medical radiation (EURAMED). The European Dosimetry Group (EURADOS) that was founded in the 1980´s as an expert group, also prepared an ambitious SRA. The newly established SHARE platform has further consolidated the expertise in social sciences and humanities in radiation protection research.

All platforms have developed specific SRAs in their field of activity and continue working on specific roadmaps. While the individual platforms have brought together European scientists and consolidated their research strategies, there is also an increased collaboration between the radiation protection platforms within the integrative work packages of CONCERT to develop priorities and the joint roadmap. Also the research projects recently funded require the collaboration of scientists from the different platforms.

A Memorandum of Understanding (MoU) was established between these platforms confirming an umbrella structure (MEENAS) to further foster and enhance European radiation protection research and support collaboration. The implementation of a Joint Roadmap for Radiation Protection Research is a key element in this MoU.

The scope of research envisaged in the joint roadmap is in the context of various existing and potential exposure scenarios, relevant from societal and radiation protection point of view. The key aim is to provide answers to open questions related to the exposure of humans and the environment, for example to reduce uncertainties in risk assessment and to provide sound, applicable solutions for risk management. Research and development are needed in every step of the radiation protection knowledge updating process, ranging from underpinning science to principles, recommendations, standards and practice, represented at the international level by UNSCEAR, ICRP, IAEA/ISO/EC and IRPA, respectively (Figure 1). This joint roadmap aims to provide an instrument designed to support the updating of knowledge. In other words, implementation of the joint roadmap for radiation protection research should provide the knowledge and expertise needed to improve the radiation protection system and its execution over the coming decades.

This report describes the joint roadmap for research on radiation protection in Europe. The Joint Roadmap is prepared within the European scope but will be shared on a global scale to stakeholders, researchers and research funding institutions, to assess the possibility of research programming and co-funding, research cooperation and collaborations beyond Europe. This document is meant to be a living document, to be updated regularly to consider advances in the state of the art and future societal challenges.

[1] https://cordis.europa.eu/docs/publications/1070/107087891-6_en.pdf

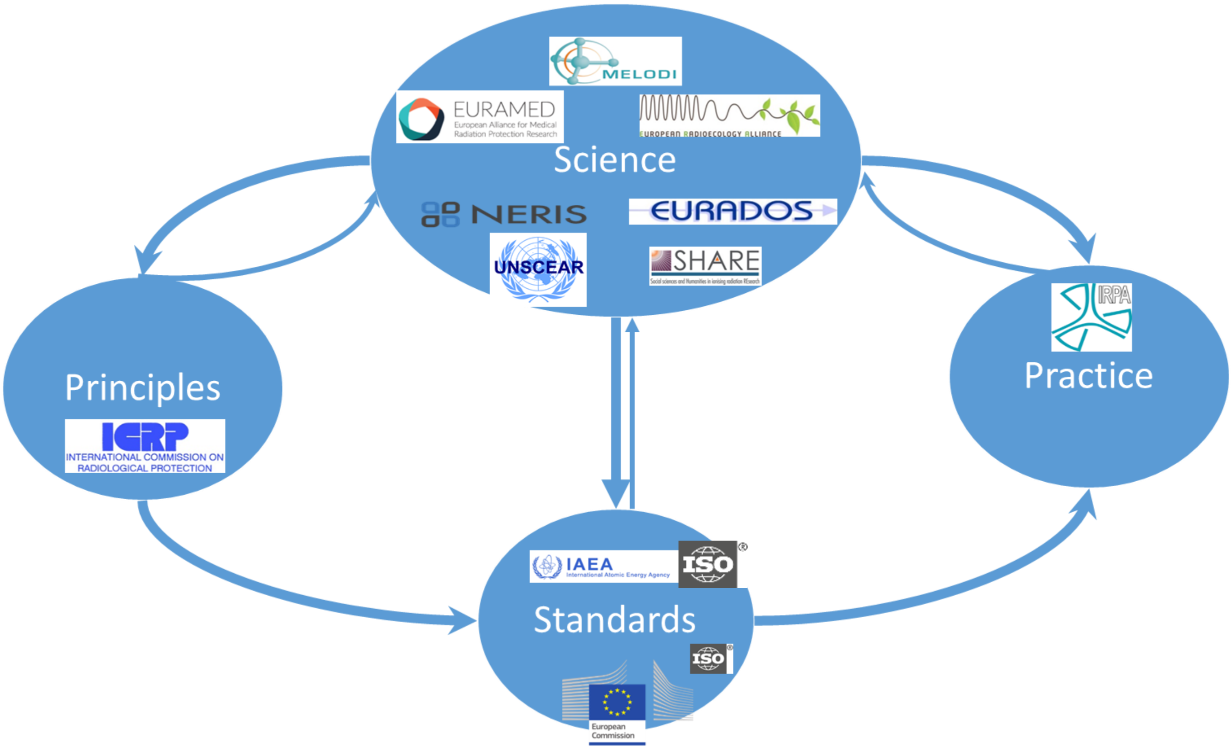


Figure 1. Role of science in the process of updating and implementing the radiation protection system. Research and development are needed in this process, ranging from underpinning science to principles/recommendations, standards and practice.

Implementation of the joint roadmap will have impact on radiation protection of humans and the environment in many ways (Figure 2). First, by consolidating our scientific knowledge the joint roadmap will support the implementation of the European Basic Safety Standards, to help cope with the new requirements and harmonize the practices throughout Europe. The joint roadmap addresses both human protection and protection of the environment. The holistic approach covers both risk assessment and risk management, as well as development of tools, methods and best practices to cope with the issues related to radiation exposure, thus making a major impact on society. Research is needed for risk prediction in specific situations and for foresight, to anticipate potential exposures. New knowledge will contribute to evidence-based recommendations at international level and informed risk communication. Research on risk management will help on risk prevention, improve the resilience of societies for emergencies, help to set up action plans and work on the mitigation and remediation. Guidelines, recommendations and regulations are needed, along with good practices and reliable methods for field and laboratory work. A graded approach in risk management is needed and research will help in putting exposures and risks in perspective. Technological development comes up with new standards, technological innovations and improved capabilities.

The research foreseen and the derived recommendations will enable consolidated, harmonised and robust decision making in the field of radiation protection throughout Europe and beyond.

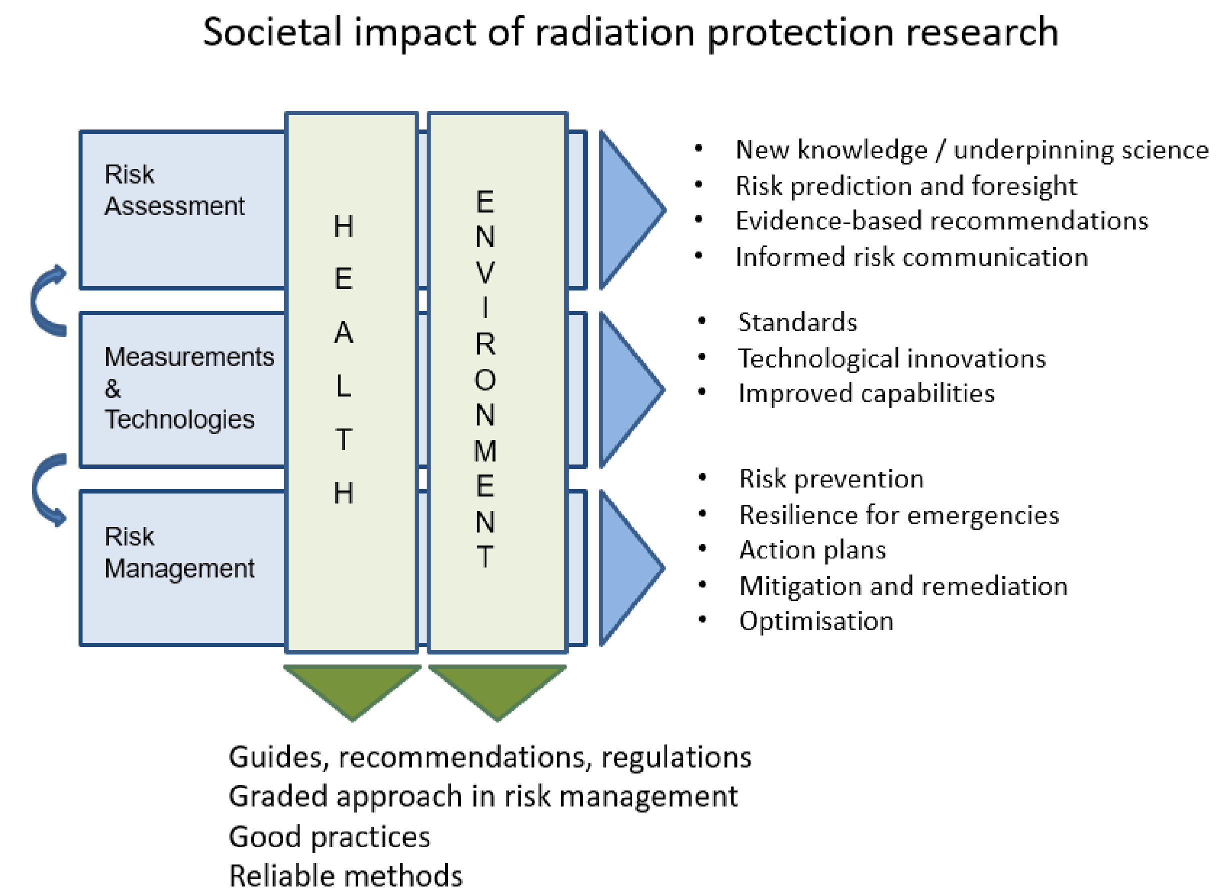


Figure 2. The research ecosystem ranges from basic research to applied research and from risk assessment to risk management. The societal impact from radiation protection research will result into improved risk assessment and risk management, both supported by technological innovations. The regulators and competent authorities on protection of health and the environment rely on the output from the research and technological development processes at all levels.

2. Scope of the research presented in the joint roadmap: exposure contexts and scenario groups

The goal of the joint roadmap is to identify the research needs and the development of tools that will further optimize the existing radiation protection system and advance radiation protection, considering the societal needs and concerns, and to plan such research. Implementation of the joint roadmap for radiation protection research will deliver the knowledge and expertise needed to further improve the radiation protection system over the next decades.
The scope of research planned in the joint roadmap is to provide information and tools for radiation protection in the context of various existing and potential exposure scenarios, driven by a societal and radiation protection point of view.

In this Chapter 2 we present the potential exposures of humans and the environment in a two-dimensional approach, with on one side **RP (radiation protection)** contexts resulting from man-made or natural sources of exposures, and on the other side **exposure scenarios** that may result from planned, existing or emergency situations. A graphical representation of this two-dimensional approach is available in Table 1.

2.1. Radiation protection contexts

Exposures to ionising radiation for which radiation protection may be required can be grouped in the four following contexts, from which the first three result from human activities, whereas the last one is inherent to the natural environment on earth, in the atmosphere and in space.

I. **Human activities related to medical therapy and diagnosis using radionuclides and X rays, electrons, protons or ions:** medical exposure of patients and the consequent exposure of personnel and the public due to medical procedures, the production and manipulation of sources/radiopharmaceuticals and related radioactive waste management.

II. **Human activities related to nuclear energy applications and other industrial applications of ionising radiation not related to medical applications**
   a. Installations from the nuclear fuel cycle: uranium mining and milling, fuel preparation, exploitations such as energy production in nuclear power plants, spent fuel reprocessing, waste management and decommissioning, research reactors and fusion research. Site contamination due to normal operation, incidents, accidents potentially resulting in legacy.
   b. Industrial and scientific applications of ionising radiation e.g. welding control, security screening, irradiators and particle accelerators.
   c. Military: former nuclear bomb testing sites, weapons fallout and nuclear-powered vessels (submarines, icebreakers and nuclear powered satellites).

III. **Human activities related to the use of natural resources, containing naturally occurring radionuclides (Naturally Occurring Radioactive Materials or Technically Enhanced NORM)**
   a. Mining, processing, waste management of natural resources containing natural radionuclides (NORM) (e.g. oil and gas extraction, NOR-rich ore mining).
   b. Use, processing, recycling and waste management of technologically enhanced naturally occurring radionuclides, including decommissioning of NORM affected industrial facilities.

IV. **Natural radiation as source of ionising radiation: telluric and cosmogenic radiation, natural events leading to radionuclide releases**
   a. High natural radiation background areas, potentially resulting in radon and thoron in indoor air and/ or in natural nuclides present in water/food.
   b. Exposure to cosmic radiation at high-altitude or in space.

2.2. Exposure scenario groups

Exposure scenarios cover a wide range of potential exposures of humans and the environment. These may originate from various anthropogenic or natural sources. Six exposure scenario groups related to the four contexts have currently been identified as shown in Table 1. The six scenario groups are presented according to the ICRP classification in planned, existing and emergency exposure situations. These scenario groups cover all the types of exposure situations potentially experienced by the public, patients, workers and the environment.

Each of the six scenario groups cover very large ranges of exposures of humans and the environment. However, the exposure scenario groups presented below provide sufficient information to deduce the joint research challenges of the joint roadmap. We have provided within the exposure scenarios, where available, indications of (collective) doses and general uncertainties or knowledge gaps to allow individual stakeholders to appreciate the relative importance of the scenarios from their perspective. The research challenges presented in Chapter 3 were developed according to these exposure scenarios, and must therefore be interpreted with the exposure scenarios in mind. More details on doses in specific exposure situations are available in UNSCEAR reports[2].

The relevance of exposure scenarios may differ in time and may vary strongly from different end users' points of view and values. A changing societal concern regarding protection of the environment may shed a different light on the relevance of some of the scenario groups. A new nuclear/radiological accident with radioactive environmental contamination may also impact on the societal concern related to radiation exposure. Global geopolitical changes could lead to uncertainties in responsibilities and emergency management. New reactor technologies or new sources such as floating reactors may induce different threats resulting in different accident scenarios. Climate change may alter environmental exposure, for example in legacy sites. Other external factors that may change the relevance of exposure scenario groups are an increased exposure of patients to medical radiation or an altered global health status, or exposure of humans and the environment to a combination of various stressors. Finally, progress in information technologies such as big data, artificial intelligence (A.I.), availability of human health data for (molecular) epidemiology and progress in emerging life sciences may positively influence the progress in radiation protection research.

[2] https://www.unscear.org/unscear/en/faq.html#Levels%20of%20radiation ,
https://www.unscear.org/docs/publications/2017/UNSCEAR_2017_Report.pdf
https://www.unscear.org/docs/publications/2016/UNSCEAR_2016_Report-CORR.pdf
https://www.unscear.org/docs/publications/2012/UNSCEAR_2012_Annex-A.pdf

Table 1. Exposure scenario groups related to different exposure situations categorised according to the ICRP classification (planned, existing or emergency exposure situations). The columns represent the different exposure sources (anthropogenic/natural) and contexts (medical, nuclear, NORM - TENORM and natural). Within the different exposure situations, various groups of exposure scenarios are identified. For emergency scenarios it should be noted that the first phase is classified as emergency while the recovery phase on the longer term is treated as legacy which is an existing exposure situation.

RP in various exposure scenarios		Anthropogenic	Anthropogenic	Anthropogenic	Natural
ICRP classification	**Contexts** ⇨ **Exposure Scenarios** ⇩	Medical therapy and diagnosis	Nuclear applications and applications of IR other than medical	Use of natural resources (NORM, TENORM)	Natural background radiation
Planned	1. Medical / Patients	Patients undergoing diagnostics or RT			
Planned	2. Industrial applications / public & environment		Discharges from nuclear sites during normal operation	Discharges from industry dealing with NORM	
Planned	3. Workers	Personnel in health care & production of radiopharmaceuticals	Personnel in nuclear installations & use of industrial IR sources	Personnel in NORM generating industries	Aviation personnel & astronauts
Existing	4. Nuclear or industry using NORM/ public & environment		Legacy from nuclear fuel cycle or other nuclear installations	NORM legacy sites	
Existing	5. Natural background / public & environment				Elevated natural background
Emergency	6. Nuclear or radiol. accident / public, workers, environment	Accident/incident with medical sources, radiopharmaceuticals	Accidents in nuclear installations	Accidental releases from NORM industry	

Scenario group 1 – Patient exposure from medical applications of X-rays, electrons or other particle radiation including the use of radiopharmaceuticals

This scenario group encompasses the medical exposure of patients to ionising radiation, for diagnosis and therapy. These exposures result in the highest average exposures to humans related to man-made sources of ionising radiation at least in developed countries e.g. in Europe, where the annual average dose of X-ray and nuclear medical imaging procedures is 1.1 mSv per caput still with a large variation between the different European countries, from which about 5% is due to nuclear medicine imaging procedures[3]. Dose ranges are very different amongst the various applications. However, there are body regions with low exposures in therapeutic applications while there are also body regions in e.g. interventional or cardiological investigations and repeated three-or four-dimensional imaging procedures with high local exposures. Thus, the scenario group will encompass all types of medical exposures.

The exposures to individual patients may vary substantially depending on their health status, the national health care system and the type of equipment technology used: For example, the average annual effective doses per caput from X-ray procedures in Europe range from 0.25 mSv in Moldova to 1.96 mSv in Belgium[4]. Each specific investigation might be performed within a large variety of parameters and settings within different countries, regions, hospitals or even departments. Many individual

[3]Study on European Population Doses from Medical Exposure (Dose Datamed 2, DDM2) Project report part 1: European Population Dose, page 9. Contract ENER/2010/NUCL/SI2.581237, 2010
[4]DDM2, table 5.13, part 1, 2010

members of the public may not receive any medical exposure in one year at all whilst some patients may undergo several abdominal CT scans each of which has an effective dose[5] of about 10 mSv.

A slightly increasing trend of average exposure per caput related to medical applications of ionising radiation is seen during the last few decades, and the awareness of adverse effects has pointed out the need for optimising imaging procedures in terms of a balance between an improved diagnostic outcome related to image quality and a reduced radiation exposure. Improving the quality of medical images usually means increasing the radiation dose to the patient, which in turn increases the radiation risks. For this reason, the objective of medical imaging is not to deliver the perfect image but one that is diagnostically adequate for the specific health problem[6]. Balancing image quality with radiation dose requires a special approach, since too low a radiation dose could be as bad as one too high: the images obtained could be of unsuitable diagnostic quality. Clinical auditing, reference levels and safety culture are among the means to improve optimisation. In addition, it is expected that technological innovations based on artificial intelligence will surpass the image detection capability of human eye after being trained by large datasets of image information. The distribution of exposures resulting from certain procedures like interventional or fluoroscopy-guided procedures can show differences in orders of magnitude resulting in local doses in the range of a few Gray. Exposure related to radiation therapy using external irradiation or radiopharmaceuticals may result in very high doses to tumours, of the order of multiple tens of Grays. Surrounding healthy tissues may also receive significant doses in the range of a few Gray, which may result in secondary effects such as acute inflammation, or late cancer / non-cancer diseases.

Especially, young children with higher radiosensitivity undergoing repeated examinations or radiotherapy may develop secondary effects. Like age, other individual sensitivities such as gender, disease-related effects, environmental risk factors like smoking or weight and genetic background are important to consider. Unravelling individual sensitivities may ultimately refine the system of radiation protection, especially in the context of medical applications.

Besides the development of direct radiation protection optimisation in terms of medical outcome per related risk through personalization and harmonisation of practices in diagnostic and therapeutic applications it would be feasible to study the secondary effects of medical exposures. However, it is important that assessment of secondary effects resulting from medical exposures takes into account the health status and drug intake of the patient.

Such research initiatives are only possible when regulations are adapted to support the harmonisation of medical practices and protocols, and to enable the use of relevant patient data for research, while respecting patient confidentiality.

The ultimate goal of research related to scenario 1 is to provide information to policy makers, national healthcare, health practitioners, patients and comforters of caregivers on optimisation strategies, to allow informed decision-making, and to adjust protocols to optimise (i) image quality and dose in diagnostics and (ii) target dose and healthy tissue dose in therapy.

[5] The meaning of effective dose in terms of medical exposures might be questionable; it should not be used for individual risk estimates. We refer to dose concepts in Challenge 2.

[6] https://www.iaea.org/topics/optimising-image-quality

Scenario group 2 – Exposure of the general public and the environment as a consequence of industrial applications of ionising radiation and the use of NORM in normal operation conditions

This scenario group covers a wide range of human activities. The operations linked with the nuclear fuel cycle (from uranium mining and milling up to final radioactive waste management, disposal and decommissioning), with industrial activities making use of ionising radiation as well as with the industries handling material containing natural radioactivity (NORM/TENORM), may lead to releases of radioactivity to the environment, which need to be controlled in order to minimise harm to individuals or to the environment.

To assess robustly the transfer and distribution of radionuclides in the environment from source to target (individuals and environment), fit-for-purpose models are required capable of capturing the required uncertainty. Uncertainties linked with exposure assessment may be related to the source characteristics, physicochemical behaviour and transport of radionuclides, transfer to biota, dosimetry and dose assessment in humans and biota.

In some cases, a full understanding of the bio-physico-geochemical processes affecting radionuclide mobility in biosphere, geosphere and atmosphere is required. This involves the development of models underpinned by dedicated laboratory and field experiments and studies and the development of dedicated data bases of parameter values. Special environments must acquire additional attention due to climate change. The representative person and reference area for biota should be adequately defined. The human and environmental exposure and impact assessment, both for predictive (e.g. newly built) and operational situations, need to consider not only the radiological component but also societal and ethical aspects.

Potential (health) effects to individuals and the environment is expected to be negligible given the generally very low dose rate/annual exposure.

Scenario group 3 – Exposure of workers in normal operational conditions.

Next to patient exposure and exposure to natural radiation, exposure of workers in normal operational conditions results in the third highest effective dose to humans. The description of this scenario group is based on a summary of data from the ESOREX[7] platform, which was developed to gather information on occupational exposures in Europe. The information gathered by ESOREX included how personalised monitoring, reporting & recording of dosimetric results is structured in European countries. The ESOREX platform also collects reliable and directly comparable individual and collective exposure data in all occupational sectors in which classified workers are employed, i.e. in the medical field (e.g., diagnostic radiology, interventional radiology, radiotherapy, diagnostic/ therapeutic nuclear medicine, dental radiology, veterinary medicine), in nuclear industries (nuclear fuel cycle for civil and military purposes), in industries using radioactive sources (e.g. industrial radiography, X ray fluorescence, industrial gauges, electro-beam welding, radioisotopes production and conditioning, industrial irradiation, security screening), in NORM-related industries (e.g. ore mining & processing, handling and storage of NORM, oil & gas industries, coal combustion) and in activities where employees are exposed to natural background radiation (e.g. air crew).

The type of occupational exposure varies and could include exposure through inhalation (e.g., of radon or radioactive dust), external whole-body exposure (e.g. in various sectors and to air crew exposure to

[7]ESOREX platform: (1) Establishment of a European Platform for Occupational Radiation Exposure –Highlights of the final report Contract n° ENER/2012/NUCL/SI2.636456, Rapport PRP-HOM 2015-00010,2015; (2) website https://esorex-platform.org/

cosmic radiation), or external exposure of extremities and eyes to gamma radiation (e.g. in the medical sector), all of them potentially resulting in different health effects.
The mean value for monitored workers in 2015[8] for all categories was 0.27 mSv/year in European countries that provided data to ESOREX[9]. On the individual level, occupational exposures may be higher: From the data available for France in 2015, the annual average dose to measurably exposed workers[10] in NORM industry is the highest (i.e. 1.94 mSv) and originating mainly from Rn inhalation, followed by workers in industry using radiation sources (1.38 mSv), nuclear industry (1.17 mSv) and medicine (0.34 mSv), mostly as external exposures. To complete the list of occupational exposures, we include the annual average aircrew exposure in Germany in 2015 (which was not measured but calculated with suitable codes that include flight route and the field of secondary cosmic radiation in the atmosphere), which was 2 mSv, with individual aircrew exposures up to 6.5 mSv. Annual collective doses in France in 2015 in NORM industries, industries using radiation sources, nuclear industry and medicine were 38 770, 17 990, 27 450 and 15 380 manSv, received by about 20 000, 33 000, 70 000 and 200 000 workers, respectively.
Although protection against radon is primarily based on measurement and optimisation, dose estimates are required for workers if, despite optimisation, radon levels in a workplace remain above the national reference level (ICRP 126). The EU Basic Safety Standards Directive 2013/59/EURATOM widens the application of radiation protection practices to previously not affected fields such as exposures to radon, thoron (including their progeny) and exposures to NORM, and demands that they are regulated in the same way as artificial sources. Many open questions remain regarding dosimetry, effects and risks of radon and NORM when occurring alone or in combination with other stressors. Further knowledge is needed to significantly reduce scientific as well as technical uncertainties in all steps of the radiation risk management cycle for radon and NORM exposure situations. Effective doses arising from unit exposure to radon and its progeny have been calculated using either dosimetric models or using the so-called 'epidemiological approach'. Both approaches give consistent results within their associated uncertainties (ICRP 137). Taking account of both methods, ICRP has recently recommended a single reference dose coefficient to be used, in most circumstances, for workers in buildings and in underground mines. Reference values are also given for specific situations of indoor work involving substantial physical activity, and for workers in tourist caves (ICRP 137). In special cases, where exposure conditions are non-typical, where sufficient reliable aerosol data are available, and estimated doses are likely to be high, site-specific dose coefficients can be calculated using the dosimetric data provided in ICRP 137. This would require a careful analysis of the European workplaces with a coordinated action with an expert group performing field measurements for dose assessments.

A large number of workers are covered by all these scenarios mentioned above, and hence efforts are needed to improve the assessment of doses and to optimize radiation protection.
Awareness of and integration of protection culture into industrial planning and the implementation of the new BSS plays a key role for an optimized radiological protection.

[8]2015 is the most actual year for which most countries have provided results in the ESOREX platform
[9]ESOREX data including data from France, Germany, Greece, Switzerland, Finland, Slovenia, Spain, Lithuania, The Netherlands
[10]There is a difference between monitored and measurably exposed workers: compared to "*measurably exposed workers*", "*monitored workers*" include individuals not having received a dose above the recording level, which is mostly equal to the applied method's detection limit, or which have received doses equal or lower than the limits to the public (≤1 mSv).

Scenario group 4 – Exposure of the general public and the environment with regard to legacy.

Past development of commercial and military uses of radioactive material and material containing naturally occurring radioactive materials (NORM), led to the development of many nuclear or NORM facilities worldwide. In many countries, these facilities were built and operated before the regulatory infrastructure was in place to ensure proper emission and residue handling and end-of-life decommissioning. This has led to legacy sites worldwide, contaminated with long-lived radioactive and other toxic residues that may pose substantial environmental and health concerns. Other type of legacy is that linked with former nuclear bomb testing sites, areas where ammunition of depleted uranium was used, areas impacted by accidents of submarine or nuclear energy-driven satellites or orphan radiological sources. Legacy sites are characterised by a large variability, complex and heterogeneous features and cover a broad range of issues. These legacy sites may cause radiological (and chemical) exposure to man and wildlife and may entail health risks and/or induce ecological damage. To robustly assess exposure to man and the environment and propose remedial options fit-for-purpose, transfer and exposure models are essential. Justification and optimisation of the remediation strategy should involve a multi-criteria approach in which stakeholders are actively involved in each step.

Exposure of human beings and wildlife is generally higher at legacy sites than at nuclear and NORM sites under normal operation. Impact assessment for individuals and environment is hence generally more crucial than for scenario 2. Since public exposure is sometimes in a dose range where there are uncertainties in the effects, scientific development is essential to predict health effects at these 'low' dose rates and related total dose.

Proper site characterization, human and environmental exposure and impact assessments, safety assessments and evaluation of remediation options (in terms of technical performance, associated exposure reduction and social impact), constitute the basis for decision making and need to be based on robust scientific and technological developments, as well as on the concerns of the various stakeholders. They ought to integrate uncertainty estimates that would help identify the priorities for scientific research to be dedicated to the most uncertain processes/parts of the assessment and take into account at the same time societal uncertainties and ethical implications of decision-making.

Scenario group 5 - Exposure of the public and the environment to the natural radiation environment

Radiation emitted from natural terrestrial sources is in most European countries responsible for about half of the average annual dose to humans. It is largely due to primordial radionuclides, mainly 232Th and 238U series, and their decay products, as well as 40K, which exist at trace levels in the earth's crust. Their concentrations in soil, sands and rocks depend on the local geology of each region in the world. The average natural radiation exposure is 2.4 mSv/y (global average)[11], but may vary strongly from place to place (from < 1 mSv/year to 100 mSv/y). Indoor radon is the largest contributor to the natural radiation exposure of the general population and the link between radon exposure and development of lung cancer is well established. Notwithstanding the recent recommendations of ICRP, there is a need to improve the knowledge of factors modifying the relationship between radon exposure and effects, as for example the interaction of radon with smoking habits or the radon-related risk for diseases other than lung cancer.

In recent years, several international studies have been carried out on the effects of background radiation on human health, but they are not fully conclusive on the specific radiation effect given the low dose rate, the impact of confounding factors etc. A more comprehensive dedicated international

[11]UNSCEAR 2008 Annex B Table 12; it must be noted that different countries apply different dose conversion factors. Therefore the average dose should be regarded as a representation of the order of magnitude of the dose.

study is required. Another uncertainty concerns the possible relationship between background irradiation and cancer incidence, particularly in children.

High background areas might be regarded as ecosystems exposed to long-term low-dose radiation. Comparison of such ecosystems with other ecosystems in areas with much lower background radiation levels might reveal important evolutionary information on various populations.

Information on scenario 5 is important to inform public and legislators about the effects of natural radiation, and to assess the eventual needs for countermeasures to be taken to reduce the exposure of the general public and/or the environment.

Scenario group 6 – Exposure of the general public, workers and the environment following a major nuclear or radiological accident or incident including long term consequences

This scenario includes all types of incidents or accidents in nuclear installations, medical facilities, transport of nuclear material, military installations and operations (e.g. 'broken arrow' incidents such as the incident at Palomares, Spain), lost sources (such as the Goiânia accident in 1987), satellite return (such as the SNAP-A re-entry event) or other events involving uncontrolled exposure or spread of radioactivity.

The impact on the affected population might range from local (e.g. a lost source) to worldwide (e.g. Fukushima and Chernobyl) and is not limited to individual health effects but may affect the environment as well as economic and social activities, e.g. all possible living conditions and lifestyle of affected people. This scenario also covers accidents related to the medical use of ionising radiation. This includes among others accidental and unintended medical exposures, overexposure and incorrect treatments of patients.

The timescales may range from days to decades or even longer, thus appropriate means must be developed to deal with the related challenges as defined in Chapter 3. Preparedness, supporting scientific tools and engagement of all relevant stakeholders are some of the necessary scientific input to deal with the consequences and mitigate them as much as possible.

3. Deriving joint research challenges and game changers from radiation protection contexts and exposure scenarios

"Joint research challenges" were developed, based on the scenario groups (section 2.2), taking into account the priorities identified in the strategic research agendas and individual roadmaps and interactions with CONCERT POMs and stakeholders. An overview of the joint research challenges is presented in Table 2. The term "joint" refers to the fact that the joint research challenges cover many disciplines, requiring collaboration of research communities of the different radiation protection research platforms. Table 2 summarises in the last column the different platforms needed to tackle the challenges. Most of the joint research challenges are relevant within various exposure scenario groups. For example, a better understanding of the human health effects at realistic low doses or dose rates is relevant in all exposure scenarios, even though the specific dose ranges or dose rate ranges and radiation qualities may differ according to the exposure situation.

Table 2 Overview of joint research challenges derived from the exposure scenario groups, addressing research disciplines available in the various radiation protection research platforms. The main platforms involved in the different research challenges are explicitly presented in the last column.

Joint Research Challenges	Scenarios	Platforms involved
A. Understanding and quantifying the health effects of radiation exposure	1-6	MELODI + All
B. Improving the concepts of dose quantities	1-6	EURADOS + All
C. Understanding radiation-related effects on non-human biota and ecosystems	1-2, 4-6	ALLIANCE, NERIS, EURADOS, MELODI, SHARE
D. Optimising medical use of radiation	1, 3	EURAMED, EURADOS, MELODI, SHARE
E. Improving radiation protection of workers	3, 6	EURADOS, MELODI, EURAMED, NERIS, SHARE
F. Integrated approach to environmental exposure and risk assessment from ionising radiation	2, 4-6	ALLIANCE, NERIS, MELODI, EURADOS, SHARE
G. Optimise emergency and recovery preparedness and response	6	NERIS + All
H. Radiation protection in society	1-6	SHARE + All

Within the joint research challenges, various "game changers" have been defined as *"Research that, when successfully executed, has the potential to substantially impact and strengthen the system and/or practice of radiation protection for man and/or the environment through 1) significantly improving the evidence base, 2) developing principles and recommendations, 3) developing standards based on the recommendations and 4) improving practice"*. As such, the authors estimate that funding research as defined in the game changers will maximise the potential to address the joint research challenges derived from currently realistic exposure scenarios.

It is important to notice that the proposed challenges and game changers are a current snapshot, sensitive to the evolution of the state of the art, or to future alteration of exposure scenarios, and accomplishment depends strongly on the resources available, as discussed in Chapter 5. Whereas the joint research challenges have already been presented to and validated by stakeholders in 2018-2019, the game changers are new and will be presented for priority setting to researchers, stakeholders and end users. To include this information, the joint roadmap will be updated in May 2020 as the last version within the course of EJP-CONCERT. The level of detail provided in the research challenges and game changers is very restricted. More detail is available for specific topics in the SRAs of the different radiation protection research platforms in Annex 2.

3.1. Challenge A – Understanding and quantifying the health effects of radiation exposure

The central aim of radiological protection is the protection of human health from the harmful effects of ionising radiation. Risks to health are the prime consideration in all situations of radiation exposure that include humans and are therefore of relevance to radiological protection in all occupational, medical and public exposure situations, under normal or emergency conditions. The ultimate goal of this challenge therefore is to have a comprehensive quantitative and mechanistic understanding of all radiogenic health effects.

Figure *3* summarises the current understanding of the relationship between radiation exposures and health effects (UNEP, 2016)[12]. In the context of the Joint Roadmap, low doses and/or low dose rates refer to a range of acute and/or protracted exposures of ionizing radiation that are typical of those encountered in the workplace, the environment and in diagnostic medicine. Moderate doses refer to doses that may be encountered by normal tissues in interventional radiography or in radiotherapy or in nuclear or radiological accidents. Doses below 100 mSv in a year may be considered low, and doses of the order of 100 – 1000 mGy are considered moderate. Doses higher than 1000 mSv are considered high and may cause symptoms of acute radiation sickness if received during a short period. Low dose rate means relatively low rate of dose accumulation. In radiological protection context, annual dose rates below 100 mSv may be considered low.

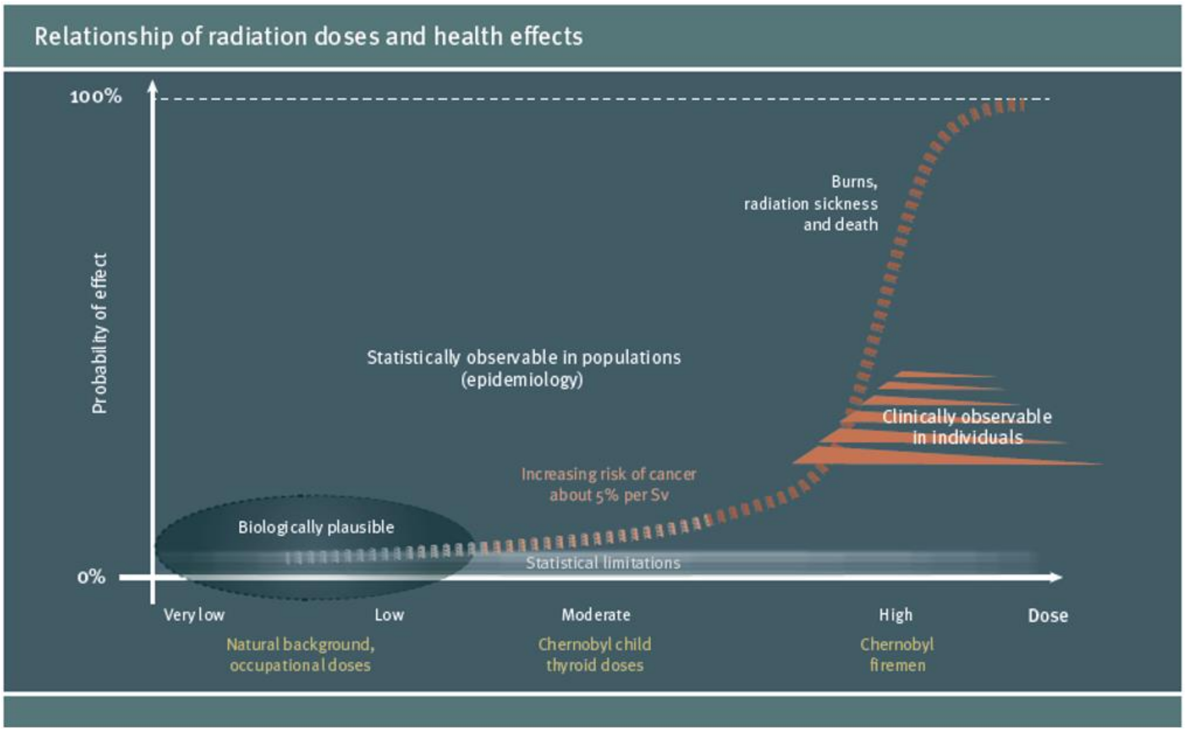


Figure 3. Relationship of radiation doses and health effects (UNEP, 2016). Dose ranges are defined in the text.

[12]RADIATION – Effects and Sources, United Nations Environment Programme, 2016, ISBN: 978-92-807-3517-8

It is important to distinguish between observations of early health effects in exposed populations from theoretical projections of potential future effects. For both situations, it is important to consider any uncertainties including those related to radiation measurements, statistical considerations or other factors. Currently, health effects can be reliably attributed to radiation exposure if early effects (e.g. skin burns) occur in individuals, e.g. after doses greater than 1 Gy (for teratogenic and other developmental effects possibly greater than 100 mGy). Using epidemiological methods, it is possible to attribute an increased occurrence of delayed health effects (e.g. cancers) in a population exposed to moderate radiation doses. However, there are no validated tumor biomarkers presently available to distinguish whether a cancer has been caused by radiation exposure or not. Where the level of radiation exposure was low or very low, changes in the occurrence of delayed health effects may be observed in epidemiological investigations; however, there are statistical and other uncertainties and a lack of full mechanistic understanding of the pathogenesis related to ionising radiation or other stressors. Unequivocal determination that cancers occurring after low dose exposures are caused by the radiation exposure is rarely possible. The LNT (Linear Non Threshold) approach suggests that epidemiological data from the higher dose range can be extrapolated to lower doses in a linear way. Understanding the mechanisms of radiation action helps in judging the biological plausibility of cancer induction by radiation exposure. Such mechanisms include the recognised DNA damage/gene mutational pathways and others such as potential epigenetic mechanisms, and disruption of mitochondrial function leading to persistent elevation of reactive oxygen species, amongst others.

Exposure limits in radiation protection are based on knowledge of radiation cancer risk derived from epidemiological studies and assumed risk of heritable effects in humans. Epidemiologically derived health risk estimates are limited in power below around 100 mSv; depending on the cancer type, the applied models for risk inference can be linear or linear quadratic. However, for risk management purposes, it is a linear non-threshold (LNT) model that is applied, justified on the basis of a biologically plausible argument that relates direct damage to nuclear DNA to mutations in specific genes that drive carcinogenesis. The mutational action of radiation may be modulated by other processes, some not well characterised throughout the prolonged periods over which cancers develop. In addition to cancer risks, there is increasing evidence of risk of non-cancer conditions, notably circulatory disease, cataracts and cognitive effects at lower doses, more than previously recognised.

Refinement of risk assessment for both cancers and non-cancer diseases can be improved by further large-scale epidemiological studies with good exposure assessment/dosimetry and integration of mechanistic biological understanding of radiation-induced disease processes. There is a need to further characterise organ-specific sensitivity and the distribution of risk within the population (evidence points to age, gender, co-morbidities, genetic factors, exposure to other environmental risk factors and life-style/behavioural factors as risk modifying factors). Information on the effects and risks associated with internal exposures, exposures to mixed radiation fields, co-exposures to radiation and chemical agents, differing radiation qualities, and inhomogeneous exposures is needed.

The major issues (‘game-changers’) to resolve with potential impact to the radiation protection system and or practice in this area are:

Game Changers	**Potential impact on the radiation protection system and/or practice**
A1. Define the risks of non-cancer diseases at low and intermediate dose levels (100 - 500 mGy and below). Priority with highest potential to advance understanding in the short term (5Y): circulatory effects at near-field / out-of-field therapeutic doses and dose-rates and following interventional radiology; Long-term research topics: cerebrovascular / neurocognitive, metabolic and immune diseases, at progressively lower doses	If present, these risks could lead to re-consideration of calculations of radiation detriment, dose limits and reference levels; there would also be a need to re-consider tissue weighting factors and potentially additional protection measures.
A2. Integration of epidemiological estimates of cancer risk with a more complete understanding of radiological disease pathogenesis to improve cancer risk assessment Priority with highest potential to advance understanding in the short term: defining processes contributing to cancer development after exposure; e.g. role of epigenetics, metabolic status, in single and multiple stressor at low doses and dose-rates Long term research topics: definition of target cell populations and cell interactions/microenvironmental effects	If a dose and dose-rate effectiveness factor is no longer needed, or requires alteration, this could lead to reconsideration of dose limits. Should a signature that unambiguously identifies radiation-induced cancers be identified, this would have impacts for compensation scheme criteria and programmes. Developing an understanding of all contributory mechanisms for radiation carcinogenesis at low dose/low dose rate, and the associated dose-response relationships, is essential for the development of risk projection models and predictive biologically based models Knowledge of the nature and size of target cell populations for radiation carcinogenesis is critical for further development of biologically based predictive modelling
A3. For deterministic and stochastic cancer and non-cancer outcomes: **Characterisation and quantification of variation in response and risk between population sub-groups/individuals due to genetic factors, sex, co-morbidities, dedicated exposure of disease areas in patients, environmental and lifestyle factors and the interactions between these depending on dose levels.** Priority with highest potential to make progress in understanding in the short term: Evaluation of potential predictive factors and correlating them with health outcomes. To improve the understanding in the difference of the dose response curve shape between males and females, as observed in the LSS cohort Longer term research topics: Integrative radiobiologically oriented systems biology, setup of	If a robust (specific, sensitive) predictive metabolic status and biomarkers or radiomic markers for radiosensitivity (tissue reactions) were found, this would allow more individualised cancer treatment. Knowledge on the range of variation in susceptibility to stochastic effects in populations would be informative for public health and development of the system of radiation protection. A better understanding of the mechanisms involved in long term effects of ionising radiation may be integrated with mechanisms resulting from exposure to other stressors or from combined exposures. On the longer term, an integrative protective system could be established to cover realistic multi-exposure scenarios. A confirmation of the difference between sexes in the shape of the dose response (males: linear-quadratic and females: linear) may lead to changes in levels of exposure limits.

adverse outcome pathways related to ionising radiation and in combination with other stressors including diseases. Seeking biomarkers of individual risk through cellular/molecular and systems biological approaches as well as radiomics investigations	Moreover, a better understanding and validation of the impact of life-style factors on the risk of stochastic and tissue effects could contribute the reduced risk by modifying life style. The dedicated response of diseased organs are of primary interest in taking care of patients since in diagnostic as well as therapeutic procedures mainly diseased organs will be exposed.
A4. For stochastic cancer and non-cancer outcomes: **Define how the temporal and spatial variations in dose delivery affect the risk of health effects following radiation exposure.** <u>Priority with the highest potential to make progress in understanding in the short term:</u> Addressing the difference between risks from acute and chronic exposures through the integration of experimental and epidemiological data applying biologically-based risk models To improve the understanding of the effects of intra-organ dose distribution through observations in patients exposed to inhomogeneous dose distributions and experiments with organotypic tissue models. <u>Longer-term research topics:</u> Addressing the difference between risks from internal and external exposures through the integration of new knowledge on the effects of chronic exposures, intra-organ dose distribution and radiation quality considering energy deposition at different scales (from intra cellular to organs).	A strengthened evidence base may impact on judgements on dose rate effectiveness factors and radiation weighting factors (potentially including those for non-cancer outcomes) as well as in the introduction of new weighting factors accounting for the effects of modulation of intra-organ dose distribution. Changes in these factors would lead to reconsideration of dose limits, reference levels, conversion coefficients and dose coefficients for intakes of radionuclides.

3.2. Challenge B – Improving the concepts of dose quantities

The dependence of biological effectiveness on radiation quality is commonly believed to be related to the differences in the energy deposition pattern on a microscopic scale. For charged particles, this pattern is called the particle track structure, where for heavy particles, such as ions, the energy transfer points are concentrated around the primary particle trajectory. Identification and quantification of the relevant statistical characteristics of the microscopic spatial pattern of interactions (e.g., spatially correlated occurrence of clusters of energy transfer points) are an essential prerequisite for improvement of present dose concepts. Micro- and nanodosimetry have provided experimental and computational techniques for the microscopic characterization of the track structure.

The overarching objective is the development of a novel, unified concept of radiation quality as a general physical characteristic of the radiation field that would allow separating the physical and biological components contributing to the eventual biological effects of radiation.

The comprehensive multi-scale characterization of the physical aspects of particle energy deposition will enable a quantitative investigation of the impact of track structure in terms of biological effects. Track structure has been proven to show a strong correlation with the induction of early biological effects, particularly the occurrence of DNA single and double strand breaks. As later biological endpoints also show dependence on radiation quality, there should also be a correlation of track structure characteristics and the probability of inducing these later effects, such as chromosomal aberrations or cell death. The ability to establish these correlations at the cellular level and investigate the response at supra-cellular organization level will form the basis for the comprehension of the radiation damage mechanism.

The major issues ('game-changers') to resolve with potential impact to the radiation protection system and or practice in this area are:

Game Changers	Potential impact on the radiation protection system and/or practice
B1. To improve the understanding of spatial correlations of radiation interaction events by improved measurement and simulation techniques.	Understanding the physical interaction between radiation and matter is a start for finding the low dose effects for different kind of particles
B2. To quantify correlations between track structure and radiation damage	This fundamental knowledge will have a direct impact in addressing current optimization criteria in diagnostics and radiation therapy and radioprotection, such as "biologically weighted" doses delivered in hadron therapy, dose calculation in inhomogeneous irradiations such as those of short-range α- and β- emitters used in nuclear medicine or in the case of internal contamination, risk estimation for low dose exposures, etc…

3.3. Challenge C – Understanding radiation-related effects on non-human biota and ecosystems

The need for an explicit demonstration of the protection of the environment (or wildlife) from radioactive releases was recognised during the last decade (ICRP, 2007; EC BSS, 2013; IAEA, 2014). Also, human health is in the long-term directly related to the fitness of the ecosystem. Environmental exposures at low dose and dose rate are relevant for many planned exposures situations under normal operation conditions (scenarios 2), existing environmental exposure scenarios with regard to legacy (scenario 4) and natural radiation (scenario 5), as well as long-term exposures after accidents (scenario 6).

The current knowledge about the radiation effects on wildlife was used in the last decade to develop appropriate radiological environmental impact assessment tools and to derive the associated protection benchmarks. For example, dose rates for reference animal or plants within which there is likely to be some chance of the occurrence of deleterious effects (DCRLs, derived consideration reference levels) were suggested from 0.1-1 to 10-100 mGy day-1, accounting for the variation in sensitivity of the considered wildlife group (ICRP, 2008). However, most of the available knowledge used to derive such benchmarks is related to the risk to individual organisms, whereas populations, ecological function and structure, and the preservation of biodiversity are more relevant from a management perspective and should be the focus of future studies.

On the other hand, there is considerable scientific disagreement on the actual extent of the radiation effects on wildlife populations in contaminated areas. Many studies have reported no significant effects of radiation on wildlife (e.g. in the Chernobyl and Fukushima exclusion zones), whereas others reported significant radiation effects on different wildlife populations at very low dose rates (below natural background exposure). This questions the robustness, the representativeness and the scientific consensus of actual diagnostic tools with regard to the long-term consequences of radiation exposure on non-human biota and ecosystems. This controversy has major implications for the robustness and the credibility of the system of radiation protection and resolving it would be a major game changer.

The robustness of radiological environmental impact assessment can be improved both by the understanding of underlying mechanisms that governs the sensitivity of wildlife populations to radiation (link with Challenge A for radiation effects on humans), and by an actual understanding of ionising radiation effects on key ecosystem processes under realistic conditions, associated with a robust exposure assessment (including internal exposure, heterogeneity, differing radiation qualities – link with Challenge B) and considering other stress factors.

To achieve this, the major issues are:

- To identify the key factors determining the vast variation in the sensitivity of wildlife populations to radiation.
- To characterise the influence of exposures on the populations currently living in contaminated environments (whole exposure assessment, including past exposures).
- To identify and validate biomarkers of exposure and effects that are relevant for effects at the population level.
- To understand the impact of multiple stressors - contaminants and other environmental factors - on the effects of radiation.
- To determine the effects of radiation on ecosystem functioning.

The major issues ('game-changers') to resolve with potential impact on the radiation protection system and or practice in this area are:

Game Changers	Potential impact to the radiation protection system and/or practice
C1. Resolving the controversy with regard to the effects on wildlife reported in the Chernobyl and Fukushima exclusion zones Short term priority activity. This requires to: - characterise the influence of exposures on the populations currently living in contaminated environments (whole exposure assessment, including past exposures), - identify the key factors determining the vast variation in wildlife populations' sensitivity to radiation, - - identify and validate biomarkers of exposure and effects that are relevant for effects at the population's level.	The re-interpretation and achievement of robust, consensus-based data on the long-term ecological effects attributable to radiation in those emblematic contaminated territories would have a very significant impact on the confidence and credibility level of the radiation protection of the environment (e.g., robustness of 'no-effect' benchmark dose-rates).
C2. Determine the effects of radiation on ecosystem functioning Longer term priority activity.	If an increased sensitivity of ecosystem processes (in comparison with the reported effects at the population level) is demonstrated, this would strongly question the robustness of risk assessments that rely only on population-effect data. On the other hand, if it is shown that the functional or structural redundancy of the ecosystems brings greater robustness against the effects of radiation, the conservatism of the current assessments would be comforted.

3.4. Challenge D – Optimising medical use of radiation

Medical use of ionising radiation is the largest source of exposure on average for the population in developed countries as in Europe. However, there is a large difference in radiation exposure due to medical applications between different European countries and there is also a difference in the medical use itself. Therefore it is of great importance for the system of radiological protection to optimise the medical application of ionising radiation and to harmonise the practices throughout Europe especially with respect to the protection of human health from the harmful effects of ionising radiation and with respect to the potential benefit of the use of ionising radiation for the individual patient. The ultimate goal of this challenge therefore is to optimise the use of ionising radiation for the diagnosis and treatment for each patient on an individualized approach in a standardized way throughout Europe. The corresponding research needs to include the basic investigations as well as the transfer into clinical routine.

The European Commission summarised the different use of ionising radiation between different European countries in terms of the average radiation exposure caused by medical applications[13]. The existing technologies are not used or available in the same way for all patients throughout Europe. This means that patients in some countries will benefit more from the use of ionising radiation than those in other countries, but also that there is potentially more detriment due to the more intensive use of ionising radiation. In addition, there are many new emerging technologies in various fields of medical applications such as targeted therapies based on ion or proton therapy or targeted radionuclide therapy, new technologies for interventional imaging procedures and molecular imaging approaches. Optimisation of existing methods can nowadays be achieved by hardware developments as well as by data processing tools. One aspect of these data processing methodologies will be the use of artificial intelligence for optimised usage of the existing data. Thus, it is obvious that sufficient data structures for research and clinical use is a prerequisite for the optimisation of the medical use of ionising radiation and the corresponding optimisation of radiation protection. For all new and emerging technologies and technological approaches it is necessary to:

- Develop potentially optimising methods and technologies depending on requirements and needs of medical specialities.
- Optimise and develop accurate individualised patient dosimetry for all organs (and even at sub-organ level)
- Optimise the protocols for performing the diagnostic or therapeutic task related to the individual patient.
- Characterise such methods in terms of related exposure, but also image quality or physical therapy quality
- Evaluate and describe their potential benefit and risk taking into account individualized patient parameters
- Transfer such optimised approaches into the clinics
- Harmonise its use throughout Europe based on evidence.
- Foster an improved radiation benefit-risk dialogue with patients and the pubic

This shows that the main focus of challenge D has to be to allow the harmonised use of the most modern and beneficial use of ionising radiation throughout Europe, taking into account individual patient conditions to guarantee the best possible radiation protection of patients throughout Europe. To establish a suitable way of harmonisation it will be necessary to rely on various methods for characterisation of the technologies which will partly interact with other challenges. The characterisation of exposure is essential especially for the patients but also for the staff involved with a practical diagnostic or therapeutic procedure. This has to take into consideration the individual sensitivity or susceptibility of the patient. Finally, there has to be a characterisation of the potential benefit i.e. the potential accuracy of the diagnostic procedure or the accuracy and related potential beneficial outcome of a therapeutic approach. Thus, the characterisation of the procedure is not only necessary in terms of exposure but also regarding image quality or therapeutic quality measures.

The major issues (‘game-changers’) to resolve with potential impact to the radiation protection system and or practice in this area are:

[13] RP 180 Medical Radiation Exposure of the European Population, Part 1 https://ec.europa.eu/energy/sites/ener/files/documents/RP180.pdf and Part 2 https://ec.europa.eu/energy/sites/ener/files/documents/RP180%20part2.pdf

Game Changers	Potential impact to the radiation protection system and/or practice
D1. Development of new medical applications or optimisation of existing ones depending on disease related applications e.g. interventional procedures, CT based approaches, targeted therapies in nuclear medicine and particle based therapies to improve patient protection relying on corresponding improved dosimetry procedures for individual patients. <u>Priority with highest potential to advance optimised use and corresponding radiation protection (5Y):</u> new interventional procedures, CT based approaches, targeted therapies in nuclear medicine and particle based therapies <u>Long-term research topics:</u> molecular imaging, theranostics	New methodologies or optimised approaches can reduce the radiation exposure to each patient while maintaining or even improving clinical outcome and help to allow similar conditions for patients within Europe and require new or even potentially additional protection measures. The development and characterisation of such technologies will need to rely on improved dosimetric methods especially those suitable for personalized patient dosimetry and quality metrices predicting clinical outcome.
D2. Application and development of AI methods to improve patient protection relying on suitable clinical data structures and taking into account the limits of the use of AI especially in the medical field. To make use of the potential of methods based on artificial intelligence to optimise and better characterise imaging and therapy techniques and to analyse patient data. <u>Priority with highest potential to make progress in applications of AI in medicine in the short term:</u> development of suitable data structures to be able to use the generated patient data for AI methodologies, to understand the limits of the use of AI especially in the medical field and develop corresponding test configurations <u>Longer term research topics:</u> Ethics when applying AI based methods for decision (support) systems especially regarding radiation based therapies, AI based optimisation of individualised procedures	AI will play a major role in optimising and individualising medical applications in all fields. However, it is of major importance, that there is a profound understanding of the limits of such approaches in terms of reliability of results but also in terms of ethical implications. AI will allow further optimisation and individualisation of procedures and thus influence the corresponding radiation protection system dramatically, but in the field of medical ionising radiation it has to be controlled very well, otherwise misleading results might result in detrimental non-helpful exposures. The European radiation protection system has to define standards allowing best potential use of AI and thus improve the system for patients and industry.
D3. To transfer the (optimised) technologies and procedures into clinical / medical practice and harmonise it throughout Europe **Investigating key challenges and problems for the transfer of developments into clinical practice, evaluating conditions leading to large differences throughout Europe, defining standards for justification of applications depending on individual patient characteristics and benefit-risk evaluations of procedures including a dedicated education guaranteeing the best possible radiation protection for patients** is of great importance.	A strengthened evidence base medicine, a better justification as well as a concept for education and training together with a clinical transfer concept will allow harmonised practises in Europe based on the optimised and individualised medical procedures using ionising radiation. Therefore the radiation protection system for medicine would be harmonised and allowing better patient care with harmonised exposures throughout Europe.

Priority with the highest potential to improve the radiation protection system in Europe in the short term: Investigating key challenges and problems for the transfer of developments into clinical practice, evaluating conditions leading to large differences throughout Europe, defining standards for justification of applications depending on individual patient characteristics and benefit-risk evaluations of procedures and including a dedicated education and training programme Longer term research topics: Evaluation of newly developed or optimised procedures regarding benefit-risk outcome (evidence based medicine) Development of a framework for clinical transfer and harmonisation.	

3.5. Challenge E – Improving radiation protection of workers

Exposure to ionising radiation continues to be an important concern in many industries and applications in Europe (e.g. nuclear, medical, air travel), including various and often complex exposure scenarios. Consequently, radiation protection of workers is a major issue that requires continued improvement.

Internal exposure assessment of occupational exposure from incorporated radionuclides is still subject to major uncertainties, mainly due to activity measurement errors, individual variability and limited biokinetic and dosimetric models. The resulting overall uncertainty in the estimated internal dose is acknowledged to be generally higher than that for external irradiation. In vivo measurements, for example, can provide information on the actual radionuclide activity within the body of an individual. However, there is no standard procedure for calibrating the required detection systems (body counters), and the anthropomorphic phantoms needed, such as those used to assess the skeletal activity of bone seeking radionuclides (e.g. plutonium and americium isotopes) are scarce.

Furthermore, biokinetic models for various radionuclides and individual parameters (which may also include changed body metabolism of patients and effects of decorporation therapies) are still limited, and their predictions would benefit from the use of available databases including human autopsy cases.

For external exposures, monitoring of individual workers will benefit from real-time monitoring of all limiting quantities (e.g. whole body, eye lens, extremities, brain, heart) including well characterized active and passive dosimeters, or computational approaches using Monte Carlo (MC) techniques.

In this context, neutron dosimetry raises particular problems. Some neutron applications in industry represent well-known but as yet unsolved problems such as the inevitable existence of photons which might interfere with the detection of neutrons. Others imply newly evolving problems due to strongly pulsed radiation or very high neutron energy ranges, i.e. radiation fields around high-energy particle accelerators and during flights at high altitudes or in space missions. For external exposures, the challenge is to assess relevant dose quantities in real-time. This should include all radiation qualities and in particular photons and neutrons, static and pulsed fields, and a vast range of radiation energies up to GeV. Appropriate neutron reference fields will need to be developed. These efforts, together with improvements in procedures for dose optimization and improved protection measures, will significantly contribute to a safer use of ionising radiation.

Leaving the Earth's surface to space, humans have to cope with numerous stressors, such as environmental changes, disrupted circadian rhythms, isolation, microgravity and heightened levels of radiation. Exposure to ionizing radiation has been one of the major concerns since the beginning of human spaceflight and represents a critical obstacle to further progress for long-term space missions, because individual doses are usually much higher than on Earth. Radiation in space is a complex mixture of all particles and energies. The particle energies range from a few eV up to 1020 eV. They are incident isotropically and are very penetrating in matter, hard to shield and of high biological effectiveness. The radiation field in space is not constant as the energy and fluence spectra are modulated by the solar cycle by a factor of two to three with sudden increases due to solar particle events (SPEs) mostly occurring during periods of increasing and decreasing solar activity. Moreover, the field is modified by planetary atmospheres and surfaces, planetary magnetic fields, spacecraft construction materials and lastly by the interaction with the molecules of the human body. Production of secondary particles in nucleus-nucleus interactions prevents adequate shielding against galactic cosmic radiation (GCR). The challenge is to provide accurate information (energy and particle spectra, dose rates, and microdosimetric quantities) in each exposure situation.

Radon is the most important natural source of ionising radiation with the most important health effect being lung cancer. In some cases, this is of relevance for workplaces (mines, water works, spas, caves). Environmental monitoring for radon and other radiation hazards needs to be improved according to the recently published ICRP Publication 137 on Occupational Intakes of Radionuclides. In addition, radon tracer methods should be included in environmental climate networks such as the Integrated Carbon Observation System (ICOS).

Finally, a key aspect across all applications and domains involving workers' exposures to ionising radiation is the development of radiation protection cultures in support of improved decision-making processes regarding the management of exposure situations and the involvement of the relevant stakeholders in the identification and implementation of radiological protection actions.

The major issues ('game-changers') to resolve with potential impact on the radiation protection system and or practice in this area are:

Game Changers	Potential impact on the radiation protection system and/or practice
E1. Development of biokinetic models and personalised dosimetry that will lead to the improvement of the assessment of internal exposure	Reduction of the uncertainty of internal dosimetry towards the level of external dosimetry
E2. Development of real time practical individual dosimetry of workers by harnessing the developments in new connected technologies	Real-time practical individual dosimetry of workers for all organs
E3. Development of a practical neutron personal dosemeter	Reduction of the uncertainty of neutron dosimetry towards the level of gamma dosimetry

3.6. Challenge F – An integrated approach to environmental exposure and risk assessment from ionising radiation

Faced with environmental exposure situations (all scenarios except scenario 1 and 3) where various environmental and human-population related factors strongly interact, holistic approaches to risk assessment are increasingly justified to ensure sustainable and safe use of radioactive substances and to protect both human and ecosystem health. Concurrently, integration of scientific, societal and economic considerations is needed, if more integrated dose and risk assessment approaches are to be developed to meet societal expectations, better inform decision-making and improve risk communication among stakeholders.

As a basis for more robust exposure assessment we need to further **improve the understanding and associated modelling of radionuclide dispersion and transfer processes** in the geosphere and biosphere. This needs to include the dispersion and transfer assessment in marine, brackish, estuarine, freshwater and terrestrial ecosystems (agricultural, forestry, natural and urban), covering the watershed continuum from the source to the ocean and ultimately at the global circulation level. The goal is to produce advanced environmental modelling to improve human and environmental dose assessment. This goal will most efficiently be reached by collaborating with wider environmental sciences. Models should be improved, or developed, to allow for the interaction at the various biosphere interfaces at the local, regional and global scales.

Specific emphasis is required on **integrated and holistic assessments**. There is a need for the improvement/development of innovative methods to characterise the source terms to delineate the multiple-hazard footprint (e.g., geostatistical interpretation of environmental, radiological, chemical data) of a site in space and time. Innovative modelling approaches are also needed to support decision making and to identify the most significant sources of uncertainty related to the impact on human and environmental health.

Such scientific advances would help in the development of improved international guidance on the management of legacy sites (e.g. from past NORM activities or accidental exposures); such sites may represent relatively higher exposure scenarios. Such sites often represent complex "objects" to be managed via a multistage process including site characterization, definition of objectives for remediation, impact and risk assessment, and evaluation and selection of remedial options. Each step comprises an associated uncertainty analysis, which is of both technical and social in nature.

The major issues ('game-changers') to resolve with potential impact to the radiation protection system and or practice in this area are:

Game Changer	Potential impact to the radiation protection system and/or practice
F1. Deriving a robust prediction of radiological contamination in the human food chain, for an integrated dose and risk assessment of post-emergency situations	If successful, the resultant models (largely improved/developed based on a thorough assessment of available data and models) will be applicable in any relevant environment, to its time-evolution, to any human/animal food. They will especially include future changes in European agricultural practices, and, since NPPs are often build on the coast, and since in the future more NPPs built on floating vessels are expected, we need further developments in marine dispersion and biota transfer models.

	Models developed will be transferable, meaning that they will already include the necessary amount of processes that allows model applicability to different scenarios. This will result in optimized management in the emergency and post emergency phase with respect to dose assessment, food chain protection and control, remedial actions, economic and societal impact.
F2. Identifying and quantifying the key processes that influence radionuclide behaviour in existing environmental contamination situations	Implementation of the new Basic Safety Standards (BSS), applying to the management and clean-up of existing sites, as well as to the licensing of future discharges and large quantities of NORM waste, developing the modelling basis for accurate dose assessment and establishment of remediation approaches is of important added value to society. This is especially important as NORM legacy or operationally impacted sites are often close to human habitation.
F3. Integrating risk assessment and management (consistent exposure assessments for humans and wildlife; risk integration for radiation and other stressors)	An integrated assessment and management approach will enable 'radiation protection' to make more balanced decision as it will take in the 'whole-picture' rather than making individually for human, wildlife, radiation, chemicals etc. It also represents a more defensible approach when communication to stakeholders (including the public).

3.7. Challenge G – Optimise emergency and recovery preparedness and response

In nuclear or radiological emergency management including accidental exposures, medical follow-up and long-term recovery the radiological impact assessment is of prime importance and demands the improvement, development and customisation of several new methodologies and advanced tools. Among them, we should consider advances in atmospheric, aquatic, terrestrial and urban dispersion models, food chain models and dose assessment models, individual monitoring of internal and external exposures and dose reconstruction and finally monitoring of the different environmental compartments, food and goods.

One of the future challenges is to develop and combine different modelling and monitoring techniques (including data assimilation techniques) to improve the predictions of the impact of an accident. Besides advancements in operational monitoring of dose rate values, nuclide-specific information and data on ground and air contamination levels, another emerging challenge would be to integrate measurements or assessments made by the public. Medical follow-up of (potentially) exposed people, depending on the received dose, requires further improvements in biodosimetry, internal and external dosimetry, dose reconstruction techniques and methods and optimised measures to reduce contamination and health effects.

To manage the radiological situation in a holistic way, and in order to better build and implement countermeasure strategies at different time frames (preparedness, response, recovery), there is a need for improved understanding of countermeasures. This includes the development of countermeasures and countermeasure strategies as well as their lifting in time. Important issues to be addressed are among others development of radiological criteria (notably, Operational Intervention Levels (OIL)), effective decontamination strategies (human & environmental), and waste handling from an accident. Improved mechanistic (process based) models will aid in better predicting where countermeasures will be required, the effect of some countermeasures in different geographical areas and also the likely length of time countermeasures will be required. It is also evident that countermeasure strategies have to deal with indirect health consequences, economic, societal and ethical aspects including the environmental characteristics.

An inclusive design and evaluation of countermeasure strategies requires the involvement of all actors, including the public in all phases (preparedness for and recovery from accidents), especially those with off-site consequences. However, the stakeholder engagement process as such is a challenge that requires further developments in the participatory processes in emergency and recovery situations. Furthermore, nuclear or radiological emergency response and recovery requires decisions to be made with high uncertainty in some critical parameters. This needs advanced decision science, situation awareness informatics and the use of big data.

Effective communication strategies during the preparedness, emergency and in the post-accident phases - even with uncertainties - are a key challenge for the success of any measure as they contribute to the development and maintenance of trust between experts, authorities and the population, helping to better implement countermeasures and manage the recovery.

Many of these topics are region-dependent. Therefore, preparedness should take into account accurate local environmental descriptions of the potential sites of nuclear or radiological emergencies. Models of the surrounding environment describing e.g. the population density, biosphere, geosphere and weather conditions should be readily available as real-time dose reconstruction and impact assessment will be needed at the time of the event to provide decision-makers with recommendations for countermeasures. Harmonisation of models across Europe, guidance, including in the availability of tools and expertise and preparedness, especially in certain areas of increased environmental and health vulnerabilities, emergency response and recovery and lessons learnt during and post the incident, would decrease the negative impacts when accidents or incidents occur. Mutual benefit can be obtained by collaboration with relevant security-related research.

The major issues ('game-changers') to resolve with potential impact to the radiation protection system and or practice in this area are:

Game Changers	**Potential impact to the radiation protection system and/or practice**
G1. Change of radiological impact assessments, decision support and response and recovery strategy by Artificial Intelligence (AI) and big data	With AI and big data, new methods for radiological impact assessment, a new DSS and improved response and recovery strategies can be developed, allowing for example the end user to define his or her objectives/goals and the system identifies the best possible strategies to achieve the specified objectives/goals with pros and cons. AI would also allow all stakeholders to evaluate the results in a more comprehensive way as all available information – needed by the AI – is available and can be searched by big data analysis approaches. This new approach requires research in the following areas: • Use of AI and big data in radiological impact assessments and measurement strategies; • Development of a new DSS that uses AI and big data capabilities to better guide the end user in countermeasure strategy definition;

	• Databases with historic and scenario information as starting point for decision making in new events, needed for the AI to learn; • Improved communication/dialogue with stakeholders due to better information availability; • Development of methods to combine uncertainties (e.g. Aleatory, Epistemological, Computational) with AI learning mechanisms.
G2. Further development of risk assessment and risk management approaches, technological capabilities to cope with novel threats and accident scenarios arising from new and future nuclear and radiological technologies, including further development of monitoring and dosimetry techniques	With the evolution of new civilian and military nuclear and radiological technologies and changing global and regional threats, risk assessment and risk management must evolve as well. In this respect, event scenarios, improved early detection, source inversion modelling and new methods to develop countermeasure strategies – based on indicators – are required. Research areas requiring attention are: • Event scenarios, including assessment of potential source terms and evolution of events; • Inverse modelling, data assimilation; • Monitoring strategies with mobile and advanced monitors, relying on citizen science approach and providing early detection of threats; • Combination of monitoring (including citizen monitoring) and simulation of an updated operational picture; • Development of indicators for strategies that can be applied even with little information on the affected area; • Establishment of dialogue/communication with decision makers and concerned stakeholders to challenge the proposed approach on risk assessment and risk management.

3.8. Challenge H – Radiation protection in society

Significant progress has been made on the inclusion of social sciences and humanities insight to the radiation protection field. Work remains to improve further integration between the technical content and the societal context within which RP operates. Therefore, research and innovation in radiation protection needs to be better aligned with the values, needs and expectations of society in order that scientific research can inform decision making more effectively and for innovations to be responsive to, and acceptable by, societal need. The character of social science and humanities research requires that attention to the Social Science and Humanities (SSH) research priorities is essential across all scenarios and is of relevance over all previously stated Challenges.

Without effective means for RP research to reach societal actors, (stakeholders, policy makers, publics) RP knowledge and innovations will fail to generate societal benefits. Concurrently, without openness to inputs from societal actors' values and perspectives, the RP knowledge and innovation communities will fail to address social concerns and political priorities. Thus, meaningful interactions between the technical and societal spheres are essential. Core SSH research concerns, therefore, relate to: defining, building and maintaining effective, two-way communications structures and cultures; development of the processes necessary for relationship and trust building; formulation of new approaches to inclusive governance; and development of novel forms of engagement to reach all relevant communities.

The RP community has to consider the social and ethical justification of exposures to ionizing radiation, under all circumstances, and, accordingly, to develop appropriate radiation protection cultures. The organisation of radiation protection research and the formulation of its policies are shaped by multiple factors (economic priorities, cultural values, institutional interests, stakeholder negotiation, the exercise of power) and these require constant, critical examination and for reflexivity within communities to be enabled. In line with global calls for Responsible Research and Innovation, radiation protection culture should support a reflexive, inclusive and anticipatory stance within the science, technology and innovation communities of the radiation protection field. Core SSH research priorities therefore include: characterization of existing structures, cultures and processes; development of novel methodological approaches to take account of socio-technical integration; and advancement of an open and transparent, anticipatory research culture among RP communities.

The major issues (game changers) that would have a substantial impact on the radiation protection system are:

Game Changers	**Potential impact to the radiation protection system and/or practice**
H1. Better alignment of research and practice in RP with the values, needs and expectations of society. This will be achieved through: - Effective research translation mechanisms; - Development of systematic approaches to inclusion of societal dimensions at all levels of the RP system and - Methodological innovation enabling transdisciplinarity in radiation protection research.	Effective research translation mechanisms will ensure generation of robust radiation protection knowledge that aligns societal and technical dimensions. This will result in new theory on knowledge exchange mechanisms between technical and societal spheres to underpin new practice; empirical evidence of the effectiveness of, and limitations to, current communicative structures and cultures to identify areas of action; and highlighting novel forms of citizen engagement, including advancement of innovative technological interventions. Development of systematic approaches to inclusion of societal dimensions at all levels of the RP system will ensure that RP research, policy and practice are responsive to the values and interests of diverse actors. Development of mechanisms for integration of responsible research and innovation within RP communities and integration of models of anticipation into RP practice will enable development of reflexive research cultures within RP and improve radiation protection. Improvements in the research, governance and practice of radiation protection will emerge that are based on advancements in the co-production of RP knowledge between science and society. This will inform RP policy and practice, through consideration of the ethical and social dimensions of the RP system, including attention to cultural diversity. Methodological innovations will enable collaboration between different disciplines and between different societal actors in transdisciplinary research environments. Development of social indicators will support the evaluation of the alignment of research and practice in RP with the values, needs and expectations of society.

3.9. Summary list of game changers

In Table 3 a summary list of game changers defined in the different research challenges is presented, together with the radiation protection research platforms involved and the potential end users interested in the execution of the research.

Table 3 Game Changer list, involvement of radiation protection research platforms and intended end users

Game Changer No	Game Changer title	RPR platforms involved	End users
A1	Define the risks of non-cancer diseases at low and intermediate dose levels (100 - 500 mGy and below).	MELODI	UNSCEAR, ICRP, IAEA, legislators, and regulators
A2	Integration of epidemiological estimates of cancer risk with a more complete understanding of radiological disease pathogenesis to improve cancer risk assessment	MELODI, EURAMED, SHARE	UNSCEAR, ICRP, IAEA, legislators, and regulators
A3	Characterisation and quantification of variation in radiation response and risk between population sub-groups/individuals due to genetic factors, sex, co-morbidities, dedicated exposure of diseased areas in patients, environmental and lifestyle factors and the interactions between these depending on dose-levels.	MELODI, EURAMED	UNSCEAR, ICRP, IAEA, legislators, and regulators
A4	Define how the temporal and spatial variations in dose delivery affect the risk of health effects following radiation exposure.	MELODI, EURADOS	UNSCEAR, ICRP, IAEA, legislators, and regulators
B1	To improve the understanding of spatial correlations of radiation interaction events by improved measurement and simulation techniques.	EURADOS, MELODI	UNSCEAR, ICRP, IAEA, legislators, and regulators
B2	To quantify correlations between track structure and radiation damage	EURADOS, MELODI	UNSCEAR, ICRP, IAEA, legislators, and regulators
C1	Lifting the controversy with regard to the effects on wildlife reported in the Chernobyl and Fukushima exclusion zones	ALLIANCE, MELODI, EURADOS, NERIS, SHARE	UNSCEAR, ICRP, IAEA, Legislators, and regulators
C2	Determine the effects of radiation on ecosystem functioning	ALLIANCE, MELODI, EURADOS, NERIS, SHARE	UNSCEAR, ICRP, IAEA, legislators, and regulators
D1	Develop new medical applications or optimize existing ones depending on disease related applications e.g. interventional procedures, CT based approaches, targeted therapies in nuclear medicine and particle based therapies, to improve patients protection relying on corresponding improved dosimetry procedures for individual patients	EURAMED, EURADOS, MELODI	Health care providers, legislators and regulators

D2	Application and development of AI methods to improve patient protection relying on suitable clinical data structures and taking into account the limits of the use of AI especially in the medical field.	EURAMED, SHARE	Health care providers, legislators and regulators
D3	Investigating key challenges and problems for the transfer of developments into clinical practice, evaluate conditions leading to large differences throughout Europe, defining standards for justification of applications depending on individual patient characteristics and benefit-risk evaluations of procedures, a dedicated education guaranteeing the best possible radiation protection for patients	EURAMED, EURADOS, SHARE	Health care providers, legislators and regulators
E1	Development of biokinetic models and personalised dosimetry that will lead to the improvement of the assessment of internal exposure	EURADOS, EURAMED, MELODI	UNSCEAR, ICRP, IAEA, legislators, and regulators
E2	The development of real time practical individual dosimetry of workers by harnessing the developments in new connected technologies	EURADOS, EURAMED	Operators, regulators
E3	Development of a practical neutron personal dosemeter	EURADOS	Operators, regulators
F1	Getting a robust prediction of the human food chain radiological contamination, for an integrated dose and risk assessment of (post)emergency situations	ALLIANCE, MELODI, EURADOS, NERIS, SHARE	UNSCEAR, ICRP, IAEA, legislators, and regulators
F2	Identifying and quantifying the key processes that influence radionuclide behaviour in existing environmental contamination situations	ALLIANCE, MELODI, EURADOS, NERIS, SHARE	UNSCEAR, ICRP, IAEA, legislators, and regulators
F3	Integrating risk assessment and management (consistent exposure assessments for humans and wildlife; risk integration for radiation and other stressors)	ALLIANCE, MELODI, EURADOS, NERIS, SHARE	UNSCEAR, ICRP, IAEA, legislators, and regulators
G1	Change of radiological impact assessments, decision support and response and recovery strategy by Artificial Intelligence and big data	NERIS, ALLIANCE, SHARE, EURADOS	UNSCEAR, ICRP, IAEA, legislators, regulators, local authorities
G2	Further development of risk assessment and risk management approaches and technological capabilities to cope with novel threats and accident scenarios arising from new and future nuclear and radiological technologies	NERIS, ALLIANCE, SHARE, EURADOS	UNSCEAR, ICRP, IAEA, legislators, regulators, local authorities
H1	Better alignment of research and practice in RP with the values, needs and expectation of society, through effective research translation mechanisms, development of systematic approaches to inclusion of societal dimensions at all levels of the RP system and methodological innovation enabling transdisciplinarity in RP research	SHARE, MELODI, EURADOS, NERIS, ALLIANCE, EURAMED	Radiation protection community and society

4. Graphical presentation of the joint research challenges and game changers

In order to estimate the type of research needed and the time frame needed to achieve the goals, the joint research challenges are presented in a graphical way. The game changers are accompanied by the number as presented in Chapter 3 and in Table 3, to show how related research could be planned when resources are available.

Some of the research shown in one particular graphical presentation may be strongly related with research in another joint research challenges. Non-exhaustive examples are studies related to individual sensitivity in Game Changer A3, which is also relevant in challenge D, or challenge G that strongly relies on new knowledge related to various other challenges. These examples show the need of concerted actions and strong collaboration between the different research fields in radiation protection.

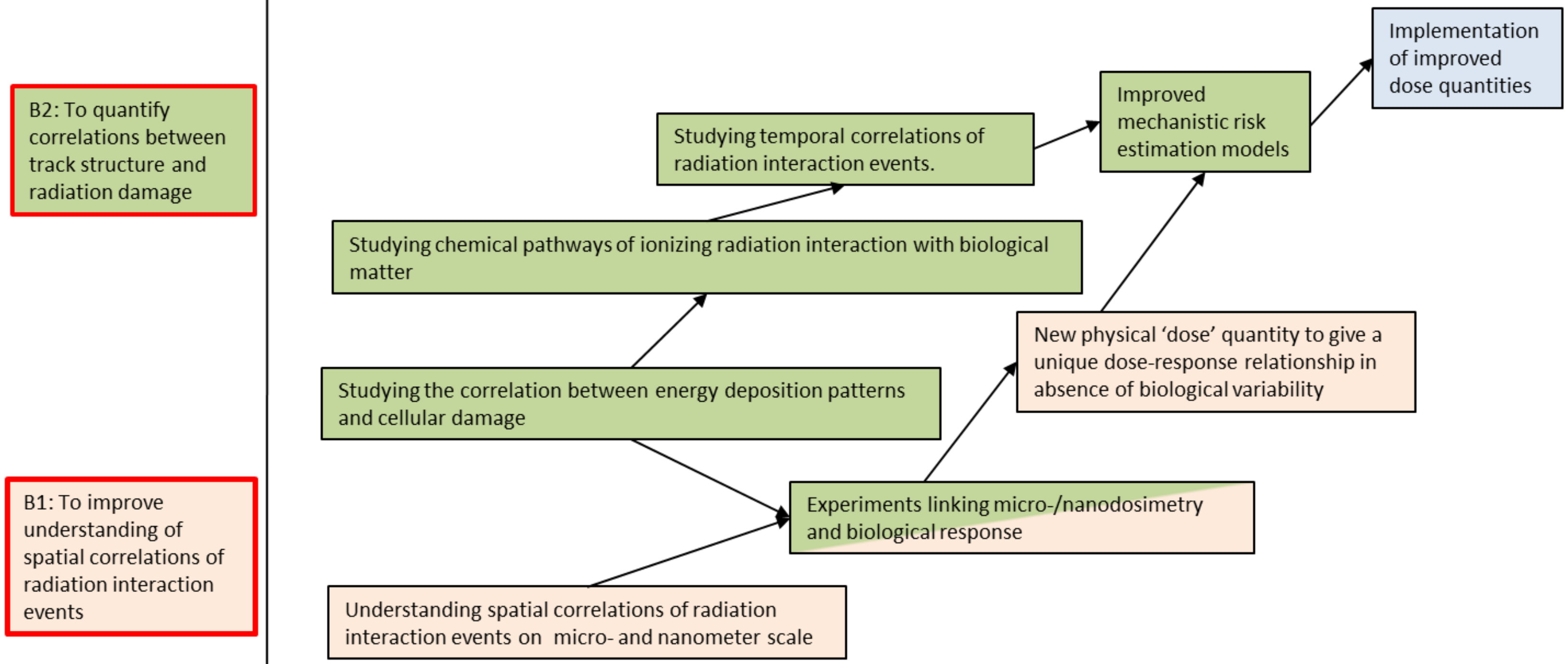
The timelines of the graphs are different, according to the ability to plan research in the different fields. The timelines should be considered as rough guides, because the implementation of the roadmap depends on the resources available as presented in Chapter 5, and on external factors such as advances in research outside the radiation protection area, or on changes in the society or the environment.

Challenge A – Understanding and quantifying the health effects of ionising radiation exposure

Drivers /Exposure situations	Where present at low doses, these risks could lead to re-consideration of dose limits as well as impact on tissue weighting factors, radiation weighting factors and calculation of detriment. A move to a more individualised approach to protection might be required. Relevant to all exposure situations
Game changers	
A1: Non-cancer disease risks – quantification and mechanistic understanding	Building and maintaining relevant cohorts; Periodic analyses; Improved risk quantification Targeted studies of potential contributory mechanisms; Building the relevant AOPs Target cell identification and quantification; Application to improve risk estimation
A2: Integration of epidemiological estimates of cancer risk with understanding of radiological disease pathogenesis	Studies of specific pathways; Identification and quantification of target cell populations; Integration into AOP Identification of mutational signatures and other biomarkers of radiation cancers Development of models to integrate mechanisms and epidemiology; Application for risk assessment Maintaining established cohorts; Evaluation of existing non-radiation cohorts; Periodic analyses
A3: Characterisation and quantification of the variation of responses and risk between population sub-groups/individuals due to genetic factors, environmental and lifestyle factors	Tissue reactions: clinical studies; mechanistic studies Late developing tissue reactions: Definition of mechanisms; population studies Cancers: continuation and initiation of epidemiological studies of risk modification experimental studies of risk modification → Development of predictive assays
A4: Define how the temporal and spatial variations in dose delivery affect the risk of health effects following radiation exposure	Improved understanding of inter and intra-organ dose distribution; Evaluation of W_T Identification of improved cohorts for epidemiological investigation – periodic analyses Experimental investigation of radiation quality effects; Biophysical modelling of dose and effects; Assessment of W_R
Required science and technology	Science: Improved epidemiological cohorts, evaluation of non-radiation cohorts, animal models of radiation disease, high-quality exposure assessment and dosimetry, application of radiobiology, molecular and cell biology, omics Technology: Low dose/dose-rate exposure facilities, advanced statistical methods, well curated bio-sample collections bioinformatics
	2020 2030 2040

Challenge B – Improving the concepts of dose quantities

Drivers /Exposure situations	Absorbed dose is not an adequately detailed description of the energy deposition for correlation with biological consequences because (a) the dose-response relation for a particular biological system depends on the radiation parameters (e.g., type, energy) and the stochastic pattern of energy deposition, (b) different biological systems have different susceptibilities for producing radiation-induced effects, (c) many biological processes are non-linear and (d) biological effects may differ depending on the temporal pattern of exposure.
Game changers	Over-all goal of challenge B: To improve protection and operational quantities used in dosimetry



Needed Science and Technology	1. Advanced detectors for measuring ionising radiation interaction at the micro- and nanometer scale 2. Metrological methods for improved detection of radiation-induced biological endpoints with automated assays 3. Improved multi-scale Monte Carlo simulations for predicting radiation-induced damage

2020 2025 2030

Challenge C – Understanding radiation-related effects on non-human biota and ecosystems

Drivers /Exposure situations

The need for an explicit demonstration of the protection of the environment from radioactive releases is now recognized. However, the available knowledge is related to the risk to individual organisms, whereas populations, ecological function and biodiversity are more relevant from a management perspective. There is still scientific disagreement on the actual extent of the radiation effects on wildlife populations in contaminated areas.

Game changers

C1: Resolving the controversy with regard to the effects on wildlife reported in the Chernobyl and Fukushima exclusion zones

Characterize the influence of exposures on populations in contaminated environments

- Re-interpretation of data on long-term ecological effects of radiation
- Field studies, transplant experiments
- Multi- trans-generational effects experiments
- Comparison between field and lab studies
- Understand hereditary & adaptation effects

Identify the key factors determining the variation in populations' sensitivity to radiation

- Variation due to genetic & metabolic factors
- Influence of species life-cycle specificities
- Population-effect benchmark derivation
- Variation due to environment & behavior
- Species Sensitivity Distribution update

Identify and validate biomarkers of exposure and effects that are relevant at the population's level

- Primary mode of action of IR – Identify biomarkers
- Adverse Outcome Pathway and Systems Biology approach
- Biomarkers testing
- Biomarkers toolbox available for application

C2: Determine the effects of radiation on ecosystem functioning

- Effects at community level (micro- meso-cosmos) & exposure characterization under realistic conditions
- Ecological models for risk assessment
- Ecosystems dynamics modelling
- Impact on ecosystem services

Required science and technology

Science: field effect data, laboratory models to identify radiation effects at the population/community level, high-quality exposure assessment and dosimetry, application of omics and AOP for the identification and validation of biomarkers

Technology: Well curated and shared datasets and sample collections from Chernobyl and Fukushima exclusion zones, Low dose/dose-rate exposure facilities, Advanced statistical methods

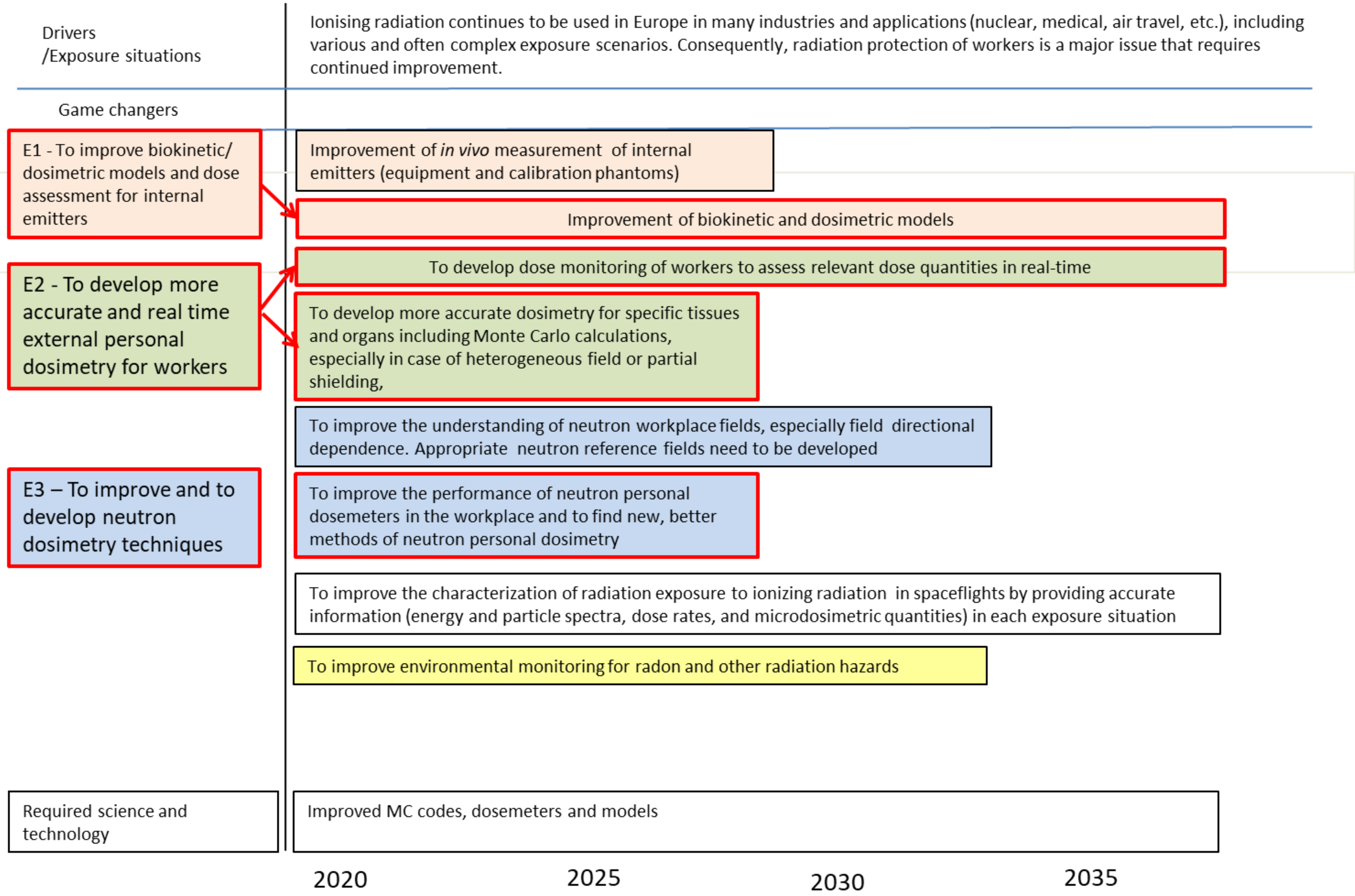
2020 2025 2030 2035 2040

Challenge D – Optimizing medical applications of ionizing radiation and harmonizing practices throughout Europe

Drivers /Exposure situations	It is of great importance to optimise the medical applications of ionising radiation for the diagnosis and treatment using individualized approaches and harmonise practises throughout Europe especially with respect to the protection of human health from the harmful effects of ionising radiation and with respect to the potential benefit of the use of ionising radiation for the individual patient.
Game changers	
D1: To develop / optimize medical applications of ionizing radiation using personalized dosimetry	Development of personalized dosimetry in diagnostic and interventional radiology, new or optimized interventional procedures and CT-based approaches, targeted therapies in nuclear medicine and particle based therapies to improve patient radiation protection. These optimized methodologies can reduce exposure while maintaining or even improving clinical outcome and harmonize medical radiation protection within Europe. Personalized dosimetry in imaging — New optimized approaches in imaging and radiation therapy — Medical RP harmonization in Europe
D2: Application and development of AI methods to improve patient radiation protection	Systematic and organized collection of big data for medical radiation protection, development of suitable national and European data structures for AI methodologies, development of AI tools to improve patient and staff radiation protection, understanding the limits of the use of AI in the medical radiation protection field. Development of imaging and dose biobanks — Development of AI methodologies — Wide application of AI in clinical practice to optimize procedures
D3: To transfer research developments into clinical practice and define standards for exposure justification	Investigating key challenges and problems for the transfer of developments into clinical practice, evaluate conditions leading to large differences throughout Europe, developing accreditation processes based on quality and safety, defining standards for justification of applications depending on individual patient characteristics and benefit-risk evaluations of procedures. Improved radiation risk appraisal — Development of accreditation processes — Clinical Decision Support in European hospitals for referral guidelines
Required science and technology	Physical and biological models and criteria for medical use of ionising radiation; Methods for individualized dosimetry, QA methodology for AI methods; New radiation generation technologies.

2020 2024 2028 2032 2036 2040

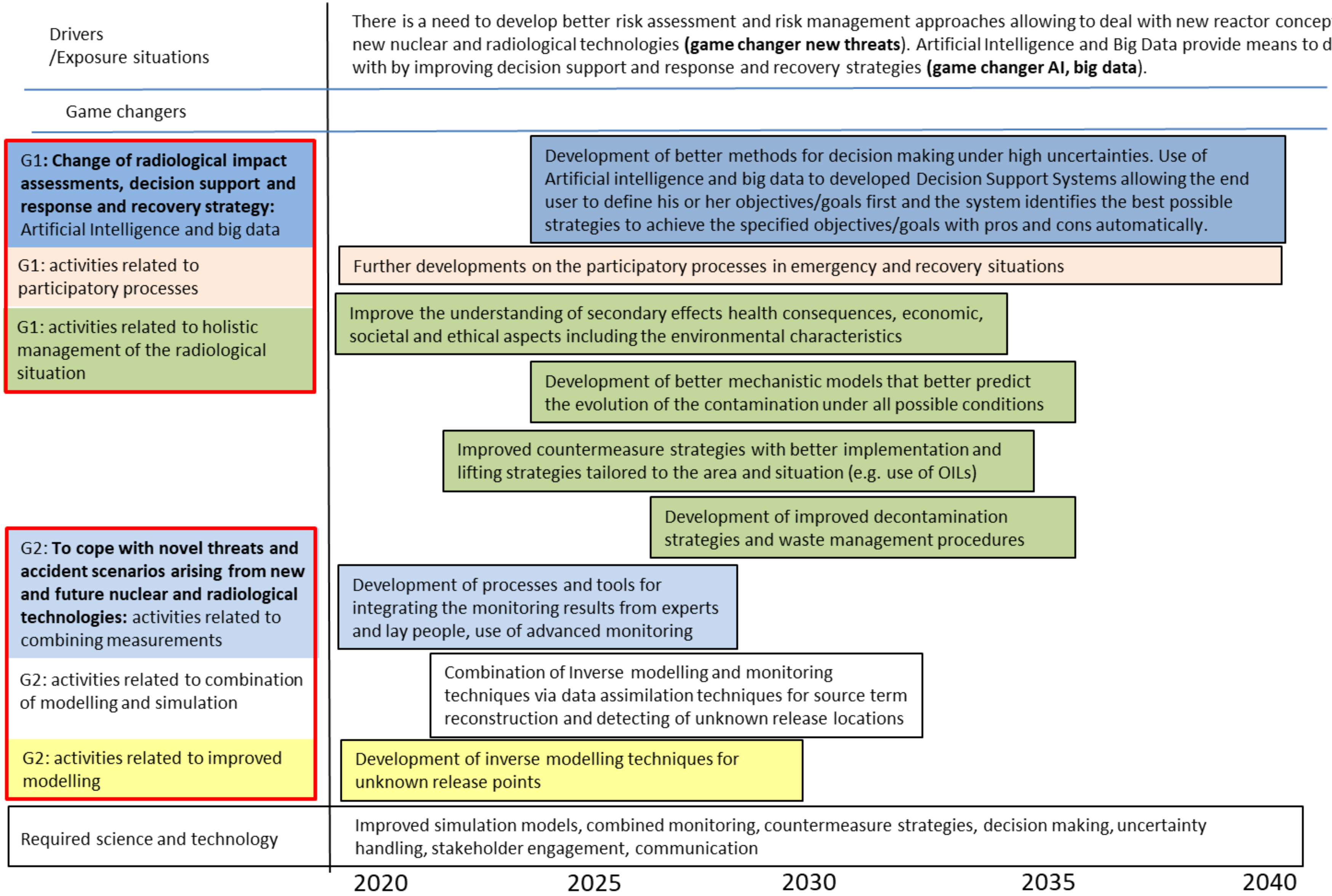
Challenge E – Improving radiation protection for workers



Challenge F – Integrated approach to environmental exposure and risk assessment from ionising radiation

Drivers /Exposure situations	Holistic approaches to risk assessment are needed to ensure sustainable and safe use of radioactive substances and to protect both human and ecosystem health. The development of improved international guidance on the management of legacy sites, that often represent complex "objects" to be managed, requires a multistage process including site characterization, definition of objectives for remediation, impact and risk assessment, and evaluation and selection of remedial options.
Game changers	
F1: Deriving a robust prediction of radiological contamination in the human food chain, for an integrated dose and risk assessment of (post-)emergency situations	• Meta-analysis and data re-interpretation, data management • Identify most promising models and adapt • Upgraded models for dispersion and transfer assessment in marine and surface water ecosystems • Upgraded models dispersion and transfer assessment in terrestrial ecosystems (agricultural, forestry, natural and urban) • Resultant models applicable in any relevant environment, time-evolution, food type
F2: Identifying and quantifying the key processes that influence radionuclide behaviour in existing environmental contamination situations	• Meta-analysis and data re-interpretation and advanced data management • Identify most relevant (mechanistic) models and adapt • Upgraded models for dispersion and transfer assessment in relevant environments/ecosystems • Models for accurate dose impact and assessment • Guidance for the sustainable management (including remediation approaches) of contaminated sites
F3: Integrating risk assessment and management (consistent exposure assessments for humans and wildlife; risk integration for radiation and other stressors)	• Identification stages of different assessment processes to be integrated and structure/construct datasets, models, DSS • Dispersion, transfer, impact assessment models (F1 & F2 outputs) • Integrate uncertainty and variability from exposure and effects characterisation into risk characterization • Integrate human and environmental protection frameworks • Integrate the risk assessment frameworks for ionising radiation and chemicals (eg. msPAF, « exposome » approach) • Provide a multi-criteria perspective including decision support systems for an optimised decision-making
Required science and technology	Uncertainty consideration in all its dimensions (monitoring, process knowledge, conceptual models, parametric, societal factors), Advanced statistical methods, advanced data management, Well curated and shared environmental monitoring datasets for models validation
	2020 2025 2030 2035 2040

Challenge G – Optimise emergency and recovery preparedness and response



Challenge H – Radiation Protection *in* Society

Drivers /Exposure situations

There is a need for further integration of ethical and societal dimensions into both RP research and development and across the whole RP system. To meet current, future and currently unknown challenges, research to better understanding and improve methods integration, allowing to deal with new technological challenges and the changing nature of society.

Game changer

H1. Better alignment of research and practice in RP with the values, needs and expectations of society:

- Effective mechanisms for RP research translation into practice, policy or further research
- Development of systematic approaches to inclusion of societal dimensions at all levels of the RP system
- Methodological innovation enabling transdisciplinarity in radiation protection research

Co-create integrated research designs to address priority research topics for each Scenario

Development of better conceptual frameworks and models to integrate diverse radiation protection knowledge for all Scenarios.

Gap analysis of ethical and societal dimensions of emerging technological research, and responses

Develop and implement novel forms of civic engagement, including advancement of innovative technological interventions.

Characterise and embed reflexive research and innovation RP practices.

Build capacity for anticipatory research culture and RP structures

Build and test new approaches to build and maintain trust

Further advance theory on science and society interactions in RP

Develop tools for anticipation, integrating perspectives from multiple voices (expert and lay)

Revise theory and tools in light of new developments

Develop combinations of qualitative and quantitative methods via novel research designs for holistic understanding of RP situations.

Test methods systematically across RP scenarios to deliver new insight.

Required social sciences and humanities

Improved methods and concepts, new theory, decision making, civic engagement, communication

2020 2025 2030 2035 2040

5. Resources for radiation protection research

5.1. Human resources: More than 200 organisations contribute to the European joint radiation protection research

A rough estimate of the research groups currently active in the integration efforts within radiation protection research in Europe can be obtained by counting the members of the European radiation protection research platforms and the research groups involved in EJP CONCERT (Annex 1). However, the list in Annex 1 is not exhaustive, and in particular many additional universities have research groups active in radiation protection research.

The platforms succeeded to gather most research groups active in their fields of research in a successful attempt to combat fragmentation of research and to pool a critical mass. More than 170 organisations are members in the six thematic platforms (associations), and more than 90 entities are involved in CONCERT. In total more than 200 organisations contribute to European joint radiation protection research. They have joined forces to create and update the strategic agendas and to carry out RP research. One third of the organisations listed in Annex 1 are universities (72/210). Within CONCERT, organisations have been mobilised in most European countries (25/28); only small countries such as Cyprus, Malta and Luxembourg apparently have not yet joined the European brainstorming task forces permitting an inclusion of their national research activities related to radiation protection.

In Table , a summary of the number of members of the different platforms is presented. It must be noted that the membership structures are different. Overall, the institutional members include research institutes, universities, National bodies, funding agencies, hospitals, associations, SMEs, International Organisations and a few individuals.

Table 4 Members of the different radiation protection research platforms. The institutional and university members represent groups of researchers active in the relevant radiation protection research disciplines. (*) Included in the category members representing multiple researchers are research institutes, universities, national bodies, hospitals and SMEs.

Platform	members representing overarching associations	members representing multiple researchers (*)	Individual members
MELODI	4: ESR, ESTRO, EANM, KVSF	40 Europe + 1 Canada	9 (7 + 2 honorary)
EURADOS	0	74	620
NERIS	1: CEPN	54 Europe + 9 Ukraine, Belarus, JP, Russia,	0
ALLIANCE	0	30	0
EURAMED	5: EANM, EFOMP, EFRS, ESR, ESTRO	7	
SHARE	1: CEPN	21	2

In this first attempt ever to provide an overview of human resources available in Europe for radiation protection research, it is not possible to obtain an exact number of researchers. However, within the different domains together, a few thousands of researchers devote at least part of their working time to radiation protection research.

Whereas the EURATOM funded projects have supported the integration between research disciplines and collaboration between the different Member States, Table and Annex 1 demonstrate through the existence of numerous research groups in institutes and universities that the majority of resources for radiation protection research is provided by their Member States. Therefore, it can be deduced that the sustainability of the research community is mostly provided by national funding sustaining research infrastructures, supporting lifelong research positions and running education programmes.

Annex 1 demonstrates the broad range of entities engaged in radiation protection research. As envisaged by the HLEG in 2009, the initial idea was to bring together national funding bodies, for the establishment of a trans-national organisation capable of ensuring an appropriate governance of research in this field, and a scientific strategy capable of structuring future research in the most effective way, taking into account available resources. Since then, it has become clear that very few of the national academies fund radiation protection research. Such funding is mainly channeled via the institutional budgets and via special budgets of the responsible ministries. While there are arrangements and dedicated programs for nuclear safety research in countries using nuclear energy, similar funding arrangements often do not exist within the radiation protection research area. Not all Member States have a national funding organization or other national programmes covering radiation protection research. This is a serious problem which is jeopardizing co-funding activities on the European level or is even inhibiting participation of research partners from specific countries to participate in this kind of European programmes.

5.2. Future resources needed for the joint roadmap

The practical implementation of the joint roadmap for radiation protection research will strongly depend on the resources available. The different Game Changers defined in Chapter 3 are graphically presented **with timelines that are subject to the availability of funding and other resources. The joint roadmap is** therefore a living document and will be updated by time. New challenges may arise that need attention while some questions may be solved sooner than anticipated.

A. Needs based on game changers

The game changers were derived from the joint research challenges from the perspective of the societal benefit, i.e. protecting the people, the environment, the society and future generations from the harmful effects of ionizing radiation, without unnecessarily limiting the application of radiation for the benefit of mankind. These game changers are highly multidisciplinary and require a supranational coordination and collaboration. Therefore, funding at European level is essential. Next to European alignment, the integrative approach may benefit from national networks, such as CORES, PEPRI and the BCRPR. These networks can strengthen the efficacy of the nationally funded research groups in the different types of institutes / universities, which are the basic foundations of radiation protection research, in need of continuous and predictable funding to ensure persisting engagement and attraction of experts and responsible for keeping up to date their infrastructures.

Whereas EURATOM is the core funding programme of nuclear and related research, the research proposed within the game changers has a broader societal perspective and some areas are strongly related to domains outside the EURATOM programme. For example, medical radiation protection research shows clear links to the HEALTH programme, topics requiring artificial intelligence would benefit from collaboration with ICT and HEALTH programmes; the radioecology related topics would benefit from collaboration with ecotoxicology or the consequences of climate change; and emergency management and preparedness may benefit from security research programmes. Similar analogies can be found for the basic research disciplines involved in radiation protection research (e.g. bioinformatics, physics, earth sciences, cancer research, etc.). Therefore, it is proposed to allow funding on national and

EURATOM level as core funding, complemented with coordinated co-funding to reach out and collaborate with related RTD programmes outside EURATOM.

B. Development of the research community: the need for education and training

The Joint Roadmap lays out an ambitious programme of radiation protection research over the next twenty to thirty years. The subject has been developing in breadth since the beginning of the use of radiation for medicine and then power generation. The early science of radiation protection was mainly limited to the physics of radiation shielding, and experimental radiobiology. The new research has split into six different areas represented by the six platforms, and has embraced new technologies including bioinformatics, powerful computing, and big data. This places great demands on the skills and resources of the research community. But, as well as changes in the scientific domain, the demographics of the community have been changing, both due to population aging, and changing pressures in the work environment. Pioneering researchers are now retiring; the subject is no longer as fashionable as it was during the infancy of nuclear power; students are struggling to find secure career appointments against competition from health and environment research.

All these factors point to the same directions: to carry out the research programmes called for here, there must be a coordinated and strongly supported built-in programme of education and training to maintain and develop the human resources. This programme must be broad in scope: attracting new entry-level students into the topic area, providing project opportunities for MSc and PhD students, continuing professional development of researchers, support for researcher career paths, and knowledge management to ensure the researchers of today benefit from the experience and knowledge of the previous generation as well as current developments.

Over the last ten years, through the Network of Excellence DoReMi and the European Joint Programme CONCERT, the EC has funded an annual programme of short courses giving students a free hands-on introduction to research topics. It has also provided travel grants to enable students and early career researchers to present their work at conferences, attend courses, or go for exchange visits to laboratories. A firm long-term commitment for this type of support will be essential. Support should also be given to EURAYS (European Radiation Research Association for Young Scientists). This is a network for early career researchers in radiation protection that was originally set up in 2013 on a pro bono basis and is now being restructured to provide sustainability. An essential part of sustainability will be attracting supporting sponsorship to cover costs.

Next to education and training of young researchers entering the field of radiation protection research there is a need for lifelong learning programmes to enable researchers to enter emerging research fields within the course of their research careers. In addition, the education and training programmes within radiation protection research are part of the dissemination needed to bring results of the research to the end users. In this perspective, we also need to link E&T activities in research with E&T organized for radiation protection practice. Education and training activities are therefore inherent to the implementation of the joint roadmap, providing research for an improved radiation protection system and practice.

C. Infrastructures under fair policies

Inventory of European infrastructures and future needs having revealed that most necessary infrastructures are already available somewhere in Europe or other countries. We need to make better use of existing competences and research infrastructures in Europe. The current challenge is to facilitate their access by increasing their visibility, to favour their sustainability beyond national short-term economic constraints and to support exchange visits for their use.

Next steps will rely into further harmonisation of quality standards, practices and protocols in relation to the use of infrastructure including the implementation of intercomparisons. Huge efforts will be dedicated to sample/data acquisition and sample/data storage with the aims to re-use of archived materials. We will propose trans-national agreement on a strategic work plan for maintenance, updating, mutual use and new needs of suitable infrastructures. Meanwhile, education and training actions will promote the use of European research infrastructures the advantage of using newer, larger, faster, more powerful infrastructures although not at the bench of each user.

6. Implementation of the joint roadmap: vision of the joint roadmap working group

The implementation of the lines of research described in the Joint Roadmap and the graphical representations in Chapter 4 call for coordination of resources and timely investments. The members of the RP research platforms represent a major resource of human competence as well as research infrastructures, focused on joint objectives. Based on the obvious success of the radiation protection research platforms and the SRAs, and on the experiences on integration of research within FP7 (mainly within the DoReMi, OPERRA and COMET projects) and H2020 (mainly within EJP CONCERT and MEDIRAD), we propose a long-term call planning system to turn the joint roadmap into reality. Efforts to integrate the research community on a national and European level should be continued and additional efforts should be devoted to international cooperation on topics of mutual interest, in order to bring together the critical mass of scientists and knowledge. On the other hand, the implementation actions should be compatible with the different financial structures in European Member States, the European level and should allow sustainability of research activities within and outside Europe.

Despite the success of the RP platforms, joint planning between the national programmes and the Euratom programme have not kept in step with each other. Requirements for national co-funding in EURATOM research has been a major issue due to the incompatibilities of EU and national rules, and the highly variable national rules. The funding rules of the European Commission and of Member States should be made compatible in a way that discrimination against research partners solely due to co-funding problems in Member States is avoided.

Open, competitive calls to organize research in radiation protection according to the joint roadmap need to be pursued. They pave the way to excellent science and to fair chances for research groups from all kind of research institutions to participate in radiation protection research in Europe based on their scientific merits. Scientific excellence should remain the major and most important criterion in peer reviewing of proposals. Further attention should be paid to the preparation of call texts and conditions in order to address special European requirements and needs in radiation protection and the added value of the European integration efforts. The management of calls by an administration that is isolated from the research community like in EJP CONCERT should be favoured. Evaluation of proposals should be provided by experts free from conflict of interest but having experience in European radiation protection needs.

Whereas EURATOM is the core funding programme of nuclear and related research, the research proposed within the game changers has a broader societal perspective and some areas are strongly related to domains outside the EURATOM programme. For example, medical radiation protection research shows clear links to the HEALTH programme, topics requiring artificial intelligence would benefit from collaboration with ICT and HEALTH programmes; the radioecology related topics would benefit from collaboration with ecotoxicology or the consequences of climate change; and emergency management and preparedness may benefit from research in other accident scenarios or security research programmes. While recognising that there are budgetary constraints to realise joint funding between programmes under separate treaties, this aim should be pursued anyway, for the benefit of science and society. Supporting research on medical radiation protection should not come on the expense of other RP research fields.

To complement the research activities, a strongly directed comprehensive programme of education and training will be needed. E&T is an essential component of the research process. As presented in Chapter 5, an actively supported programme of E&T is needed to develop and maintain the research community. Further to this, all research projects must be required to allocate a proportion of their budget to E&T activities. Horizon 2020 has set a minimum level of 5% and this should at least be continued. The E&T activities would include provision of project opportunities for MSc and PhD students, as well as hosting seminars, workshops, and courses on topics in the research area. E&T is an important element of dissemination and impact creation, providing an outreach to related professionals and stakeholders, both for communicating new knowledge and for seeking feedback. For such a comprehensive E&T programme to function in a coordinated way there must be top-down direction and support. This requires dedicated funding, either as part of an umbrella programme such as an EJP, or as a separate call.

The establishment of a sustainable European radiation protection research programme could be facilitated by (1) co-programming, (2) by a strong European joint programming consortium linked with the wider research community and allowing open calls with co-funding rules that do not exclude any potential partners, and by (3) an institutionalised permanent joint programme secretariat suited for long term challenges and priorities. Beside strong institutional partners from member states responsible for running national radiation protection research programmes and/or funding such programmes, the platforms should be involved to sustain and further improve the network of the radiation protection research community and assessment of state of the art and priority setting. These options need to be investigated thoroughly and the best option selected to meet the needs described in this chapter. Essential elements are open, competitive calls to organize research in radiation protection according to the joint roadmap, the implementation of an independent call management unit operating behind a firewall to restrain undue interference by potential applicants, and inclusion of E&T activities, such as project opportunities for MSc and PhD students. A long-term commitment of EURATOM would allow for the implementation of an ambitious, integrative and sustainable radiation protection research roadmap shaped by societal challenges.

7. Annexes

7.1. Annex 1: List of Platform members and EJP-CONCERT partners

Organization Acronym	Name Organization	Category	Country	EJP-CONCERT	MELODI	ALLIANCE	EURADOS	NERIS	EURAMED	SHARE
AIST	National Institute of Advanced Industrial Science and Technology	Research Institute	Japan					1		
AIT	Austrian Institute of Technology GmbH	Research Institute	Austria				1			
ALLIANCE	ASSOCIATION ALLIANCE EUROPEENNE EN RADIOECOLOGIE	Association	France	BEN						
ANR	ANR - Agence National de la Recherche, France	Funding Agency	France	BEN						
APA	Environmental protection agency - Portugal	National Body	Portugal	BEN				1		
APHP	Assistance Publique Hopitaux de Paris	Hospital	France	TP						
AWE	Atomic Weapons Establishment plc.	Research Institute	United Kingdom				1			
Berthold	Berthold Industries	SME	Germany				1			
BfS	Bundesamt für Strahlenschutz, BfS	Research Institute	Germany	Coord/ BEN	1	1	1	1	1	1
CAATS	Centre d'Assurance de qualité des Applications Technologiquesdans le domaine de la Santé	SME	France	TP						
CAM AC UK	University of Cambridge	University	United Kingdom	Subco ntract				1		
Cavendish Nuclear	Cavendish Nuclear Ltd	SME	United Kingdom				1			
CC UOI	University of Ioannina	University	Greece					1		
CEA	Commissariat à l'Energie Atomique et aux Energies Alternatives	Research Institute	France	BEN	1	1	1			
CEH	Centre for Ecology and Hydrology (CEH)	Research Institute	United Kingdom	LTP		1				
CEPN	radiation protection R&D center - NPO	Association	France	LTP				1		1
CERAD-NMBU	Centre for Environmental Radioactivity (CERAD)	Research Institute	Norway	LTP	1	1		1		1
CERN	European Organisation for Nuclear Research	International Organization	Switzerla nd				1			
CESNEF	Politechnico di Milano	University	Italy				1			
CIEMAT	Centro de InvestigacionesEnergéticas Medioambientales y Tecnologicas	Research Institute	Spain	BEN		1	1	1		1

CLOR	CentralneLaboratoriumOchronyRadiologicznej (CLOR)	Research Institute	Poland			1				
CND	Centro Nacional de Dosimetrica	Research Institute	Spain				1			
Collegium Civitas	Collegium Civitas	Research Institute	Poland							1
Controlatom	VincotteControlatom	Research Institute	Belgium				1			
CRIEPI	Central Research Institute of Electric Power Industry	Research Institute	Japan	TP				1		
CTU	CESKE VYSOKEUCENITECHNICKE V PRAZE Czech Technical University	University	Czech Republic				1			
DEMA	Danish Emergency Management Agency (DEMA, Denmark)	National body	Denmark	BEN				1		
Dialogik	Dialogik	non-profit research institute	Germany	TP						
DIT	DUBLIN INSTITUTE OF TECHNOLOGY, DIT	Research Institute	Ireland	TP						
DMI	Danish Meterological Institute	Research Institute	Denmark	LTP				1		
DOSILAB	DOSILAB AG	SME	Switzerland				1			
DOZIMED	Dozimed Ltd	SME	Romania				1			
DSA	Norwegian Radiation and Nuclear Safety Authority	National body	Norway	BEN	1	1	1	1		
DTU	Technical University of Denmark	University	Denmark	LTP				1		
DurhamUni	UNIVERSITY OF DURHAM	University	United Kingdom	LTP						
DWD	Germany's National Meteorological Service	National body	Germany					1		
EANM	European Association of Nuclear Medicine	Association	Austria		1				1	
EEAE	The Greek Atomic Energy Commission	National body	Greece	BEN	1		1	1		1
EFOMP	European Federation of Organisations for Medical Physics	Association	United Kingdom		1				1	
EFRS	European Federation of Radiographer Societies	Association	The Netherlands		1				1	
EIMV	Milan Vidmar Electric Power Research Institute	Research Institute	Slovenia					1		
Else Nuclear	Else Nuclear srl	SME	Italy				1			
ENCONET	nuclear research institute	Research Institute	Croatia					1		
ENEA	National Agency for New Technology, Energy and the Environment	National body	Italy	BEN	1		1	1		

ENSTII	EUROPEAN NUCLEAR SAFETY TRAINING AND TUTORING INSTITUTE	Association	France	LTP						
EPA	Environmental Protection Agency	National body	Ireland	BEN		1		1		
ESR	European Society of Radiology	Association	Austria		1				1	
ESTRO	the European SocieTy for Radiotherapy & Oncology,	Association	Belgium		1				1	
EURADOS	EUROPEAN RADIATION DOSIMETRY GROUP	Association	Germany	BEN			1			
EURAMED	EUROPEAN ALLIANCE FOR MEDICAL RADIATION PROTECTION RESEARCH (EURAMED)	Association	Austria	BEN					1	
Faculty of Medicine	Faculty of Medicine, University of Osijek	University	Croatia				1			
FANC	Federal Agency of Nuclear Control	National Body	Belgium					1		
FCT	FCT - Fundacao para a Ciencia e Tecnologia / Foundation for Science and Technology, Portugal	Funding Agency	Portugal	BEN						
FEERCObninsk	Federal Environmental Emergency Response Centre of Roshydromet	National Body	Russia					1		
FMBA	Federal Medical Biophysical Centre	Research Institute	Russia				1			
FMU	Fukushima Medical University	University	Japan	TP				1		
FOPH	Federal Office of Public Health	National body	Switzerland	BEN				1		
FSS-Uni-LJ	UNIVERZA V LJUBLJANI	University	Slovenia	LTP						
FU	Fukushima University	University	Japan			1		1		
GIG	Główny Instytut Górnictwa (GIG)	Research Institute	Poland	BEN		1				
GRS	Global Research for Safety - non profit organisation	Research Institute	Germany					1		
GSI	GSI HELMHOLTZ ZENTRUM FUER SCHWERIONENFORSCHUNG GMBH	Research Institute	Germany	LTP						
GU	University of Gothenburg	University	Sweden					1		
GUF	Goethe-University, Frankfurt am Main	University	Germany	TP						
HMGU	Helmholtz Zentrum München, Deutsches Forschungszentrum für Gesundheit und Umwelt	Research Institute	Germany	BEN	1	1	1			
HU	Hiroshima University	University	Japan					1		
HUG	HôpitauxUniversitaires de Genève	Hospital	Switzerland	TP						
HZDR	Helmholtz-Zentrum Dresden-Rossendorf (HZDR)	Research Institute	Germany	LTP		1				

IAEA	International Atomic Energy Agency	International Organization	Austria				1			
IFA	IFA - Institutul de FizicăAtomică, Romania	Research Institute	Romania	BEN						
IFIN-HH	INSTITUTUL NATIONAL DE CERCETARE - DEZVOLTAREPENTRUFIZICA SI INGINERIENUCLEARA "HORIAHULUBEI" (IFIN-HH)	Research Institute	Romania	LTP						
IFJ	Institute of Nuclear Physics	Research Institute	Poland	LTP			1			
JSI	Jožef Stefan Institute	Research Institute	Slovenia	BEN			1	1		
IMP	Nofer Institute of Occupational Medicine	Research Institute	Poland				1			
IMROH	Institute for Medical Research and Occupational Health	Research Institute	Croatia	BEN	1	1		1		
IN2P3	National Institute of Nuclear Physics and Particle Physics (IN2P3 - CNRS)	Research Institute	France			1				
INFN	IstitutoNazionale di FisicaNucleare	Research Institute	Italy		1		1			
IORH	SERBIAN INSTITUTE OF OCCUPATIONAL HEALTH	Research Institute	Serbia				1			
IOV	IstitutoOncologico Veneto	Research Institute	Italy	TP	1					
IPCESCOLA S	*IPC-Escola Superior de Tecnologia da Saúde de Coimbra*	University	Portugal						1	
IPH	Institute of public Health	National body	Macedonia				1			
IPOP	InstitutoPortugues de Oncologia do Porto	Research Institute	Portugal				1			
IR	Institute of Radiobiology of NAS of Belarus	Research Institute	Belarus					1		
IRA	University Institute for Radiation Physics	Research Institute	Switzerland		1		1			
IRSN	Institut de Radioprotection et de SuretéNucléaire	Research Institute	France	BEN	1	1	1	1	1	1
IS CAS	Institute of Sociology of the Czech Academy of Sciences	Research Institute	Czech Republic							1
IS Global	Institut de Salut Global	Research Institute	Spain	LTP	1			1		1
ISS	InstitutoSuperiore di Sanita	Research Institute	Italy	BEN	1		1			
IST	Instituto Superior Técnico	Research Institute	Portugal	LTP	1	1	1	1		
IU School	IU School	Association	United States	TP						
JCU	University of South Bohemia	University	Czech Republic		1					1

JRC-ISPRA	European Commission – Joint Research Centre	Research Institute	International					1		
Juelich	FORSCHUNGSZENTRUMJULICH GMBH	Research Institute	Germany	LTP						
JYU	University of Jyväskylä	University	Finland							1
KCOR	National Centre for Radiation Protection in Health Care	National body	Poland				1			
KIT	Karlsruhe Institute of Technology	Unversity	Germany	LTP	1		1	1		
KNMI	The Royal Netherlands Meteorological Institute	Research Institute	The Netherlands	TP						
KU	Kingston University, London	University	United Kingdom							1
KVSF	Network of Competence in Radiation Research ,	Association	Germany		1					
Landauer	Landauer	SME	France				1			
LARUEX	University of Extremadura: LARUEX	University	Spain			1				
LEGMC	Latvian Environment, Geology and Meteorology Centre (LEGMC)	National Body	Latvia				1			
LUH	Leibniz Universität Hannover	University	Germany			1				
MarkkuLehtonen	historian/nuclear governance	individual	Finland							1
MBS AC UK	Manchester business school	University	United Kingdom					1		
MED LU	Lund medical faculty of medicine	University	Sweden					1		
MedUni Vienna	MedUni Vienna - Medical University of Vienna, Austria	University	Austria	BEN	1					
MELODI	Association Melodi	Association	France	BEN						
MERIENCE	Promoting dialogue to inspire solutions for complex environmental & socio-technical challenges	SME	Spain							1
MET.no	Norwegian Met Institute	National body	Norway	TP						
MetOffice	MET OFFICE	National body	United Kingdom	LTP						
MINECO	MINECO-Minesterio De Economia y Competitividad	Funding Agency	Spain	BEN						
Mirion	Mirion Technologies - Dosimetry Services Division	SME	United States				1			
MP	Medical Physics, Lund university	University	Sweden				1			
MSKCC	Memorial Sloan Kettering Cancer Center	Research Institute	United States	TP						
MTA EK	Hungarian Academy of Sciences, Centre for Energy Research	Research Institute	Hungary	BEN	1		1	1		

MUTADIS	risk governance R&D team	SME	France	LTP				1		
Nadia Zeleznik	psychologist/nuclear physics/president Nuclear Transparency Watch	Individual	Slovenia					1		1
NCBJ	National Centre for Nuclear Research	Research Institute	Poland				1	1		
NCRRP	Ministry of Health, National Centre of Radiobiology and Radiation Protection ,	Research Institute	Bulgaria	BEN	1					
NCSRD	The National Center for Scientific Research "Demokritos" (NCSRD)	Research Institute	Greece	LTP		1		1		
NERIS	ASSOCIATION DE LA PLATEFORME EUROPEENNE NERIS	Association	France	BEN						
NIPH	Norwegian Institute of Public Health	Research Institute	Norway		1					
NIPNE	Horia Hulubei National Institute for R&D in Physics and Nuclear Engineering	Research Institute	Romania					1		
NNCRK	National Nuclear Center of the Republic of Kazakhstan	Research Institute	Kazakhstan			1				
NPL	National Physical Laboratory	Research Institute	United Kingdom				1			
NRG	Nuclear Research and Consultancy Group	SME	The Netherlands			1	1			
NRI	UJVREZ, a. s.	University	Czech Republic	LTP						
NRIRR	Frédéric Joliot-Curie National Research Institute for Radiobiology and Radiohygiene	Research Institute	Hungary	BEN	1		1			
NTUA	NATIONAL TECHNICAL UNIVERSITY OF ATHENS - NTUA	University	Greece	LTP						
NU	Nagasaki University	University	Japan					1		
Nuvia	Nuvia Ltd	SME	United Kingdom				1			
OBU	OXFORD BROOKES UNIVERSITY	University	United Kingdom	LTP						
PAAGOV	national atomic energy agency	National body	Poland					1		
PDC-ARGOS	software system to support the emergency organization	SME	Denmark	LTP				1		
PHE	Public Health England-Department of health	Research Institute	United Kingdom	BEN	1		1	1		
PHI	Public Health Institute	Research Institute	Bosnia and Herzegovina				1			
PRI	Institute of Radiation Protection	Research Institute	Ukraine				1			

PSI	Paul Scherrer Institut	Research Institute	Switzerland				1			
PTB	Physikalisch-Technische Bundesanstalt	Research Institute	Germany	LTP			1			
RBI	Ruder Boskovic Institute	Research Institute	Croatia	LTP			1	1		
REC	REGIONAL ENVIRONMENTAL CENTER FOR CENTRAL AND EASTERN EUROPE -REC	Research Institute	The Netherlands	TP						
RIKILT	Institute of Food Safety	Research Institute	The Netherlands	TP						
RISOE	Risoe National Laboratory	Research Institute	Denmark				1			
RIVM	National Institute for Public Health and the Environment	Research Institute	The Netherlands	BEN	1			1		
RPII	Radiological Protection Institute of Ireland	Research Institute	Ireland				1			
RSC	Radiation Protection Centre	Research Institute	Lithuania	BEN			1			
RTU	RIGASTEHNISKAUNIVERSITATE	University	Latvia	LTP						
SCIENSANO	Institut Scientifique de Santé Publique,	Research Institute	Belgium		1					
SCK•CEN	Studiecentrum voor Kernenergie - Centre d'Etude de l'Energie Nucleaire	Research Institute	Belgium	BEN	1	1	1	1	1	1
SERGAS	Servizo Galego de Saúde	Research Institute	Spain		1					
SIS	National Institute of Radiation Hygiene	Research Institute	Denmark				1			
SL	Seibersdorf Laboratories	Research Institute	Austria	LTP			1			
SMHI	Swedish Meteorological and Hydrological Institute	Research Institute	Sweden					1		
SMU	Slovak Medical University	University	Slovak Republic				1			
SSM	Swedish Radiation Safety Authority	National body	Sweden	BEN	1	1	1	1		
St James's Hospital	St James's Hospital, Dublin	Hospital	Ireland	TP			1			
STUK	Radiation and Nuclear Safety Authority	Research Institute	Finland	BEN	1	1	1	1		1
SU	Stockholm University Centre for Radiation Protection Research	University	Sweden	LTP	1					
SUBI	Southern Urals Biophysics Institute (SUBI)	Research Institute	Russia	TP						
SURO	National Radiation Protection Institute	Research Institute	Czech Republic	BEN				1		
SYMLOG	Symlog	SME	France							1
TECNATOM	nuclear engineering company	SME	Spain				1	1		

THUNEN	Thünen Institute of Fisheries Ecology (THUNEN)	Research Institute	Germany			1				
TU Delft	Delft University of Technology	University	The Netherla nds							1
TUDr	Technische Universitaet Dresden	University	Germany				1			
UA	University of Aveiro (UA)	University	Portugal			1				
UAB	Universitat Autònoma de Barcelona	University	Spain	TP	1					
UAM	Madrid Autonomous University,	University	Spain		1					
UB	University of Barcelona (UB)	University	Spain			1				
UCEWP	Ukrainian Centre of Environmental and Water Projects	National body	Ukraine					1		
Ucrete	University of Crete	University	Greece						1	
UEF	University of Eastern Finland	University	Finland	BEN	1					
UFC	Université Franche-Comté (UFC)	University	France	TP						
UGR	University of Granada (UGR)	University	Spain			1				
UHasselt	Hasselt University	University	Belgium							1
UHCZ	University Hospital Centre Zagreb	University	Croatia				1			
UHL	University Hospital Limerick	University	Ireland	TP						
UJF	Nuclear Physics Institute ASCR	Research Institute	Czech Republic	LTP			1			
UK	University of Kragujevac	University	Serbia				1			
UL	UL - LatvijasUniversitate, Latvia	University	Latvia	BEN						
UL	Lund University (UL)	University	Sweden	TP						
ULg	UNIVERSITE DE LIEGE	University	Belgium	LTP						
ULISBOA	Universidade de Lisboa	University	Portugal		1					
UMB	Matej Bel University	University	Slovak Republic							1
UNEX	University of Extramadura	University	Spain	TP				1		
unibremen	Bremen University	University	Germany					1		
UNIMI	University of Milano	University	Italy	LTP				1		1
UNINA2	Second University of Naples (SUN)	University	Italy		1					
Unipa	Universita di Palermo	University	Italy				1			
UniPavia	Uni Pavia - University PAVIA, Italy	University	Italy	BEN	1					
UnivDublin	University College Dublin	University	Ireland						1	
University of Exeter	University of Exeter	University	United Kingdom							1

University of Valencia	University of Valencia	University	Spain					1		
Univmainz	Medical university Centre Mainz	University	Germany						1	
UOA	University of Antwerp	University	Belgium							1
UOWM	Universtity of Western Macedonia	University	Greece					1		
UP	University of Porto (UP)	University	Portugal			1				
UPC	Universitat Politècnica de Catalunya	University	Spain	LTP			1			
UPM	Universidad Politécnica de Madrid	University	Spain				1	1		
UPV	University of the Basque Country (UPV/EHU)	University	Spain			1				
UROS	Universitaet Rostock	University	Germany		1					
URV	Rovira I Virgili University, Laboratory of Toxicology and Environmental Health	University	Spain		1					
USP	Universitadegli Studi di Pisa	University	Italy				1			
UT	UT - University of Tartu, Estonia	University	Estonia	BEN						
UTA	TAMPEREENKORKEAKOULUSAATIO SR	University	Finland	LTP						
UU	Uppsala University	University	Sweden				1			
UZH	University of Zurich	University	Switzerland	TP						
VIN	Institute of Nuclear Sciences - Vinca	Research Institute	Serbia	TP			1			
VUJE	nuclear power engineering company	SME	Slovak Republic	BEN				1		
WarwickUni	THE UNIVERSITY OF WARWICK	University	United Kingdom	LTP				1		
Wiv-ISP	Belgian Scientific Institute of Public Health	Research Institute	Belgium	TP						

7.2. Annex 2: Strategic Research Agendas of the Radiation Protection Research Platforms

Strategic Research Agenda of the Multidisciplinary European Low Dose Initiative (MELODI) – 2019

S. Bouffler, A. Auvinen, E. Cardis, M. Durante, J.R. Jourdain, M. Harms-Ringdahl, M. Kreuzer, B. Madas, S. Pazzaglia K. M. Prise, R. Quintens,
M. Blettner, A. Ottolenghi, L. Sabatier (SRA working group observers)

MELODI Working Group SRA

Simon Bouffler, PHE, UK (chair)
Anssi Auvinnen, University of Tampere, STUK, Finland
Elisabeth Cardis, ISGlobal, Spain
Marco Durante, TIFPA, Italy
Jean-René Jourdain, IRSN, France
Mats Harms-Ringdahl, University of Stockholm, Sweden
Michaela Kreuzer, BfS, Germany (vice chair)
Balázs Madas, MTA, Hungary
Simonetta Pazzaglia, ENEA, Italy
Kevin Prise, University of Belfast, UK
Roel Quintes, SCK-CEN, Belgium

Observers from other MELODI WGs

Andrea Ottolenghi, University of Pavia, Italy (Education & Training WG)
Laure Sabatier, CEA, France (Infrastructure WG)

Observer from MELODI Scientific Advisory Committee (SAC)

Maria Blettner, formerly Johannes Gutenberg Medical University, Mainz, Germany (retired)

Contents

1. Executive Summary

The Multidisciplinary European Low Dose Initiative (MELODI) is a European Platform dedicated to low dose ionizing radiation risk research. The challenge is to improve the quantification of risks and reduce the uncertainties in the risk estimates, as well as to develop and validate risk models that best characterise health effects at low doses, drawing on both epidemiological and radiobiological understanding. In 2010, MELODI was founded as a registered association with 15 members; membership has now increased to 44 institutions.

A major activity of MELODI is the establishment and periodic revision of a long term Strategic Research Agenda (SRA) for research on low dose risk for radiation protection in Europe. MELODI considers low doses to be those where there remains substantial uncertainty on the magnitude of health risk. The SRA is intended to guide the priorities for national and European research programmes and the preparation of competitive calls at the European level in order to fill research gaps and test the hypotheses on which the current RP system is based. The ultimate goal is to provide an improved evidence-based protection of the population. A key priority for radiation protection research is to improve and reduce the uncertainties associated health risk estimates for exposures at low doses and dose rates that are relevant for the dose limits for occupational exposures, reference levels for the exposure of the population in emergency situations, diagnostic reference levels for medical exposures, damage to normal tissues during radiotherapy, reference levels for radon exposures in buildings and occupational compensation scheme claims, amongst others. The approaches have to be multidisciplinary and innovative to provide the best opportunities for advancing understanding of low dose and low lose-rate effects. Incorporation of expertise outside of the conventional fields of radiation research is essential to widen the prospects for broadening approaches and adopting novel methods in health research in the assessment of health risk relevant to radiation protection. MELODI is also concerned to ensure the availability of key infrastructures as an essential basis for research activities, and to maintain competences in radiation research and health risk assessment in the long term via an integrated European approach for training and education. For these purposes, in February 2014, MELODI established three working groups (WGs), one on the MELODI SRA, one on Infrastructures and a third on Education and Training.

The SRA is periodically updated by the MELODI SRA Working Group (WG), systematically taking into account results of recent research and emerging radiation protection research issues. Open consultations via website and the annual MELODI workshops are regularly conducted, the results of which are taken into account in the revised SRA. Prior to calls from the European Commission (EC) or EC-funded projects in radiation protection, in addition to the SRA, a short MELODI statement presenting the top priorities is developed by the MELODI WG SRA and an open consultation process initiated.

In recent years, large parts of radiation protection research in Europe have been organized within a European Joint Programme (EJP), CONCERT. The aim of the EJP was to bring together relevant funding agencies from the EC and its Member States to integrate European research and to administer calls for research proposals in radiation protection on behalf of the EC. This activity is built upon and aimed to promote integration of the SRAs from six European radiation protection research platforms and aims to establish interaction and synergies between the different areas of expertise: MELODI (low dose and dose-rate risk research), ALLIANCE (Radioecology), NERIS (Emergency management), EURADOS (Dosimetry issues), EURAMED (Medical associations), and SHARE (social sciences/humanities). Research findings arising from projects funded by the CONCERT calls have, along with other developments, contributed to updating the SRA. When CONCERT comes to an end, it is not clear how future integrated European radiation protection research will be funded. Some follow-on project(s) to CONCERT may emerge, alternatively the EU EURATOM programme may directly fund research or substantial national programmes may be launched, either way the SRA aims to provide a guide for these funding routes.

The activities of MELODI can be seen to be complementary to other co-ordination activities elsewhere such as the IDEA initiative in the USA, the Japanese PLANET initiative and others. Most recently the OECD's Nuclear Energy Agency Committee on Radiation Protection and Public Health (https://www.oecd-nea.org/rp/crpph.html) has been working to co-ordinate efforts on a global scale.

The current 9th MELODI SRA for the year 2019 describes two research topics and two cross cutting topics (which are relevant for both of the research topics) in low dose or low dose-rate radiation risk research. The topics relate to the diseases of concern, (1) cancers and (2) non-cancer diseases. The cross-cutting topics that are relevant to both of these disease categories are (3) individual variation in risk and (4) effects of spatial- and temporal-variation in dose delivery on disease risk. Each if these is considered in detail in the SRA.

The research required to improve the evidence base for each of the four topics may be grouped into two categories:

1) Research to improve understanding of the mechanisms contributing to radiogenic diseases following low dose and dose-rate exposures
2) Epidemiological research that integrates, where possible and informative, biological and molecular markers to improve health risk evaluation of radiation exposure

The current and former versions of the MELODI SRAs and statements can be downloaded from the following website: www.melodi-online.eu. The current SRA structure is outlined in **Figure 1**.

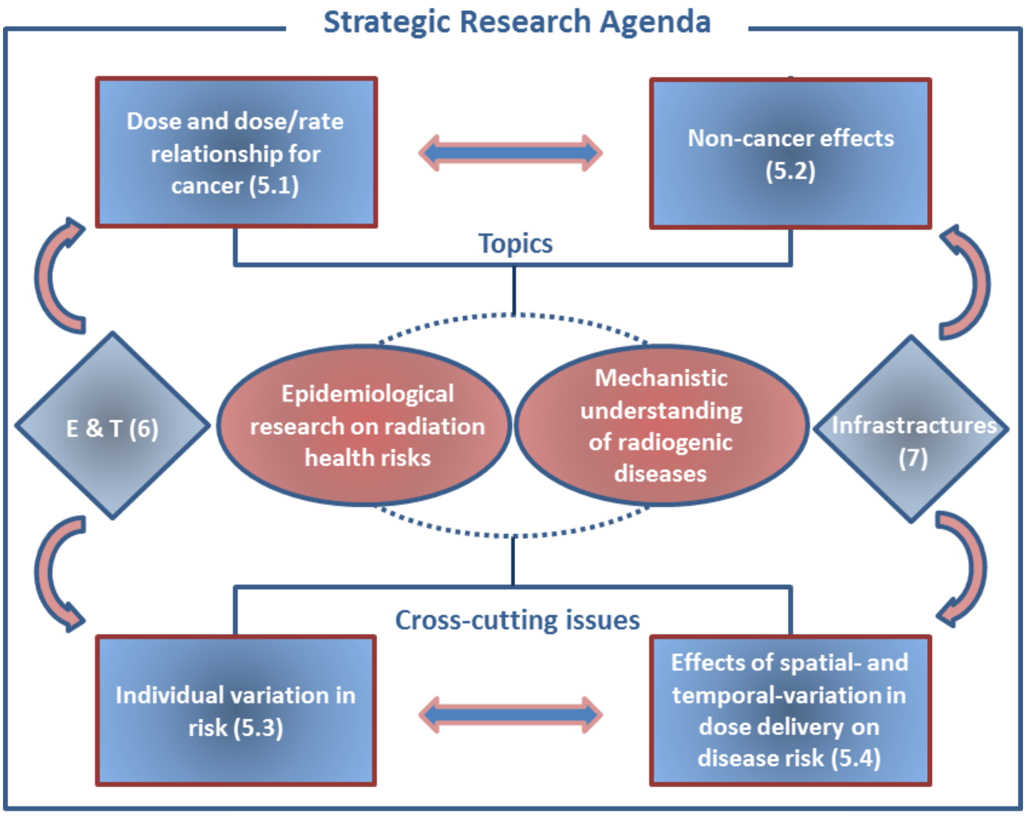


Figure 1: Outline of the structure of the Strategic Research Agenda (SRA), numbers in parentheses refer to the SRA section dealing with each topic/issue.

2. Importance of low dose radiation health risk research

Exposure to ionizing radiation is unavoidable. Everybody encounters exposure from a range of natural and artificial sources. Medical and natural sources are the largest components of the average dose received by the general public. Exposures to artificial sources can vary between individuals depending on their occupation (e.g. employment in the nuclear industry, in air transport and in medicine, particularly interventional radiologists), medical exposures (diagnostic and therapeutic procedures) and in somecases due to environmental contamination. Exposure from naturally occurring radiation involves background from terrestrial and cosmic sources, and internal exposure from radioisotopes such as radon and uranium, there is notable geographic variation in radon exposure. There are many and varied uses of radiation in modern society. Nuclear power generation is viewed as a carbon neutral and efficient energy source; industrial radiography plays important roles in safety assessment; medical uses of radiation for diagnostics and therapy are extensive and rapidly increasing. Long distance air travel can lead to exposures, typically 0.08 mSv for a transatlantic flight though altitude, duration and other parameters can affect the actual exposure level. Other sources are exposures to 'NORM' (Naturally occurring radioactive materials) in the oil extraction and other industries. Broadening access to space travel is anticipated, with both longer exploratory missions likely as well as some commercial space travel under development.

Not only is exposure to ionizing radiation unavoidable and variable in the population, but it is known to damage health at certain exposure levels. At very high doses radiation exposure can be lethal, while tissue damage can occur following more localized high dose exposures. Whole body exposures at these levels are very rare, but for localised exposures, severe tissue damage can be observed in some patients following radiotherapy for cancer.

Evidence accumulated over many decades demonstrates that radiation can cause cancer in humans following acute exposure in the dose range of a few Gy down to 100 mGy or less, with children often showing higher sensitivity. There are indicationss that these more moderate exposures may also be associated with other conditions such as circulatory diseases, cataracts, cognitive impairment, immunological effects – collectively described as 'non-cancer diseases' and effects on future generations (hereditary or transgenerational effects). The risks to humans in terms of cancer are established down to around 100 mGy in adults, for circulatory diseases and lens opacities down to about 500mGy and about 200mGy for defects on brain development and cognition after prenatal exposure during neurogenesis. The risks to human health below these levels, especially following protracted or other non-homogenous exposures are less certain. Currently, the system of radiation protection aims to avoid tissue injury and minimize the risk of cancer and the possibility of hereditary disease. For radiation protection purposes, risks of cancer and possible hereditary effects below 100 mGy are regulated on the basis of an assumed linear non-threshold (LNT) relationship between dose and incidence. However, there remains uncertainty about the exact dose-response relationship for such low-dose exposures, and the impact of protracting exposures over long periods such as during a working lifetime.

Striking the appropriate and acceptable balance between the benefits accrued from activities involving exposure to radiation on the one hand and the health risks posed on the other is important. The regulation for protection of individuals and populations comes at a financial cost – there are, therefore, disadvantages to both under- and over-protection. This applies in all situations – existing elevated exposure situations such as high radon areas, occupational settings such as the nuclear industry and the medical sector, and accidental situations where difficult decisions on countermeasure implementation such as sheltering and evacuation are required. In all these contexts, it is critical to utilise robust and accurate information on the magnitude of health risks posed by given radiation doses, ranging from high to low.

The main uncertainties in radiation health risk evaluation are in the magnitude of cancer risk at low and protracted doses below 100 mGy, the magnitude of non-cancer effects below 500mGy, the variation in individual risk within the population, and the variation in risk with dose distribution in space and time. These are therefore the key areas requiring further exploration to provide better and more reliable evidence for appropriate decision making in all areas of radiation protection. Accurate and reliable low dose human health risk estimation is an essential foundation for a robust and acceptable system of radiation protection.

2.1 *Dose and dose rate ranges to be considered*

For the purposes of this document, MELODI considers low doses to be those where there remains substantial uncertainty on the magnitude of health risk. For low LET radiations these are taken to be those of 100 mGy and below when considering cancer risks, and 500 mGy and below when considering non-cancer diseases as recognised by international organisations such as the
United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the International Commission on Radiological Protection (ICRP). In the context of cancer risk, moderate doses are those between 100 mGy and 2 Gy, with high doses being those above 2 Gy. For non-cancer diseases, MELODI considers moderate doses as those between 500 mGy and 5 Gy, and high doses those above 5 Gy. Low dose-rates are those of 0.1 mGy min^{-1} or less for low LET radiation, or one-track traversal per cell per hour for high LET radiations. These definitions apply both for organ and whole-body doses. Note that units of Sievert (effective dose, a radiation quality and tissue sensitivity weighted quantity) are frequently used for cancer risk. Effective dose, as defined by ICRP, relates specifically to cancer and hereditary effects, it is therefore not appropriate to use for non-cancer outcomes. Sieverts are also not directly quantifiable and sothe absorbed dose units of Gray are generally used in this document; furthermore, these are the units used for dose quantification in experimental and epidemiological investigations.

3. MELODI

The purpose of the MELODI Association, as given in its Statutes, is to constitute a European Research Platform in the field of low dose ionizing radiation health risk assessment and its application for radiation protection and to coordinate and promote research and long-term competence on effects and risks to human health associated with low-dose and low-dose rate exposures to ionizing radiation.
MELODI currently has 44 members including national bodies responsible for defining, funding and implementing research on low dose risk, as well as universities and research institutes committed to contribute to R&D efforts. It is a research association that contributes to the definition of priority objectives in low dose risk research, fostering of research programmes and initiatives to achieve these objectives, assessment of results obtained, and promotion of communication on these issues between the various parties involved as well as sustainability of key research capacity and infrastructure. These functions are performed by organizing scientific and stakeholder workshops,

promoting the visibility of the research area, establishing working groups on specific topics and facilitating collaborative research.

To achieve these goals, the establishment and regular updating of a long term (>20 years) SRA for research to improve protection from low dose health risks in Europe remains a major activity of MELODI. It provides guidance on the priorities for national and European research programmes and the preparation of competitive calls at the European level. Furthermore, MELODI supports the availability and maintenance of key infrastructures as an essential basis for research activities, and the retention and development of competences in radiation research and health risk assessment in the long term via an integrated European approach for training and education. As the primary aim of the MELODI SRAs is to provide Euratom, national authorities and funding agencies with scientific research agendas to guide the preparation of calls and areas for prioritization, the significance of this work should periodically be evaluated for its impact on the content of calls and research prioritizations, and advances made through funded projects. Ultimately, the research guided by the SRA is anticipated to make an impact on radiation protection policy.

Following the recommendations and roadmap established by the High Level and Expert Group on European Low Dose Risk Research (HLEG) in 2009 (https://cordis.europa.eu/docs/publications/1070/107087891-6_en.pdf), and supported over time by DoReMi, OPERRA and CONCERT, the latter moving to integrate SRAs covering all aspects of radiation protection research in Europe, the radiation protection research community within Europe has been progressively more deeply integrated over the past decade.

In October 2010, the first draft of a MELODI SRA was published on the MELODI Website and opened for public consultation. The contents were based on the considerations and key priority issues formulated by the HLEG and DoReMi. In February 2014, the MELODI Board of Directors (BoD, now re-constituted as the MELODI Executive Committee) established three working groups (WG's), on the MELODI SRA, Education & Training and Infrastructures. The MELODI SRA is updated periodically by the SRA WG, taking into account recent and emerging research results and radiation protection research issues. The updated draft and a short MELODI statement (usually in years where an EC or EC-funded project call will be launched), presenting the top priorities, is posted on the public MELODI website, usually before the annual MELODI workshop - now European Radiation Protection Week (ERPW), and an open consultation process is set-up via the website and the workshop to seek input from other scientists and stakeholders before the SRA´s and statement's revision. The updated SRA and MELODI statement are also sent to the independent Scientific Advisory Committee of MELODI for comment. The final SRA and MELODI statement are prepared for approval by the MELODI Executive Committee. The current edition of the SRA will be the ninth version.

3.1 MELODI in the context of other radiation research platforms

Currently, large parts of European radiation protection research are organized within the CONCERT European Joint Programme (EJP). The EJP has brought together relevant funding agencies from the EC and Member States to integrate European research, and to administer calls for research proposals in radiation protection on behalf of the European Commission. This activity builds upon the Strategic Research Agendas from six European radiation protection research platforms, MELODI, ALLIANCE (radioecology), NERIS (emergency management), EURADOS (dosimetry issues), EURAMED (medical associations), and SHARE (social sciences and humanities), and aims to establish interaction and synergies between the different areas of expertise. Integration across the different platform areas is being fostered and developed through the drafting of a roadmap to guide all research related to radiation protection, and further integration can be anticipated in future years. CONCERT will come to an end in 2020, and it is not yet clear if any similar cross-platform integration will continue to be funded.

MELODI's activities can be seen to be complimentary to other co-ordination activities elsewhere such as the IDEA initiative in the USA (see Cool, 2019, Int J Radiat Biol. 95(10):1358-1360), the Japanese PLANET initiative and others described by Cho et al (Cho et al, 2019, Int J Radiat Biol. 2019 95(7):816-840, Repussard, 2019, 95(10):1354-1357 . Most recently the OECD's Nuclear Energy Agency Committee on Radiation Protection and Public Health (https://www.oecd-nea.org/rp/crpph.html) has been working to co-ordinate efforts on a global scale. Furthermore, MELODI aims to be responsive to the key challenges in the system of radiation protection as identified by international organisations such as UNSCEAR and ICRP.

4. Summary of Developments since last SRA update

Recent advances in radiation epidemiology are starting to provide evidence of risk to health at doses below the 100 mGy level used to define low dose exposure. The INWORKS series of pooled occupational exposure studies suggests that significantly increased risks of solid cancer and leukaemia can be detected at doses of 100 mGy when delivered over a working life. Though the subject of continued debate, several studies of cancer risks associated with exposure to CT scans in childhood suggest significant increases in leukaemia and brain cancer risk at 50 mGy and above. Likewise, some studies have shown increased risk of childhood leukaemia from natural background radiation, though the evidence is not consistent and dose assessment often not based on individual measurements. Thus, this SRA edition is being written at a time of strengthening evidence of cancer risks at 100 mGy and below, even when exposures are protracted over time. Much of this evidence has been drawn from European cohort studies.

When this SRA was last updated the research projects running under the CONCERT European Joint Programme were starting and results of the 2017 and 2018 EURATOM calls were not available. The research areas covered by these projects is summarised here.

The 2016 and 2017 CONCERT calls have funded nine projects. Those most relevant to MELODI are:

- LDLensRad – an investigation of mechanisms underlying radiation-induced lens opacities and dose/dose-rate effects at low exposure levels. The project relates to SRA topic, Non-cancer disease, basic mechanistic investigations.
- LEU-TRACK – an investigation into the role of micro-vesicles and their 'cargo' in radiation leukaemogenesis. The work relates to SRA topic, Dose and dose-rate dependence of cancer risk, basic mechanistic investigations.
- SEPARATE – concerns the effects of partial body irradiation, particularly out-of-field effects, and how they may affect health risk following exposure. This project relates to SRA topics, Non-cancer diseases, basic mechanistic investigations and consideration of spatial/temporal variation of dose delivery.

In 2017 EURATOM ran a call for research in medical radiation protection that resulted in the funding of one project:

- MEDIRAD – is a wide-ranging project with elements of epidemiology, real time organ dose estimation from diagnostic and nuclear medicine procedures, testing of multinational image and dose repositories, experimental work and modelling, relating mainly to impacts of therapeutic and diagnostic medical exposures on cancer and non-cancer diseases, including consideration of individual variation in response. This project relates to SRA topics, Dose and dose-rate dependence of cancer risk/non-cancer diseases/individual variation in risk by mechanistic and epidemiological investigations.

In 2018 a further EURATOM call in radiation protection resulted in the funding of one project:

- HARMONIC is a large multi-disciplinary project to contribute to improvements in the understanding of health effects of medical IR exposure of paediatric patients, focusing on two distinct scenarios: (1) Paediatric patients undergoing modern radiotherapy (including proton therapy); (2) Paediatric patients undergoing interventional cardiology. The project will explore potential effects at very early ages, exposure to a wide range of doses from photons, protons and secondary neutrons radiation. It will also build European cohorts and registries for long term follow-up in the context of very rapid technology evolution. The study will use state-of-the art dosimetry, complemented by non-invasive imaging and molecular epidemiology to assess: endocrine dysfunctions, cardio and neurovascular diseases, societal impact and cancer. The project will also investigate radiation-induced cellular responses in samples of blood and saliva, and the mechanisms involved in the processes that may lead to cancer and vascular diseases. Ultimately, HARMONIC will develop tools and allow definition of guidelines on optimization techniques to guide treatments toward reduction of patient doses in paediatric cardiology and oncology. Relates to SRA topics, dose and dose-rate dependence of cancer risk/non-cancer diseases, individual variation in risk and consideration of spatial/temporal variation in dose delivery by mechanistic and epidemiological investigations".

Additionally, MELODI has sponsored two workshops, one concerning individual sensitivity to radiation and another concerning non-cancer disease. Outputs and recommendations from the former are currently under review, in press or published (Gomolka et al, 2019, Int J Radiat Biol. Jul 26:1-17. doi: 10.1080/09553002.2019.1642544, Seibold et al, 2019, Int J Radiat Biol. 2019 Sep 20:1-16. doi: 10.1080/09553002.2019.1665209, and further publications submitted or in press). Key recommendations for research from these publications will be considered here when available.

Beyond the activities of MELODI, there have been documents of relevance to this SRA publushe dby UNSCEAR in recent years – most notably UNSCEAR 2017, Annex B - Epidemiological studies of cancer risk due to low-dose-rate radiation from environmental sources and the UNSCEAR 2018 White paper, Evaluation of data on thyroid cancer in regions affected by the Chernobyl accident. There have been no publications directly relevant to MELODI from ICRP since the last SRA edition. NCRP have publlshed in 2018 its Report No. 181 – Evaluation of the Relative Effectiveness of Low-Energy Photons and Electrons in Inducing Cancer in Humans, and Commentary No. 27 – Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection; and in 2019 its Report No. 183 – Radiation Exposure in Space and the Potential for Central Nervous System Effects: Phase II.

5. Strategic Research Agenda

Radiation protection is one particular area of health protection concerning the prevention of radiation induced non-communicable diseases and tissue damage, notably cancers and some non-cancer diseases in the general public, patients and workers. The health impacts of radiation generally concern diseases or biological effects that are multi-factorial in origin, with both intrinsic and extrinsic risk factors. The intrinsic, non-modifiable risk factors, include age and sex as well as less well characterised genetic and other factors, all of which, in addition to being important risk factors in themselves, may also modify the health impact of radiation. There is also, a wide range of modifiable risk factors affecting the incidence of these diseases, including 'lifestyle' factors such as diet, tobacco smoking and exercise, as well as natural and human-made environmental factors including co-exposures to other environmental and occupational carcinogens and medicinal drugs. Radiation protection research therefore needs to be viewed in this wider context where any radiation exposures and effects on health are rarely, if ever, experienced alone; rather individuals and their disease risk can be influenced by their genome, epigenome, exposome, microbiome and other factors. This wide range of influences on individual and population health risk can pose problems for discerning the impact of radiation exposures, especially when exposure levels are low. As stated earlier, radiation protection is but one element of general health protection relevant in public, occupational and medical exposure settings.

The MELODI SRA is based on the key policy goals defined by the HLEG (*www.hleg.de/*) to address the robustness of the current radiation protection system (see **Figure 2**).

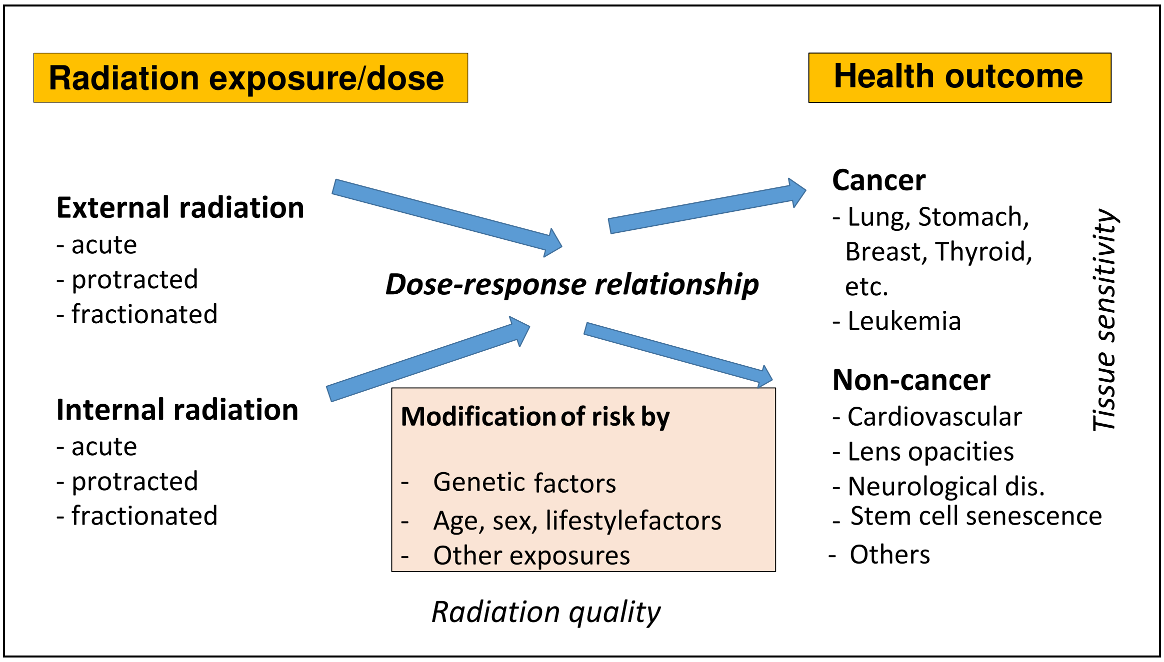


Figure 2: Key policy issues in European low dose radiation risk research defined by the High Level and Expert Group (https://cordis.europa.eu/docs/publications/1070/107087891-6_en.pdf)

The key policy issues identified in the HLEG report are:

- The shape of the dose-response for cancer;
- Tissue sensitivities for cancer induction;
- Individual variability in cancer risk;
- The effects of radiation quality (type);
- Risks from internal radiation exposure;
- Risks of, and dose response relationships for, non-cancer diseases and hereditary effects.

For the purpose of the MELODI SRA, these issues were restructured into two topics relating to disease types and two cross-cutting issues (**Figure** 1):

TOPICS
(1) Dose and dose-rate dependence of cancer risk;
(2) non-cancer effects;
CROSS-CUTTING ISSUES
(3) individual variation in risk; and
(4) effects of spatial- and temporal-variation in dose delivery

As discussed by the HLEG and confirmed by MELODI, research at low dose-rates or low doses presents significant challenges in the investigation of both radiation-related health effects and underlying biological mechanisms, because the magnitude of health risk and biological effects is expected to be low. A multidisciplinary approach is therefore essential, both epidemiological and experimental studies will also require sufficient statistical power and sample sizes to be effective, nested case-control study designs are likely to be suitable, as well as "meet in the middle approaches" for example.

For these reasons, discussion of each key question is sub-divided below into two categories:

- Research to improve understanding of the mechanisms contributing to radiogenic diseases following low dose and dose-rate exposures.
- Epidemiological research that integrates, where possible and informative, biological approaches to improve health risk evaluation.

5.1 Dose and dose-rate dependence of cancer risk

Current risk estimates used in radiation protection are based upon epidemiological studies of exposed populations. Radiation protection standards aim to avoid tissue reactions and minimize the incidence of the late developing stochastic effects of cancers and possible hereditary effects in future generations. Thus, it is of fundamental importance to radiological protection that the health risk estimates are evidence-based, robust, and credible. Most important among the epidemiological studies are the follow-up studies of Japanese populations exposed as a consequence of the atomic bombings of Hiroshima and Nagasaki that provide risk estimates per unit dose for cancer and, more recently, non-cancer effects. While the Japanese studies remain the main basis for the cancer risk estimates used in radiation protection, they relate to a specific population and a specific exposure scenario. The exposure was essentially an instantaneous, high dose rate total body gamma ray exposure with a small neutron component. Information about cancer risk from the A-bomb survivor studies is, to an increasing extent, complemented by studies of occupational, environmental and medical exposures, which allow direct investigation of effects of fractionated or protracted exposures in current European populations.

As noted earlier, epidemiological studies provide direct evidence of dose-related increases in total cancer risk after acute exposures with doses of about 100 mGy and above. Recent studies have provided better evidence of risk at doses below 100 mGy and with protracted exposure. Some reports indicate a possible increased risk of childhood leukaemia from doses below 100 mGy due to natural background gamma radiation and from paediatric CT imaging..

Nevertheless, there are major uncertainties concerning (i) the magnitude of total and organ-specific cancer risks following specific exposure situations such as protracted exposure encountered in the environment as well as in occupational and medical settings, and when the dose is inhomogeneously distributed more particularly after internal contamination; (ii) the risk for individual cancer sites due to possibly different tissue sensitivities, and (iii) the best evidence-based models to infer risk at doses and dose-rates that are lower than those for which direct epidemiological evidence is available. In this context, there are also a number of ethical questions that need to be addressed, such as the use of the LNT model for extrapolation to very low doses, and whether other risk factors may substantially modify radiation risks.

Classical epidemiological studies will need to be continued to refine the knowledge of risk directly in human populations, particularly in the context of low dose, protracted and non-uniform exposures. Accuracy of risk estimates can potentially be increased by more precise dose estimation and outcome assessment, larger studies or pooling of data from several studies. Mechanistic and epidemiological approaches should be integrated whenever feasible to address cancer risks from acute whole-body exposures with low-dose (<100 mGy) or from fractionated, protracted and inhomogeneous exposures resulting in low-to moderate dose. Studies also need to address the impact of different radiation qualities and effects of both internal and external exposures, alone and in combination. Knowledge of health risks from low dose-rate exposures is of direct relevance for radiological protection in emergency situations, in medicine (with children, who are known to be more sensitive than adults, easily receiving doses of several hundred mGy to the brain from multiple brain CT scans), and in occupational settings, with the current dose limit of 20 mSv/year averaged over 5 years with no single year exceeding 50 mSv. Radiation protection in the medical context is particularly important as exposures have been increasing, and novel radiation modalities are both in use and under development. Clear and coherent principles for justifying the long-term risks with more immediate benefits are needed. Radiation protection in the context of long-term space travel, where radiation exposures have some very specific characteristics and differ from terrestrial exposures, is likely to grow in importance in the future. Beyond studies of specific irradiated populations, there exist some major cohorts established and followed primarily for reasons other than the assessment of radiation risk, some consideration of the benefits of utilising such cohorts and adding radiation exposure information may be of use in the future.

Research line: Health risk evaluation

Quantification of cancer risk at moderate dose or dose-rates from acute or protracted non-uniform exposure, and at low dose or dose-rates from acute, homogenous exposure are key challenges for improved radiation risk assessment. The large size of epidemiological studies required to detect small increases in cancer risk at low dose and dose-rates, the need to capture all major sources of radiation exposure, and the potential for bias and confounding present practical challenges, particularly at the lowest doses. The priorities in this area include the maintenance and improvement of key cohorts by continued follow-up, pooling of different studies, collection of information on confounders and reduction of misclassification of dose and health data. Key cohorts are characterized by large populations with exposure conditions and dose distributions that are relevant for radiation protection, good individual dosimetry, long and complete follow-up with good quality of health outcome data, particularly in relation to cancer occurrence; and the possibility of collecting information on relevant potential confounders either on the whole cohort or through targeted nested case-control studies.

These studies should include, where possible and likely to be informative, the collection and appropriate storage of a large number of relevant biological samples, including tissue samples from cancer cases and somatic tissue from affected individuals; while this is generally difficult in large scale cohorts, it can be integrated in nested case-control studies. Through identification, validation and integration of relevant biological endpoints and markers into epidemiological studies, further insights will be gained into the risks associated at the population and individual level with such exposures. The integration of both epidemiological and mechanistic studies will improve cancer risk evaluation through molecular epidemiological studies or by mechanistic modelling.

Priority research areas are:

- To determine the shape of the dose and dose-rate response relationships in humans for total cancer, and where possible specific cancer sites, based on key informative epidemiological studies, including medical and occupational cohorts as well as those accidentally exposed.
- To determine the risk for different cancer sites based on key cohorts (see above) in order to investigate differences in tissue sensitivity.
- To evaluate the dose-response for tumour types, ideally defined by molecular characterisation
- To investigate pre-stages of cancer in any available biological samples, e.g. tissue or saliva/blood and by imaging methods in study populations with well-characterised exposure to allow modelling of carcinogenesis, including adverse outcome pathway approaches.
- To identify and validate biomarkers of exposure and health effects related to cancer, both working from early exposure biomarkers through intermediate steps to disease, and from epidemiological studies to disease markers and back to exposure – the 'meet in the middle' approach (Vineis and Perera, 2007, Cancer Epidemiol Biomarkers Prev. 16(10):1954-65).
- To determine the value of evaluating cancer risks through systems biological analyses and models of carcinogenesis based on mechanistic studies and epidemiological data, and integration of the two.

Research line: Basic mechanisms

An LNT extrapolation model is currently used to estimate risk at low doses from higher dose epidemiological data. An important aspect of the justification of using this model is that radiation carcinogenesis is assumed to be primarily driven by damage to DNA and subsequent mutation of growth-regulating genes in target cells. Yet, a number of other potential mechanisms contributing to and modulating radiation carcinogenesis have been proposed, including epigenetic mechanisms of gene regulation such as DNA methylation and miRNA expression, transmissible genomic instability, bystander effects and adaptive response, and it is important to determine their roles. The extent to which these modulating effects and non-mutational mechanisms challenge the validity of the LNT risk extrapolation model needs to be determined. For this purpose, the use of well validated animal and human cellular / tissue models of radiation carcinogenesis (both solid cancers and leukaemias) is required.

Priority research areas are:

- To determine the nature,roles and radiosensitivity of the various target cells for radiation carcinogenesis. The most important of these are generally taken to be stem and progenitor cell populations, which may have specific responses to radiation.
- To determine the contribution of DNA damage / mutational processes at low doses and dose-rates and with differing radiation qualities.. Further information on the specific genes affected at low doses in the development of specific cancers and quantitative aspects can contribute to refining risk extrapolation models and the identification of radiation exposure and cancer biomarkers.
- To determine the contribution of epigenetic modifications. Gene function and cellular processes can be regulated at the epigenetic level, the extent to which radiation affects epigenetic states that relate to carcinogenesis needs to be elucidated, and also how epigenetic factors affect response to radiation.
- To determine the influence of cell micro-environmental, non-targeted and systemic processes that may promote or restrict the growth of pre-malignant cells in tissue, and how radiation exposure affects the tissue environment to facilitate or retard the growth of (pre)-malignant cells. For example, the influences of low dose radiation exposure on inflammatory reactions and effects of radiation on of immune surveillance against cancer cells.
- To examine the extent to which any of the above are different at high dose / dose-rate by comparison with low dose / dose-rate.

5.2 Non-cancer effects

It has been traditionally assumed that health effects other than cancer and hereditary diseases show a threshold (defined as the dose required to lead to 1% excess incidence) at doses that are well above the levels of exposure typically encountered in the public environment, at work or in diagnostic medical uses of ionizing radiation. Recent results from epidemiological and experimental studies indicate possible increased risks of circulatory diseases, cataracts, cognitive/neurological effects and others not only at high doses but also at down to 500mGy and, possibly even lower. Based on these findings the ICRP issued in 2011 a statement on tissue reactions (formerly termed non-stochastic or deterministic effects) that noted evidence that the threshold in absorbed dose for effects on the lens of the eyes is of the order of 500mGy (acute and protracted exposure). Consequently, a recommendation was made for a reduction in the annual equivalent dose limit for the eye lens to 20 mSv per year averaged over 5 years, with no one year exceeding 50 mSv. In addition, ICRP suggested that the dose threshold for circulatory diseases may be as low as 500mGy.

Evidence for radiation-related hereditary effects is based on experimental animal studies. There is no direct evidence for hereditary/transgenerational effects from human studies, though 2nd and 3rd generation studies are likely to be feasible in specific cohorts, e.g. in the Urals. The as yet uncertain contribution of hereditary risk to overall risk is expected to be small in comparison with that of cancers. While the system of radiation protection includes hereditary effects in the calculation of low dose detriment along with cancers for risk management purposes, the range of diseases occurring among the offspring of irradiated parents includes both cancer and non-cancer diseases

For all outcomes, there are uncertainties and concerns about possible effects at low doses, which may have important implications for radiation protection. Results of available epidemiological studies are not always consistent, as in the case if cancers the risk estimates are prone to bias and confounding, and the biological mechanisms of relevance for health risks at these low doses are not known. The possibility of a stochastic nature of non-cancer effects without dose thresholds raises a wide range of questions and needs further investigation. In contrast to cancer, knowledge on the underlying biological mechanisms for radiation-related non-cancer effects in the moderate and low dose range is very sparse. Therefore, research to understand the mechanisms is necessary. In addition, epidemiological research of key cohorts with good information on potential confounding factors is needed to provide information on radiation-related risk of non-cancer diseases following low dose, protracted or fractionated exposure, relevant for radiation protection. Individual variation in risk, mixed exposures and impact of characteristics of radiation exposure will also need to be explored.

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Research line: Health risk evaluation

Quantification of non-cancer disease risk in humans at moderate or low doses or dose-rates is a key and difficult challenge for radiation protection, because the magnitude of risk due to radiation is expected to be low and the potential for bias and confounding is high. Informative epidemiological studies in this field will be characterized by cohorts of large size with exposure scenarios and dose values relevant for radiation protection, good dosimetry, high quality of health data, long follow-up and the possibility of collecting information on relevant potential confounders either on the whole cohort or through nested case-control studies. In addition, these studies should include – where possible and informative – collection of biological samples, relevant tissue samples from the relevant organ to allow mechanistic investigations, and extensive data on the health status during follow-up.

Through improvement of key epidemiological studies (e.g., increasing the statistical power by pooling studies using standardized study protocols; improvement of appropriate organ and tissue dose assessment, e.g. different parts of the heart, main arteries and veins, as well as blood, brain, eye lens, etc) and, where possible and informative, the identification and integration of relevant biological endpoints and markers into epidemiological investigations further mechanistically-informed insights will be gained into the risks associated with such exposures.

Priority research areas are:

- To determine the shape of the dose-rate and dose-response relationship, notably the presence or absence of threshold doses, in humans for non-cancer outcomes at low or moderate doses based on key informative epidemiological studies (molecular or otherwise, as appropriate). While increasing numbers of studies concern circulatory diseases, little work is available on cognitive impairment and neuropathies, and there is little current work on hereditary and transgenerational effects. Any such studies require careful and explicit definition of the disease outcomes being assessed.

- To identify, develop and validate biomarkers for exposure (especially for low doses and protracted/inhomogeneous exposures), early and late non-cancer effects. Relevant tissue banks are currently available. The development of such biomarkers should allow better estimation of the actual doses received and inform the evaluation of the dose-response relationship of non-cancer effects.
- To investigate early stages in the progression of non-cancer effects in tissue or disease-related endpoints in biological samples from members of appropriate epidemiological studies or individuals with similar living conditions and known exposure in order to understand spontaneous pathogenesis. This is a pre-requisite to understand radiation effects on pathogenesis.
- To evaluate non-cancer risk through systems biological analyses and mathematical models combining and integrating mechanistic studies and the epidemiological data.

Research line: Basic mechanisms

Deterministic effects or tissue reactions are classically thought to arise as a consequence of cell killing or functional inactivation by high radiation doses. They are characterised by steeply increasing dose-response relationships at doses exceeding a defined threshold. It is unlikely that cell killing/inactivation will explain fully the effects of lower radiation doses on circulatory diseases, cataract and cognitive dysfunction. Epidemiological investigations of populations with well-characterised exposures require support from studies to identify the underlying mechanisms that lead to each of the non-cancer diseases. Each disease may have a different mechanistic basis, and it is not clear, if there will be any similarity with the mechanisms that lead to radiation related cancers.

Low dose radiation may induce cellular senescence. The occurrence of this phenomenon in tissue stem cell compartments is an event that could have profound pathophysiological consequences. Alteration of stem cell functions may impair tissue renewal and homeostasis or on the contrary may promote non-cancer diseases or cancers.

Priority research areas are:

- To develop animal and *in vitro* models of radiation-related non-cancer diseases (circulatory diseases, cataract, cognitive/neurological dysfunctions, hereditary/transgenerational effects and other non-cancer effects), including organoids (e.g. cerebral, retinal, and others) derived from human pluripotent stem cells in order to clarify the pathways involved and conduct appropriately powered induction studies. In particular early stages of disease should be explored to define adverse outcome pathways for radiation-induced non-cancer effects.

- To apply a full range of analytical methods including ‘omics’ technologies and consideration of the target cells and surrounding microenvironment. In this context emerging technological innovations including single cell ‘omics’ may help to identify differences in radiation sensitivity between relevant cells and tissues. The mechanistic knowledge gained is likely to be useful for the identification of relevant biomarkers, e.g. specific metabolic and pathological changes that are clearly radiation-induced, and the development of mechanistic models of disease development.

- To determine the contribution of radiation-related changes in the immune function and inflammatory processes in the pathogenesis of non-cancer effects at low doses and dose-rates.

- To determine if other pre-existing conditions, such as neuropathies, inflammatory conditions or metabolic and mitochondrial diseases for example, affect the incidence of radiation-induced non-cancer outcomes
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5.3 Individual variation in risk

Individual variation in radiation-related cancer risk is a key area to address for radiation protection. Differences in the magnitude of radiation-induced risks between individuals, or groups, may relate to sex, age at exposure, state of health, genetic and epigenetic make-up, lifestyle, and attained age. Such differences, if significant, raise the very important ethical and policy questions as to whether some individuals or groups are inadequately- or over-protected by the present system and regulations. Similar concerns on variation in risk between individuals apply to non-cancer outcomes.

At present, there is insufficient information about the size of the differences in response between individuals or groups of individuals and their consequent influence on risk estimates at low doses and dose-rates. In order to address policy questions, it is necessary to obtain better scientific information on the extent of the variations in sensitivity in the population, in the sizes of the variations, characteristics affecting the variation and in the proportions of the population that are affected. Importantly, reliable and robust biomarkers predictive of individual risk need to be identified and characterised through basic mechanistic research before application in epidemiological studies.

Healthy aging is an increasing concern in western countries, since there is a progressive aging of extant populations. Research in this field aims to improve quality of life for elder people. In this situation, any unnecessary or overlooked stresses have to be avoided.

Treatments with low dose radiation for medical purposes is increasing worldwide. These procedures are beneficial to the patient. Nevertheless, there is scant awareness of health risk associated with their uncontrolled use. In particular, health risk may be higher in elderly patients due to increased vulnerability and poor recovery of homeostasis following a stress such as low dose radiation exposure.

Consideration of how individual differences affect the relationship between absorbed dose (and dose distribution) and risk is required. For internal intakes of radionuclides, the dose and dose distributions can be very different in individuals for the same exposure because of anatomical and physiological differences (e.g. in airway morphology or breathing mode). These variabilities should be taken into account by accurate dosimetric and physiologically relevant biokinetic models. In addition, the nature of the interaction of ionizing radiation with co-exposures to other agents (e.g. tobacco smoke, heavy metals) and existing risk-modifying conditions (e.g. iodine deficiency for thyroid cancer) for the onset of various cancers and diseases are important in considering risk transfer between different populations.

Research line: Health risk evaluation

The quantification of the contribution that individual variation in response to radiation makes to radiation health risk on both an individual and population level is a key question. Realistic estimates of the magnitude of differences in response between individuals and groups are needed.

Priority research areas are:

- To identify and validate candidate biomarkers of individual sensitivity identified from mechanistic or clinical studies in cohorts of exposed and non-exposed subjects who have developed cancers or non-cancer diseases. As few suitable large cohorts with biological samples are currently available, proof-of principle studies with higher dose exposed cohorts should be conducted to refine methodologies and to extrapolate to low doses.
- To improve or set-up molecular epidemiological cohorts or case-control studies to determine factors (host and environmental) that modify individual risk of radiation-induced cancer and non-cancer effects and quantify their effects.
- To quantify the variation in risk between different population groups and the impact of different factors, for example, age at exposure, and attained age, as well as co-exposures and host factors, including anatomical and physiological differences. Knowledge of the nature of possible interactions between ionizing radiation and these factors on health risk (e.g. multiplicative, additive) is important in considering risk transfer between different populations.
- To develop mechanistic or other mathematical models of radiation-induced disease pathogenesis that can account for individual risk factors.

Research line: Basic mechanisms

Basic research is needed to establish which factors and processes (including genetic, epigenetic and environmental factors/processes, co-morbidities, co-exposures and lifestyle factors) lead to greater individual risk of late effects in terms of cancer or non-cancer diseases. This includes the discovery of genetic, phenotypic and molecular markers of these pathways, and the integration of mechanistic studies in the quantitative evaluation of health risks. A major focus should be the understanding of how these different factors may modify risk, keeping in mind that the radiosensitive phenotype is likely to be multifactorial. Another important question is whether biomarkers of radiation normal tissue reactions are related to risk of developing late effects following exposure to low and protracted doses of different LETs including internal exposures.

Priority research areas are:

- To develop an understanding of the cellular, organ and systemic responses determining individual susceptibility to radiation-induced health effects including, for example, inflammatory processes and immunological states) so that differences between individuals in the response pathways can be predicted, and biomarkers be identified.
- To investigate mechanisms by which age at exposure, attained age, sex, lifestyle and other factors, including co-exposures to other agents and diseases affecting dose from a given exposure may modulate radiation risk.

- To investigate the impact of anatomical and physiological differences between individuals on radiation dose and dose distributions.

- To start to explore modelling methods to predict differences in outcome at both individual (qualitative changes affecting health-relevant pathways) and population (quantitative changes in health outcomes) levels.

5.4 Effects of spatial and temporal variation in dose delivery

In the system of radiological protection, risk mainly depends on absorbed dose averaged over a given target mass. The biological outcome of the exposure is determined not only by the dose but also by the time frame of the dose delivery, and by the specific kind of radiation responsible for the energy deposition (radiation quality). In order to account for the effects of temporal variation in dose delivery, a single dose- and dose-rate effectiveness factor (DDREF) is currently applied for low LET radiation in radiation protection; however, the evidence base for this judgement continues to be debated. Concerning spatial variation, radiation weighting factors are currently applied for radiation protection purposes to account for the difference in the spatial pattern of energy deposition at the subcellular scale, due to different radiation qualities. At a larger scale, the effects of intra-organ (but supra-cellular) variation in dose delivery are not considered: the same health risk is assumed for all exposure types if they result in a given amount of absorbed energy, independently of whether the energy is absorbed by a single target cell or homogeneously distributed among all target cells of the same organ. However, the biological effects and so the health consequences are unlikely to be the same.

Inhomogeneity in dose delivery, both at the temporal and spatial level, is a real feature of many environmental, medical and occupational exposure scenarios. Mechanisms responsible for biological effects of different dose-rates or of inhomogeneous dose deposition are not fully characterized: at the cellular level they can be investigated with in vitro studies, but when it comes to how they finally affect health risk (both for cancer and non-cancer diseases) few relevant experimental models or valid datasets exist. In many situations, mixed field exposures are also relevant, but again there are few studies that consider risk in such exposed populations.

The effects of spatial and temporal variation in dose delivery are also gaining importance because of the more wide-spread availability of external beam hadrontherapy, where out-of-field doses by scattered neutrons are of concern, the increasing clinical use of radionuclides, and the perspective of longer duration space travel (as well as space tourism) in the future. There is also a need to characterize how internal exposure, dose inhomogeneity and radiation quality influence the formation of candidate biomarkers so-far identified in response to low LET external exposure.

Research line: Health risk evaluation

Quantification of health risk at low/moderate dose or dose-rates from internal exposures and from inhomogeneous dose distribution from external exposures is a key challenge for improved radiation risk assessment. As exposures frequently involve all three features noted above (effects of dose rate, radiation quality, and intra-organ dose distribution), relevant cohorts have to be identified or consolidated, where the separate effects of these three variations can be studied. In addition, collection and maintenance of relevant biological sample collections, including tissue samples from cancer cases and somatic tissue from affected individuals may also help to estimate the contribution of the effects of these three exposure characteristics. Sound individual dosimetry is particularly important in case of internal exposures.

Priority research areas are:

- To determine cancer and non-cancer risk related acute and chronic internal emitter-exposures in epidemiological studies, incorporating detailed dosimetric assessment and evaluation of dosimetric uncertainties and, where appropriate, microdosimetric considerations. Where feasible and informative, these studies should include collection of appropriate biological samples and analysis of biomarkers of dose.
- To determine the Relative Biological Effectiveness (RBE) for selected endpoints in epidemiological studies for specific cancer sites through comparison of risk related to low- and high-LET radiation exposure.
- To better determine the risk (as well as possible countermeasures) associated with protracted exposure to the space radiation environment, in view of future interplanetary missions, both for cancer and non-cancer diseases (*e.g.* targeting possible impairments of cognitive and cardiovascular functions).
- To develop and apply more detailed biokinetic and dosimetry models in order to better characterize dose distributions.

Research line: Basic mechanisms

Effects of radiation quality and dose-rate on individual cells and at the cell population level are well documented. Many biological endpoints show a dose-rate dependence (notably DNA damage response) and data supporting an inverse dose-rate effect also exist. This raises the question of the effects of protracted exposures, particularly at low dose and low dose-rate. It is recommended to consider fluence (in addition to dosimetric information) when dealing with exposures to charged particles (particularly for high LET). Concerning spatial variation at the sub-cellular level, the biological outcome is clearly modulated by radiation quality indicators such as LET. Using *e.g.* microbeam irradiations, mechanisms determining the response to a highly inhomogeneous energy deposition can be addressed under controlled conditions.

To provide further insights in the effects of intra-organ dose distribution, experiments with organotypic tissue models and animal models are required. The effects of locally high doses, when small parts of the tissue/organ are irradiated with high doses while the average dose remains low have to be quantified and compared to homogeneous exposures. Whether and how effects of the locally high dose propagate in the less exposed tissue also deserves investigation. Organotypic tissue models and animal models also allow to study the changes in tissue architecture in order to analyse the effects of intra-organ dose distribution.

Priority research areas are:

- To conduct experimental studies in vitro and in vivo to test exposure scenarios where dose/fluence modulation plays a role, *e.g.* localized versus uniform exposures, acute versus protracted exposures, to inform specific biomarker development and risk quantification.
- To further develop suitable tissue and in vivo models for the quantification of the impact of dose inhomogeneity and radiation quality.

- When addressing the effects of internal contamination, specifically consider the role of chemical speciation in determining spatial distribution (at all scales) and biokinetics of radionuclides.
- For all adopted experimental models, to develop in parallel modelling approaches able to tackle and quantify inhomogeneity at all scales: nano- (radiation track structure) and microdosimetric, dosimetric and biokinetic models at different levels of biological organisation.
- To study mechanisms elicited by inhomogeneous dose deposition, integrating "dynamic" dose assessment and identification of relevant pathways (both for cancer and non-cancer diseases) in a systems biology approach, in order to characterize the response of the complex system as a whole.
- To develop innovative ways in experimental studies to determine the Relative Biological Effectiveness (RBE) at low doses to determine/compare the effects of to low- versus high-LET exposure. To characterize how internal exposure, dose inhomogeneity and radiation quality will affect the nature of candidate biomarkers so-far identified in response to low LET external exposure.
- To develop experimental and modelling strategies to characterize the effects of exposures to mixed fields.
- Build on knowledge acquired from basic mechanisms to identify relevant pathways for the quantification of the risk for cancer and non-cancer diseases, also using an adverse outcome pathway approach, determining those operating in case of inhomogeneous exposures

6. Education and Training

6.1 The role of education and training in low-dose radiation research

The HLEG Report of 2009 (http://www.hleg.de/fr.pdf) identified a problem with the maintenance in Europe of the range of expertise essential to an effective programme of research into the risks to humans from low-dose radiation. The report advises that specific programmes aiming at knowledge management across generations have to be designed in order to achieve sustainable continuity and development.

A large proportion of the groundwork of research is carried out as student projects and thesis work. For this reason, the research effort relies on a continuing relationship with universities, and on a healthy stream of high-level students. It is essential that this symbiosis is recognised and taken into account in research funding structures.

A further intrinsic role of E&T within any specialized research area is in dissemination of new technologies, skills, and knowledge. To obtain maximum impact and benefit from research there should be an actively managed programme of workshops, seminars, summer schools, etc. which is integrated into the design and funding structure of all research. The programme should be aimed both at the sharing knowledge within the European low-dose research community and also at the wider radiation protection field including radioecology, emergency response, and the medical use of radiation.

6.2 Priorities for strategic support of E&T

Following the comments in the previous section, support for E&T has two priority areas: support for students and young scientists, and promotion of E&T for dissemination.

Support for students and young scientists

- Students need to be able to find places at universities and placement with research groups for project/dissertation work. This requires that the places must be available, but also that there are sufficient incentives to attract top students. Universities are autonomous and develop new courses in response to a perceived need, taking account of staff expertise and specialization. Financial support from outside is not needed to achieve this end, although there is a role for influencing the perceived need. On the other hand, increasing the access to students Europe-wide to university courses through industry-funded scholarships could significantly help to attract students. Setting up such a post-graduate scholarship scheme for attendance at approved universities should be seen as a priority.
- In order to complement support at the post-graduate level and to help provide a career path for the most promising graduates, a scheme for provision of one or more post-doctoral fellowships should also be offered, to be taken up at approved research institutions.

Promotion of E&T for dissemination

- It should be explicitly in the wording for RTD calls that proposals will be judged favourably if a plan is included that explains how E&T will be integrated into the overall research programme, providing workshops or training courses dedicated to the presentation of new science/technology which is being used or developed in the project.
- Parallel to the E&T supported by the RTD calls, it is seen as essential that a separately funded body (or part of a body with a ring-fenced budget) is responsible for the organization and sponsorship of targeted initiatives in order to promote the specialized skills and knowledge needed to maintain the full competence of the low-dose research community. These will be made readily available to postgraduate students and scientists. The benefit to the former will be the provision of supplements to their university courses and to give them experience of the different areas of science on offer to them in their future careers. For the latter, this will be a very effective way of providing continuing professional education, and for sharing knowledge with other research and educational institutions.

Coordination and collaboration of E&T providers

In order to get maximum benefit from E&T in the low-dose research area (both that which is already provided and the new initiatives proposed here) there should be an overall coordination of resources within the European community. Recommended priority actions are as follows:

- Continuation and extension of the MELODI Education and Training Forum in order to bring together all platforms and other interested parties regularly to discuss needs and broaden the awareness of what is happening in EU member states. This should be seen as both a problem-solving and an advertising forum. There should be active participation by all other platforms involved in radiation protection (ALLIANCE, NERIS, EURADOS, EUTERP, EURAMED etc.) in order to share mutual experience and resources.

- There should be an active cooperation among groups promoting and supporting E&T in the radiation protection and research area (EURAYS, ENEN, etc.) and possibly use of mailing lists or social media to advertise programmes, courses, scholarships, fellowships, etc.

7. Infrastructures

One of the roles of MELODI is to ensure the availability of and facilitate ready access to the state of-the-art research infrastructures required to support the research efforts of radioprotection researchers. The priority is to promote the use of mature and up-to-date infrastructures and avoid unnecessary duplication. Furthermore, an effort should be made to harmonize practices amongst multiple facilities. Finally, the sustainability of rare but necessary facilities (such as those for internal contamination) needs to be guaranteed. This should include recommendations on the provision of the financial means to harmonize, sustain and access these facilities.

Infrastructures include so-called large infrastructures such as exposure facilities such as those for animal experimentation, as well as the collection and storage of cohort data, data bases, biobanks and analytical platforms.

Within the project DoReMi, an extensive list of relevant infrastructures was generated for low dose research in particular irradiation facilities for internal and external exposure. In order to assess which infrastructures meet the needs of radioprotection scientists, it is necessary to develop and apply quality criteria determined by experts, specific to each type of infrastructure, for the listed large infrastructures. Financing for access to these facilities to support specific topics can then be included in future calls in which the selected facilities are partners in the future projects.

Within the project DoReMi, a list of relevant cohorts was established and is currently being updated. Priority should be given to cohorts and biobanks that permit studies to improve the quantification of the risk associated with low dose and low dose-rate radiation exposure, for cancer and/or non-cancer diseases and/or to identify groups of individuals with specific sensitivity. In the relative short-term, some of the existing epidemiological cohorts can be used to support modelling and/or, in general through nested case-control studies, molecular epidemiological studies. In the long-term, new prospective cohorts can also be envisaged, as well as the development of new collections of biological material that will be necessary to support radiation research in the next decades.

Within CONCERT infrastructures are highlighted via AIR2 bulletin and AIR2D2 Database. A webhandbook is ongoing, describing exposure facilities, cohorts, data bases, biobanks and analytical platforms.

Within the EU-funded project STORE, an internet-based platform for sharing data from epidemiological studies, as well as data and biological samples from radiation experiments (new and past), has been developed and has been further carried forward and supported first by DoReMi then by CONCERT. Going forward, it will be necessary to promote activities to maintain the STORE data base by supporting the service of a curator, to further update and continuously expand the content of the data base, and to elucidate to what extent data from other radioprotection platforms (ALLIANCE, NERIS and EURADOS, EURAMED, SHARE can be incorporated into STORE or whether a separate but comparable data base would be more appropriate.

The use of STORE as a repository for data linked to all publications arising from EU-funded projects in radioprotection research should be required, where appropriate and possible (ethics requirements and informed consent in epidemiological studies may prevent the data to be uploaded into STORE, though collaborations with these studies can be envisaged) in line with the recent guidelines for H2020 supported projects.

Furthermore, pointers to existing data sets from cohort studies or from radiological experiments (with animals or from the radioecology field) will need to be maintained and strengthened, and it will need to be indicated to what extent biological material is available. This should include the support of activities to identify valuable materials and archives that could be included in the database and the tissue bank, as well as to maintain relevant biobanks and rescue material from endangered biobanks. Furthermore, the use of biobanked material, where applicable, should be encouraged by including its use in future calls either indirectly for all relevant proposals or by specific topics dedicated to its use. In addition, funding should be included to support the biobanking of samples arising from Euratom/H2020 funded projects where appropriate. In addition to studies of specific irradiated populations, there exist several major epidemiological cohorts established and followed primarily for reasons other than the assessment of radiation risk, some consideration of the benefits of utilising such cohorts and adding radiation exposure information could be assessed in the future.

The maturation of the so-called ‘omics technologies, imaging and systems biology may offer novel opportunities for European radiation protection research. As the quality of the technologies and supporting managerial and technical support varies widely, quality criteria will need to be established and applied in order to determine a limited number of facilities in each area which best meet the needs of radioprotection research. The use of these facilities should be linked to receiving funds in future calls, or at the very least a procedure will need to be put into place to assure the quality of those facilities outside of those on the list of recommended sites, such as for example, testing an agreed upon standard sample set, already tested by the listed facilities, within the scope of the funded projects.

It is obvious that in the case of a major nuclear accident or attack, analytical platforms such as RENEB are accessible for the assessment of radiation exposure in order to differentiate “exposed” and “worried well” as support for medical triage, but later potentially for long-term risk assessment and subsequent screening of individuals. In addition to the use of such platforms in the cases of emergency, they can also contribute to research, e.g. for molecular-epidemiological studies or long-term follow up, when large numbers of bio probes need to be analysed. Therefore, the use of RENEB for research purposes needs to be actively pursued and supported in future calls where appropriate.

Next steps will rely on further harmonisation of quality standards, practices and protocols, and co-operation between the European radiation protection research platforms in relation to the provision and use of infrastructure. Huge efforts will be dedicated to sample/data acquisition and sample/data storage with the aims to re-use of archived materials. There is a need need of trans-national agreement on a strategic work plan for maintenance, updating, mutual use of suitable infrastructures. Meanwhile, education and training actions will promote the use of European research infrastructures the advantage of using newer, larger, faster, more powerful infrastructures although not at the bench of each user.

Priority areas are:

- Improvement of the access to infrastructures
- Favour open access to radiation research data within STORE

- Re-use of archived materials and existing epidemiological studies using specific retrospective approaches
- Enlargement and sustainability of RENEB including inter-comparison exercises
- Improvement of the awareness of existing infrastructure via E&T courses

8. Research priorities (MELODI Statement)

The purpose of the MELODI Association is to define priority scientific goals and to encourage the implementation research in the field of low dose rate radiation research. The Strategic Research Agenda of MELODI identifies these priority goals and the specific resources, infrastructures and training capabilities needed to further develop low-dose risk research within a time frame of 20 years.

Planning for the next EU research framework, Horizon Europe, is underway and this Statement strongly recommends the continuation of EU-funded radiation protection research to ensure that citizens are adequately and appropriately protected from radiation health risks. This is at a time when exposures are increasing in the medical area, will continue to be a concern for members of the public in areas surrounding nuclear installations, and when terrorist threats remain a concern for many.

The key priority for radiation protection research is to improve health risk estimates for low dose and dose-rates exposures encountered in occupational, medical and public/emergency situations. The approaches will need to be multidisciplinary and innovative. The integration of expertise outside of the conventional fields of radiation research will widen the possibilities to integrate modern technologies in health research in the assessment of health risk relevant to radiation protection.

The ongoing MEDIRAD EU project has a specific focus on cardiovascular effects and diseases from radiotherapy in breast cancer patients and cancer following CT-scan among children, which constitute very specific exposure situations in specific populations. The HARMONIC project focuses on paediatric patients, undergoing interventional cardiology or proton therapy. As proton therapy applications in the clinic are relatively recent, this 5-year project will focus on short to medium term non-cancer outcomes (endocrine dysfunctions, cardiovascular toxicities and neurovascular damages) and will not assess cancer or cardiovascular risk directly. The objective of the WP on interventional cardiology, however, will be to assess risk of cancer.

The ongoing LDLensRad, LEU-TRACK and SEPARATE projects, respectively focusing on dose and dose-rate effects on lens opacity, role of exosomes in radiation-induced leukaemogenesis and out-of-field effects in normal tissues, are the only CONCERT-funded projects covering topics relevant to MELODI related to basic mechanistic investigations.

While no specific EU- or EU-funded project calls for proposals are currently anticipated, the priorities may be used by national funding agencies, and are suitable for longer-term planning

Priorities for 2020 – 2025 period:

- To explore and define the shape of the dose-response relationships for radiation-induced health effects (cancer and non-cancer outcomes, in particular cognitive and neurodevelopmental effects and immunological effects) (Overall priority)

- To identify, explore and define adverse outcome pathways AOPs) for radiation-induced health effects, and determine if those operating at low doses and dose-rates are the same as those operating at higher levels of exposure, and when the triggering of an AOP is sufficient to disrupt normal homeostasis

- To explore and define the role of epigenetic modifications in radiation-induced health effects

- To identify, develop, validate and implement the use of biomarkers for exposure, and for early and late effects for cancer or/and non-cancer diseases.

- To understand the potential impact of individual susceptibility on radiation-induced health effects.

- To understand the health effects of inhomogeneous dose distributions, radiation quality and internal emitters.

- To identify and enumerate the specific target cells for radiation-induced late developing health effects

The current and previous MELODI statements can be found on the MELODI website. They generally provide information about short-term research priorities for specific calls. The definition of research priorities for the medium and long-term ("roadmap") is currently under development.

MELODI encourages, where appropriate, (1) the use of archived biological materials from prior EU funded research, (2) the integration of experienced laboratory networks (such as e.g. RENEB), (3) the consolidation and use of important epidemiological studies (both radiological and non-radiological) where feasible, (4) the integration of expertise from outside the conventional fields of radiation research.

9. Abbreviations, Websites

ALLIANCE (European Radioecology Alliance) http://www.er-alliance.org/

DoReMi Network of Excellence (Low Dose Research towards Multidisciplinary Integration) www.doremi-noe.net

CONCERT https://concert-h2020.eu

EURADOS (The European Radiation Dosimetry Group) www.**eurados**.org/

EURAMED (European Alliance for Medical Radiation Protection Research) http://www.eibir.org/scientific-activities/joint-initiatives/european-alliance-for-medicalradiation-protection-research-euramed/

HLEG (High Level expert group) http://www.hleg.de/

MEDIRAD **(**Implications of Medical Low Dose Radiation Exposure**)** http://www.medirad-project.eu/

MELODI (Multidisciplinary European Low Dose Initiative) http://www.melodi-online.eu/

NERIS (European Platform on preparedness for nuclear and radiological emergency response and recovery)
http://www.eu-neris.net/

OPERRA (Open project for European Radiation Research Area) http://www.melodi-online.eu/operra.html

SHARE (platform on social science and humanities)
http://sites.exeter.ac.uk/nuclearsocieties/shine/

STORE (platform for the archiving and sharing of the primary data outputs from research on low dose radiation) https://www.storedb.org

EURADOS
European Radiation Dosimetry Group e. V.

EURADOS Report 2014-01
Braunschweig, May 2014

Visions for Radiation Dosimetry over the Next Two Decades - Strategic Research Agenda of the European Radiation Dosimetry Group

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ISSN 2226-8057
ISBN 978-3-943701-06-7

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Braunschweig, May2014

Visions for Radiation Dosimetry over the Next Two Decades – Strategic Research Agenda of the European Radiation Dosimetry Group

W. Rühm[1], E. Fantuzzi[2], R. Harrison[3], H. Schuhmacher[4], F. Vanhavere[5], J. Alves[6], J.F. Bottollier-Depois[7], P. Fattibene[8], Ž. Knežević[9], M.A. Lopez[10], S. Mayer[11], S. Miljanić[9], S. Neumaier[4], P. Olko[12], H. Stadtmann[13], R. Tanner[14], C. Woda[1]

[1] Helmholtz Center Munich, Institute of Radiation Protection, Neuherberg, Germany

[2] ENEA, Radiation Protection Institute, Bologna, Italy

[3] University of Newcastle, Newcastle, UK

[4] Physikalisch Technische Bundesanstalt (PTB), Braunschweig, Germany

[5] Belgian Nuclear Research Centre (SCK-CEN), Mol, Belgium

[6] Instituto Superior Técnico (IST), CTN, Portugal

[7] Institut de Radioprotection et de Sûreté Nucléaire (IRSN), Fontenay-aux-Roses Cedex, France

[8] Istituto Superiore di Sanità (ISS), Rome Italy

[9] Ruđer Bošković Institute (RBI), Zagreb, Croatia

[10] Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas (CIEMAT, Madrid, Spain

[11] Paul Scherer Institut (PSI), Villigen, Switzerland

[12] Instytut Fizyki Jądrowej (IFJ), Krakow, Poland

[13] Seibersdorf Laboratories, Seibersdorf, Austria

[14] Public Health England, Chilton, Didcot, United Kingdom

ISSN 2226-8057

ISBN 978-3-943701-06-7

Imprint

Issued by:
European Radiation Dosimetry e. V.
Bundesallee 100
38116 Braunschweig
Germany
office@EURADOS.org
www.EURADOS.org

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Content

1 Foreword

The European Radiation Dosimetry Group (EURADOS) comprises a self-sustainable network of more than 60 European institutions and 300 scientists active in the field of radiation dosimetry. The aim of the network is to promote research and development and European cooperation in the field of dosimetry of ionizing radiation. For this, EURADOS has established Working Groups (WGs) in various dosimetric disciplines such as harmonization of individual monitoring, environmental dosimetry, computational dosimetry, internal dosimetry, dosimetry for medical applications, retrospective dosimetry, and dosimetry in high energy radiation fields.

In autumn 2012 EURADOS decided to develop a Strategic Research Agenda (SRA) which will contribute to the identification of future research needs in radiation dosimetry. The SRA of EURADOS will be used as a guideline for the activities of the Working Groups. Moreover, the EURADOS SRA is an input to the recently launched OPERRA (Open Project for European Radiation Research Area) project funded by the European Commission (EC) that aims to build up a coordination structure that has the legal and logistical capacity to administer future calls for research proposals in radiation protection on behalf of the EC. Other projects such as the recent European Joint Programme Co-fund Action (EJP) intended to implement activities to attain objectives common to Horizon 2020 are also expected to benefit from this SRA.

Since autumn 2012, each EURADOS WG has collected proposals for topics related to dosimetry which are believed to be important to the future of radiation research. During the EURADOS Annual Meeting that was held in February 20013 in Barcelona, Spain, the EURADOS Council established an SRA Working Group (members: W. Rühm (chair), E. Fantuzzi, R. Harrison, H. Schuhmacher, F. Vanhavere) who put together all collected information and – after the July 2013 Council meeting in Berlin, Germany – began to draft the SRA.

The present document formulates – based on input from EURADOS Working Group members – five visions in dosimetry and defines key issues in dosimetry research that are considered important for the next decades, for radiation research in Europe. This document was prepared for the EURADOS Annual Meeting to be held in Budapest, Hungary, in February 2014, where it was further discussed both at the EURADOS General Assembly and at Working Group meetings. A round of input from the EURADOS voting members was also organised. Thereafter the document was finalized and published as the EURADOS Strategic Research Agenda (first version). This version will then be the basis for a second round of improvement including stakeholder input.

The present SRA was put together by the EURADOS Editorial Group on "Developing a Strategic Research Agenda". The authors of this SRA (members of this group, members of the EURADOS Council, and the Working Group chairs) appreciate the input from the various EURADOS Working Groups.

2 Executive Summary

The European Radiation Dosimetry Group (EURADOS) comprises a self-sustainable network of more than 60 European institutions such as reference and research laboratories, dosimetry services and companies, as well as more than 300 scientists active in the field of radiation dosimetry. The aim of the network is to promote research and development and European cooperation in the field of dosimetry of ionizing radiation and its implementation in routine practice, in order to contribute to compatibility within Europe and conformance with international practices. For this, EURADOS has established Working Groups (WG) on various dosimetric disciplines such as harmonization of individual monitoring, environmental dosimetry, computational dosimetry, internal dosimetry, dosimetry for medical applications, retrospective dosimetry, and dosimetry in high energy radiation fields. These groups demonstrate EURADOS' capacity to develop, test and compare novel dosimetric techniques and, consequently, reduce uncertainty in dosimetry. This expertise is also considered important for tackling problems arising from new fields of applications of ionizing radiation needed to contribute to science-based policy recommendations in this area. The aspect of harmonization and education and training are also very important activities for EURADOS, by the organization of intercomparisons and training courses.

At the end of 2012, EURADOS initiated a process for the development of a Strategic Research Agenda (SRA) which is designed to define which topics, if critically addressed over the next decades, are needed to significantly advance dosimetry in various applications. In the future, the EURADOS SRA will be an input for the recently launched OPERRA (Open Project for European Radiation Research Area) project funded by the European Commission (EC) that aims to build up a coordination structure that has the legal and logistical capacity to administer future calls for research proposals in radiation protection on behalf of the EC. Other projects such as the recent European Joint Programme Co-fund Action (EJP) intended to implement activities to attain objectives common to Horizon 2020 are also expected to benefit from this SRA. The efforts of EURADOS to develop an SRA for dosimetry, complement efforts of other platforms such as MELODI, ALLIANCE and NERIS which are developing their own SRA in the fields of low-dose research, radioecology, and emergency preparedness, respectively. Taken together, these SRAs will allow identification of research needs in Europe, in the general scientific field of radiation research with the final goal of improving radiation protection of workers and the public.

Although the present document was based mainly on contributions from EURADOS members, it does include some indirect input from other institutions such as the International Commission on Radiological Protection (ICRP), the International Commission on Radiation Units and Measurements (ICRU), associations from the medical field and the International Organization for Standardization (ISO), because a number of EURADOS members are also members in these institutions. A more formal process of stakeholder involvement will be initiated at a later stage of SRA development.

The present document formulates – based on input from EURADOS Working Group members – five visions in dosimetry and defines – for each vision – two to five challenges that are worked out in more detail by means of specific research lines.

Vision 1: Towards updated fundamental dose concepts and quantities

- To improve understanding of spatial correlations of radiation interaction events
- To establish correlations between track structure and radiation damage
- To improve understanding of radiation-induced effects from internal emitters
- To update operational quantities for external exposure

Vision 2: Towards improved radiation risk estimates deduced from epidemiological cohorts

- To improve exposure pathways not yet considered or validated
- To improve retrospective dosimetry for exposure pathways already considered

Vision 3: Towards an efficient dose assessment for radiological emergencies

- To identify and characterize new markers of exposure
- To develop strategies and methods to increase measurement capacity
- To quantify doses after accidental internal contamination

Vision 4: Towards integrated personalized dosimetry in medical applications

- To improve out-of-field dosimetry for photon and particle therapy
- To develop microdosimetric models for imaging and radiotherapy
- To improve dosimetry in modern external beam radiotherapy
- To optimize dose and risk estimations in interventional radiology
- To establish reliable patient dosimetry in CT examinations

Vision 5: Towards improved radiation protection of workers and the public

- To implement new biokinetic models for intake of radionuclides
- To develop calibration procedures for partial body counters
- To develop accurate and on-line personal dosimetry for workers
- To improve neutron dosimetry techniques
- To include nuclide-specific information in dose rate measurements in the environment

Because an important aim of EURADOS is to keep, circulate and improve knowledge in the field of dosimetry, EURADOS organizes training and education actions such as Winter Schools, Scientific Symposia and Training Courses. These actions are also described and future needs are discussed.

Harmonisation of dosimetric practices in Europe is an additional field that is an important part of the EURADOS mission. Scientific work must generate reliable and reproducible results. Harmonization as applied to the deliverables of research work will enhance the consistency and coherence of scientific results, increasing reliability and improving accuracy. For this reason, actions such as intercomparisons and surveys of practices are described here in a separate chapter and their importance in future activities is highlighted.

3 Strategic Research Agenda

3.1 Towards updated fundamental dose concepts and quantities

To protect humans and the environment from excessive exposure to ionizing radiation, it has been necessary to develop systems for quantifying the radiation and its likely effects. The absorbed dose, the mean value of the energy imparted by ionizing radiation to a volume of interest divided by the mass of that volume, is defined on pure physical grounds, and generally provides a "quantitative description" of the interaction between ionizing radiation and exposed materials. However, for the purpose of radiation protection, the absorbed dose is not based on an adequately detailed description of the energy deposition for correlation with biological consequences. This inadequacy is due to the interplay of several factors: First, the dose-response relation for a particular biological system depends on the radiation quality, i.e. the spectrum of particles and their energies, and the stochastic pattern of energy deposition. Second, different biological systems, such as e.g. different tissue types in the human body, have different susceptibilities for producing radiation-induced effects. Third, as many biological processes are non-linear, the overall response of a biological system may be significantly different for inhomogeneous exposure. For the same reason, the biological consequences of an exposure may also differ depending on the temporal pattern of the irradiation (effects of dose rate and fractionation).

In current radiation protection practice, the issue of radiation quality is taken into account for external exposures through the pragmatic approach of the operational quantities, developed by the International Commission on Radiation Units and Measurements (ICRU), which are based on the *dose equivalent, H*, obtained from the absorbed dose by introducing quality factors that are defined as functions of the linear energy transfer (LET) of the radiation involved.

On the other hand, ICRP has defined a set of protection quantities that could be applied to all relevant exposure situations (internal and external, exposures with various radiation qualities, etc.). For these, the contributions to absorbed dose from different radiation qualities are multiplied by appropriate radiation weighting factors and added to obtain the *equivalent dose*, H_T, in an organ or tissue, which in turn is multiplied by tissue weighting factors and summed over all organs and tissues, to obtain the *effective dose, E*. Additionally, for radiation protection purposes, the linear-no-threshold (LNT) hypothesis is assumed to be valid.

A major challenge to this current-practice dosimetric system arises from radioactive material incorporated in biological systems. The incorporation may result from unintentional uptake of natural or anthropogenic radionuclides from the environment or from the administration of radionuclides to an individual for diagnostic or therapeutic purposes. In all cases, the internally deposited energy is highly heterogeneous due to the uptake, biokinetics, retention and physical characteristics of the incorporated radionuclide and the transport within the body of the radiation emitted due to its decay. Therefore, averaging over certain tissues and organs as done for the calculation of *E* might be too simple.

The goal should therefore be to provide physically and conceptually sound quantities to be used in radiation protection. The current system of dose quantities has unnecessary complexity and incoherence and a system of radiation protection quantities that avoids the unnecessary duality of dose equivalents vs. equivalent dose is desirable.

For the vision of updated fundamental dose concepts and quantities the following challenges were identified:

- To improve the understanding of spatial correlations of radiation interaction events
- To quantify correlations between track structure and radiation damage
- To improve the understanding of the biokinetics of internal emitters
- To update operational quantities for external exposure

These challenges are described in detail in the following.

3.1.1 To improve understanding of spatial correlations of radiation interaction events

Introduction

The dependence of biological effectiveness on radiation quality is commonly believed to be related to the differences in the energy deposition pattern on a microscopic scale. For charged particles, this pattern is called the track structure, where the loci of interaction events are concentrated around the primary particle trajectory. For photon irradiation, the pattern is given by the tracks produced by the electrons (and positrons) liberated in inelastic photon interactions, and for neutrons by the tracks of the recoil protons. At higher primary particle energies, further secondary particles produced such as alpha particles might also be of relevance. Information on spatial distribution and correlation of secondary particles from models (validated by measurements) should be important, for a fundamental understanding of microscopic dose and dose concepts and the associated uncertainties.

Microdosimetry has provided experimental techniques for characterizing particle track structure in terms of the probability distribution of the stochastic quantity lineal energy, which is based on the energy transferred by a passing particle to a simulated microscopic target volume of typically few µm in size, i.e. in the order of the magnitude of cell nuclei. On the other hand, studies based on detailed numerical simulations of track structures provided evidence that the biologically relevant target size might be in the range of few nanometers where experimental microdosimetric techniques fail to be applicable. This led to the development of nanodosimetry where track structure is characterized in terms of the probability distribution of the number of ionizations produced by a particle track in a target volume of few nm in size. Similar to microdosimetry, the microscopic target is experimentally simulated by an equivalent gas target of macroscopic dimensions and use of theoretical density scaling relations.

Micro- and nanodosimetry provide a pure physical characterization of microscopic track structure based on time and space correlations of the radiation interaction events. This could pave the way for new concepts for quantifying radiation effects in terms of radiation field properties, separating the physical and biological aspects involved in the biological effects of different radiation qualities. The goal would be a novel unified concept of radiation quality based on measurable properties of the particle track structure; its experimental realization and implementation with 'dosimeter standards' and traceable easy-to-use end-user measurement devices.

Research lines

In principle, nanodosimetry enables a three-dimensional characterization of the particle track structure including the statistical correlations between different target volumes which may be decisive for biological effects of different radiation qualities. Such a comprehensive characterization of track structure is the prerequisite for an unbiased identification of the biologically relevant target size, which may depend on which biological endpoint is considered. In practice, however, the few existing nanodosimeters developed so far simulate only a single target volume and, as such, of different sizes. Only recently first attempts were made to develop track structure imaging techniques, on the one hand, and to investigate the relation between track-structure characteristics measured with different instruments, on the other. In this context, the establishment of uncertainty budgets for measured nanodosimetric quantities is an important task for the future, where the budget needs to take into account all sources of uncertainty including bias introduced through incomplete collection of the ions produced in the target. Apart from laying the basis for the development of detection systems for practical use, the research on experimental track structure characterization also provides a benchmark for the validation of track structure simulation codes. In the long run, these activities need to be expanded to experimental investigation of radiation interaction with real nanometric objects in the condensed phase, such as, for instance, nano-droplets of DNA or proteins clustered with water molecules or nano-structured solid-state devices.

Deriving estimates of the uncertainty of nanodosimetric characteristics of track structure is also a major need for the computational methods used for numerical simulation of particle tracks. These numerical methods are, in principle, well suited for studying particle track formation and for obtaining the probability distributions for micro- or nanodosimetric quantities. Some codes have been developed for this purpose by different groups. Using track structure simulation, first attempts to investigate correlations between nanodosimetric characteristics for different target volumes along the track and between target volumes of different size have been made. Further steps along this line towards a 'multi-scale' characterization of particle track structure need also to include studying the link between nanodosimetry and microdosimetry. In this context also the relevance of using interaction coefficients with biological molecules (DNA, proteins, etc.) as opposed to water, on whose radiation transport properties most track structure codes are based, needs to be investigated.

Numerical simulation techniques for track structure are mostly based on Monte-Carlo techniques that take into account each individual interaction (step-by-step simulations as opposed to the common condensed-history approaches). Two major concerns have recently been raised against this approach. One is that in this Monte Carlo approach the ionizing particles are basically treated as classical particles for which location and momentum can be defined at the same time. Particularly for electrons with energy below 1 keV, i.e. for the vast majority of electrons produced in ionizing interactions, this is in contradiction to the Heisenberg uncertainty principle. The second challenge is related to the use of the cross section concept in a context where subsequent interactions occur at average distances in the nm range, so that they cannot be considered as independent. Some alternative methods for simulating track structure characteristics without using Monte Carlo techniques have been developed which, however, also rely on albeit effective cross sections.

With respect to the aim of developing measurement devices for track structure properties with the potential for practical applicability, the most advanced developments are miniaturized tissue-equivalent proportional counters and solid-state microdosimeters based on silicon. In addition, also calorimetric microdosimeters are under development whose major potential lies in their capability to measure energy deposition directly in tissue-equivalent material, such as to obtain a means of 'calibration' for the other types of miniaturized microdosimeters. For nanodosimetry, first attempts are in progress to develop measurement devices for track structure that are based on the radiation-induced change in resistance of electrical circuits built from DNA molecules.

3.1.2 To quantify correlations between track structure and radiation damage

Introduction

The comprehensive multi-scale characterization of the physical aspects of particle track structure will enable a quantitative investigation of the impact of particle track structure in terms of biological effects at the subcellular and cellular level. To this end, radiobiological experiments and radiobiological modelling need to be included. In order to obtain a quantitative and comprehensive characterization of the correlation between microscopic particle track structure and radiation damage to biological cells, biological cells need to be exposed to single particle tracks. In these radiobiological experiments, information on the geometrical relation between the particle track and the exposed cells is required such as to be able to relate the features of the track to the biological outcome.

Track structure will most likely show a strong correlation with the induction of early biological effects such as the occurrence of single and double strand breaks of the DNA. As later biological endpoints also show a dependence on radiation quality, there should also be a correlation of track structure characteristics and the probability of inducing these later effects, such as chromosomal aberrations or cell death. It is not obvious a priori whether the same characteristics (e.g. probability distribution of the number of ionizations for a particular size of the target volume) will be of relevance for different biological endpoints.

Many radiobiological assays available to date are often dependent on the availability of a large number of exposed cells, as intermediate steps in the applied protocols may have a limited selectivity for the cells of interest. This often leads to outcomes of limited statistical power. Furthermore, for many assays functioning protocols can only be established for a limited choice of cell types, and there is often a strong dependence on the human factor and a number of unknown factors which can jeopardize the success of the assay and appear to be beyond the control of the experimenter. For a high significance of the sought correlation between track structure characteristics and biological effects, an improvement of the dependability of radiobiological assays would be desirable. This would also be beneficial for biodosimetry as a tool for radiological emergencies.

Research lines

The method of choice for the purpose of overlaying particle track with biological cells under defined geometrical conditions are microbeams offering targeting capabilities for individual cells and compartments of cells. Ion microbeams that provide primary particles with pronounced track structure can allow exposure to a controlled number of tracks per cell. Alternatives to ion microbeams are methods based on nuclear track detectors and biological assays that maintain the geometrical relation between cells and tracks.

In these experiments, radiobiological assays are carried out on the irradiated cells to obtain the yield of a particular biological endpoint for a particular radiation quality and a particular geometrical arrangement of the particle track and the irradiated cell. A multi-scale characterization of the physical characteristics of the track structure would also be carried out by using nanodosimeters with multi-scale measurement capabilities or by employing track structure simulation codes that have been benchmarked with nanodosimetric measurements. Statistical cross-analysis would then be carried out to identify, for instance, correlations between the yield of a particular biological endpoint for different radiation qualities and nanodosimetric probability distributions for particular target sizes, such as to identify the most relevant target size for this endpoint.

Depending on the biological endpoint, radiobiological modelling will be involved to a different extent in establishing these correlations. Benchmarking will therefore be essential. This could for instance be achieved by exposing cells to ‘equivalent’ combinations of particle tracks of different radiation quality. These ‘equivalent’ combinations could be found using simulations of track structure and would be defined by producing the same combined probability distributions used as track structure characteristics (for the identified ‘relevant’ target size). The benchmarking would require cells exposed to particle tracks of mixed radiation quality, which would need appropriate irradiation setups to be developed.

The correlation between yields of certain biological endpoints and track structure characteristics would have to be systematically studied for a variety of human cell types of different differentiation and coming from donors of different age and gender such as to obtain information on the presence or absence of age and sex dependent differences as well as on interpersonal variability. The goal would be to find potential weighting functions for track structure characteristics that allow predictions of biological effects based on track structure measurements. This would be a prerequisite for new dosimetric concepts quantifying radiation effects at the level of individual cells or small compartments of tissue. If the sought correlations should predominantly occur for a specific value of target size, nanodosimeters simulating this target size could be used for the realization of these new dosimetric quantities. Otherwise, measurement techniques for their realization would need to be developed from scratch.

3.1.3 To improve understanding of biokinetics and dosimetry of internal emitters

Introduction

One of the key issues in internal dosimetry is how information on dosimetry and biokinetics of internal emitters can be used to improve our understanding of radiation-induced effects and mechanisms of effect occurrence.

Low concentrations of incorporated radionuclides are characterized by spatially and temporally inhomogeneous dose distributions within a tissue or organ. The spatial inhomogeneity of target cells as well as the sensitivities of various cells in a given tissue or organ may result in different health effects. Additionally, the temporal exposure inhomogeneity, that is acute, chronic or fractionated irradiation, and the dynamic behaviour of radionuclide distribution within tissues and organs may affect the biological outcome. Thus, average quantities like average absorbed organ doses may not be appropriate for the estimation of biological effects of low doses. This is partly taken into account by the latest ICRP models which for example consider the inhomogeneous distribution of target tissues in the skeleton and (on a larger scale) of deposited activity in the respiratory tract.

Radiologically important radionuclides in internal dosimetry which may require a microdosimetric approach are alpha and beta emitters, such as isotopes of plutonium and strontium in the skeleton or short-lived radon progenies in the lungs, and Auger emitters, such as iodine isotopes, in the thyroid. For example, in case of inhalation of short-lived radon progeny in the lung, highly localized deposition of alpha-emitting radon and thoron progeny may induce very high doses on a very local (a few hundred micrometer) scale that may even lead to cell killing, although the mean organ absorbed dose to the lung might be quite low.

One of the most important issues in low-dose research is the analysis and characterization of possible thresholds in observed health effects. By decreasing the dose, its role may become negligible compared to the role of confounding factors or compared to the repair mechanisms of cells and tissues. Another consequence of inhomogeneous cellular dose distributions is that modelling of tissue response instead of single cell responses becomes even more important because of interaction among adjacent cells.

Low-dose effects of high and low LET radiation are quite different. High LET radiation reaches only a small number of cells depositing a high amount of energy whilst low LET radiation affects more cells with a smaller amount of energy imparted. Thus, alternative ways of assessing high and low LET exposures should be investigated such as fluence, hit probability and microdosimetric energy distributions. Improving dosimetric quantification can decrease the uncertainty of the dose effect relationships.

Research lines

Characterisation of the spatial inhomogeneity of dose and its effects on different scales from individual molecules to the whole body is needed, with a particular focus on the development of calculation tools for alpha microdosimetry. Other scenarios of interest are the deposition of ^{90}Sr within femur bone, radon and thoron in the lung, deposition and clearance models for inhaled radon progeny, cellular effects of low doses and low dose rates with the focus on DNA damage and stress response, simulation of microdosimetry in a virtual cell and track-structure-based calculations of initial radiation damage and its effects on the DNA, tissues and organs. This will require the study of deposition of radioactive material on different scales from organelles to the whole body including benchmarking of Monte Carlo codes – from micro to macro dosimetry. At the very end of this line, alternative quantities based on nano- and microdosimetry instead of absorbed dose may be developed to predict health effects.

These efforts must be accompanied by the development of more realistic models of radionuclide deposition in the various regions of the lung than are currently available, describing the energy deposition of incorporated alpha emitters on a micrometer and nanometer scale and estimating the corresponding local biological effects. The results should be combined with epidemiological observations, for example after residential radon exposure or inhalation of plutonium (occupationally or accidentally). The same approach can be applied to the development of more realistic thyroid models that permit studying deposition of electron and photon emitters in the thyroid after accidental intakes of radioiodine isotopes; this study will focus on public exposures, taking into account a wide range of ages from foetus to adolescents and also adults. This research may even include development of new dose concepts that are described in Chapter 3.1 of this report.

There is increasing evidence that the tissue response after irradiation with high LET radiations may be different from that observed in individual cells, e.g. through the interaction of cells via bystander mechanisms. To extrapolate from effects in single cells, where experimental information is currently available, to biological effects in tissue, which may be related to epidemiological findings, requires research on radiation effects in 3D tissue models, both experimentally and theoretically. In terms of dosimetry, this raises the question, whether currently identified progenitor cells are indeed the primary target cells or whether all surrounding cells may contribute through bystander mechanisms.

For radiation protection purposes, carcinogenesis is the most important radiologically induced health effect at low doses. It is common practice in cancer research to assume a multi-step model, including initiation and promotion mechanisms. Initiation is currently assumed be related to cellular transformation in single cells and thus depends on the local dose. An important promotional factor is inflammation of the irradiated tissue, which is again related to local dose. Hence from a dosimetric point of view this raises the question of which cells in a tissue are the primary targets for initiation and promotion, and, consequently, which are the relevant cellular doses. In the case of lung tumors, cigarette smoke is the most important promoting agent, as evidenced by epidemiological studies, whose deposition pattern follows very similar biokinetics as that of inhaled radionuclides.

3.1.4 To Update Operational Quantities for External Exposure

Introduction

The protection quantities cannot be physically determined by measurement. In order to answer both social needs and metrology, a quantity, or set of quantities, is required that can be related to the protection quantities for the purpose of the safe control of ionizing radiation and legislative requirements, and can be determined by measurement. The quantities must be: self-evident (obvious); comprehensible to the users (simple); as easy as possible to determine; stable; without ambiguity for defining all the components of the radiation field at a point or at a position on the body; having mathematical properties (additivity, linearity). The role of the operational quantities is to provide a reasonable estimate of the protection quantities for optimization and in assessing compliance with the limits. The operational quantities must be defined, without restriction, for all particles and energies for which the protection quantities are provided.

Research lines

The current operational quantities were defined by ICRU. Conversion coefficients for the operational quantities and the protection quantities were published by ICRU and ICRP for photons, neutrons, and electrons.

ICRP has recently published revised formulations of the protection quantities (Publication 103), a standard set of male and female anthropomorphic phantoms (Publication 110), and a set of conversion coefficients for the updated protection quantities (Publication 116). In the new compilation, particle type and energy range of the conversion coefficients are extended compared to earlier publications. The conversion coefficients calculated using full transport of particles, are presented for photons (up to 10 GeV), neutrons (10 GeV), electron/positrons (10 GeV) plus protons (10 GeV), muons (10 GeV), pions (200 GeV) and He ions (100 GeV/nucleon). The extension of particle type and energy range is intended to meet a need for exposures in high-energy particle accelerators, aircraft and space. The operational quantities will be needed for these particles over the whole energy range in order to adapt the new protection quantities to the system of radiation protection. In this context, further consideration is being given to the definitions of the operational quantities: any changes made to the definitions can have an impact on the design of area monitors, personal monitors, and calibration procedures.

As far as operational quantities are concerned, neither $H_p(0.07)$ nor $H'(0.07)$ may provide the best assessment of the stochastic or deterministic effects in skin. Thus, a modified system of operational quantities (addressing for example the control of exposure due to hot particles and other external sources of skin irradiation) is needed.The operational quantities used in radiation protection practice including those mentioned above for skin dose assessment must be capable of being measured with simple monitoring instruments, and they should provide a sufficiently conservative estimate of organ and tissue equivalent doses and effective dose limits. Therefore, it is very important to consider the availability of device and calibration facilities as well as the establishment of calibration procedures to define the operational quantities for new particles and extended energy ranges.

3.2 Towards improved radiation risk estimates deduced from epidemiological cohorts

Radiation dosimetry for irradiated humans is important (i) for the treatment, diagnosis and protection of the individual and (ii) for the understanding of the effects of ionising radiation on humans. Current knowledge of relationships between dose and radiocarcinogenic risk, non-cancer diseases and other radio-induced pathologies (e.g. eye lens opacity, fibrosis) depends largely on the analysis of situations where large populations have been exposed to ionizing radiation, e.g. acutely at the Japanese bombings and some medical exposures, or chronically by radionuclide releases from the Mayak nuclear facilities in the Southern Urals). The basis for all risk estimates is absorbed dose. In order to give maximum support for future epidemiological studies, and to underpin theoretical radiobiological developments, dose distributions in the body following exposures from all known sources of radiation should be quantified and evaluated, in particular for mixed radiation fields which were present for example at work places of nuclear workers, or if there were multiple exposures to ionizing radiation in medical applications (diagnostics and therapy).

Radiation research is performed to quantify the radiation risk involved in a certain exposure situation, in order to judge whether this exposure can be justified or not. In this context the concept of risk coefficients, i.e. the risk of a certain outcome per unit dose, is a central element. In a dose-response curve, the risk coefficient can be interpreted as the slope of the curve which corresponds to the ratio of the risk and the dose, at a given dose. From this it is evident that uncertainties in quantification of the outcome (risk) or uncertainties in quantification of the dose would both contribute to the uncertainty of risk coefficients. In this sense, radiation dosimetry must be considered as an essential foundation of radiation risk estimates. Dosimetry therefore represents an essential input to radio-epidemiological studies, whether in radiotherapy and diagnostic imaging follow-ups, studies on occupational exposure and exposure of the general population, or accidental exposures.

Presently the most important radio-epidemiological cohort is the cohort of atomic bomb survivors from Hiroshima and Nagasaki which has been followed-up by the Radiation Research Effects Foundation (RERF; former ABCC) since 1950. Although considerable efforts have been made since the 1950s to quantify the doses of the survivors included in the so-called Life Span Study (LSS) on an individual level – with the DS02 Dosimetry System being the most advanced of a number of consecutive dosimetry systems – still a number of fundamental open issues have been defined recently.

Other cohorts include populations exposed at the Techa River area from releases of the Mayak nuclear facility, after the Chernobyl accident (thyroid cancer) and more recently after the Fukushima accident. Among occupationally exposed groups, uranium miners, radiation technologists, Chernobyl liquidators, Mayak workers, other nuclear workers, air crew etc. are of concern, while other studies include individuals exposed due to radiotherapy (tinea capitis, hemangioma, breast cancer, thyroid cancer, etc.).

In a few years, follow-up of a number of studies will finish, due to the aging of the involved cohort (e.g., LSS) and consequently other cohorts of irradiated humans may become more and more important in the future, including offspring cohorts of exposed parents. Cohorts such as radiotherapy and diagnostic imaging patient populations, for example, are useful candidates because of the large number of individuals involved, the medium-high doses, and especially because patient doses are well controlled and documented. For this reason, development and harmonization of medical dosimetry is important. Other efforts include the establishment of national cohorts of individuals of the general populations.

In the past, in most cases incidence and/or mortality of various cancer types were of major concern (all solid tumours combined, tumours at certain organs, leukaemia, thyroid cancer, etc.) while more recently, cancer diseases following in-utero exposure, and non-cancer diseases such as cardiovascular diseases, neurological impairments, or eye lens opacities have become of increasing concern.

In order to improve risk estimates deduced from such cohorts, a number of dosimetric improvements are required:

- Quantification and validation of exposure pathways that have not yet been considered so far for certain cohorts. This includes doses to certain organs and tissues that need specific attention (e.g. eye lens, brain, foetus), doses to substructures of certain organs (e.g. heart arteries and walls), and determination of the micro-distribution of doses in certain tissues (e.g. in the lung after inhalation of alpha emitters)
- Improvements in techniques of retrospective dosimetry for historical cohorts and validation of the doses estimated (e.g. for Chernobyl liquidators, Techa River populations, LSS, Mayak and Sellafield nuclear workers, uranium miners)
- Improvement of uncertainty evaluation of doses estimated by retrospective dosimetry techniques

For the vision of improved radiation risk estimates deduced from epidemiological cohorts the following challenges were identified:

- To explore exposure pathways not yet considered or validated
- To improve retrospective dosimetry for exposure pathways already considered

These challenges are described in detail in the following.

3.2.1 To explore exposure pathways not yet considered or validated

Introduction

While considerable efforts have been made in the past to quantify exposure of individuals in cohorts used to deduce various radiation-induced risks for various endpoints (e.g. solid cancer, non-cancer diseases, chromosome aberrations, cataracts, etc.), we have identified a number of exposure pathways that have not yet been included or validated in dose estimates of relevant radio-epidemiological cohorts. These cohorts include, for example, atomic bomb survivors, aircrew, medical radiotherapy cohorts, Techa River population, and national cohorts of populations currently being established in a number of countries. For the pathways identified the corresponding doses must be quantified in an effort to establish an integrated individual dosimetry to be used for deduction of reliable dose-response curves from epidemiological cohorts.

We also note that for a number of tissues and organs that are important for radio-epidemiological cohorts, exposures cannot adequately be calculated yet. For example, cancer following prenatal exposures, and non-cancer effects induced by ionizing radiation such as cardiovascular diseases, neurological (cognitive) impairments or lens opacities (cataracts) are of increasing concern, and a number of epidemiological studies have already provided some evidence for statistically significant radiation-induced non-cancer effects and cancer risk due to in-utero exposure (e.g., atomic bomb survivors, Mayak workers, Techa River population). For the establishment of reliable dose-response relationships for these endpoints, realistic dose estimates to the organ of concern must be available. Such doses are, however, not yet fully considered in dosimetry and have to be developed.

Research lines

Recently, open issues in a-bomb survivor dosimetry of the Life Span Study were discussed and it was felt that exposure from residual radioactivity induced by neutrons in the environment and some internal exposure pathways need still to be addressed. Biodosimetric methods such as EPR on tooth enamel or measurement of stable chromosome aberrations (translocations) in peripheral blood samples of survivors may help to quantify individual exposures. Neutrons are still of some concern and although neutron activation products have recently been successfully measured in tissue samples (enamel) from survivors, calculated fast neutron doses for the Nagasaki cohort still require experimental validation of environmental samples.

In the case of air crew exposed to secondary cosmic radiation during flight, considerable efforts have been made in the past to quantify – mainly by simulations that were validated by measurements – annual effective doses. These efforts showed that in many countries pilots and cabin crew is the cohort with the highest occupational exposure (both in terms of mean annual effective dose and mean annual collective dose). Dose contributions from Solar Particle Events, that may increase the dose rate from secondary radiation in the atmosphere by 1-2 orders of magnitude for several hours, however, have not yet been addressed. Some efforts must be made, in particular with respect to quantification of the energy distributions of primary protons emitted by the Sun during such events and with respect to measurement campaigns onboard aircraft, before reliable dose estimates can be made. This also holds for astronauts in space, and may also be important, for example, for studies on electronic effects (Single Event Upsets) to electronic components used in aviation and space, keeping in mind that highly-engineered modern societies are particularly vulnerable if SPEs affect electronic communication and GPS navigation.

Epidemiological studies of second cancers following radiotherapy must have a specification of dose to the patient. In some studies, however, it has not yet been possible accurately to determine dose to the tissue at the site of the second cancer. By harmonizing out-of-field dosimetry techniques for radiotherapy patients, and dosimetry for various diagnostic procedures, EURADOS can contribute significantly to future epidemiological studies by developing “the complete dose specification” from all sources of radiation (see also section 3.4). This may even include dose contributions calculated on a sub-organ level as described below.

Currently, in a number of countries such as Germany there are efforts to establish national cohorts. These efforts aim to investigate causes of common diseases among the general population such as, among many others, cardiovascular diseases and cancer, quantification of risk factors, and identification of prevention strategies (see e.g. http://www.nationale-kohorte.de/index_en.html for Germany). Due to the large number of individuals included (about 200,000) and the planned length follow-up (10-20 years) such cohorts may also be suitable for the investigation of the role of ionizing radiation in the induction of the various investigated endpoints. A prerequisite is of course reliable dosimetry for the participants. While this will not be possible for all participants, we expect that in these cohorts, sub-groups will be defined for which sophisticated determination of all relevant exposure pathways from natural sources of ionizing radiation (cosmic radiation, terrestrial radiation, radon, internal) will be performed. Methods need to be developed to measure these exposure pathways on an individual level without compromising the daily life of the participants.

Exposure scenarios typical for the population at the Techa River are particularly complicated because they include a combination of external and internal exposures. For an integrated individual dosimetry of the members of this group, a combination of dosimetric techniques must therefore be applied. Physical dosimetry on environmental samples using TL, and analysis of radionuclide composition in historical water samples as well as historical dose rate measurements in the environment have already been used to validate assumptions on the source terms of the Mayak releases. Biological dosimetry such as fluorescence in situ hybridization (FISH) techniques to identify stable chromosome aberrations and EPR on tooth enamel should be complemented by internal dosimetry techniques (in-vivo and in-vitro bioassay methods) quantifying the dose from incorporated long-lived radionuclides such as 90Sr or plutonium isotopes. The radiation-induced EPR signals result from combined contributions of external exposure and radionuclides incorporated in tooth tissues. Techniques for assessment of the internal dose to tooth tissues and data analysis must be improved to enhance discrimination of external and internal dose components and to separate contributions of natural background radiation and atmospheric radionuclide releases. The effects of radiation may be altered by the presence of confounding factors or of other contaminants or stressors which may be the case when cytogenetic methods of dose reconstruction are used; this will require further analysis.

After the Fukushima accident in Japan, a considerable number of members of the public were exposed to released radioiodine isotopes. EURADOS has been collaborating with the National Institute of Radiological Sciences in Japan (NIRS) since 2012 in a project for the reconstruction of early internal doses in the TEPCO Fukushima Daiichi Nuclear Power Station Accident. For this project, computational dosimetry is used as an alternative tool in internal dosimetry when physical phantoms are not available for in-vivo calibration of whole body counters. Monte Carlo simulations using voxel phantoms permit calculation of counting efficiency of the detectors used for measurements, for different ranges of age of the exposed population, resulting in more accurate calculation of activity of radioiodine deposited in the thyroid. This approach should be implemented to improve the on-going process of reconstruction of doses to workers and the population affected by the Fukushima accident, but can be also applied in other scenarios.

Furthermore it is our vision that during the next decades, models of critical organs such as the heart, the brain or the eye lens with high spatial resolution will become available that allow quantification of absorbed doses in substructures of the organs of interest. This will require development of voxel phantoms of these organs with voxels on a sub-mm size that will allow – in combination with radiation transport calculations in the human body – calculation of absorbed doses from primary and secondary particles in organ sub-structures such as, for example, the arteries of the heart. The final goal of this research will be to establish fluence-to-dose conversion coefficients for organ sub-structures of interest, for relevant radiation types. This research should include organs of various sizes, and in particular organ sizes that are typical for children and young adults (adolescents). The radiation to be studied depends on the exposure scenario of the investigated cohort and may include photons (medical cohorts, e.g. CT exposures), a mixed photon and neutron field (a-bomb survivors), combined photon, proton, neutron, and ion exposure (particle therapy), photons and alpha particles from incorporated alpha-emitters (Mayak workers), beta particles (90Sr in Techa River, radioiodine intakes due to Chernobyl and Fukushima accidents or in radiotherapy patients), or even mixtures of external exposures and internal exposures due to a variety of incorporated radionuclides (Techa River populations, Chernobyl population, uranium miners, nuclear workers).

For any organ of interest, the computational efforts described above should be complemented by development of miniaturized detectors that will allow measurement of doses from various radiation types within small substructures of a suitable phantom, or even within a patient during irradiation (e.g., brachytherapy).

3.2.2 To advance retrospective dosimetry for exposure pathways already considered

Introduction

Retrospective dosimetry consists of methods that measure persistent chemical, biological or physical changes, in biological tissues or inert materials, which can be directly related to the absorbed dose of ionizing radiation. In other words, retrospective dosimetry measures markers of exposure which persist long enough to measure doses received weeks or years before sampling. In epidemiological studies, these methods are appealing because they complement conventional dosimetry, such as film badges, when this is not available or reliable, and allow for a dose estimate which is independent of the analytical models. Retrospective dosimetry has indeed helped significantly to validate analytical model-based doses either of environmental samples, or of individuals such as inhabitants of contaminated territories and Mayak and other nuclear workers, in the largest epidemiological studies. In particular, long-lived (i.e. for years) markers of exposure have been valuable tools for dose assessment of historical and chronic cohorts (e.g., survivors in Hiroshima and Nagasaki, inhabitants of the Southern Urals).

The ideal objective is to use retrospective dosimetry for molecular epidemiology, i.e. to provide individual doses having little bias and small random errors, and to permit discrimination between different pathways of exposure (i.e. internal vs. external) and radiation qualities. In our vision, this long term objective can be approached through the following research lines.

Research lines

In all the epidemiological studies of historical cohorts, the dose estimates fell mainly in the low-intermediate dose range. Currently, the most consolidated long-lived markers (EPR with teeth, FISH of stable translocations in lymphocytes, TL/OSL in ceramics) have a detection limit in the 25-300 mGy dose range. These levels should be reduced in an effort to reduce the uncertainties at low doses. Markers of exposure with higher sensitivity and lower detection limit than those currently used should also be investigated.

Approaches to both reliably assessing and reducing the uncertainties associated with estimated dose should be explored. Possible ways to do this are: inter-laboratory comparisons and error propagation from the single sources of uncertainty, e.g. by Monte Carlo calculation.

Epidemiological studies of long-term effects are usually carried out between six months and some decades after exposure, so the marker must be stable enough to provide significant dose estimates after this time. EPR of tooth enamel, TL/OSL of ceramics and FISH of stable translocations in lymphocytes are nowadays considered the most reliable markers for dosimetry in cases of radiation exposure that occurred many years ago. Other stable markers should be identified, including those that are suitable for molecular epidemiological studies.

To reduce the bias in retrospective dosimetry, confounding factors should be identified and reduced. Especially, how the effects of radiation are changed when other contaminants or stressors (chemical, biological or others) are present should be studied. Other sources of bias might be age- or gender-dependent. It will be necessary to characterize further the dynamics of lymphocyte homeostasis and circulation within the body and the effect of radiation on these processes.

As a general rule, in epidemiological studies, sampling should be as minimally invasive as possible. In historical cohorts, in some cases, tissues can be collected as they become available over the years, as, for instance, tooth enamel for which large sample banks exist. However, for other tissues, such as blood, storing can affect the quality of samples or the information contained therein. Appropriate sampling and storing methods have therefore to be identified and harmonized.

The number of subjects studied using retrospective dosimetry in epidemiological studies has been relatively small because of the relatively low capacity of measurement and because of the invasive sampling. For instance, one single EPR laboratory can measure, full time, about 150 tooth samples in one month. Possible ways to enlarge the measurable cohort are, in our vision: a) developing faster and minimally invasive techniques, such as *in vivo* EPR on teeth or mini-biopsies techniques in combination with high frequency EPR, b) surveying high throughput biological techniques, c) making techniques easier to perform, field deployable and cheaper (for instance using cheaper reagents), d) considering web scoring of cells, and e) making use of an analysis network consisting of several laboratories working with standardized and harmonized protocols for both, biological sample handling and analysis of biomarkers. The last approach (e) could clearly improve retrospective dosimetry results in molecular epidemiological studies, e.g. long-term follow up of exposed person groups. Such an infrastructure, which could act as a research service network and offer a high cell scoring capacity, is currently being established within the RENEB collaboration.

The improvement of the dosimetry of internal exposure in epidemiological studies is expected to come from the improved realism of updated reference biokinetic and dosimetric models as well as from the collection of information on measurement techniques and on individual exposure. The characteristics of measurement techniques and exposure depend on countries, sites, and time periods in history. The collection of individual specific information on measurement techniques is important in interpreting the available data correctly, especially where they are reported as less than a detection limit. The understanding of exposure is important in the correct application of the dosimetric models by specifying a realistic time course of intake, deposition and absorption rates of radionuclides, depending on the working or living habits and the physicochemical form of the radionuclides.

The measured dose should be easily related to a single organ. This is not always achieved for the currently available methods, especially for internal contamination. Exposures to penetrating external radiation result in fairly uniform irradiation of body tissues, hence similar doses to all tissues, for which FISH and EPR dosimetry can provide a reliable measure of this whole body dose. However, intake of radionuclides by inhalation or ingestion may result in retention in specific organs and tissues, so that the distribution of dose is highly heterogenous. For radionuclides emitting short-range radiations (e.g. alpha particles), this heterogeneity can apply to dose delivery within tissues and between cells within tissues. Work is ongoing in an attempt to address the question of whether FISH provides valid estimates of cumulative red bone marrow radiation doses in cases of incorporation of radionuclides or combined external and internal exposures. To date, research in this area has been chiefly focused on data from the Mayak and Techa cohorts and by considering evidence regarding the origin and lifetime dynamics of lymphocyte subsets in the human body in relation to the localized delivery of dose from the internal emitters strontium-90 and plutonium-239. Although it is currently accepted that the FISH translocation assay can be usefully applied for detecting internal and combined external gamma and internal doses from internally deposited strontium-90, with fairly large uncertainties, much work remains to be done in terms of establishing and validating dose-response relationships for plutonium-239, as well as other radionuclides. A key component of this work will be establishing the relative biological effectiveness of the different types of radiation, as there is currently a distinct lack of conclusive evidence with regard to formation of stable chromosome aberrations, in the published literature.

A reliable assessment of uncertainty of individual internal doses in epidemiological studies such as that on the Techa River population, or that of the Mayak workers, Russian and UK plutonium workers, European uranium miners and workers, is expected to improve evaluation of any dose response function and of its statistical significance. The assessment of dose from internal exposure to radionuclides is subject to uncertainty due to activity measurement errors, individual variability, imperfection of biokinetic and dosimetric models, and unknown parameters of exposure. The uncertainty on the estimated dose is acknowledged to be generally higher than for external exposure, but is usually not evaluated in practice.

Discrimination of acute/chronic exposures, or different radiation quality might be achieved by a multiparametric approach, i.e. merging the results from several retrospective dosimetry techniques. This should be feasible especially for neutrons.

In the short term, retrospective dosimetry will continue to be used for validation of analytical model-based doses in representative groups. However, there is a difficulty in obtaining biosamples from a representative group of persons and there can be a factor of 100 between the number of collected samples and the number of samples to represent a group adequately. Sharing of data and biosample banks within the international scientific community should therefore be encouraged.

Development of new methods and improvement of the existing ones should be tested on a significant number of samples. This is hampered by the difficulty of assessing biosamples for single laboratories. Development and validation of the existing exposure markers have been mainly achieved in the course of large epidemiological studies. Biosample banks should be made available for the purpose of research.

Multiparametric approaches should be also developed to distinguish partial/total body exposure.

As far as Chernobyl dosimetry is concerned, a couple of years ago the FP7 ARCH (Agenda for Research on Chernobyl Health) project was carried out which produced a scientifically sound prioritized list of studies of post-Chernobyl effects in the most relevant cohorts. The studies suggested also the inclusion of some work on dosimetry, although the major foci were medical and biological follow-up studies (http://arch.iarc.fr/). Further validation and retrospective recalibration of historical official dose records could be considered as well as improvement of eye lens beta dosimetry, as a further development of the UACOS (Ukrainian-American Chernobyl Ocular Study) dosimetry. Possibly, some critical review and summary of dosimetric monitoring practices, retrospective dosimetry efforts and evaluation of radiation protection approaches might be of value as a lesson and recommendation for the future.

Further development of the time-and-motion approach to reconstruct radiation exposures might be of use. This should include elaboration of methods for assessment of uncertainties in the information obtained by interviews of individuals who were exposed some time ago. Development of computer-assisted interview techniques, that include a virtual 3-D representation of the local exposure situation, is also considered helpful, in an effort to facilitate recall of those exposed.

3.3 Towards efficient dose assessment in case of radiological emergencies

Radiological emergencies are considered a major challenge of modern societies. These emergencies may include

- incidents that have an impact on large geographical areas (such as the Chernobyl or the Fukushima accident) and lead to exposure of large groups of the general populations,
- terroristic attacks using for example dirty bombs that involve conventional explosives and (allegedly) radioactive material, and
- accidents that involve radiation sources used for example in industry or medicine.

Each of these exposure scenarios is associated with specific problems in determining the radiation doses and the radionuclides involved, identifying individuals who are at highest risk (triage), and deciding the best method to be applied for evacuation, medical treatment and remediation. All this must be considered keeping in mind some loss in infrastructure (disturbed electricity, destroyed roads, problems in transportation and electronic communication, traffic jams, etc.).

In handling such events, many aspects need to be considered which are beyond the scope of the present SRA. These aspects include information strategies, risk communications, evacuation concepts, treatment of radiation injuries, etc. and should be dealt with by networks such as NERIS or – if distribution of radionuclides in urban and other environments are concerned – STAR. A quick, efficient and reliable estimate of doses to affected individuals or groups of individuals involved in such an incident is, however, a prerequisite which must be known before any further decisions can be made by the responsible authorities and decision makers. Dose assessment is complicated because a number of different exposure scenarios might be of concern including internal exposures from incorporated radionuclides or external exposures from various possible sources. Moreover, real-time monitoring data might be scarce and those which are available may rapidly change with time. In order to provide an efficient assessment of potential exposures and doses in a radiological emergency, a number of dosimetric improvements are required, to allow decision makers to initiate the most urgent actions, including those allowing for a) rapid identification of individuals with high risk of developing radiation-induced injuries (external exposure), b) handling of a large number of dosimetric samples in a short time (external exposure), and c) improvement of methods to assess and reduce doses after internal contamination.

For the vision of an efficient dose assessment in case of radiological emergencies the following challenges were identified:

- To identify and characterize new markers of exposure
- To develop strategies and methods to increase measurement capacity

- To quantify doses after accidental internal contamination

These challenges are described in detail in the following section. To meet those challenges, a multidisciplinary approach involving scientists operating in biological, physical and clinical dosimetry is required.

3.3.1 To identify and characterize new markers of exposure

Introduction

If a large number of individuals is potentially exposed in a large-scale accident, then it will be of utmost importance to separate the truly exposed from the vast majority of the "worried-well" and to identify those whose exposure is so severe that immediate medical car is needed. This has to be accomplished while taking into account additional, independent information on doses, exposure scenarios (external, internal), time constraints and number of affected individuals involved. An effective triage is important because the available infrastructure or stocked medicine to treat radiation injuries will be limited, and medical care should be first focused on highly-exposed individuals. Realistically, very few or even none of the affected individuals will have worn a radiation dosimeter. Thus, initial dose estimates must be made based on expert judgement and rough calculations, and any means that would provide additional dose information will be helpful.

Research lines

Currently efforts are being made towards identification of materials of daily life that could be used as fortuitous dosimeters. These objects could be personal items worn on or close to the human body such as portable electronic devices, chip cards, glass, clothing, shoes, plastics, and precious and semi-precious stones, measureable by EPR, OSL and TL. The same measurement techniques can also be applied to biological materials tooth enamel, bones, finger nails and hairs. Other objects that are not worn by individuals but were exposed at a certain place could also be used to estimate the radiation field during an emergency. These objects may include household salt or sugars, bricks or other domestic or industrial materials. In all these cases, the response of the chosen material to different radiation qualities (alpha, beta, gamma, neutrons) must be investigated, the stability of the radiation-induced signal be quantified, and measurement protocols identified to allow a quick and efficient first determination of the radiation dose involved.

For biological samples, there is a large interest and potential for mobile systems for application in the field. In order to avoid invasive sampling, research on *in vivo* EPR of tooth enamel is focused on development of spectrometers with portable magnets. Different approaches for the *in vivo* EPR measurements are under investigation: continuous wave with low microwave frequency or pulsed with X band microwave. The development of a suitable *in vivo* method using a portable OSL reader supplied with optical fibers for tooth enamel measurements is also of interest. Alternatively, further research on tooth enamel mini-biopsies (2-5 mg) measured by high frequency EPR to minimize the invasive sampling and EPR/TL/OSL analysis of fingernail clippings is also desirable.

While the above includes well established techniques such as TL, OSL, or EPR, investigation of other physically based analysis techniques (pulsed EPR, radioluminescence, cathodoluminescence, ionoluminescence, Raman, Infrared, UV spectroscopy) could widen the range of materials that can be used as a dosimeter, and offer further options in an efficient dose assessment. On the other hand, OSL offers the unique possibility to expand the range of stimulation and emission wavelengths to possibly identify signals with greater stability and/or sensitivity.

As for genetic techniques, research is currently focused on further development of the use of microarray and quantitative polymerase chain reaction (PCR) technologies, which should enable gene expression assays to produce and validate a reliable signature of human exposure to ionizing radiation in the near future. This signature will probably not allow prediction of a given dose but will rather allow a distinction between exposed and non-exposed individuals, and as such could be helpful in identifying an exposure above a dose threshold, provided that the post-exposure time is within a defined time period.

Immunocytochemical techniques are relatively new, and thus a large amount of work will be required before they can be used as reliable dosimeters. Nevertheless, protein biomarkers such as γ-H2AX, CRP or serum amylases have some advantages over cytogenetics assays. For example, results can be obtained within hours rather than several days after sampling; sample processing and analysis can be optimized and automated for high throughput; non-invasive sampling may be possible (saliva, buccal cells, hair), depending on the marker, and deployable assay formats already exist or are in development. However, a number of issues have to be considered before these techniques can really be used as robust biodosimetric tools: a) as they are not as specific for ionizing radiation as for example the dicentrics assay, confounding factors need to be fully characterized, b) several calibration curves for different post-exposure times and exact timing between exposure and sampling are required, c) in contrast to cytogenetic and DNA damage foci assays, dose response curves for CRP and amylase cannot be performed *ex vivo*; *in vivo* experiments with suitable animal models and validation studies with radiotherapy patients are therefore required but the translation of animal or cancer patient data to the response of 'normal' humans needs to be considered carefully, d) available data suggest a larger variation than seen for the dicentrics assay and finally, e) there is very little known about their response to different radiation qualities.

Computational techniques are quite straightforward in their concept, but their implementation often requires sophisticated solutions, in particular in urban environments. For this reason the automatic direct input of dose rate measurement data into the databases, powerful interpolation and extrapolation algorithms and tools for prediction of doses are the main routes of further development of time-and-motion techniques. In addition, unlike other retrospective dosimetry techniques, computational methods have the potential for conversion into prognosis and optimization tools for planning of post-accident response, finding the safest evacuation/transportation routes, optimization of the activities of responders and public in different ways – i.e. by collective or individual doses, time before withdrawal from radiation hazard zone, etc. Once implemented, this approach would allow provision of retrospective assessment of individual and collective doses and estimation (prediction) of doses at subsequent time intervals

Whatever technique and dosimetric material is used, the following properties are usually indicated as ideally necessary in retrospective dosimetry in an emergency situation: a) specificity to ionizing radiation, b) reproducibility of the measurements, c) a discernible dose range from 0.5 Gy to tens of Gy, d) good signal stability to allow analysis of recent and distant exposures, e) ability to estimate the extent of partial body exposure, f) ability to discriminate between internal and external exposure, g) well defined dose response relationships for different radiation qualities and dose rates, h) possibility of generating an *in vitro* calibration curve, i) possibility of assessing the uncertainty of the dose estimate, j) low inter-individual variation, k) controllable impact of confounding factors, l) non- or minimally invasive sampling, and m) standardized, rapid (automated if possible) and cheap sample processing and analysis. These characteristics need to be investigated in detail before a material can be considered as suitable to be used as a dosimeter in an emergency situation.

Despite the importance of research, some of these and other radiation markers may not be suitable as stand-alone biodosimeters or physical dosimeters but would work as part of a multi-parametric dosimetry system which produces a dose-dependent signature. This situation will most probably never change despite ongoing research to improve each method because each tool is inherently limited with respect to the above mentioned requirement.

More and more dosimetric applications on smartphones, using the CMOS camera of the smartphone itself or an external detector, are available and can be used very easily by the public. The main advantage of such public applications is that a huge amount of geo-localized data could be potentially available in "real time" and could be very useful, especially in case of large-scale accidents (like Fukushima). Nevertheless, the major disadvantage is that the quality of the data is strongly dependent on the application and the methodology used to do the measurements. So, it is of great importance to establish protocols for validation of doses measured by the public using smartphone applications.

3.3.2 To develop strategies and methods to increase measurement capacity

Introduction

In an emergency situation involving many potentially exposed individuals, measurement of a large number of samples may be required that could far exceed the capacity of nearby dosimetric laboratories. This may be due to the fact that the required dosimetric method is not practiced there, the laboratory equipment is limited, the number of available skilled staff members is too low, or problems in infrastructure after the emergency may prevent optimal use of the existing facilities. In general, a solution to this problem is automation of sample preparation and measurement, development of rapid screening methods for radiation exposure, and improved world-wide networking.

Research lines

Analysis of dicentric chromosomes and micronuclei is performed in a computer assisted mode. The metaphases are identified, recorded and captured fully automatically while the final step of the analysis (evaluation of metaphase) is performed by eye. This last step could also be fully automated and there is already some experience in some laboratories that should further be broadened. Even then, however, the comparatively slow autocapture of metaphase images limits the throughput to ~75 tests per day per system. More focus should be given to the development of methods for high throughput and cheap measurements – such as gene expression or protein biomarkers. Despite their potentially larger variability, these assays could at least serve as initial triage tools to enable rapid identification of any critically exposed individuals among hundreds or even thousands of 'worried-well'.

Web-based scoring of captured images is emerging as a fast and easy method of performing chromosome analysis whilst involving laboratories spread all over the world. Meanwhile the meaning and usage of such an approach is generally accepted and platforms are being developed to disseminate huge numbers of images easily.

Moreover, networking of laboratories has been identified as a very useful approach to get fast and reliable results of dose estimation. Such networks need to be established and their functionality has to be trained and practiced. Major attention has to be given to quality assurance (QA) and quality management (QM), to guarantee operational readiness of the network and its members and reliability of the results produced. In other words, a great potential for workload sharing through national and international networks, such as the RENEB or the WHO BIODOSENET networks, is expected.

The current situation is characterized by a lack of linkage among retrospective (bio and others), clinical/medical, and physical dosimetry. Therefore, closer collaborations between the laboratories involved in these disciplines should be set up. Development of the complementarity of all the different techniques will be required, as worldwide networking efforts lead to a greater need for comparisons between techniques as well as laboratories. Efforts are required to standardize the new methods and develop rigorous statistical analysis methods to enable formal comparisons of techniques. This particular task was, and is currently being addressed through the EU FP7 MULTIBIODOSE collaboration as well as the RENEB collaboration. Availability of techniques in Europe and around the world is also of interest, and current efforts are additionally focused on training and dissemination of information about the different techniques, which is also expected to reduce measurement uncertainties through inter-laboratory comparisons (see also Chapter 4 on Education and Training, and Chapter 5 on Harmonization and Practice).

3.3.3 To quantify doses after accidental internal contamination

Introduction

So far, not much work has been done to link internal dosimetry from incorporated radionuclides with biological dosimetry methods. Biological dosimetry is well established and validated for providing dose estimations following external radiation exposures. In contrast, internal exposures are generally regarded as 'difficult' – experienced bio-dosimetrists try to avoid these because interpreting biodosimetry data in such cases is very challenging, and the standard calibration curves generated *in vitro* are often not valid. Less experienced colleagues who are unaware of all the complicating factors frequently provide dose estimates for internal exposure cases, naively assuming that comparison with their standard calibration curves is all that is needed. Additionally, *in vivo* data derived from animals can be misleading because of differences between species in the spatio-temporal dynamics of radionuclide and lymphocyte distributions in tissues. The current method of choice for estimating internal doses is based on biokinetic modelling of radionuclide measurements in urine and faeces.

On other hand, in cases of high level of internal exposure, bioligands or chelators are commonly administered as a treatment after incorporation of radionuclides of high radiotoxicity such as actinides. Decorporation therapy with DTPA (Diethylentriamene pentaacetate) is a treatment applied after incorporation of significant amounts of plutonium or other transuranium elements. Generally, chelating agents disturb the regular human biokinetics by enhancing their excretion. However, the resulting decrease in radiation dose is currently not well understood and difficult to predict. As a consequence of this the assessment of the final dose does not guarantee a reliable result of the actual internal exposure, or an accurate result of the averted dose.

Moreover, in case of an emergency with suspected incorporation of radioactive materials of a large number of individuals, specific emergency bioassay methods may be needed that have not yet been developed. Dose estimation in cases of mixed external and internal exposure presents a particularly complex challenge.

A specific issue of concern is accidental intake of radioiodine. In such cases, different types of detectors may be used for thyroid counting, and exposed individuals of different ages (foetus, infants, children, teenagers, adult males and females) and sizes may need to be measured for dose evaluation. Intakes of, and doses from, radioiodine accumulated in the thyroid can be also assessed using Monte Carlo (MC) simulations combined with patient-based computational phantoms (voxel phantoms, NURBS phantoms).

Research lines

In general, areas to be investigated are (i) the definition of reliable biological end-points which are radiation-specific, stable with time and particularly suitable for the case of a chronic exposure with variable dose-rate; (ii) the definition of the proper dosimetric quantity to be compared to the biological end-point (a major deficit of most of the current studies is use of wrong dose indicators, e.g. administered activity). Cases of accidental and occupational internal exposures from literature should be identified for which biological dosimetry has been performed and for which bioassay data (e.g. in-vitro measurement of activity in urine samples) are available and sufficient for reliable physical internal dosimetry. Special models have to be developed for reliable blood dosimetry, to determine the blood dose and to assess how and to what extent this dose is correlated with the information provided by biological assays. At the moment it is difficult to evaluate this correlation correctly because a) calibration curves for biological dosimetry are usually generated using external radiation; and b) it is not clear against which dose (blood dose, marrow dose, or total body dose) the results of the biological assays should be tested. The situation could be clarified by performing investigations with nuclear medicine patients including evaluation of time-activity curves in blood by means of dynamic acquisitions, and simultaneous collection of blood samples at consecutive times for performing the biological assay. From the time-activity curve in blood, the blood dose at different time post-administration can be assessed, and compared to the results of the biological assay. These kinds of experiments should be conducted in cooperation with nuclear medicine departments. They will have the advantage that in this way it will be possible to assess for each patient an individual rather than an average blood dose.

If investigations are performed using different radiopharmaceuticals, it will be possible to investigate if and to what extent radiation type and quality (energy) influence the response of the biological assay. These experiments, combined with the aforementioned literature survey should enable the assembly of a comprehensive set of *in vivo* human reference data for biodosimetry following radionuclide intake which, in turn, could significantly improve the quality of biological dose estimates for intake and mixed exposure cases. This activity could also be seen as an important contribution to setup and validate dosimetry techniques that are needed for the implementation of point 2.3.3 of the MELODI SRA (individual radiation sensitivity).

For accidental intakes of high radiotoxic radionuclides (alpha emitters like actinides, the beta emitter ^{90}Sr and others), rapid methods for in-vitro monitoring of these radionuclides must be developed and validated. For other radionuclides this approach may be complemented by in-vivo monitoring. For example, protocols for the determination and/or screening of radioiodine (^{131}I, ^{133}I) in the thyroid in case of a nuclear emergency should be developed and complex intake scenarios (interference of other radionuclides) should also be considered. Additionally, application of available computational phantoms of the thyroid and development of new thyroid voxel phantoms for children of different ages and for adults of different sex, age and size may be useful, based on CT scans provided from hospitals. Validation of MC results will be obtained by proper in-vivo measurements, while development of reference data on thyroid doses to individuals of different ages from measurements using various types of detectors (e.g. Geiger counters) will help responders in public health management. These efforts are expected to help in the reconstruction of thyroid doses of the population exposed after the Fukushima accident in Japan.

In order to understand the reduction of radiation dose from incorporation of plutonium or other actinides after administration of DTPA, a reference biokinetic model for plutonium under DTPA therapy should be developed to improve the reliability of dose assessments for individuals internally exposed (e.g. in Mayak facility and U.S. Uranium and Transuranium Registries (USTUR)). In-vitro studies and targeted animal investigations will be performed to further investigate the mechanisms involving the chelation route due to DTPA administration. The "physiological realism" approach will be considered, integrating more knowledge of the basic physiological processes into the models for radionuclides. The aim here is to provide a more realistic description of the processes behind the metabolic behaviour of the considered radionuclides, and to understand the factors that change their biokinetics. The latter could be used to adapt the model to the individual, therefore sensitivity analysis for identification of the relevant parameters is required, and to find physiological indicators that can be measured in the individual; the results of this study will help the development of more advanced chelating agents. To achieve all these goals, both *in vitro* cell/tissue experiments and animal experiments will be required. In particular, in-vitro studies (e.g. speciation studies with bioligands and chelators) will provide a fundamental understanding of the complex physiological mechanisms behind the biokinetics of decorporation, which can then be implemented in the models to improve them further. This study will contribute to the definition of an operational tool that will be useful and easy to apply in the case of emergency situations.

3.4 Towards an integrated personalized dosimetry in medical applications

Modern medicine offers a variety of diagnostic methods and tools that include imaging techniques where the diagnosed individual is not exposed to ionizing radiation, such as ultrasound and magnetic resonance imaging. In contrast, other methods do involve ionizing radiation such as X-ray imaging, CT scans, PET and others. In many European countries, for example, the use of CT scans has continuously increased over the last decade and this trend is expected to continue. As a result, even if averaged over the whole population of a certain country, medical exposures are largely responsible for exposure from man-made sources of ionizing radiation, and optimization of the received doses is very important.

Additionally, in European countries a considerable fraction of the population will face a cancer diagnosis at a certain time in life, and radiotherapy (using ionizing radiation) represents one of the major methods of treatment. Approximately half of all cancer patients will receive radiotherapy at some point in their illness. A large world-wide population of patients is therefore exposed to high target doses (mainly using photon beams) in a controlled and well-documented way. The distribution of dose within the body following radiotherapy varies considerably with many factors: the size and shape of the patient, the anatomical location of the target volume, the prescribed dose and the type and energy of radiation (photons, electrons, hadrons) and its application (external, internal). In all cases, doses can vary spatially from tens of gray to milligray. All parts of the dose-risk curve for subsequent cancer induction are therefore involved, from low dose effects including regions where non-linear mechanisms have been postulated (e.g. bystander effects), through the region defined largely by the Japanese lifespan study, to the further non-linear region at high doses where cell kill and re-population effects are known to occur.

The development of dosimetry techniques and the measurement of doses is an important pre-requisite for advancing this field of study which will need major efforts in the future. As described in chapter 3.2, epidemiological studies of second cancers following radiotherapy require a specification of dose to the patient at the site of the subsequent malignancy, making out-of-field dosimetry an important field of dosimetric development. Moreover, because additional dose contributions may come from diagnostic procedures, epidemiological studies will require quantification of all sources (therapy and/or imaging), for an estimation of combined risk. Finally, some of the sections in this chapter (e.g. sections 3.4.4 and 3.4.5) may have direct links to chapter 3.5 (e.g. section 3.5.3).

For the vision of integrated personalized dosimetry the following challenges were identified:

- To improve out-of-field dosimetry for photon and particle therapy, including the development of analytical models for out-of-field dosimetry calculations
- To improve dosimetry (including the development of 2D and 3D dosimetry techniques) in modern external beam radiotherapy and brachytherapy. This should also include photon and charged particle radiotherapy, including perhaps boron neutron capture therapy (BNCT) and the development of microdosimetric models for incorporated particles
- To optimize dose estimations in interventional radiology
- To establish reliable patient dosimetry in CT examinations

These challenges are described in detail in the following.

3.4.1 To establish out-of-field dosimetry for photon and particle therapy

Introduction

In order to estimate and quantify the risk of second cancers that may occur even decades after treatment of the primary tumour, an overall assessment of patient dose is required. However, to gain a complete picture of the out-of-field (i.e. outside the target volume) dose distribution following radiotherapy is not trivial, because it is necessary to estimate and combine the dose contributions from a) the primary beam to regions outside the target volume in the therapeutic beam path, for photons, electrons and hadrons; b) scattered photons from the patient and linear accelerator leakage; c) neutron production at higher photon energies, and for hadron (protons, carbon ions) therapy; and d) imaging exposures used as part of the radiotherapy process (e.g. treatment planning and verification imaging, at diagnostic and therapeutic x-ray energies).

In addition to second cancer risk estimation, out-of-field dosimetry data will be also important for estimating (i) risks of deterministic effects, (ii) foetal doses and risks for radiotherapy patients treated whilst pregnant, (iii) risks of non-cancer stochastic effects (e.g. heart & respiratory disease), (iv) risks of cardiac pacemaker malfunction, and (v) genetic risks.

These data will also be important in the development, testing and validation of analytical models for calculating out-of-field doses. Such models are useful since it is impracticable to measure out-of-field doses under all possible combinations of treatment parameters.

In this context, specific emphasis should be placed on paediatric radiotherapy because (i) risk factors for children and young adults are higher than in later life and (ii) many paediatric treatments have a good prognosis and patients may be expected to live for periods greater than the latent period for expression of a second cancer.

Research lines

The strategic goals to be achieved in the next 20 years are a) to develop and harmonize dosimetry techniques for the measurement and estimation of the complete dose specification from all sources (therapeutic and diagnostic) to patients receiving radiotherapy, (b) to develop analytical models for the calculation of doses at any point in the body from all sources of radiation c) to use the complete dose specification as input to risk models for deleterious effects of ionizing radiation, and d) to support future epidemiological studies of second cancer incidence following human exposure to ionizing radiation (see section 3.2) by developing and harmonizing techniques for comprehensive dose measurements over the whole body.

A prerequisite of this challenge is the development and harmonisation of methods for the synthesis of the total out-of-field doses to patients from all sources (therapy & imaging) during radiotherapy, and the estimation of combined risk. This requires strategies to quantify and store patient-relevant doses and to communicate radiation risks to the public and the medical profession. The challenge of integrated patient dosimetry also requires the consideration of potential doses to the patient from radiotherapy imaging procedures. These may include CT scanning, the combination of PET and CT imaging, MV and kV cone beam CT for treatment planning, localisation, verification and image-guided radiotherapy (IGRT). Studies of the relationship between image information and patient dose in supporting imaging examinations are important, with the final goal of optimising patient doses from imaging procedures.

Modern radiotherapy includes irradiation modalities featuring – among others – photons with energies above 10 MeV, high-energy protons of about 200 MeV and more, and carbon ions with typical energies of several hundred MeV per nucleon. In all these cases, secondary neutrons may be produced in surrounding materials (linear accelerator components and treatment room structures) and within the patient. These neutrons are of particular concern because they are not confined to the target volume (tumour) but are distributed throughout the patient and contribute to the overall patient dose. Precise dose quantification is desired in particular for tumours with good prognosis, as a successful treatment resulting in a long life expectancy will – through aging of the patients – be associated with an increased risk of neutron-induced secondary cancers. It is our vision that novel small-scale detectors for neutrons and photons be developed that could be used to measure the dose distribution – preferably with a spatial resolution that allows deduction of organ doses or sub-organ doses, thus accounting for potential dose variations within an organ – within suitable phantoms irradiated according to typical radiotherapy modalities. Ideally, these dosimeters can be arranged in a phantom as row, matrix or cubic combination for volumetric dose mapping, without significantly disturbing the dose fluence. Given the fact that some of the radiation sources used in radiotherapy are operated in a pulsed mode, and new such sources are currently being developed such as laser-induced proton sources, special attention should be given to the behaviour of these neutron and photon detectors at high dose rates. These dosimeters must be compared and evaluated, and the associated measurement uncertainties quantified. Special attention must be given to the detection of high-energy neutrons (above 20 MeV) which are a typical component of the energy distribution of secondary neutrons produced in proton radiotherapy (see chapter 3.5.3).

These developments must be accompanied by development of a variety of anatomical or semi-anatomical phantoms including water tanks, BOMAB-like phantoms, anthropomorphic phantoms for dosimeter comparisons and clinical simulations, with special emphasis on paediatric phantoms.

Once suitable detectors and phantoms have been developed, measurements of out-of-field doses in photon and particle radiotherapy based on the simulation of clinical treatments need to be performed. It is anticipated that these measurements would form part of a pan- European project in which many radiotherapy centres would participate, sharing expertise and equipment, and progressing towards harmonisation of out-of-field dosimetry techniques.

It is apparent that detector and phantom developments need to be complemented by simulation of the complex mixed fields of photons, protons and neutrons that is used in these treatment modalities. This includes simulation of the primary particle field produced by various medical accelerators, and interaction of this field with the patient and the materials present in the therapy room. The final goal should be calculations of energy distributions of all particles that contribute significantly to patient dose. This is particularly important for proton and heavy ion radiotherapy where again particular emphasis must be placed on particles with energies above 20 MeV, and currently open questions at those high energies such as missing cross sections, production of secondary particles, validation of Monte Carlo transport codes, nuclear reaction models, etc. need to be investigated in detail.

The results of extensive measurement campaigns, performed using optimized dosimeters and phantoms for currently used radiotherapy beams, verified and extended by Monte Carlo radiation transport calculation, should become available in a dedicated database. An ultimate goal of this research is to develop a set of analytical algorithms for calculation of photon and neutron doses, which can easily be incorporated into modern Treatment Planning Systems (TPS) used in radiation oncology. These analytical functions implemented into TPS would enable the calculation of a complete map of doses for each patient which could be used to assess doses in future epidemiological studies or even, in some special cases, for optimization of radiation therapy of young patients.

Both development of devices for detection of neutrons above 20 MeV and simulation of detector responses and patient doses require reference fields for quasi-monoenergetic high-energy neutrons where these devices and simulations can be benchmarked. We note that in the very near future, it is most likely that in Europe such a facility will no longer be available.

3.4.2 To improve dosimetry in modern external beam radiotherapy

Introduction

Radiation therapy plays a major role in treating about half the number of cancer patients. It is very important to be able to measure the dose distribution given to the tumor, in an effort to check if this agrees with the treatment plan. However, *in vivo* dosimetry during external beam therapy could benefit from the development of improved dosimetry techniques. Next to this, the rapid development in new radiotherapy techniques (flattening filter free (FFF) fields, volumetric arc therapy, small fields, proton and heavy ion therapy, microdosimeric characterization for hadrons, etc.) requires a continuous effort in dosimetry research, not only to develop on-line dosimetry techniques, but also to improve calibration techniques.

Research lines

Novel dosimeters (boron doped diamond detectors, liquid-IC, scintillator, luminescent techniques, etc.) should be developed, which can be arranged within a phantom as row, matrix or cubic combination for volumetric dose mapping, without disturbing the dose fluence, and which can be used for *in-vivo* dosimetry. In this context, development of smaller and more accurate electrometers, capable of working without cables would also be useful. Further, rapidly developing techniques of 2D and 3D dosimetry which use extended dosimeters such as polymer gels, capable of millimeter resolution, should also be developed and applied to volumetric dose mapping.

Improving the dosimetric performance for special radiotherapy techniques such as flattening filter free (FFF) fields, volumetric arc therapy, small fields, proton and heavy ion therapy, microdosimeric characterization for hadrons is also required

3.4.3 To include internal microdosimetry in radiotherapy and medical imaging

Introduction

X-rays and radiopharmaceuticals have been used in medical imaging and radiotherapy, respectively, to diagnose and to treat cancer and disease for human health care. The unique features of cellular and molecular radiobiological effects depend strongly on the spatial and temporal distributions of initial physical tracks, on induced chemical radicals and later on dynamical molecular biological progresses. Risk assessment after application of alpha- and Auger-emitters and beta radiations in radiotherapy requires knowledge of the fundamental pattern of the inhomogeneous absorption of radiation energy in organs and tissues at the molecular and cellular levels. In additional to the conventional average organ dose approach, modern approaches of microdosimetry and nanodosimetry represent powerful tools to describe the stochastic nature of the energy depositions and the induction of radicals, and to characterize the health and biological effects of internal emitters.

The analysis of radiation covers – as a first approach – alpha- and Auger-emitters and beta radiation. The analyses will include levels of molecule, cell, tissue, organ and organism. Several types of methods will be applied: *in-vivo* experiments, animal experiments, application of epidemiological data, computational modelling and integrated approaches. Furthermore, the potential application of gold nanoparticles in medical diagnostic imaging and radiotherapy will be investigated. Molecular biological experimental and theoretical Monte Carlo simulation studies are considered important to reveal the correlation between the experimental biological findings at the cellular level in specific organs, like the lungs and kidneys, and the microdosimetric and nanometer scale doses of these emitters.

Research lines

The local radiation dose at the molecular level of the Auger-emitter ^{125}I needs to be simulated. The experimental investigations described in the literature on DNA damage and cell survival and cell killing of cancer cells incorporated with ^{125}I should be used to indicate the possibility of applying ^{125}I in genetic radiotherapy.

To investigate the potential application of nanoparticles in radiotherapy, Monte Carlo programs may be used to simulate the interactions between the gold nanoparticles and x-rays. In these simulations, the geometry of the cells can be assumed spherical and/or ellipsoidal, and different concentration distributions and sizes of the gold nanoparticles in and around the cells must be tested. The simulations can be complemented by experiments where cancer cells coupled with and without nanoparticles are exposed to x-rays of various energies. The physical interactions between x-rays and secondary electrons with soft tissues and gold nanoparticles should be followed.

We expect spectral CT medical imaging with gold nanoparticles as a contrast agent to be investigated with Monte Carlo methods in an effort to identify the smallest percentage of gold nanoparticles needed to be used as a CT contrast agent in humans. The quantity of gold nanoparticles which is specifically targeted to malignant tissues can be investigated with cell culture experiments as well. The tumor specific monoclonal antibody cmHsp70.1 could be conjugated to gold nanoparticles with a diameter of 50 nm, and the actual location of the gold nanoparticles in and around the cells be visualized by transmission electron microscopy (TEM).

The medical internal radiation dose (MIRD) committee provides some of the necessary tools that will allow estimation of the absorbed dose at the cellular level. These tools take the form of cellular S-values (absorbed dose per unit cumulated activity). S-values can be used to calculate the radiation dose received by a target region when the radioactivity is distributed in a source region. S-values can be calculated by using Monte Carlo codes.

Knowledge of the spatial distribution of energy deposition in cellular and subcellular structures is important for understanding the biological effects of radiation. Such information is crucial with regard to developing new pharmaceuticals for cancer therapy and to choosing the suitable labelling radionuclide. For modelling the distribution of a local energy deposit as well as radiation effects, Monte Carlo track-structure codes can be used for simulating event by event the slowing-down process of all generations of particles.

3.4.4 To optimize dose estimations in interventional radiology

Introduction

The dose to patients in interventional procedures can be high, leading even to deterministic effects. Thus, an improved system of dose calculation and dose monitoring in interventional radiology (IR) for adult and paediatric patients needs to be developed. This would enable assessment and improved use of diagnostic reference levels (DRLs), achievable dose levels (ADLs) and skin dose alert (trigger) levels for optimization of patient doses, improved accuracy of skin and other organ doses, and improved accuracy of population dose estimation.

If this vision is realized, patient-specific real time dose mapping of skin dose, other organ doses, effective doses and practical dose quantities (Dose Area Product (DAP), Cumulative Air Kerma (CK)) will be possible, with known uncertainty and with efficient use of DICOM information. Thus, based on DRL and ADL values, practical systems of patient dose monitoring for local as well as wide-scale evaluation and comparison of patient doses will be available. These systems can be used to estimate patient doses and radiation-induced risks, and to prevent accidents.

Research lines

Practical methods of skin dose measurement need to be developed and tested (using large area detectors, TLD methods and advanced detectors) and the related uncertainties in skin dose measurements and dose mapping need to be evaluated. New systems of automatic dose mapping tools, based on DICOM information, are becoming available in modern equipment. These should be applied, tested and calibrated.

Determination of, and recommendations on, skin dose alert (trigger) levels are still needed, including the investigation of the correlation between skin dose and dosimetric indicators for several IR procedures, including paediatric IR. This will require collaboration with industry and standardization bodies, in order to implement the concept of dose alert for daily use.

DRLs and ADLs for different levels of complexity of IR procedures need to be defined and measured, as well as an improved methodology on their determination and requirements on statistics. Studying the feasibility of using continuous DRL-curves with the possibility of introducing different levels of complexity in accordance with achievable values can be done.

A similar concept to DRLs for patients should be developed for equipment used in IR procedures. For this purpose it is necessary to collect and to compare equipment dose rates for different IR procedures, establish calibration procedures for dose measuring devices, and to organise intercomparisons between clinics involved in such procedures.

Ideally, online patient dosimetry in different imaging modalities should become available. This will require adequate dosimetric quantities for fluoroscopy, computed tomography, cone beam CT and hybrid imaging. In collaboration with industry, improved dosimetric information must be identified that should be provided by future x-ray units for different imaging modalities. Also the possibilities of keeping dose records of patients should be improved through collaboration with the industry. Following online patient dosimetry all the relevant dosimetric quantities and risk evaluators (like effective dose and organ doses) should become available automatically; this will need calibration and testing.

3.4.5 To establish reliable patient dosimetry in CT examinations

Introduction

For CT examinations it is important to develop systems of dose monitoring and scanner calibration (with known uncertainties) in order to provide easy use of DRLs, improved optimization of patient doses, improved accuracy of organ dose determination for risk estimations and improved accuracy of population dose estimation. The focus should always be put on paediatric patients.

Research lines

Automatic dose mapping systems should be developed. The research line to be followed will include definition of the parameters of interest for dose mapping, analysis of commercially available and individually developed systems, and evaluation of the feasibility of using automatic systems that allow collection of patient dose data on a regional or national scale, in particular for the establishment of DRLs and the estimation of population dose. Harmonisation is a key feature that should allow – in collaboration with industry and standardization organizations – promotion of the practical implementation of these automatic systems.

Harmonisation is also important because there are currently different approaches for patient dose determination and scanner calibration (International Electrotechnical Commission (IEC), American Association of Physicists in Medicine (AAPM), ICRU). These approaches must be tested (e.g. the IEC pragmatic approach with different size of detectors) and compared, and their feasibility for clinical implementation must be investigated. In particular, the impact of applying these approaches for the determination and use of DRLs must be studied and the added value of using dose estimates that depend on patient size (Size-Specific Dose Estimates – SSDE) must be quantified.

Another field of improvement concerns the use of phantoms for scanner calibration and QA measurements in clinical practice, in particular for modern cone beam CT where the use of flat panel detectors poses some dosimetric problems. There are various phantoms proposed and used, and these need to be tested and compared in clinical practice (e.g., ICRU phantom). In particular, with respect to feasibility and practicability, the use of only single-size phantoms requires investigation, and the aspect of using phantoms to evaluate image quality vs. dose should be addressed. Finally – again in collaboration with industry and standardization organizations – the most promising phantoms must be identified, produced, and widely distributed.

In an effort towards personalized dosimetry, methods of patient dose determination should cope with varying patient sizes (e.g. the approach proposed by the AAPM). This needs investigation of the optimum parameters for size specification of patients, tests of the use of SSDE as a DRL quantity in various CT examinations and the possible added value to the Computed Tomography Dose Index (CTDI), studies of the use of the product of SSDE and scanning length as a DRL quantity in various CT examinations and the possible added value to Dose Length Product (DLP). Again, particular emphasis should be placed here on the determination of DRLs for paediatric examinations. Appropriate and practical quantities that can be used for patient dosimetry in CT, and that can take into account the fast evolution in CT modalities, should be developed.

It is our vision that in the end, patient-specific conversion factors from SSDE to organ doses should be available for risk estimations and population dose estimation. This may be achieved by means of Monte Carlo calculations for SSDE and organ doses in various CT examinations for a range of patient sizes, complemented by an experimental determination of SSDE and organ doses for a few cases, to verify the MC calculations. This can include the development of individualized voxel phantoms of patients from CT images in real-time. Such organ doses can help in epidemiological studies of radiosensitive organs, such as eye lens and cataract development, or for the heart to investigate cardiovascular effects.

3.5 Towards improved radiation protection of workers and the public

Much research and technical development in radiation protection dosimetry for workers and the public has been carried out, to a large extent within projects funded by the EC. The results of these developments have been transferred to operational radiation protection, including guidelines and technical recommendations. Despite of these efforts, a couple of areas exist in which the status is unsatisfactory, necessitating further research. For the vision of an improved radiation protection of workers and the public the following challenges were identified:

- To improve, validate and implement new biokinetic models
- To develop accurate and on-line personal dosimetry for workers
- To improve neutron dosimetry techniques
- To include nuclide-specific information in environmental monitoring

These challenges are described in detail in the following.

3.5.1 To refine, validate and implement new biokinetic models

Introduction

The assessment of dose from internal exposure to radionuclides is subject to uncertainty due to activity measurement errors, individual variability, imperfection of biokinetic and dosimetric models, and unknown parameters of exposure. The resulting overall uncertainty in the estimated internal dose is acknowledged to be generally higher than that for external irradiation, but is usually not evaluated in practice. Thus, in a very general sense, improvements in internal dosimetry are needed, with potential benefits in radio-epidemiology (see also chapter 3.2), diagnostic and therapeutic nuclear medicine, and radiation protection of workers and the public. In this context, the availability of databases including autopsy cases should be acknowledged and used to validate any developed new biokinetic model.

Research line

It is intended to implement the latest biokinetic models which will be published in the new ICRP documents on Occupational Intake of Radionuclides (OIR). These new models are very complex and difficult to apply in individual dose assessment. A EURADOS report should be written with recommendations and guidance on how to use these complex ICRP models for individual dose assessment. The reason for this task is to be able to obtain the most realistic individual dose assessment not only for monitoring purposes but also as a fundamental basis for research on dose response relationships.

The assessment of the effects on internal dose of using sex-dependent biokinetic parameters must be considered as well as the implementation of the new OIR systemic models, including quality assurance of the model results and model formulation. In this context, the National Council on Radiation Protection and Measurements (NCRP) Wound model requires validation with human data, using real cases from databases of the EU-funded project IDEAS and from USTUR (United States Transuranium and Uranium Registries).

While biokinetic models for workers and members of the public used for radiation protection purposes consider the biokinetic behaviour of radionuclides in healthy reference persons, radiopharmaceuticals are administered to patients who may suffer from diseases which might change the biokinetic behaviour of the radiopharmaceutical. Currently, dose assessment is done based on state-of-the-art biokinetic models used in radiation protection. It is obvious, however, that in nuclear medicine therapy, individual dose assessment is essential rather than doses to reference persons and consequently, biokinetic models that take into account the influence of certain diseases need to be developed.

An additional aspect also deserves attention when biokinetic models are used for dose assessment of patients after application of radiopharmaceuticals: because of the short half-lives of radioisotopes used in nuclear medicine, a more realistic modelling of blood retention and urinary bladder voiding is needed. For radiopharmaceuticals which are secreted into the gastro-intestinal tract, consideration of the secretion pathway via the gall bladder may also be relevant, together with a gall bladder voiding model.

The reliable assessment of uncertainties in individual doses would enable epidemiological studies of internal exposure to radionuclides to improve the evaluation of the dose response function and its statistical significance.

3.5.2 To develop calibration procedures for partial body counters

Introduction

Dose assessment of individuals with internal contamination is subject to uncertainty due to many factors. Retrospective dose assessment is based on in-vitro and in-vivo measurements. In vivo measurements represent a highly valuable method since they provide actual information on radionuclide activity within the body of an individual. It has many beneficial aspects, but requires a detection system to be properly calibrated in order to obtain quantitative and accurate results. Calibration is usually performed by an object (physical phantom) which resembles as closely as possible the anatomy of the human body or one of its parts. There is no standard procedure to calibrate a partial body counter, and anthropomorphic phantom(s) such as those used in order to assess the skeletal activity of bone seeking radionuclides (e.g., plutonium and americium isotopes) are scarce. Skeletal activities are usually assessed from measurement positions at the knee, elbow or skull. It important to note that calibration based on available skull phantoms, for example, may differ by a factor of two. This is partially caused by individual body parameters such as head size, and by properties of different phantoms (e.g., differences in the construction or activity distribution).

Research line

It is intend to develop and implement standard physical and mathematical phantoms and procedures for calibration of partial body counters. Newly developed physical phantoms should improve currently available phantoms and provide a reliable base for general calibration. These phantoms should be complemented by their mathematical representation (voxel, mesh, non-uniform rational basis spline (NURBS) phantoms), in order to account for individual variability of the persons to be measured.

Improved and standardized calibration procedures will be beneficial for two reasons. Firstly they will directly reduce the uncertainty of the measurement and thus affect final dose assessment. Secondly, more accurate and unified data will provide a better basis for design and improvement of anthropomorphic models.

3.5.3 To develop accurate and on-line personal dosimetry for workers

Introduction

The challenge is to provide reliable, accurate and on-line personal dosimetry for occupationally exposed workers. This requires monitoring the workers in real time for all limiting quantities (whole body, eye lens, extremities, brain, heart), regardless of the protection methods used, and to provide input for the optimal application of the ALARA principle. Dosimetric research for personal dosimetry should deliver good characterized active and passive dosimeters for all relevant dosimetric quantities, and good computational tools using advanced tracking technology.

Research lines

Active dosimeters need to be developed for all radiation fields relevant for occupational exposure. Many devices exist already, but they are not suited for all of these fields. These active dosimeters should be developed in a way that they can also be used for official dose records. For fields that are used in medical applications and in particular for pulsed fields, improvements are still needed, and for example the dependence of active dosimeter response on dose rate must be investigated. Besides that, all existing devices must be tested for all relevant fields in which they are used. Active dosimeters should also be developed for eye lenses and extremities. Improvement of active dosimeters is also needed so that the measured dose is visible to the operator on-line and that the results can be easily implemented in advanced staff databases.

There is still quite some work on eye lens dosimetry to be done. For example formalisms to measure eye lens doses, to develop practical eye lens dosimeters, and to test and compare different eye lens dosimeters are needed. There is also a lack of data for eye lens doses of workers in different fields such as those present in medical applications, where correlations of eye lens doses with other dose quantities, determination of reference eye lens doses for different procedures, and testing and improvement of the efficiency of different protection measures like lead glasses need to be explored. Particularly, the development of a dosimetry protocol to assess eye lens doses when protective eye glasses are used is urgent. However, the reduction in the dose limit for the lens of the eye to make it equal to the whole body dose limit makes it potentially the limiting quantity in any field where the dominant direction of radiation is from the front, even for fields for which neutrons contribute a significant component of absorbed dose. There is hence an urgent need to assess where eye lens doses are limiting across the breadth of industries where radiation protection is required.

There is also still a lack of practical and reliable extremity dosimetry. Therefore, development of practical extremity dosimeters are called for, to test and compare different extremity dosimeters, to explore correlations with other dosimetric quantities, and to improve dosimetry in mixed beta/gamma fields, especially low-energy beta fields.

In the medical field, there is the special problem of whole body dosimetry in case of lead shielding (lead apron, thyroid shield). This requires determination of the best algorithm for double dosimetry and development of the best method to monitor effective doses in case of inhomogeneous irradiation (which is typically the case when a lead apron is used).

In the future, the inclusion of dosimetry of other potentially radiosensitive organs (brain, heart) might also be needed. Dependent on the outcome of biological research on brain and cardiovascular risk, for example, doses to these organs might need to be determined.

3.5.4 To develop neutron dosimetry techniques further

Introduction

Neutron sources are intentionally used and/or incidentally created in various scientific areas and technical applications (e.g. electricity generation, radiography and tomography, materials research, activation analysis, fundamental research, military activities, production of radioisotopes/radiopharmaceuticals). Some of the fields represent new challenges due to strongly pulsed radiation or very high energy ranges, i.e. radiation fields around high-energy particle accelerators and at flights at high altitudes or space missions.

On the other hand, external dosimetry for neutron radiation, which is inevitably accompanied by a photon component, still presents challenges despite many years of development of neutron personal dosimeters. Neutron dosimetry is still a very challenging task as neutrons are present in mixed-fields, they are indirectly ionizing particles and pose more problems for their detection than other types of radiation. Their energy may cover extremely large energy ranges from 9 (nuclear industry) to 12 (particle accelerators, flight altitudes) orders of magnitude, and their “quality” and subsequently their conversion coefficients from fluence to dose varies by a factor of 50 over the entire energy range. At certain work areas neutrons can dominate the total dose received. However, the higher detection threshold of neutron personal dosimeters can lead to underestimation of the collective dose received from neutrons: this detection threshold remains one of the main deficiencies of neutron personal dosimetry relative to that for photons.

The accuracy required for routine neutron dosimetry is not at the same level as for photon radiation in most workplaces, though this is not always true. Previous studies carried out have clearly shown that responses of personal neutron dosimeters in various workplace fields in the nuclear industry can show over- and under- responses of up to an order of magnitude. Therefore workplace monitoring is a prerequisite to achieve sufficient accuracy, i.e. by evaluating a spectrum correction factor to be applied.

Whilst neutron dosimetry concerns a relatively small fraction of all exposed workers and the usual neutron $H_p(10)$ contribution is often small compared with the dose limit; for some workers, such as air crew, it can be a significant component of total dose equivalent; it cannot be disregarded and reliable dosimetry with higher accuracy should be pursued.

Research lines

Improvements of the existing dosimeters are required not only through improvements of existing techniques and/or development of new ones but also through the development of reference radiation fields to determine their response. Unfortunately, the actual reference radiation fields do not cover the required overall ranges in energy and angles encountered in the workplace. Because a facility that provides suitable neutron reference fields is extremely expensive and challenging, a European effort to develop and realize improved neutron testing and calibration facilities is the best way to achieve overall better results.

Furthermore there is a need to characterize simulated workplace fields at a reference laboratory and radiation fields at the working area in terms of personal dose equivalent $H_p(d)$. Workplace monitoring is well-established, and is performed mainly with multi-sphere spectrometers or simply by area monitors, both of which do not provide information on the directional distribution of neutrons. Therefore the results obtained are not sufficient to determine personal dose equivalent. The simultaneous measurement of energy and directional distributions is still a matter for research.

Calibration of neutron personal dosimeters requires specific attention. In standard laboratories it is not possible to reproduce the variety of conditions (mixed-fields and wide energy and angle of incidence ranges) in which dosimeters are then used in workplace fields. Essential tools to guide a development in neutron dosimetry are regular intercomparisons either in standard laboratories or “in-field” conditions. Such intercomparisons are usually not achievable in only one country and therefore European efforts in designing and planning such testing sessions are needed (see chapter 5).

There are specific needs for calibration of detectors and instruments in high-energy and pulsed neutron fields. Currently, reference high-energy fields are strongly dependent on simulation tools, with the measurements themselves being dependent on those same simulation tools for calibration. There is the additional problem of under-reading by active detectors in pulsed fields. Research is required into the appropriate dose rates for high energy and pulsed neutron fields.

3.5.5 To include nuclide-specific information in environmental monitoring

Introduction

In March 2011, the nuclear power plant accident in Fukushima Daiichi demonstrated the indispensable need for permanent and reliable environmental radiation monitoring. At present, in Europe more than 5,000 stations allow radiological monitoring data to become available in nearly real-time. In case of a nuclear emergency, national dose rate data have to be provided to the European Commission (EC) on an hourly basis, via the European Radiological Data Exchange Platform (EURDEP). Based on these and other radiologically relevant data, the EC, which is in charge of the European Community Urgent Radiological Information Exchange System (ECURIE) may issue recommendations to the EU member states which could affect millions of people and may have severe economic and sociological consequences.

Currently most dosimetry network stations in Europe are equipped with conventional dosimetry detector systems, which do not provide any nuclide-specific information. However, in case of a major radiological emergency, in addition to reliable data of dose rates values, nuclide-specific information and data on ground and air contamination levels are of key importance for adequate governmental decisions, and first efforts are currently being made (e.g. in Finland and Germany) to improve the situation.

Research lines

In order to improve environmental radiation monitoring in Europe, we expect novel and improved instrumentation for field-station use to be developed, to allow for measurement of dose rates and collection of nuclide-specific information. New and improved measurement systems based on "high-resolution" spectrometric detectors such as NaI(Tl), $LaBr_3$, or Cd-Zn-Te, which are in principle all well suited for this purpose, require comprehensive scientific investigations of detector features, spectra evaluation, and deconvolution methods, in order to fulfil today's QA standards. These spectrometry systems could become the core instrumentation of the next generation of environmental radiation monitoring networks in Europe. They could also be used – through measured in-situ gamma spectra – to validate Monte Carlo simulations of dose rate and contamination levels.

In a complementary effort, the use of passive dosimetry systems should also be explored for environmental radiation monitoring, and their advantages and disadvantages systematically discussed and compared with existing and other newly developed systems.

3.6 Concluding remarks – the role of computational methods in dosimetry

In many of the areas of research described above, computational methods play an important role. The domain of computational physics is not solely reliant on the Monte Carlo method, but also incorporates deterministic methods that attempt to solve the Boltzmann transport equation, and unfolding methods used to derive neutron energy distributions from experimental data. These other methods are important and should not be overlooked, but the availability of modern codes and powerful computers has made the Monte Carlo method dominant in radiation protection and dosimetry. Important areas of research where computational methods are needed also include representations of the human body at the macroscopic, microscopic and nanometric level. To give another example, the operational quantities used in radiation protection are defined in a manner that only permits their values to be calculated via Monte Carlo calculations. This is equally true for the protection quantities, which are defined in voxelized phantoms that cannot be constructed physically but must be simulated. The availability of Monte Carlo methods has allowed this system of radiation protection to be developed, which makes it an integral part of the field. Consequently, computational methods play a crucial role in most of the radiation protection fields where further research is needed.

4 Training and Education

Education and training (E&T) has always been a key issue in EURADOS activities. For example, EURADOS Working Groups often allow attendance of corresponding members or observers in order to offer the chance to scientists, especially young scientists, who can listen to scientific discussions and be updated on the actual scientific programmes, thus allowing their participation in the future. In addition, EURADOS regularly organises specific training events like training courses, winter schools and scientific symposia.

As for training courses, they usually last 3 to 5 days, with limited participation to about 40 attendees and they are related to specific topics in the field of the EURADOS Working Groups. In the past, some of the training courses had two or more editions and were slightly updated if necessary, according to the demand. EURADOS *Winter Schools* have taken place at EURADOS Annual meetings since 2007. They usually last one or half a day and they provide "refresher courses" on topics relevant to radiation dosimetry. In contrast, scientific symposia also organized at EURADOS Annual Meetings, are usually related to research topics or results from EURADOS Working Groups or related research projects. Proceedings of the symposia have been published in peer-reviewed journals.

EURADOS E&T actions are generally organised in an effort to maintain the competence in the field of dosimetry, in Europe. These actions are considered important and will be continued in the future including training on upcoming new dosimetric techniques. Coordination with E&T efforts of other platforms is recommended, in order to guarantee efficient use of techniques in dosimetry in all relevant research disciplines where exposure quantification is needed.

As an additional aspect, experience after the Chernobyl and Fukushima accidents demonstrated that much fear among the population arose from lack of information about what radiation is and what "dose" means. It is thus believed that a constantly improved education of the general public and especially of key figures (physicians, physics teachers, journalists) is needed, aiming at a better understanding of ionizing radiation and radiation dose, as well as development of emergency programs to educate and train a large number of people (especially journalists, representatives of local authorities, etc) about technical terms involving radiation and dose.

4.1 Implementation of EC directives and technical recommendations into practice

Recently EURADOS has prepared training courses on "Implementation of RP 160 and on lessons learned from intercomparison exercises". This course was held for the first time in 2012 in Krakow, Poland, with 41 attendees from Europe and Japan. Among others, the course was very instrumental in defining the future strategy needed for a better harmonisation of dosimetric practice: Participants in the WG02 training course have identified the need for more practical information on a) the work necessary to apply for accreditation, b) information on how to use the results of type testing and/or intercomparisons in the uncertainty budgets, and c) guidance on a practical assessment of uncertainties.

Future training actions in this field will be based on this experience and on the input by the individual monitoring service (IMS) community. It is desirable that IMSs will regularly attend the

EURADOS Annual Meetings and discuss issues of common interest. On the other hand, the analysis of QA/QC surveys organized on a regular basis is a means of identifying topics where training actions might be needed and welcomed by IMSs. To meet the request of attendants to the 2012 training course the 2013 version had more emphasis on the practical implementation of EN/ISO/IEC 17025 as requested. Further planning of training courses should be linked to the needs of the IMS community.

4.2 Training courses on novel or improved dosimetric methods

EURADOS continues to organize a number of training activities, in order to maintain competence in the field of dosimetry. Past training courses included were “Methods in Radiation Measurement”, “Internal Dosimetry”, “Use of MCNP in Radiation Protection and Dosimetry”, “Voxel Phantom Development and Implementation for Radiation Physics Calculations”, etc. (see Appendix for more details).

In case of internal exposures, training for fundamentals of internal dosimetry will be required in many scenarios, covering knowledge about quantities, monitoring techniques, biokinetics of incorporated radionuclides, interpretation of monitoring data, dose assessment, uncertainties and quality management. Reference publications, software and other tools required are, among others, ICRP OIR reports, ISO Standards, IDEAS Guidelines and NCRP Models and Reports.

Other activities that were carried out and which need to be continued in the future include training on upcoming new dosimetric techniques such as, for example, EPR/OSL and TL dosimetry.

4.3 Winter schools, workshops and scientific symposia

In the past, Winter Schools were held on the general topics of "Relative Biological Effectiveness, radiation weighting factor and quality factor: their role in quantifying effectiveness of ionizing radiation" (AM2014), “Status and Future Perspectives of Computational Micro- and Nanodosimetry” (AM2012), “Radiation Protection for Medical Staff” (AM2011), “Radiological Emergencies – Internal exposures” (AM2010), “Low-Dose Radiation Effects” (AM2009), “Retrospective Dosimetry” (AM2008), and “Uncertainties in Radiation Dosimetry” (AM2007). These efforts will continue in the future, on general topics which are thought to be important for the EURADOS community.

Scientific workshops and symposia have been organized in the past on actual research topics where EURADOS Working Groups are involved. Typically, proceedings of these workshops are published in peer-reviewed journals. The following topics were addressed in the past: “Dosimetry for second cancer risk estimation in radiotherapy” (AM2012), “Accelerator radiation protection and shielding” (AM2010), “Cosmic Radiation and Aircrew Exposure” (AM2009), “Dosimetric Issues in the Medical Use of Ionizing Radiation” (AM2008), “Characterization of Workplaces for the Assessment of the Doses to Individuals” (AM2007), “Uncertainties in Dosimetry – Principles Through to Practice” (AM2006), “Radiation Protection Dosimetry and Dosimetry for Medical Applications” (AM2005), and “Biological and Physical Dosimetry for Radiation Protection” (AM2004) (see Appendix for more details). These actions will also continue in an effort to present new research findings that were gained from various EURADOS WG actions.

5 Harmonisation and Practice

The goal of harmonisation of dosimetric procedures in Europe is central to the overall EURADOS vision. It is obvious that every strategic objective discussed in the above Strategic Research Agenda has an element of harmonisation. That is, for all areas of research where dosimetry is required (epidemiology, occupational exposures, environmental monitoring, emergency preparedness, medical applications, etc.) a consistent approach in determining individual doses of exposed subjects and/or ambient dose rates is indispensable.

As far as individual monitoring is concerned, the European Commission acknowledged the need for harmonisation in dosimetric practices in Europe, and publication of the Council Directive 96/29 EURATOM (13 May 1996) had major implications for individual monitoring. This document requested individual monitoring to be performed by approved dosimetry services, generalized the use of the operational dosimetric quantities, and placed an increased importance on quality assurance (QA) and quality control (QC) measures and their application to the routine work of individual monitoring services (IMSs). In reaction to the initiative of the European Commission, in December 1996 EURADOS set up an action entitled "*Harmonization of dosimetric quality assurance in individual monitoring of external radiation*" with the main aims of assisting the consolidation within the EU of the quality of individual monitoring using personal dosimeters and to facilitate harmonized procedures. Meanwhile requirements on individual monitoring services (IMS) were defined and quality management standards were set that highlight the technical competence of staff, and requests technical procedures to be used, in order to guarantee that any IMS is capable of generating technically valid results. These standards also require IMSs to regularly take part in inter-laboratory comparisons.

In some countries, national performance tests are offered, and successful participation is necessary for an IMS to be officially approved and allowed to maintain the activity as a service provider. In other countries, however, such organized exercises do not exist and it seems likely that the International Atomic Energy Agency (IAEA) will favour regions of the world other than the European region. EURADOS experience in this field may prove useful in the future.

As far as environmental monitoring is concerned, in Europe, at present, more than 4,500 stations provide almost real-time radiological monitoring data. In case of a radiological emergency with trans-boundary implications in Europe, national dose rate data must be reported to the European Commission (EC) on an hourly basis, via the European Radiological Data Exchange Platform (EURDEP). Based on these and other radiologically relevant data, the EC – being in charge of the European Community Urgent Radiological Information Exchange System (ECURIE) – may issue recommendations to the EU member states which could affect millions of people and may have severe economic and sociological consequences. Thus, reliable monitoring data of ambient dose rates, coordinated with data from other international radiological networks, are indispensable for adequate environmental radiation monitoring in Europe. The harmonisation of ambient dose rate measurements in Europe is a prerequisite for the reliability of the ECURIE system and an important contribution to its quality assurance.

In view of the need to harmonize dosimetric practices (both for individuals and the environment), and based on the interest of the European Commission and the earlier EURADOS activities described above, EURADOS will continue with such activities in the future. These are described in the following sections.

5.1 Intercomparison for dosimeters used in individual monitoring

For individual monitoring it is our vision to create a long-lasting self-sustained system of actions that ensures harmonised dosimetric practises in Europe and that will contribute through participants from overseas (US, Japan) to a world-wide system of harmonised individual monitoring services.

First, this requires a network of contacts that in the ideal case should include one person per interested country, who would participate in and contribute to the relevant EURADOS activities. Depending on the type of information necessary, this individual would contact the IMSs and/or national radiation protection authorities in his/her own country and/or neighbouring countries. At present such a network has already been established including contacts with persons of all EU member states as well as Switzerland, Norway, Ukraine and Turkey. Keeping our vision in mind to extend this concept to regions outside Europe, this network needs to be expanded in the future and strategic contacts need to be established with regions outside Europe.

Second, this requires organisation of intercomparison exercises at accredited (EN ISO/IEC 17025) metrology laboratories for the required irradiations, collection and analysis of results declared by participants, preparation of certificates to participants, and eventually organization of a participants' meeting to report and discuss the overall results. In general, such a meeting is held at EURADOS Annual Meetings. Dissemination of the results will be done through EURADOS reports, presentations at conferences attended by the community and publications in peer-reviewed scientific journals.

So far, three whole-body photon intercomparison exercises were organized with a two-year interval (see Appendix). This meets the IMS needs to comply with EN/ISO/IEC 17025 requirements for accreditation. This concept proved very successful and it is our vision that it will be continued in the future on a regular basis. More specifically, our future plans include organisation of intercomparisons for whole-body dosimeters for photon fields, every 2 to 3 years, and with a smaller frequency for extremity dosimeters and neutron dosimeters (3 to 5 years interval).

The experience gained by EURADOS in the realization of such actions in the past may prove useful to other organizations such as IAEA and collaboration may be useful in organising similar actions in other parts of the world.

5.2 Intercomparison for early-warning systems used in environmental monitoring

For environmental monitoring it is our vision that contamination levels down to a few kBq/m^2, which correspond to an increase of the ambient dose equivalent rate ($H^*(10)$) of about 5 nSv/h (about 5 % of the natural background) from, for example, ^{137}Cs, can be determined in the fastest possible way. We note that in case of a major radiological emergency, an early and reliable assessment of contamination levels of farmland and of dose rate levels in urban areas are of key importance for the protection of the health of the public against dangers arising both from direct external radiation and from intake of radioactivity from foodstuffs.

Validation of procedures and the traceable calibration of any detector systems used to supply data to monitoring networks, e.g. EURDEP, will be required. For this purpose, existing reference field stations, such as Intercal of BfS in Freiburg, Germany, and those presently under construction, e.g. the future underground calibration facility of IFIN-HH at Slanic-Prahova in Romania, should be metrologically linked with the primary standard facilities available for dosimetry at low dose rates. Currently, there is only one traceable calibration service for low dose rates (100 nSv/h and below) available worldwide, i.e., the underground facility UDO II, operated by PTB in Braunschweig, Germany. The Romanian installation may help to improve the calibration capabilities, especially for East-European countries which have not yet participated in intercomparison exercises such as those organised by EURADOS.

EURADOS intends to support operators of national early warning dosimetry networks and consult regulatory bodies and the Joint Research Centre (JRC) Ispra concerning legal aspects of environmental radiation monitoring, especially those related to Article 35 and 36 of the Euratom Treaty. The stimulation of cooperation, especially between the Institute for Environment and Sustainability (IES) with regard to EURDEP (European Radiological Data Exchange Platform) and EURADOS is considered to be a key element in developing further the idea of harmonisation in environmental monitoring. This will also include definition of standards and publication of technical recommendations.

5.3 Surveys on practical dosimetry

Accreditation is gradually becoming more and more important for European IMS, and quality assurance and quality control is a central element. Here EURADOS can play a leading part in the future, if the actions mentioned above (intercomparison exercises, training courses) can be organised in a self-sustained manner. Monitoring the success of these actions is of course important, and regular surveys should be instigated by EURADOS, to document the quality of dosimetric practises in Europe and to compare it to that in other regions of the world. A survey organised by EURADOS in 2012-2013, for example, indicated that the profile of QA is high amongst the responding IMS and that most are following good practice. The majority of services are certified (around 70%) or declared themselves compliant to quality standards, mostly in accordance with EN/ISO/IEC 17025 (or with ISO 9001). These results, while in general very promising, suggest that further and continuous efforts must be made to guarantee a sustained, long-lasting, and consistent quantification of exposures to ionizing radiation.

In general, dissemination of the results should be done through EURADOS reports, presentations at conferences attended by the community and publications in peer-reviewed scientific journals. To support dissemination, the EURADOS network is involved in the organization of the conferences on individual monitoring as members of the scientific committees, invited lecturers, session chairs, co-chair and rapporteurs, referees for the preparation of proceedings, etc. So far Individual Monitoring conferences were organized in 2000 (Helsinki, Finland), 2005 (Vienna, Austria), and 2010 (Athens, Greece), and another is planned to take place in 2015 in Bruges (Belgium).

To ensure optimum use of the lessons learned from surveys and intercomparison exercises, a regular analysis of results must be ensured, reasons for observed deviations be identified, and suggestions for an improvement of dosimetric quality be made. This will require maintaining, updating and extending the contact details of interested IMS, regularly assessing the performance of the participating IMS, in compliance with reference documents that are based on the analysis of EURADOS surveys and intercomparison results, and preparing training courses adapted to the identified lessons learned.

In order to keep dosimetric practises up-to-date, current and future ICRP and ICRU concepts and recommendations as well as corresponding EU Directives must be continuously scrutinized and their potential implications on measurement quantities, phantoms, etc. evaluated. Additionally, any new technical developments with respect to passive dosimeters (traditional film, TLD, OSL, track-etch, etc.) and in particular to active personal dosimeters must be also included in this evaluation.

Following the publication of ICRP60 in 1991 and ICRP103 in 2007 and although the radiation and tissue weighting factors were revised, the system of quantities suggested by ICRP and ICRU seems to be stable, namely, H_p(d) for the next period. However, recent work on radiation effects suggested that the H_p(3) quantity might deserve further attention, particularly with the decrease of the corresponding annual dose limit for the lens of the eye. As a consequence, the measurement of this quantity received increased importance as the output of recent projects show: (i) dedicated dosimeters have been proposed for the measurement of H_p(3) closer to the eye lens; (ii) a cylindrical phantom as surrogate of the head instead of the slab phantom to be used for calibration of eye-lens dosimeters has been proposed; (iii) conversion coefficients for $H_p(3)/K_a$, $H_p(3)/\Phi$ for photons, electrons and neutrons (for both cylindrical and slab phantom) have been published by various authors in the open literature to complement the values published by ICRU/ICRP as international agreed values for H_p(10), H_p(3) and H_p(0,07); (iv) international standards on procedures for the calibration of dosimeters in terms of H_p(3) have not been updated yet. In the near future, the use of H_p(3) in routine and related measurement procedures may be expected. Important QA and QC issues for H_p(d) might also include the quantity H_p(3) and related measurement issues and/or problems.

5.4 Intercomparison of dose assessment in cases of internal exposures

Doses from intakes of radionuclides cannot be measured directly but are estimated from monitoring data of activity in total/partial body and in excreta samples (urine and faeces). Such assessments require application of biokinetic and dosimetric models, and assumptions about the pattern of intake and the properties of the radioactive material inside the body. Past intercomparison exercises (Doerfel 2000, Hurtgen 2005) have shown a wide range in doses that can be obtained from the same data set from different assessors demonstrating the need for guidance on harmonising internal dose evaluations.

Intercomparison exercises of dose assessment in cases of internal exposures are required to validate the capability of the dosimetrists in the correct interpretation of monitoring data to provide the best estimate of the intake and Committed Effective Dose E(50).

The last international intercomparison exercise on internal dose assessment was organized by the IDEAS Group (IDEAS Project,EU Contract No. FIKR-CT2001-00160) in 2005. A new action is required taking into account the state-of-the-art tools currently available and forthcoming publications as follows:

- ICRP/OIR Reports: Occupational Intakes of Radionuclides (in progress). A series of documents that will replace the ICRP Publications 30, 54, 68 and 78, to provide revised dose coefficients and bioassay data for occupational intakes of radionuclides by inhalation and ingestion. The revised dose coefficients have been calculated using the ICRP100 Human Alimentary Tract Model (HATM) and a revision of the Publication 66 Human Respiratory Tract Model (HRTM). In addition, information will be provided on absorption in blood following inhalation and ingestion of different chemical forms of elements and their radioisotopes. Revisions have been made of many systemic models with more physiologically realistic representations of uptake and retention in organs and tissues and of excretion. The reports will also include some guidance on monitoring programmes and interpretation of bioassay monitoring data.
- Revised IDEAS Guidelines for the Estimation of Committed Doses from Incorporation Monitoring Data (EURADOS Report 01-2013, Casstellani et al). The IDEAS Guidelines are based on a general philosophy of a) harmonisation – by following the Guidelines any two assessors should obtain the same estimate of dose from a given data set, b) accuracy – the "best" estimate of dose should be obtained from the available data, and c) proportionality – the effort applied to the evaluation should be proportionate to the dose – the lower the dose, the simpler the process should be.
- ISO Standards in internal dosimetry, generated by ISO TC85/SC2/WG13

EURADOS has been involved in the organization of intercomparison exercises on dose assessments at an international level for many years and will take the initiative in organizing the next exercise after the publication of the new ICRP/OIR Reports. A plan of intercomparisons and training actions will be established for the next decades to help the internal dosimetry community to deal with intakes of radionuclides.

5.5 Intercomparisons of computational methods in dosimetry

Computational methods form a part of the work programme of all EURADOS Working Groups and a high fraction of papers published in radiation protection and dosimetry. These methods have moved from the domain of experts to become routine tools, which are commonly given to the most junior scientists in research teams, partly because of their IT skills. Those scientists may have the poorest understanding of the physics issues which are, however, crucial to the correct application of the code. Many of the codes that are now available can be obtained and installed with relative ease, and the manual may be used instead of any formal training, or the training may be provided informally in-house by those who are not expert and but who may already employ some practice.

Intercomparisons have been performed on modelling tasks ranging from simulations of accelerators to unfolding of neutron energy distributions, all of which have shown the potential for good agreement between solutions and also the potential for large systematic errors in results. Consequently, where misapplied, these methods can cause the cost and time savings available to be lost. Worse, they can lead to underestimates of risk or overprotection where, for example, vastly more expensive shielding is installed than is necessary.

Recent and ongoing intercomparisons have included:

- Design and calibration of a linac: a complex modelling problem involving the full design process and the characterization of the radiotherapy radiation field.
- Neutron energy distribution unfolding: computer models have been developed in which the neutron field is simulated. Bonner sphere detectors have been placed within these models to simulate the response and provide data for the unfolding process.
- Implementation of the ICRP reference phantoms: these are supplied in voxel form for the used to convert to the appropriate input for their computer code. This intercomparison will test both the ability of the user to construct the voxel phantom from the data provided, but also their ability to use the model to calculate the appropriate dose quantities.
- Micro and nano scale track structure: these studies are fundamental to the radiation damage to human tissue that leads to detriment. These calculations are at the cutting edge of Monte Carlo methods, since they are pushing at the boundaries of the data that are available and even the uncertainty principle.
- To summarize, computational methods are important for help with planning and design, interpretation of results/experiments and for more fundamental studies, there is scope for poor application. Questionnaires performed by EURADOS in the past showed the poor level of quality assurance performed by those using these methods, a situation that is likely to have got worse as their use has become more and more widespread.

Although computational methods are important for help with planning and design, interpretation of results/experiments and for more fundamental studies, there is scope for poor application. Questionnaires performed by EURADOS in the past showed the poor level of quality assurance performed by those using these methods. This situation is likely to become even more critical in the future because it is likely that these codes will become more and more widespread. EURADOS continues to perform modelling intercomparisons, commonly as collaborations between Working Groups. These efforts need to be intensified.

Appendix

A.1. History of EURADOS

During a meeting of scientists involved in contracts with the European Commission held in September 1981 at Homburg/Saar, Germany, EURADOS was conceived. It was decided that the activities of EURADOS would be focussed on the collection, processing and dissemination of information on research in dosimetry of all types of ionising radiation, and on the practical co-ordination of ongoing research projects and joint planning of future programmes.

The required financial support was received within the various Framework Programmes of the EC. Over the years this changed from general support for the network to dedicated support for projects. In this period EURADOS was fully dependent on EC funding.

EURADOS has mainly been operated by setting up Working Groups on particular topics. Such groups were installed for performing specific tasks and are usually dissolved after these tasks have been fulfilled. Examples were Working Groups on skin dosimetry, assessment of internal dose, criticality accident dosimetry, development of individual dosimeters for external penetrating radiation, basic physical data for gas ionising devices, and radiation exposure of air crews. Often a Working Group organised a workshop or seminar at the end of its work programme, presenting and discussing its results and/or published a detailed report.

EURADOS was registered in 2001 as a "society with restricted authority" at the chamber of commerce in the Netherlands. In particular the fact that the personal liability of the Council members was not restricted no longer allowed EURADOS to be a direct contractor in EC-funded projects. In addition, EURADOS was unable to organize self-supporting actions, such as intercomparison exercises, which may include a financial risk.

In 2007 the General Assembly initiated the change of EURADOS into a self-sustained network and a new legal entity. This was accomplished in 2008.

In the past, the European Commission has continuously shown interest in dosimetry issues. For example, end of 2006 the Commission issued a call for tender for the preparation of new European technical recommendations for monitoring individuals occupationally exposed to external radiation that would replace EUR 14852. In the resulting EU-Trimer project, EURADOS was instrumental in establishing a consortium and writing a document that was the result of a wide consensus of national radiation protection bodies, national metrology laboratories, authorities, standardization bodies (ISO, IEC), European IMS, etc. The final document was approved by the Group of Experts established under Article 31st of the EURATOM Treaty, and published by EC DGE as Radiation Protection n. 160 in November 2009.

A.2. Current Status of EURADOS

The European Radiation Dosimetry Group (EURADOS) comprises a network of more than 60 European institutions (Voting Members) and 300 scientists (Associate Members). The aim of the network is to promote research and development and European cooperation in the field of dosimetry of ionizing radiation. It includes experts, reference and research laboratories, and dosimetry services. This enables appropriate specialist groups to be formed in a timely manner to solve scientific problems or promote research identified within EURADOS or upon request from external bodies.

EURADOS e. V. was registered 2008 in the German Register of Societies as non-profit association, exempted from income tax. The rules of the association are governed by a constitution, complemented by "Rules of Procedure" to define further details. EURADOS Voting Members are institutions performing or promoting research in dosimetry. Each Voting Member nominates a permanent representative (delegate) who attends the General Assembly. The General Assembly is responsible for the governance of EURADOS and for the approval of objectives and strategy. The General Assembly elects the Chairperson and Vice-Chairperson of EURADOS. EURADOS is administered by this Council consisting of at least eight but no more than twelve associate members. The elected Chairperson and Vice-Chairperson are automatically members of the Council. Four Council members, so-called officers (Chairperson, Vice-Chairperson, treasurer, secretary) comprise the Executive Board which runs the daily work of EURADOS. The Council itself can install or close Working Groups, which in turn are comprised of individuals – so-called Associate Members – whose application must be approved by the Council. EURADOS may be supported by "Supporting Institutions" such as dosimetry services, manufacturers, and other institutions such as ICRU, ISO, IAEA etc. The main bodies of the association and their relationship are shown in Fig. A.1.

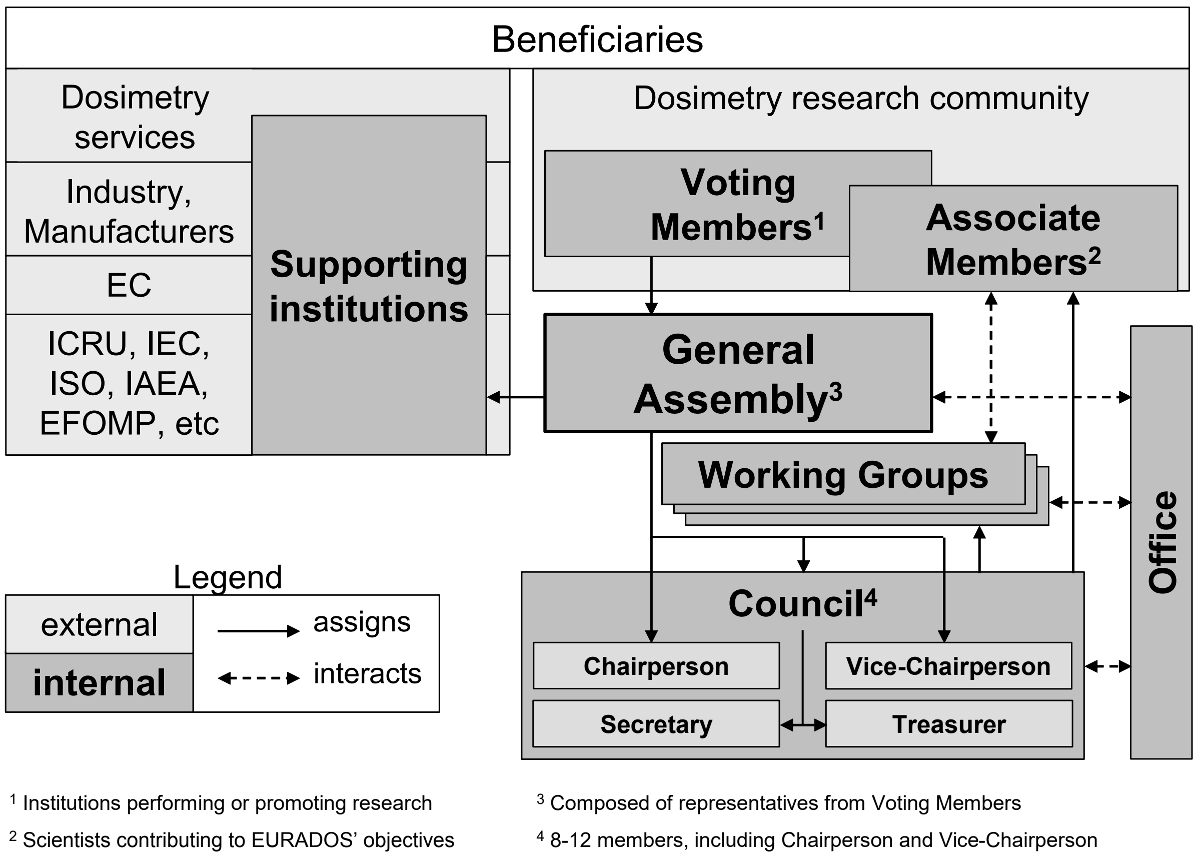

Fig. A.1: EURADOS as an organisation

The network's financial resources originate from sponsoring institutions, from voting members, from levies raised for activities organized by EURADOS (annual meetings, training courses and intercomparison exercises), and from projects funded by the European Commission. Due to this structure, EURADOS is a self-sustainable network.

Areas of activities – science

EURADOS activities encompass a) coordination of Working Groups that promote technical developments in radiation dosimetry and their implementation in routine work which contribute to compatibility and harmonisation within Europe and conformance with international practices, b) organization of scientific meetings and training activities and c) organization of dosimetry intercomparisons and bench mark studies.

The core of EURADOS activities is aimed at promoting scientific and technical research and development in the field of ionizing radiation. The work is performed in Working Groups (WG) which are composed of Associate Members. Scientific actions include individual monitoring for external exposure, individual monitoring for internal exposure, retrospective dosimetry, environmental radiation monitoring, diagnostic and interventional radiology, nuclear medicine, radiation therapy, and computational dosimetry. These scientific areas are reflected in the various Working Groups established by EURADOS. Currently (May 2014) EURADOS includes eight Working Groups that deal with certain aspects of research and harmonization in dosimetry:

- WG2: Harmonization of individual monitoring in Europe: Chair - João Alves, IST, PT
- WG3: Environmental dosimetry - Chair: Stefan Neumaier, PTB, DE
- WG6: Computational dosimetry - Chair: Rick Tanner, PHE, UK
- WG7: Internal Dosimetry - Chair: Maria Antonia Lopez, CIEMAT, ES
- WG9: Radiation protection dosimetry in medicine - Chair: Roger Harrison, Newcastle, UK
- WG10: Retrospective dosimetry - Chair: Clemens Woda, HMGU, Germany
- WG11: High energy radiation fields - Chair: Werner Rühm, HMGU, Germany
- WG12: European Medical ALARA Network - Chair: Zeljka Knezevic, Croatia

Members of Working Groups, Voting Members, and Council members meet regularly once a year during the Annual Meeting typically held end of January or early February. Annual Meetings are an opportunity for Working Group members to meet for 1 to 2 days and at the same time participate in Winter Schools and Workshops, and the representatives of voting members may take part in the General Assembly. A reasonable attendance fee is generally necessary to cover the organizing expenses and generate a small, positive balance.

Additionally, the Working Groups meet in summer or autumn for plenary Working Group meetings, complemented if necessary by meetings of task groups as defined within the Working Groups.

Areas of activities – training and education

EURADOS training actions include winter schools, workshops and training courses. In order to respond to the need for training in the field of radiation dosimetry, EURADOS Winter Schools were included in the Annual Meetings for the first time in 2007. Topics are selected based on suggestions from Voting Members or the Council. In addition various training courses have been organised. A list of past Winter Schools, Workshops, and training courses is given below.

The following Winter Schools were held during Annual Meetings:

- Relative Biological Effectiveness, Radiation Weighting Factor and Quality Factor: Their Role in Quantifying Effectiveness of Ionizing Radiation (AM2014)
- Status and Future Perspectives of Computational Micro- and Nanodosimetry (AM2013):
- Radiation Protection for Medical Staff (AM2011)
- Radiological Emergencies – Internal exposures (AM2010)
- Low-Dose Radiation Effects (AM2009)
- Retrospective Dosimetry (AM2008)
- Uncertainties in Radiation Dosimetry (AM2007)

The following Workshops were held during Annual Meetings:

- Dosimetry for second cancer risk estimation in radiotherapy (AM2012)
- Accelerator radiation protection and shielding (AM2010)
- Cosmic Radiation and Aircrew Exposure (AM2009)
- Dosimetric Issues in the Medical Use of Ionizing Radiation (AM2008)
- Characterization of Workplaces for the Assessment of the Doses to Individuals (AM2007)
- Uncertainties in Dosimetry – Principles Through to Practice (AM2006)
- Radiation Protection Dosimetry and Dosimetry for Medical Applications (AM2005)
- Biological and Physical Dosimetry for Radiation Protection (AM2004)

The following education and training actions were held as self-supporting actions:

- 2nd EURADOS Voxel Phantom School (HMGU, Neuherberg, 2014)
- 2nd EURADOS Training Course: European Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation (RBI, Zagreb, 2013).
- EURADOS WG7 - KIT Training Course on Monte Carlo Methods for calibration of body counters (KIT, Karlsruhe 2013)
- EURADOS Training Course: European Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation (CTU, Prague, 2012)
- EURADOS School on Retrospective Dosimetry – Practical exercise in Solid State & Cytogenetic dose reconstruction (HMGU, Neuherberg, 2012)
- EURADOS Voxel Phantom School (IRSN, Forntenay-aux-Roses, 2011)
- EURADOS/IAEA Regional Training Course on Advanced Methods for Internal Dose Assessment (CTU, Prague, 2009)

Areas of activities – intercomparisons

Intercomparisons and benchmark exercises are important tools for quality assurance. EURADOS carried out such activities on the areas of Individual Monitoring of External Radiation, Early Warning Radiation Monitoring Systems, Computational Codes in Radiation Dosimetry, Neutron Spectrometry, and Internal Dosimetry

The more recent actions (in brackets the Working Groups which carried them out) were:

- EURADOS Intercomparison 2014 for whole body photon dosimeters (IC2014) (WG2)
- EURADOS Intercomparison 2014 for passive environmental dosimeters (WG3)
- EURADOS Intercomparison 2012 for whole body neutron dosimeters (IC2012n) (WG2)

- EURADOS Intercomparison 2012 for whole body photon dosimeters (IC2012ph) (WG2)
- 6th EURADOS Intercomparison 2012 of Early Warning Dosimetry Network Systems (WG3)
- Measurements at high-energy neutron fields 2011 (WG11)
- EURADOS Intercomparison 2010 for whole body dosimeters (IC2010) (WG2)
- Intercomparison 2010 on Monte Carlo modelling of *in vivo* measurements of lung contamination with a Livermore phantom (WG6 and WG7)
- 5th EURADOS Intercomparison 2009 of Early Warning Network Systems (WG3)
- EURADOS Intercomparison 2009 for extremity dosimeters (IC2009) (WG2)
- EURADOS Intercomparison 2008 for whole body dosimeters (IC2008) (WG2).
- 3rd EURADOS Intercomparison 2006 to harmonise European early warning dosimetry systems (WG03):

Participation in such intercomparison exercises has always been successful and is even increasing; it now also includes IMSs from outside Europe, as data reported in the following table show:

IC exercise	Number of participants	Number of dosimetry systems	European countries	non European countries
IC2008	52	62	19	2(i)
IC2009	44	59	18	
IC2010	70	85*	27	3(ii)
IC2012ph	76	88	25	5(iii)
IC2012n	27	34	15	3(iv)
IC2014	97	112	27	8(v)

(*) IC2010, the participation of 9 systems was sponsored by the IAEA
(i) Turkey and Ukraine
(ii) Argentina, Turkey and Ukraine
(iii) Argentina, Israel, Turkey, Ukraine and USA
(iv) Israel, Japan and USA
(v) Argentina, India, Israel, Japan, Lebanon, Turkey, Ukraine, USA

Sources of income and self-sustainability

In all undertaken actions (intercomparison exercises, training courses, training schools, annual meetings) the revenue from the participants' fees is used to cover all expenses and preferably generate a positive balance.

In general, actions are carried out by an organizing group suggested by the Working Group and appointed by the Council following the analysis of a calendar and the approval of a preliminary budget. The budget includes manpower costs for the co-ordinator and collaborators respective institutes, consumables, travel and subsistence and other costs depending on the action, e.g. irradiation costs in the case of intercomparison exercises. Although travel and subsistence are covered at real costs, EURADOS counts on the collaboration of the home institutes particularly for manpower charges, that is, manpower is not charged at the real cost of dedicated amount of time and/or work. On the other hand, the institutes also recognise the importance of the activity and increased visibility for their institution within the dosimetric community by taking part in the action.

At present 32 institutions and companies annually support EURADOS with a sponsorship fee.

Other Conferences with support from the Eurados network

EURADOS actively initiates and supports the continuation of a series of conferences on Individual Monitoring (IM) and Neutron- and Ion Dosimetry (NEUDOS). Past examples were IM2005 (Vienna), IM2010 (Athens), NEUDOS9 (Delft, Netherlands, 2003), NEUDOS10 (Uppsala, Sweden, 2006), NEUDOS11 (Cape Town, South Africa, 2009) and NEUDOS12 (Aix-en-Provence, France, 2013). In these cases, the EURADOS council took the initiative by calling for proposals to host the respective conference. The selection of the organizer and venue was then done by the EURADOS Council and the members of the scientific committee of the previous conference.

In addition, EURADOS provides financial support for other conferences where dosimetry is an important topic. Examples are EPR-BioDose 2010 (Mandelieu-La-Napoule), France, and 2013 (Leiden, The Netherlands) and the 5th MELODI workshop (Brussels, Belgium, 2013).

Insights Imaging (2017) 8:183–197
DOI 10.1007/s13244-016-0538-x

STATEMENT

Common strategic research agenda for radiation protection in medicine

European Association of Nuclear Medicine (EANM)[1] · European Federation of Organizations for Medical Physics (EFOMP)[2] · European Federation of Radiographer Societies (EFRS)[3] · European Society of Radiology (ESR)[4] · European Society for Radiotherapy and Oncology (ESTRO)[5]

Received: 12 December 2016 / Accepted: 14 December 2016 / Published online: 15 February 2017

Abstract
Reflecting the change in funding strategies for European research projects, and the goal to jointly improve medical radiation protection through sustainable research efforts, five medical societies involved in the application of ionising radiation (European Association of Nuclear Medicine, EANM; European Federation of Organizations for Medical Physics. EFOMP; European Federation of Radiographer Societies, EFRS; European Society of Radiology, ESR; European Society for Radiotherapy and Oncology, ESTRO) have identified research areas of common interest and developed this first edition of the Common Strategic Research Agenda (SRA) for medical radiation protection.

The research topics considered necessary and most urgent for effective medical care and efficient in terms of radiation protection are summarised in five main themes:

1. Measurement and quantification in the field of medical applications of ionising radiation
2. Normal tissue reactions, radiation-induced morbidity and long-term health problems
3. Optimisation of radiation exposure and harmonisation of practices
4. Justification of the use of ionising radiation in medical practice
5. Infrastructures for quality assurance

The SRA is a living document; thus comments and suggestions by all stakeholders in medical radiation protection are welcome and will be dealt with by the European Alliance for Medical Radiation Protection Research (EURAMED) established by the above-mentioned societies.

Main messages
- *Overcome the fragmentation of medical radiation protection research in Europe*
- *Identify research areas of joint interest in the field of medical radiation protection*
- *Improve the use of ionising radiation in medicine*
- *Collect stakeholder feedback and seek consensus*
- *Emphasise importance of clinical translation and evaluation of research results*

Keywords Radiation protection · Research · Optimisation · Justification · Medicine · Dosimetry

Preamble

Reflecting the changing funding strategies of research projects within Europe and the goal of jointly improving medical care by sustainable research efforts, the following medical societies involved in the application of ionising radiation, namely,

✉ European Society of Radiology
E-mail: kathrin.tauer@european-radiology.org

European Association of Nuclear Medicine (EANM)

1 EANM, Schmalzhofgasse 26, 1060 Vienna, Austria

2 EFOMP, Fairmount House, 230 Tadcaster Road, York YO24 1ES, UK

3 European Federation of Radiographer Societies, Catharijnesingel 73, Utrecht 3511 GM, The Netherlands

4 ESR, Neutorgasse 9, 1010 Vienna, Austria

5 ESTRO, Rue Martin V 40, 200 Brussels, Belgium

European Association of Nuclear Medicine (EANM)
The EANM is the umbrella organisation representing nuclear medicine in Europe and represents 40 National Member Societies, approximately 3200 individual members and around 30,000 professionals working in Nuclear Medicine in Europe. EANM aims to advance science and education in nuclear medicine for the benefit of public health, relating to the diagnosis, treatment, research and prevention of diseases through the use of unsealed radioactive substances and the properties of stable nuclides in medicine, throughout Europe.
European Federation of Organisations for Medical Physics (EFOMP)
The EFOMP serves as an umbrella organisation representing 35 national member and affiliated organisations of more than 7000 physicists and engineers working in the field of medical physics in Europe. EFOMP aims to harmonise and advance medical physic in both its professional clinical and scientific expression throughout Europe by bringing about and maintaining systematic exchange of professional and scientific information, through the formulation of common policies, and by promoting education and training programmes.
European Federation of Radiographer Societies (EFRS)
The EFRS is the non-profit umbrella organisation representing 39 professional societies and 51 educational institutions representing over 100,000 radiographers across Europe. The aims of the EFRS are to represent, promote and develop the profession of radiography in Europe, across medical imaging, nuclear medicine and radiotherapy areas of radiography practice.
European Society of Radiology (ESR)
The ESR is a non-profit organisation representing the general interests of radiology in Europe. The aims of ESR are to serve the healthcare needs of the general public through the support of science, teaching and research and the quality of service in the field of radiology as well as the promotion and coordination of the scientific, philanthropic, intellectual and professional activities of radiology in all European countries. The ESR has over 69,300 individual members as well as 59 institutional member societies of which 44 are national radiology societies and 15 are European Radiological Subspecialty Societies and European Allied Sciences Societies.
European Society for Radiotherapy and Oncology (ESTRO)
The ESTRO is a non-profit scientific organisation representing radiation oncologists, medical physicists, radiobiologists and radiation therapists with over 5000 members both within and outside Europe. ESTRO aims to foster the role of radiation oncology in order to improve patient care in the multimodality treatment of cancer by promoting innovation, research and dissemination of science through its congresses, special meetings, educational courses and publications.

decided that it was necessary and would be helpful to develop a corresponding common Medical Strategic Research Agenda (Medical SRA) to overcome current and future deficits and to be a constructive partner in European radiation protection research. To this end, research areas of interest have been jointly identified and agreed upon in this common SRA endorsed by the medical societies.

The effort of the medical societies in developing an SRA for the medical application of ionising radiation complements the efforts of other European platforms such as MELODI, EURADOS, ALLIANCE and NERIS, which have developed or are developing their own SRAs in the fields of general low-dose research, dosimetry, radioecology and emergency preparedness, respectively.

In a memorandum of understanding (MoU) signed by the medical societies, MELODI and EURADOS in 2014, it was decided to cooperate in order to promote the integration and the efficiency of European radiation protection research, to maintain and use a common European infrastructure for this research as well as to bring forward scientific education and training in the field of radiation protection for medical applications of ionising radiations.

The mission is to achieve the following objectives:

- Ensure an adequate level of information exchange between the signatories in the fields of joint interest within the scope of the MoU;
- Identify gaps of joint interest in existing SRAs with respect to RTD needs for improving radiation protection in the medical field, or for improving the effectiveness/exposure ratio of medical protocols based on the use of ionising radiations, so as to optimise the SRA contents and avoid duplication of efforts;
- Identify research areas of joint interest where progress may benefit from contributions from signatory organisations, or the members thereof, e.g. some low-dose effects or dosimetry research projects may benefit from contributions in a clinical environment, conversely, some medical protocol research may benefit from advanced dosimetry or radiobiology developments;
- Develop joint documents to support the elaboration of research and technological development (RTD) calls in the framework of the Horizon 2020 programme, both in the EURATOM/Fission and in the Health programmes;
- Optimise and coordinate the dissemination of scientific knowledge resulting from research, particularly through education and training actions.

The stakeholders are involved through a formal consultation process that has been initiated, is ongoing and will be reflected in future updates of the SRA presented here.

Summary

Reflecting the change of funding strategies for research projects within Europe, and the goal of jointly improving medical care by sustainable research efforts, the medical societies involved in the application of ionising radiation have identified research areas of interest and agreed upon these in this common SRA endorsed by the medical societies.

The research that is seen to be necessary and most urgent for effective medical care, under the best harmonised practice, and efficient in terms of radiation protection can be summarised to the following five main topics:

1. Measurement and quantification in the field of medical applications of ionising radiation
2. Normal tissue reactions, radiation-induced morbidity and long-term health problems
3. Optimisation of radiation exposure and harmonisation of practices
4. Justification of the use of ionising radiation in medical practice
5. Infrastructures for quality assurance

The subtopics defined for each topic describe the specific research aspects that are identified as areas of great importance regarding research for establishing optimal radiation protection in the field of medical applications. These descriptions can be found in Chap. 3.

It is important to highlight that the approach to improve the use of ionising radiation in medicine by pure fundamental research would lack impact and influence unless having immediate consequences for and being translatable to everyday clinical practice. It is also important that the results of the research are not only translatable but really translated into daily routines. Therefore it is essential that the research is undertaken in a concise manner by persons educated and trained for good medical practice. The results have to be evaluated in clinical practice and have to be made public in a way that it is easy to access (results and implementation guidelines available on the internet) and to implement the methodologies developed. It is also essential that the same level of importance is placed on educating the staff working in the field to guarantee a direct clinical impact and to ensure high-level, standardised medical care and related radiation protection fully exploiting and profiting from all research conducted with regard to radiation protection in the medical field throughout Europe. This aspect of the SRA is reflected in Chap. 4.

Background

Over the last 5 to 10 years the structure of research funding by the European Commission (EC) has gradually changed. The intention is to bring together all interested parties to facilitate European research projects in the field of radiation protection research and "*to set up a European umbrella structure for the administration of radiation protection research calls*". To this end, SRAs have been developed or are currently under development.

Therefore, a medical SRA is especially important in view of the applications of ionising radiation in the medical field, since the medical use of ionising radiation is the largest man-made source of exposure to the human population. The advantages of such SRAs include:

- Providing guidance on/help to identify the most relevant and urgent research topics in the fields they cover
- Demonstrating the importance of research areas to the stakeholders
- Justifying research expenditure in defined areas
- Facilitating discussions with other members of the scientific community in the field of radiation protection
- Determining important topics and influencing research calls of the EC, OPERRA and CONCERT.

Since medical applications are among the most important contributors to exposure of the population in Europe to ionising radiation, for medical radiation protection research to be effective, it is critical that the results of the research projects are directly transferred into clinical practice, i.e. translational research.

This SRA has been the cornerstone for a common platform of the European medical societies dealing with topics related to the use of ionising radiation. In September 2016 the **European Alliance for Medical Radiation Protection Research** (**EURAMED**) was launched by EANM, EFOMP, EFRS, ESR and ESTRO and is currently run as a joint initiative under the umbrella of the European Institute for Biomedical Imaging Research (EIBIR). The medium-term goal is to establish EURAMED as a separate legal entity with a sustainable governacne and membership structure to allow other stakeholders to participate actively in the platform. Updates are available at www.euramed.eu.

Research topics

Measurement and quantification in the field of medical applications of ionising radiation

A key priority for radiation protection research in radiation oncology, nuclear medicine and also interventional and diagnostic applications of ionising radiation is to improve techniques and methods for measurement and quantification. The research approaches will need to be multidisciplinary and innovative. The key research questions in measurement and quantification research are:

Characterisation of exposure

The basic quantity for the characterisation of exposure is the absorbed dose, so whereever possible dose measurements or calculations/calibrations should be stated in terms of absorbed dose (1–3). One of the main challenges for future research is the pronounced anatomical heterogeneity of (absorbed) doses within and between critical organs in all areas of medical uses of radiation. This needs to be supplemented by optimisation of models and model parameters to translate absorbed doses into equivalent, organ, biologically effective doses or any other indirect dose entities. Accurate and precise measurements with known uncertainty (4,) are a prerequisite for the adequate implementation of dosimetric techniques into medical practice and medical routines, specifically for different types (qualities) of radiation and levels of spatial resolution. Therefore, the following issues need to be addressed in research:

- Calibration of dosimeters for medical applications is currently performed using secondary standards non-specific to the radiation fields used in medical application of ionising radiation leading to undefined measurement uncertainties. Therefore, exact measurements require calibration against radiation fields specific to medical applications.
- There is a limited availability of dosimeters for use inside the human body; this implies that currently simulations of radiation transport and deposition are necessary, e.g. using Monte-Carlo (MC) methods (6, 7), as is normalising them to measured quantities.
- Real-time measurement of doses is relevant to reduce doses to staff. Therefore, the development of specific dosimeters is required, allowing real-time monitoring, e.g. of eye structures and extremity/finger doses, from interventional radiology/cardiology and nuclear medicine. The existing dosimeters are either not for online measurements or they suffer from technological limitations in terms of highest dose rates as in pulsed radiation fields or size or practicability.
- Non-uniform spatial (3D) and temporarily varying (4D) dose distributions can lead to differences of up to several orders of magnitude in local dose distributions (8). Therefore, micro-dosimetric measurement devices and techniques for use within and between cells, the anatomical structures of organs and the human body are necessary, e.g. for dosimetric use with regard to individual structures in the eye, the brain and the heart, and also other organs depending on the basis of future research results.
- Different types of radiation (photons, electrons, protons, heavy ions, secondary neutrons) are used for and/or associated with medical purposes. Correct determination of doses to and dose-distributions within patients at different levels of spatial resolution is necessary depending on the required purpose in terms of radiobiological questions or optimisation of procedures. Also mixed fields and energy spectra need to be taken into account for reliable measurements and calculations of dose-distributions.
- Knowledge on track structure and/or microdosimetry of internal emitters (alpha, beta, Auger) is a prerequisite to predict the associated biological effects (9). Therefore, computational methods need to be further developed and connected to the results of corresponding research on measurements and calibration procedures (see above).
- Development of updated or alternative quantities and concepts for describing the anatomical dose distributions within organs, tissues and the body as the basis for predicting health effects rather than mean absorbed doses (e.g. dose averaged over an organ) or dose volume histograms.
- Methodologies have to be developed for determination, description measurement and calculation of doses outside the planning target volume (PTV) for radiation therapy, i.e. the peripheral dose. This is urgently required to build and optimise prediction models for secondary tumours, but also tissue effects, and to enable comparison of different techniques and/or technologies.

This research would be a prerequisite for the accurate and precise evaluation of the dose as the basis for better radiation protection of the patient and medical personnel as explained below.

Individual dosimetry

Individualised patient dose assessment methods, e.g. by adjusted phantoms for measurements (10), size-specific conversion factors, dose measurements taking into account imaging parameters shielding, etc., are needed to allow for accurate patient dose estimation (2) and risk assessment (11). Many dose distributions would depend on individual patient constitution (e.g. size, weight, shape, age and biological factors such as the distribution and kinetics of radioactive markers () or susceptibility to different therapeutic procedures). Therefore, the following dosimetric procedures need to be addressed in research:

- Development of computational methods for dose distribution calculations based on patient-specific and equipment-

specific characteristics for all medical procedures using ionising radiation, including for example CT, interventional and nuclear medicine procedures as well as radiotherapeutic procedures avoiding different dose indicators for different types of procedures in order to get comparable meaningful information about organ doses of individuals.
- Development of optimal measurement protocols in nuclear medicine for accurate estimation of absorbed doses using patient-specific and equipment-specific characteristics. Refinement, validation and implementation of new biokinetic models for dosimetry in molecular radiotherapy using for example physiologically based pharmacokinetic (PBPK) models for the individual assessment of biokinetics (13), including uncertainty budgets (14).
- Development of methods to estimate or measure the actual delivered radiation dose in radiotherapy.
- Development of a unique dose indicator that describes the absorbed dose to organs in order to perform risk assessment.

This research would be essential for accurate and precise determination and evaluation of indication-, therapy- and/or subgroup-specific doses and therefore risks of radiation-induced morbidities of individual patients and thus on a per-patient basis for better radiation protection of patients and medical personnel.

Quality metrics for diagnostic imaging and therapy

For the use of quantitative imaging approaches, standardised protocols for each clinical indication and/or specific disease common clinical indication need to be developed (15). Therefore, the following issues need to be addressed in research:

- Development of dosimetric and image quality metrics to fully assess the impact of novel detector technologies (e.g. low or lowest noise as well as energy-resolving detectors) and image reconstruction methods available for reducing radiation exposure to the patients. To this end, research is needed on which requirements (system stability, noise reduction, influence of individual patient characteristics, iterative reconstruction parameters) have to be met for quantitative imaging to yield reliable and reproducible results.
- Measuring methods (e.g. phantoms, reading protocols, etc.) need to be improved or developed and standardised to address the improvements in medical technology as well as new methods, e.g. particle therapy or new molecular imaging technologies.
- There is an increasing need also for quality metrics of treatment plans to allow easier quality assurance to facilitate comparability of methods used in radiation therapy and to allow more standardised research regarding clinical treatment outcomes.
- The concepts and the use of diagnostic reference levels (DRLs) and achievable dose levels (ADLs) have to be redefined to meet the requirements of organ-specific dose distributions or critical organ structures doses.

This research enables the translation of quantitative techniques to widespread clinical use for the benefit of the patient. In addition, this research is also a prerequisite for the harmonisation of practices and quality assurance.

Sources and influences of uncertainty

Uncertainties need to be determined for all techniques described above, be it measurements or computations. Many components independently contribute to the uncertainty in the determination, reporting and performance of medical applications and in its characterisation (4, 16). It is of utmost importance to develop methods to assess the contributions of different stages in the chain of medical interventions to be able to define the relevant points of optimisation, which means putting effort into those parts of a medical application scheme where there is the highest benefit. Therefore, the following issues need to be addressed in research:

- Quantification of the influence and sensitivity of different parameters (technique dependent, system dependent, patient dependent, medical staff dependent).
- Development of methodologies for classifying different influencing parameters and to build a system that allows the optimisation of medical applications of ionising radiation for individual patients or methods.

Knowledge of the integral uncertainty and its components is key to identifying the most relevant steps, to allow for prioritisation and targeted optimisation, thus making more effective use of clinical and research resources.

Normal tissue reactions, radiation-induced morbidity and long-term health problems

A key priority for radiation protection research in radiation oncology, nuclear medicine and also interventional and diagnostic applications of ionising radiation is to improve health risk estimates. The corresponding research approaches will need to be multidisciplinary and innovative. The key research questions in tissue reactions and biological risk research are:

Exposure-associated cancer risk: dose, dose distribution and dose-rate dependence

Knowledge of the dose dependence of the radiation induction of primary or secondary cancers, in particular in relation to dose inhomogeneities and dose rate, is of major importance to optimise therapeutic efficiency and reduce unwanted side effects. In radiation oncology, this refers to high doses within the planning target volume (PTV) as well as to out-of-PTV doses, e.g. low to moderate doses, in particular in intensity-modulated and image-guided radiotherapy, but also in brachytherapy and molecular (radionuclide) radiotherapy (17). It also needs to include other, additional treatment modalities, particularly chemo- and biologically targeted therapy. Diagnostic procedures must also be considered, especially in view of interventional or fluoroscopic procedures or nuclear medical imaging techniques and those applied in preparation for treatment.

Non-cancer effects in various tissues and radiobiology-based effect models for individual morbidity endpoints

Radiation-induced morbidity (cancer and non-cancer diseases and disorders) may be observed early or late (occurring after 3 months to 5 years after radiation exposure), not only in the tissues and organs exposed to high doses. Also, very late health effects (occurring after more than 5 years to many decades after exposure) may not only be observed in high-dose radiotherapy (>5 up to 50 Gy) but also in the intermediate (0.5 to 5 Gy) or low-dose (<0.5 Gy) ranges. Examples of these very late occurring normal tissue morbidities, which may be induced by localised radiation exposure outside the planning target volume of radiotherapy or by repeated interventional procedures, are: cardiovascular or cerebrovascular diseases, functional or structural damage to eye structures, various delayed, persistent immunological changes, progressive microvascular injuries, but also late and very late developmental and functional detriments after radiation exposures in diagnostic procedures and paediatric radiotherapy and many more radiation-associated health disorders. The contribution of other treatment modalities, particularly chemo- and biologically targeted therapy, to the development of very late side effects is currently poorly understood and needs also to be considered along with any diagnostic procedures, especially for interventional or fluoroscopic and nuclear medicine procedures and those applied in preparation for treatment.

Current morbidity risk models and normal tissue complication probability (NTCP) models are largely empirical or based on hypothetical data-fitting models of assumed processes of damage development and lack the evidence of a mechanistic basis. Moreover, they do not consider the influence of the position of the doses within one organ or the interaction of dose distributions in "corresponding" organs, such as lung and heart, or the effect of additional treatments, such as chemotherapy (18, 19). These factors, however, must be included to get appropriate estimates for the patterns of risk of any individual patient with regard to modern techniques in radiotherapy, nuclear medicine and radiological diagnosis.

Individual patient-related radiation sensitivity and early biomarkers of response and morbidity

The individual sensitivity of patients may be considered in the choice of specific diagnostic procedures and/or therapeutic strategies. This can be based on intrinsic factors (age, gender, genomics, proteomics) of their tumours or different normal tissues, but also on concomitant diseases impacting on general or specific normal tissue tolerance, lifestyle (e.g. reduced lung/liver tolerance due to smoking and alcohol consumption) or previous/parallel treatments.

In a number of tumours, biological factors affecting radiosensitivity, i.e. predictive factors, such as local hypoxia, tumour heterogeneity, or viral infections, were identified. Such investigations need to be extended and may also consider the early response of the tumour to a specific treatment. Imaging biomarkers of tumour radiosensitivity are needed in this context, as well as biomarkers of morbidity, which can be identified before or early in the treatment phase and may help in the selection of the adequate treatment of the individual patient. These have so far been rarely studied. However, patients with a high risk for a certain, severe, morbidity symptom may require a change in dose distribution or in treatment strategy, or follow-up protocols may need to be adjusted to the individual morbidity risk pattern based on early biomarker expression ().

Radiobiological mechanism of radiation-induced side effects and protective strategies

The radiobiological molecular mechanisms of radiation-induced morbidities in normal tissues and organs are very complex and vary between different signs and symptoms of morbidity in the same organ and between different organs. Also the tumour responses to therapeutic exposure to ionising radiation, including radiotherapy using hadrons, are currently largely unknown. The radiobiological molecular mechanisms are even more complex for combined radiotherapy and chemo- or biologically targeted treatment strategies. These mechanisms need to be clarified for specific clinical morbidity endpoints in order to develop specific strategies for protection, mitigation or management of the clinical consequences of exposure. They are even more important for medical radiation procedures in paediatric patients given the evidence showing that the complexity and severity of morbidities and developmental injury and the risks of therapy-induced malignant diseases are particularly high after radiotherapy (in almost all instances in combination with chemotherapy).

Similarly, novel strategies for improving the diagnostic and/or therapeutic efficacy for the application of ionising radiation may be based on the synergistic combination with upcoming technologies such as combinations with high-intensity focussed ultrasound and biology-based approaches relying on tumour genomics, proteomics or metabolomics including local enhancement of drug delivery.

Both the protective and sensitising strategies need to be established and validated in preclinical as well as in subsequent clinical studies. These investigations need to focus on the efficacy of the novel approaches and also on their selectivity for the respective target tissue to guarantee a therapeutic gain.

Optimisation of radiation exposure and harmonisation of practices

According to the European Basic Safety Standard (BSS) (2013/59/EURATOM) (21), the radiation protection of individuals subject to public or occupational exposure must be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable (ALARA) taking into account the current state of technical knowledge, economic and societal factors. The optimisation of the protection of individuals subject to medical exposure should be consistent with the medical purpose of the exposure.

The EU Directive on patients' rights in cross-border healthcare (2011/24/EU) (22) calls for a concerted strategy in terms of harmonisation of clinical practices, meeting patients' expectations of the highest quality healthcare, including when they seek treatment away from home.

According to the literature, high variability of mean effective doses or organ doses of patients across Europe persists across all medical ionising radiation procedures and is seen across single countries, hospitals or even at the departmental level (23), despite technological developments facilitating reductions in patient dose, thus highlighting the importance of harmonisation of ionising radiation procedures and the development of new and more efficient optimisation methods including evaluation criteria. For this optimisation, there needs to be a general definition as to what is an acceptable level of quality, what kind of optimisation should be performed and what is the optimal level. With the main goal of maximising the clinical outputs of the procedures while minimising the exposure of patients and staff, the key research questions are:

Patient-tailored diagnosis and treatment

The comprehensive tailoring of imaging and therapeutic procedures in terms of the clinical question, anthropometric and physiological parameters of each patient, especially children, and lesion-specific characteristics is a key challenge that is largely yet to be fully addressed. Furthermore, imaging is essential to patient-tailored therapy planning, therapy monitoring and follow-up of disease, as well as targeting non-invasive or minimally invasive treatments, especially with the rise of theranostics (combination of diagnostic and therapeutic procedures to optimise treatment).

For the reasons given above, and in view of reducing radiation exposure to the patients by individually tailoring their diagnosis and treatment, research needs to be conducted with regard to the following currently unresolved issues:

- Development of quantitative imaging biomarkers for each common clinical indication and/or specific disease/organ and their standardisation with regard to required image quality in conjunction with related radiation exposure.
- Recent advances in imaging using specific radiotracers will provide additional tools for better characterisation of a lesion at the molecular level. This will provide an insight into lesion heterogeneity and targeting, with perspectives in guiding biopsy of lesions, prediction of treatment response and image-guided therapy.
- For optimal treatment prescription in targeted radiotherapy the knowledge of the dose-response relationship is essential. In targeted radiotherapy, patient-specific dosimetry is essential for both the prediction of the adverse events of a treatment and of the tumour response (24).
- Research on the requirements that have to be met for quantitative imaging to yield reliable and reproducible results, e.g. in view of system stability, image reconstruction techniques, influence of individual patient characteristics and applied radiation exposure.
- Development of approaches for low-dose time-resolved volumetric imaging (4D), e.g. of blood flow or volume distribution (perfusion) as well as organ-motion dependent imaging, especially in view of therapy planning and treatment response imaging.
- Development of body-mass index (BMI)-specific image acquisition protocols and specific dose-reduction algorithms for obese patients, since obese patients require higher than average radiation doses, and exploitation of techniques normally used for radiation exposure reduction to achieve diagnostic image quality.
- Development of approaches for low-dose treatment response and follow-up imaging solely focussing on the detection of "change" (relative to a standardised baseline acquired at higher radiation exposure) providing reliable diagnostic assessment, e.g. through development of standardised disease- or treatment-specific imaging protocols especially for those patients frequently imaged.
- Research for identifying underlying relationships among demographic, disease-related and 'omics' biodata and image and treatment data for fully developing personalised medicine in order to offer the best medical diagnostics and

treatment associated with the lowest possible dose to each individual patient.

The benefit of this research could be to develop systems for diagnosis and treatment allowing for more efficient treatment techniques, which may also offer economic benefits. This research could also provide further insights into disease processes of individual patients and therefore foster precision medicine.

Full exploitation and improvement of technology and techniques

Despite the potential for the exponential growth in the technological features of medical imaging equipment to decrease patient doses, such benefits are not always realised in daily clinical practice (25).

Therefore research on development, improvement, clinical applicability and full clinical exploitation of (new) technology and techniques for offering diagnosis and treatment delivery associated with the lowest technically possible radiation exposure to the patients is required. In this context, currently the following topics need to be addressed by research:

- Low-dose CT imaging enabled by low tube potentials and current-time products in view of its clinical applicability, indication, standardisation as well as its potential diagnostic and technical limitations.
- Novel image reconstruction techniques enabling low- or lowest-dose image acquisitions, with regard to their routine clinical applicability and their limitations in view of ensuring diagnostic accuracy and reliability.
- Novel detector technology in medical imaging in view of its clinical applicability and potentially associated technical limitations.
- Diffraction enhanced imaging and other newly developed approaches.
- Further development, implementation and application of patient- and disease-adapted techniques and protocols of combined modalities as for example SPECT/CT (26), PET/CT, PET/MRI and LINAC-MRI.
- Optimisation of image guidance procedures in radiotherapy.
- Strategies for a reduction in peripheral doses in radiotherapy, e.g. by defining indications for ion therapy.
- Research for, and production of, novel radionuclides and radiopharmaceuticals for either improving diagnostic and therapeutic outcome or reducing associated exposure.
- Data-crawling and -mining approaches based on large-scale data contained in imaging and treatment biobanks, e.g. for extracting indication-specific acquisition or treatment protocol parameters along with associated patient exposure data for the purposes of diagnosis and treatment optimisation, standardisation and harmonisation (through the definition of European DRLs) as well as for extraction of higher-order patterns of disease, its diagnostics and treatment along with associated doses, and the possible interrelation of this data, e.g. to genomic data (radiogenomics).

While research with regard to technology development may remain basic research that is institution- or manufacturer-driven and controlled, though requiring and relying on input and feedback from medical research and routine clinical applications, research on clinical applicability, improvement and full exploitation of technology and techniques enabling radiation exposure reduction is driven by, and requires, active medical research in the fields of radiological diagnosis and radiopharmaceutical and therapeutic treatment. There needs to be an emphasis on the close link between technology developments at research institutions, especially at manufacturers' sides, and the clinical research facilities with feedback options and especially to define a process to consolidate the achievements in terms of harmonisation.

Any optimisation in medical imaging techniques, including dose reduction strategies, must be evaluated thoroughly in terms of the resulting image quality. In determining whether an image is diagnostic or fit for purpose, it is important to take into account not only the physical measurements of image quality [e.g. signal-to-noise ratio (SNR), modulation transfer function (MTF) and detector quantum efficiency (DQE)] but also to include psychophysical methods (e.g. contrast detail assessment and spatial resolution assessment) and clinical, diagnostic performance approaches such as visual grading analysis (VGA), receiver-operating characteristic (ROC) and psychometric scales. The current variability and absence of validated approaches and guidelines represent a significant barrier to effective optimisation research. The 1996 European Guidelines on Quality Criteria for Diagnostic Radiographic Images (27) aimed to provide some assistance with image quality assessment but these were very limited, have deficiencies, were never validated and are now dated. There is thus an urgent need for establishment of robust, validated approaches to facilitate this critical aspect of optimisation research.

Technologically meaningful developments, with respect to the possible output for patient, staff and public, are at varying levels of maturity in terms of a technologies status as a product line and their applications in the medical environment.

In this context, multi-professional engagement together with educational institutions and equipment manufacturers will facilitate the required development of strategies for the harmonisation of ionising radiation procedures and standards of practice, since several studies have highlighted the heterogeneous use of technology and the unanticipated patient and staff dose increases. This is of particular importance in paediatric populations as well as for patient cohorts requiring multiple consecutive diagnostic, radiopharmaceutical or therapeutic procedures.

Clinical and dose structured reporting

Clinical reporting: Medical imaging procedure workflow involves several steps, ending with a clinical report. Currently, medical imaging reports are often presented with little or no structure to the text. This can present difficulties in understanding the content of the report for both referring physicians and patients. The development of a structured reporting system will improve the clinical outcome of a medical imaging procedure, by focussing on the essential message, in a harmonised way, thus facilitating the communication process along the clinical pathway of the patient.

There are many advantages of such reports, including improved follow-up for returning or chronic patients, easy retrieval of pertinent information enabling clinical and translational research, integration of the information in imaging biobanks and automated translation.

Another related issue is the lack of a centralised medical databank on imaging procedures for each individual patient on a national and European level, often leading to unnecessary repeated diagnostic procedures and hence unnecessary radiation exposure. Harmonisation of clinical reports could facilitate the development of such a centralised medical registry at a European level. Also, a centralised dose data collection algorithm for therapeutic procedures would allow for improved analyses of dose-effect relationships for adverse events, including stochastic radiation sequelae.

Dose reporting: Structured dose reporting in radiation diagnostics and therapy (or documentation of administered activities in nuclear medicine) is a growing area of focus and will benefit all professions directly involved in the ionising radiation procedures and patients undergoing such procedures in the years to come. However, the adequate specification of dose distributions has not been addressed yet in research and clinical practice sufficiently (1). In radiation oncology structured dose reporting needs to address absorbed doses in organs at risk and/or at their subvolumes, relevant for adverse event endpoints. The latter needs to be specified and their scaling to be defined. Moreover, anatomy-related dose distributions in the irradiated volume and in the periphery, at least down to the 1% isodose, need to be reported or re-constructible from the documented treatment information and then specifically related to potential radiation sequelae.

The main benefits would be:

- To establish a model for providing information, in radiation diagnostics and nuclear medicine, about patient dose exposure in an easily accessible way (e.g. by integrating visual scales for the referring physicians to understand the level of exposure).
- To facilitate the rapid determination of local, national and European DRLs.
- To facilitate establishment, in radiation oncology, of dose response relationships for adverse events in organs at risk as well as for stochastic radiation effects both close to the PTV and in the periphery of the patient.

Structured dose reporting in radiation diagnostics (or documentation of administered activities in nuclear medicine) is an essential tool for the harmonisation of the dose management systems and the comparison of doses, creating a comprehensive, common language for health professionals. Structured dose reporting in radiotherapy is essential to establish firm dose-effect relationships for adverse deterministic and stochastic events.

Protection of staff, patients, carers and the general public

Aside from the optimisation of protocols and procedures, their standardisation and their personalisation, it is most important to optimise radiation protection using existing radiation protection measures (28). To optimise radiation protection in terms of applicability and best benefit for staff and patients, the establishment of key indicators of safety and quality in radiation protection is essential according to the general ALARA principle discussed before. The primary goal of the development of safety programmes is to reduce morbidity risks from excessive exposure to ionising radiation for specific procedures and populations, e.g. interventional radiology and the paediatric population. Another focus is on cost-benefit analysis of the implementation of radiation protection devices and safety programmes. Neither proven criteria of cost nor proven criteria of benefit have been established so far. Research must explore both external and internal radiation exposure and their associated protection measures.

Justification of the use of ionising radiation in medical practice

The principle of justification is one of the key pillars of radiation protection underlined in the recently revised European BSS Directive (21). This principle focusses on weighing the benefits versus the risks. Further important elements are patient communication, as the basis for shared decision-making including the patient rights for influencing the decision, as well as the appropriateness of the radiological procedure with respect to the clinical setting. The key research questions in research into the justification of the use of ionising radiation in medical practice are:

Benefit/risk assessment and communication

While the clinical benefit of a diagnostic or interventional imaging procedure is assumed to be established, an estimation of the risk related to effective dose exposure for a given patient is a difficult step because the current estimations are for a general population. The current uncertainties in this area make the establishment of a reliable benefit/risk assessment virtually impossible.

Therefore there is the urgent need for research aimed at risk estimation for an individual patient. However, it is unclear how this can be implemented for the stochastic mechanisms based on epidemiologic data. Increased risk factors for organ-specific patient groups or patient-parameter-based changes on optimal imaging procedure setups may however be investigated. For the development of such a research programme for diagnostic imaging and interventional procedures, reference to a centralised repository of imaging data would be an important resource for data mining and the following risk assessment (see Sects. 3.5.1 and 3.5.2).

The proposed research will have a direct benefit for the patient in general and especially in the context of screening methods based on the use of ionising radiation.

Most new therapeutic radiation technologies are clinically introduced to reduce exposure to healthy tissue. In the near future, an increasing number of cancer patients will be treated with particles (e.g. protons and carbon ions). Although particle therapy will result in lower dose levels to many critical structures as compared to the currently used photon-based technologies, the consequences in terms of reduction of late and very late side effects remain to be determined and have to be weighed against the higher costs.

In the context of the current drive for patient empowerment and involvement in the decision-making process, the development and subsequent evaluation of novel tools for patient communication have become necessary. Some professional organisations such as the ACR, ESR, RSNA and national clinical societies have developed communication guidelines and platforms for diagnostic imaging; however, a unified approach regarding methodology and content is currently missing.

The proposed research work will aim to develop a European evidence-based electronic communication platform focussing on all types of diagnostic imaging using current information technology that is endorsed by the relevant professional organisations, patient organisations and other relevant stakeholders. The European platform will be designed in a way to allow for localisation and adaptation to the national/regional settings. The establishment of such a system has to be based on the successful completion of the cost-benefit research activities outlined above.

Improvement of use of evidence-based guidelines

Clinical imaging guidelines are intended to help physicians decide when an imaging study would be useful and identify the most appropriate examination for a particular patient. In recent years, imaging guidelines, in view of the referral process, have received much attention from the radiation protection community and international organisations given the increasing number of medical imaging procedures and studies that have shown that about 30% of the imaging procedures performed in Europe were found to be inappropriate (29). The recently revised European BSS Directive (27) requires that clinical imaging guidelines are available in all EU Member States.

In 2011, the European Commission awarded a European tender project to assess the availability and implementation of clinical imaging guidelines in EU member states. One of the key conclusions, also highlighted in subsequent studies, was the recommendation that the awareness and use of clinical imaging guidelines in Europe need to be improved and novel approaches are needed for that purpose (30).

The proposed research work should identify and develop methods to improve the use of clinical imaging guidelines in Europe especially in view of the referral process at large, e.g. through incentives, regulatory requirements, IT tools, etc. The research work is related to a key priority in medical radiation protection as outlined among others in the Bonn Call for Action (31) and must be relevant for all diagnostic applications of ionising radiation. To define the proposed methods, an evaluation and impact assessment of the use of currently existing European and national guidelines must be performed with an emphasis on evaluating the usability of the guidelines and their impact on daily clinical practice (29, 32).

The outcome of the proposed research work should be a European recommendation paper on how to improve the dissemination, integration into the clinical workflow and use at large of clinical imaging guidelines in view of the referral process. In addition methodologies and guidelines for adoption/localisation/adaptation of the guidelines need to be proposed.

The recommendation paper shall serve as guidance for professional societies and policy-makers in Europe.

Infrastructure for quality assurance

To perform investigations on tissue reactions, optimisation procedures as well as risk and benefit evaluations, it is important to rely on optimal, quality assured data, which are gathered under defined conditions and which are necessary for various reasons including legal questions pertaining or specific to the research to be performed. In addition, the clinical system of medical applications of ionising radiation has to be standardised (33) and evaluated concerning its effectiveness in radiation protection.

Data coding, collection and management

It is crucial for the future of medical imaging in Europe to develop a European medical imaging coding system (EMICS) including radiology and nuclear medicine imaging procedures. EMICS should apply to all medical procedures based on ionising radiation, giving policy makers and healthcare providers an objective and clear view, on a procedure-level basis, at the national and EU levels. This would be a fundamental tool for future studies such as population dose studies and/or parameter-dependent image quality studies. According to the recently published Dose DataMed 2 report "*in order to compare x-ray examination frequency data between countries*, *and to assign typical effective dose values to examinations*, *it is crucial that an* '*X-ray examination*' *is defined and counted in a consistent way*" (34). Therefore, the development of EMICS, based on an alphanumerical code structure, must be facilitated and must be integrated into all HIS/RIS systems.

EMICS would also support the harmonisation of the "language" for medical imaging and therapy across Europe giving healthcare providers a powerful tool for the future planning of health systems at local, regional, national and European levels. This should be extended to the acquisition of data on the long-term consequences of radiation exposure, diagnostic or therapeutic, potentially in combination with other therapeutic procedures, to allow structured long-term follow-up, assessment and documentation of treatment-related morbidity and the possibility to relate morbidity to anatomical dose distribution. Requirements and structures, along with administrative characteristics, including data protection issues, need to be defined. Such data management structures will provide a basis for epidemiological investigations into relevant medical questions. Data should be collected throughout Europe according to this standard using defined mandatory and where possible additional data regarding exposure and if possible image quality as well as certain patient-specific data.

Comprehensive medical database/imaging biobank

Biobanks are repositories for the storage and retrieval of biological samples of a large number of subjects. A major goal of biobanks is the organised collection of biological material and associated information to spread access among scientists requiring this information. Extending this concept to medical imaging and especially to radiation protection is needed to collect radiation protection metrics and to allow for long-term follow-up for specific cohorts, which will be called a comprehensive medical database or imaging biobank. It might be important for various reasons:

Importance for dose collection: The concepts and the use of DRLs and achievable dose levels (ADLs) have to be redefined to meet the requirements of organ-specific dose distributions or critical organ structure doses as mentioned in Sect. 3.1. Large-scale (national, regional) patient inter- and intra-organ dose distribution monitoring is necessary for the purpose of definition, optimisation and periodic assessment of DRLs and ADLs. This aim can be achieved by developing large-scale archives and automatic data analysis using the recently developed standards allowing sending and archiving of dose information.

The development of automatic methods for phantom image quality assessment (and patient image quality assessment) together with the use of advanced IT technologies (e.g. large-scale archives, data-mining methods, expert system technique) is required for supporting users in the optimisation process.

Importance for long-term follow-up of cohorts: There is clear evidence that radiotherapy may cause, in organs and tissues close to the PTV but also in organs in the periphery, an increased risk for late and very late side effects that are clinically relevant and have a major impact on quality of life. Although there is an increasing awareness of radiation-induced very late side effects, the infrastructure to systematically collect relevant data to get more insight in the factors that contribute to these risks is largely lacking.

The proposed research work should involve the development of a structure for a European imaging biobank infrastructure integrated with a European radiation oncology biobank infrastructure.

Developing key performance indicators for quality and safety

Key performance indicators (KPIs) have been successfully introduced as a performance measurement in many areas of healthcare in line with the EU Agenda on Quality of Health Care and Patient Safety put forward by the EC DG SANTE. Currently there is no recognised gold standard in the fields of medical imaging or radiation therapy. A general concept of performance indicators for imaging and radiation therapy is thus needed and should also include indicators for the safety of patients and of procedures and how to maintain safety standards, according to the optimisation and justification processes.

The proposed research work will consist in the establishment of KPIs for the quality achieved regarding specific medical procedures and in general terms of radiation protection and harmonisation at the European level. For integration into the workflow, pilot studies in dedicated centres and impact assessment before dissemination are envisaged.

Audit systems

Clinical audit is a tool designed to improve the quality of patient care, experience and outcome through formal review of systems, pathways and outcome of care against defined standards, and the implementation of change based on the results. Audit cannot be carried out without a preset standard against which performance can be assessed.

As laid down in the revised European BSS Directive (21), Member States shall ensure that clinical audits are carried out in accordance with national procedures. Clinical audit is a relatively new concept in radiation protection. It seeks to improve the quality and outcome of patient care through structured review of medical radiological practices, procedures and results, whereby these are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary.

In October 2009, the EC published guidelines relating to clinical audits for radiological practice, including all investigations and therapies involving ionising radiation (35). In spite of this document, clinical audit is still clearly underdeveloped in Europe. To address this shortcoming, the proposed research must aim to develop an easy-to-use, cost- and time-effective European clinical audit tool taking into account existing initiatives from professional organisations. The tool will facilitate implementation of the relevant requirements in the European BSS Directive and could potentially provide the basis for future European accreditation processes based on quality and safety.

Education and training metrics

There is a strong demand for new education and training models in medical radiation protection because of the rapid development of medical techniques based on ionising radiation, growth of hospitals and the continuous need to produce competent health professionals. The major challenge is addressing the variety of professions and professionals, with different knowledge background and different needs, but all working towards the same objective: patient and staff safety (36, 37).

To achieve that objective it is necessary to establish a harmonised and sustainable safety culture in radiation protection amongst health professionals through specifically oriented education and training courses. External assessment of the quality of education or training provision is needed (37) and should be provided by a European accreditation body.

It is important to develop through research:

- A metric system to measure the knowledge, skills and competence outcomes from education and training in radiation protection for the different health professions involved in ionising radiation procedures.
- An assessment system to measure:

– the impact of the implementation of a continuous professional development model for education and training in radiation protection;
– the type of needs for education and training, considering the installation of new equipment and/or new procedures.

There is a need to create a European certification system for education and training in radiation protection, based on the development of standards of proficiency for health professionals, as an instrument to guarantee safety procedures to European citizens, through harmonisation of practice through education and training.

Education and training

As highlighted in the recent EC Radiation Protection No. 175 '*Guidelines on radiation protection education and training of medical professionals in the European Union*' there is a continuing and growing need for high-quality education and training in the field to ensure the radiation protection of patients, staff and the public. This education and training must be accessible and delivered at an appropriate level for all professionals working in the field of medical ionising radiation as well as those utilising the services provided by medical ionising radiation professionals. EC Radiation Protection No. 175 came about as an outcome of the MEDRAPET project and describes education and training in radiation protection using the European qualifications framework (EQF), knowledge, skills and competence (KSC) structure and European credit transfer system (ECTS) (38).

It is essential that any research in the area of medical ionising radiation is translated into clinical practice to ensure that patients and staff see the direct benefits of this research. As highlighted in Sects. 3.3 and 3.4 of this SRA, there is evidence that this translational research often fails because of the absence of parallel education and training programmes. High-quality education and training programmes will raise awareness of ongoing EU research projects and initiatives and ensure their uptake into clinical practice at local, national and European levels. Separately, there has been an identified need to also develop high-quality education and training specifically for researchers to help strengthen the medical ionising radiation research community.

Education and training may consist of traditional, face-to-face lectures and practical sessions but should also focus on becoming more clinically focussed and case based. Online, or e-learning, approaches to the delivery of content at all levels utilising mobile devices is a key consideration, which includes the development of dedicated appropriate e-learning tools, e.g. facilitated by a multidisciplinary European e-learning platform.

Education of staff

In the former chapters necessary and relevant topics for research related to the optimal use of ionising radiation and radiation protection in medical applications have been explained. Also, measures have been mentioned concerning how these optimisation have to be implemented throughout European by means of standardisation and harmonisation. However, it is obviously not sufficient just to define methods for harmonisation but this has to be reflected within the education of the staff (28, 39).

This education needs to reflect the basic aspects of:

- radiation physics,
- radiation biology,
- radiation protection,
- radiation communication and
- specific parts for the procedures/areas that are supposed to be covered by the staff.

Therefore, within this SRA it is proposed to develop a standardised education rule describing topics that have to be covered. In addition there is a need for securing the highest level of knowledge transported reflecting state-of-the art technology as well as standardisation and harmonisation efforts. Finally, establishment of a European certification approved by the medical societies issuing this SRA should also be covered, not only after the completion of initial training, but also throughout the whole professional life of each professional.

Education of researchers

To provide valuable research dealing with these identified relevant topics with potential impact, it is important to perform well-founded and structured research along certain lines. To do so, it is also necessary to train researchers in performing research according to the best practice. This especially holds true for research working with humans or biological material, but also with any data related to humans. There has to be a standardised training structure also reflecting the actual state of the art for research procedures with the goal of fostering the efficiency of projects reflecting the research topics identified above especially in terms of optimal patient care and radiation protection.

In this respect it is important to deal with best practice regarding:

- literature and citation practices;
- statistical power of investigations;
- uncertainty budget calculation of measurements and calculations/simulations;
- clear hypothesis-driven project definition;
- pre-research feasibility estimates of proposed outcomes.

ACR, American College of Radiology; ADLs, Achievable Dose Levels; ALARA, As Low As Reasonably Achievable; ALLIANCE, European Radioecology Alliance; BMI, Body-Mass Index; BSS, Basic Safety Standard; CT, Computed Tomography; CONCERT, European Joint Programme for the Integration of Radiation Protection Research; DE, Dual-Energy; DRLs, Diagnostic Reference Levels; EANM, European Association of Nuclear Medicine; EC, European Commission; ECTS, European Credit Transfer System; EFOMP, European Federation of Organisations in Medical Physics; EFRS, European Federation of Radiographer Societies; EMICS, European Medical Imaging Coding System; EQF, European Qualifications Framework; ESR, European Society of Radiology; ESTRO, European Society for Radiotherapy and Oncology; EU, European Union; EURADOS, European Radiation Dosimetry Group; EURAMED, European Alliance for Medical Radiation Protection Research; HIS, Hospital Information System; IR, Interventional Radiology; IT, Information Technology; KPIs, Key Performance Indicators; KSC, Knowledge, Skills and Competence; LINAC, Linear Accelerator; MC, Monte Carlo; MEDRAPET; Medical Exposures Directive's Requirements on Radiation Protection Training of Medical Professionals in the EU; MELODI, Multidisciplinary European Low Dose Initiative; MRI, Magnetic Resonance Imaging; NERIS, European Platform on Preparedness for Nuclear and Radiological Emergency Response and Recovery; NTCP, Normal Tissue Complication Probability; OPERRA, Open Project for European Radiation Research Area; PBPK, Physiologically-based Pharmacokinetic; PET, Positron Emission Tomography; PTV, Planning Target Volume; RIS, Radiology Information System; RSNA, Radiological Society of North America; RTD, Research and Technological Development; SPECT, Single Photon Emission Computed Tomography; SRA, Strategic Research Agenda; TCP, Tumour Control Probability

Acknowledgements The Common Strategic Research Agenda for Radiation Protection in Medicine was developed by the following individuals on behalf of the five medical societies: John Damilakis, Wolfgang

Doerr, Guy Frija, Gerhard Glatting, Christoph Hoeschen, Hans Langendijk, Jonathan McNulty, Kristoff Muylle, Graciano Paulo, Wolfram Stiller and Virginia Tsapaki with the support of Monika Hierath, European Institute for Biomedical Imaging Research (EIBIR)and Nina Petoussi-Henß, Helmholtz Zentrum München. The initiative was partly supported by the EC-funded project OPERrA (project-ID 604984 funded within FP7-EURATOM-FISSION programme) and motivated by a memorandum of understanding between the medical societies and MELODI and EURADOS.

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European Platform on Preparedness for Nuclear and Radiological Emergency Response and Recovery

Strategic Research Agenda of the NERIS Platform

Version November 2019

NERIS

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1. FOREWORD

The NERIS Platform (The European Platform on Preparedness for Nuclear and Radiological Emergency Response and Recovery) was established in June 2010 in Helsinki. The vision of the Platform was published in 2011 (http://www.eu-neris.net/). The Platform was established to be a forum where joint European arrangements for nuclear and radiological emergencies can be developed and improved in the future. The Platform addresses all notable trends, arrangements and capabilities in the area of response to and recovery from nuclear and radiological emergencies.

Since August 2012, the NERIS Platform is registered as a legal association under the French Law of the 1st of July 1901. Today, the NERIS association comprises 49 organisations, with 21 supporting organisations and is driven by a management board of 10 organisations. The participating organisations represent stakeholders with a wide range of backgrounds, e.g. authorities, emergency centres, research organisations and the academic community.

The main objectives of the NERIS Platform are to improve the effectiveness of current European, national and local approaches for preparedness concerning nuclear or radiological emergency response and recovery, promote more coherent approaches in Europe through the establishment of networking activities, maintain and improve know-how and technical expertise among all interested stakeholders in Europe by developing a supranational training programme, and to identify needs for further research and development and address new and emerging challenges.

The Platform intends to enhance confidence in the solutions, reduce overlapping work, produce savings in total costs of research and implementation, and make better use of existing competences and research infrastructures in Europe.

The NERIS Strategic Research Agenda (SRA) provides the basis for priorities regarding R&D (research & development), in particular the Key Topics to be dealt with in order to achieve the Vision. This document therefore communicates the future research & development needs, but will also be an instrument for creating synergies, co-operation and coordination internally between the NERIS participants and externally with activities taking place within the European Joint Programming for Radiation Protection Research and within other international forums.

2. INTRODUCTION

A total of 183 nuclear power reactors are operational in Western, Central and Eastern Europe today [1], as well as many other nuclear facilities, such as research reactors. In addition to this, transports of radioactive materials are organized on a regular basis throughout European countries. Being aware that every man-made facility, equipment or activity is always at risk for malfunction or an accident, it is more than likely that bigger or smaller nuclear or radiological incidents and accidents may happen in the future. Significant efforts for the safety of nuclear installations in Europe have been achieved, but when the risk comes true it will have multidimensional consequences in the society. The accident at the Fukushima Daïchi nuclear power plant has reinforced the concern of all stakeholders on this issue and called for an improvement of the safety as well as the preparedness for managing short and long term consequences of nuclear events. Furthermore, it demonstrated that accidents at large distances from Europe, 448 nuclear power reactors are operational worldwide [1], call for response within Europe to protect European Citizens in the affected regions, to provide assistance to the affected countries and to monitor economic activities such as the import of foods or contaminated goods.

Apart from nuclear facilities, there are thousands of smaller installations using radioactive sources and materials. Of course, incidents and accidents in connection with these facilities would have more limited radiological consequences compared with big nuclear facilities. However, sources could possibly be stolen or bought by persons with malicious intent and purposely applied in devices designed to harm people and create anxiety and disruption. These possibilities stress the links between safety and security issues.

Nuclear and radiological safety and security have common goals. In the past 25 years, major progress has been made at the International, European, national and regional levels in the management of response to and recovery from nuclear and radiological emergencies. Notwithstanding the provisions now in place in most European countries and internationally, complacency would be misplaced and continuing vigilance remains important. Improvements, of a technical, organisational or political nature supported by important R&D efforts are still needed in emergency management. In addition, general technological evolutions such as the increasing computer power, the growth of social networks, big data and the availability of low cost radiation monitoring capabilities bring challenges for emergency management, not existing a decade ago.

The accident at the Fukushima Daïchi nuclear power plant in Japan in March 2011 proved that an event regarded as almost impossible was possible and a very small risk became reality. The Fukushima accident also demonstrated that consequence assessments and actions were needed also in Europe although the accident itself happened far away. In connection of remote accidents, European authorities and decision makers have to react to protect their own citizens staying close to the accident site. The more coherent the decisions are in different European countries the more confidence they arouse among the public.

Europe is a heterogeneous array of independent and sovereign countries having different cultural and political background and polity. The countries also have different threats as far as nuclear or radiological emergencies are concerned depending on their geographical location and distance from major nuclear installations. Therefore attempts to implement Europe-wide arrangements, in operational way, in the use of compatible systems and tools in radiation monitoring, decision making, and in communication between different actors is very complex. Interactions with scientific, technologic, economic and social areas and involvement of competent authorities at national and European levels are necessary. Thus, a full set of competencies is needed to address the challenges of conducting necessary actions in a nuclear or radiological emergency and recovery at local, national, regional and European levels.

R&D in the field of nuclear emergency preparedness, response and recovery including different disciplines is in the above mentioned context of utmost importance to further improve the operational management of nuclear and radiological threats.

3. FRAMEWORK OF THE STRATEGIC RESEARCH AGENDA (SRA)

An integral part of the mission of NERIS is to identify gaps and needs for further research and developments and addressing new and emerging challenges in the field of preparedness for nuclear or radiological emergency response and recovery. The Strategic Research Agenda (SRA) of NERIS, coordinated by the NERIS R&D Committee, identifies the research areas and topics important for improving the nuclear and radiological emergency management in the preparedness, response and recovery phase of an accident. An overview of the different phases considered and related terminology used within the SRA is given in Figure 1.

<table>
<tr><th>PREPAREDNESS</th><th>PRE-RELEASE PHASE / THREAT PHASE</th><th colspan="3">EMERGENCY RESPONSE</th><th>RECOVERY PROCESS</th></tr>
<tr><th></th><th></th><th colspan="2">EARLY PHASE</th><th>INTERMEDIATE PHASE</th><th>LONG TERM PHASE</th></tr>
<tr><th>PREPAREDNESS STAGE</th><th colspan="3">EMERGENCY RESPONSE PHASE</th><th>TRANSITION PHASE</th><th>PLANNED OR EXISTING EXPOSURE</th></tr>
<tr><th></th><th colspan="2">Urgent Response Phase</th><th>Early Response Phase</th><th></th><th></th></tr>
<tr><td>Nuclear and Radiological Emergency Planning
Stakeholder participation
Education and training, Including Exercises
R&D</td><td>Implementation of early countermeasures</td><td>Precautionary and urgent protective actions</td><td>Early protective actions and other response actions</td><td>Lifting of early countermeasures
Implementation of transition/intermediate phase countermeasures
Preparing long term remediation</td><td>Resumption of normal living conditions</td></tr>
<tr><td>Normal Exposure Situation - Planned Exposure Situation</td><td>Normal Exposure Situation</td><td colspan="3">Emergency Exposure Situation</td><td>Existing exposure situation
Planned Exposure situation
Normal Exposure situation</td></tr>
</table>

Declaration of Emergency   **End of Emergency Response phase**   **Termination of Emergency**

Figure 1. The different phases and terminology used in emergency management and recovery. It has to be noted that different phases can take place in different locations at the same time, and some phases can be missing depending on the nuclear or radiological event. (Terminology adopted in General Safety Guide GSG-11, IAEA in blue/ Terminology adopted by ICRP in green

The NERIS SRA has a clear focus on **off-site** emergency preparedness, response and recovery. However, it does not exclude links with on-site emergency preparedness and response. Emergency management has many different perspectives. As NERIS is a radiation protection platform, this SRA focuses on the radiation related aspects of nuclear and radiological emergency management, but also includes non-radiological aspects such as socio-economical and ethical factors, not excluding links with other perspectives.

The following threats were identified. These are in general considered as potential nuclear and radiological events for which emergency preparedness, response and recovery is required:

- Incidents and accidents (including criticality accidents) in Nuclear Installations (Power generation, research reactors, *etc.*)
- radioactive waste repositories;
- Transport accidents of radioactive material;
- Lost/orphan sources;
- Terroristic threats involving radioactive material/ionizing radiation;
- Military installations and operations (including submarines);
- Satellite re-entry with radioactive sources;
- Other events involving the non-controlled exposure or spread of radioactivity (Hospitals, Medical & Industrial Isotope Production Facilities, Space Weather, *etc.*).

Decision support systems, such as ARGOS and JRODOS have been developed over the past decades and are regularly updated with new tools, developments and demands from end-users. They focus on simulation models for all phases of an emergency, impact assessment, countermeasure strategies, consequence assessment and application at various levels of decision making (local to national). Stakeholder engagement related to the evaluation of countermeasure strategies is an important aspect for the realisation of management options in the simulation models.

3.1. Process of development of the Strategic Research Agenda (SRA)

A short history of the NERIS SRA development is given in Annex 1. The current version of the NERIS SRA is based on:

- Discussions within the NERIS R&D Committee meetings. The current composition of the NERIS R&D Committee can be found on the NERIS website (http://www.eu-neris.net/);
- Results and insights gained by past and running European projects: NERIS-TP [4], PREPARE [5], SHAMISEN, ENGAGE, CONFIDENCE, TERRITORIES;
- Identified operational challenges: e.g. linked to the European Basic Safety Standards and international recommendations such as the ICRP. Operational and general challenges are also addressed in the NERIS working groups;
- Discussions and outcomes of the NERIS working groups, currently defined as:
  - Working Group N°1 on the practical implementation of the ICRP recommendations on emergency and rehabilitation;
  - Working Group N°2 on processes and tools for emergency and rehabilitation preparedness at community level;
  - Working Group N°3 on contaminated goods;
  - Working Group N°4 on Information, Participation and Communication.
- Findings from work presented at the NERIS Workshops 2016 [6], 2017 [7], and 2018 [8];
- Findings from work presented and meetings during the 2016, 2017 and 2018 European Radiation Protection Week.
- Consultation with NERIS Supporting Organisations, the members of the CONCERT stakeholder group, the associated CONCERT Projects leaders, and Research Platforms correspondents.

The current update of the NERIS SRA is largely done in context of the 'CONCERT-European Joint Programme for the Integration of Radiation Protection Research' under Horizon 2020 (http://www.concert-h2020.eu/)

3.2. Identifying, characterizing and prioritizing of topics of SRA

The structure and the topics included in this version of the SRA are largely based on the previous version (NERIS SRA version 4 of 22 December 2017). Three key areas are defined with a total of 10 key topics. An overview is given below and a detailed discussion of the key topics is found in the next section.

Research area 1. Challenges in radiological impact assessment during all phases of nuclear and radiological events

Within this area all research challenges are aimed to improve the radiological impact assessment in all phases of a nuclear or radiological event. It includes improvements in modelling, monitoring and the combination of both (data assimilation for e.g. source term estimation) for human dose and environmental impact assessment. This includes research related to impact assessments for planning, real-time impact assessments during the response phase, dose reconstruction in a later phase, uncertainty quantification of the impact assessment and visualization.

Research area 2. Challenges in countermeasures and countermeasure strategies in emergency & recovery, decision support & disaster informatics

This research area covers all challenges related to decisions on and implementation of protective actions during an emergency, including justification and optimization. It comprises: countermeasures and countermeasure strategies including lifting of countermeasures and transition from emergency to existing exposure situation; formal decision support, including multi criteria analysis and disaster informatics; the study of the use of information technology in the preparation, mitigation, response and recovery phase of a nuclear or radiological disaster.

Research area 3. Challenges in setting-up a trans-disciplinary and inclusive framework for preparedness for emergency response and recovery

The third research area focuses on the overall emergency response and recovery framework, including reference levels, stakeholder engagement, the involvement of the public, communication research and non-radiological perspectives such as health, ethical and societal aspects. This area also integrates multi-disciplinary research to cope with incomplete information, typical for of emergency situations, and improved decision making under high uncertainty.

4. KEY TOPICS OF THE STRATEGIC RESEARCH AGENDA (SRA)

Research area 1. Challenges in radiological impact assessment during all phases of nuclear and radiological events

The following key topics and subtopics are defined:

Area 1. Key topics	Sub-topics
Key topic 1. Improved modelling	Atmospheric transport and dispersion modelling (ATM/ADM)
	Hydrological transport modelling
	Dose modelling
	Environmental modelling
Key topic 2. Improved monitoring	Monitoring techniques and strategy
	Data collection & sharing
	Optimisation
Key topic 3. Data assimilation	Improved source term estimation
	Improved impact assessment
	Big Data, Data fusion

Key topic 1. Improved modelling

Objective: To make more reliable and accurate forecasts on dispersion of radioactive materials in different media, human radiation doses and effects on the environment, taking into account uncertainties

Expected results: Models and Decision Support Systems (DSSs) with extended capabilities.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent & running projects and other SRA's
Atmospheric transport and dispersion modelling (ATM/ADM)	ATM/ADM at different scales and complexity is the basis for the impact assessment of releases to the atmosphere as well in the planning phase (preparedness), the response phase and for dose reconstruction. It includes forward (prognostic) modelling as well as inverse modelling (e.g.; source term reconstruction). Currently following challenges are identified: • **Modelling approaches for complex settings (urban or confined spaces):** development of models for the intentional or accidental releases of radiological or nuclear material in complex environments (e.g.; urban, near range). Combination of complex (e.g.; CFD- Computational Fluid Dynamics) modelling with more simple approaches; • **Non-conventional emissions:** extension of capability of dispersion models in existing DSSs to treat detailed information for particular types of sources (e.g.; explosions, two-phase, aerosol sprays, fires, general short-term releases), and to simulate dispersion of particular substances (aerosol, phase-changing, particles with spectrum of different size, chemical transformations); And specific scenarios such as transport of sources, releases from waste repositories, etc. • **Fine-tuning modelling parameters and algorithms:** Extension of capability of dispersion models in DSSs to treat phenomena that currently are not fully considered, in particular for low wind speed, very stable conditions, high precipitation and different forms of precipitation. • **Uncertainty quantification:** ensemble calculations, Quantification/assessment of ATM/ADM uncertainties: uncertainties due to input meteorological data, through the use of e.g., meteorological ensemble forecasts; uncertainties due to other input data (source term, physical properties of dispersed material, etc.); uncertainties due to modelling assumptions / approximations / parameterizations; uncertainties due to natural variability of the atmosphere / assessment of probability density functions / highest or most probable expected values for concentration, exposure, etc.; ensemble dispersion modelling	Projects: PREPARE, HARMONE, CONFIDENCE

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent & running projects and other SRA's
Hydrological transport modelling	Dispersion modelling in different hydrological systems is the basis for impact assessments of liquid releases and atmospheric releases with deposition resulting in aquatic contaminations in the planning phase (preparedness), response phase, for reconstruction and for guiding recovery. Currently following challenges are identified: • **Urban hydrology** o Contamination of urban fresh water supply: Development and implementation in existing DSSs of models to predict the activity concentrations in the urban fresh water supply system due to contamination of freshwater basins from radioactive cloud; o Waste water from urban decontamination: Development and implementation in existing DSSs of models to estimate the activity concentration in the waste water due to washout of deposited radionuclides in urban areas; o Better representation of wash-off processes linked to actual or prognostic information on precipitation events (plus essentially the same for food producing areas). • **Models for coastal areas:** Development and implementation of relocatable hydrodynamic 3D models of coastal circulation for real time predictions of transport of radioactivity in the coastal zone; • **Coupling with weather forecast models:** Coupling with weather forecast models to provide forcing for wave models; • **Runoff to sea:** Coupling with runoff (land to river to sea) models for the emergency phase and long term phase calculations in the case when the power installation is located near the coast – combination with deposition maps of fall-out on the land near the coast; • **Uncertainty quantification**: As for atmospheric dispersion, uncertainties have to quantified for the hydrological models. This includes approaches for transport and dispersion models as well as approaches for the integrated food chain as is typically the case for box models. Here the movement of the marine species between boxes has to be considered	Projects: PREPARE Platforms: ALLIANCE

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent & running projects and other SRA's
Dose modelling	Dose models aim at estimating the dose to humans (retrospective and/or predictive: e.g.; first year dose) in different environments (urban, agricultural, forest, …) and conditions (normal living, applying certain countermeasures, …) • Intercomparison between different models; • Evaluation of dose models along available data from past accidents; • Extending dose modelling to a wider range of radiological events (criticality) and exposures (direct exposure, cloud shine); • Development of dose models for population movement; • Impacts of population changes over time.	Projects: HARMONE, TERRITORIES, CONFIDENCE Platforms: EURADOS
Environmental modelling	Modelling the behaviour and the effect of radioactive substances in the biosphere. It comprises source term and release, transport through the abiotic part of the biosphere, food chains, intake and distribution in humans and the effect of radiation on living organisms. Here are excluded the atmospheric and hydrological dispersion. Currently following challenges are identified: • **Marine food chain** • **Customising of the existing environmental models into the regional circumstances in Europe (close co-operation with the Radioecology Alliance):** revision of model parameters as FDMT[1] • **Local radio-ecological models:** Development of local radio-ecological models interlinked with monitoring information and the more global and food chain dose models, integrated in general DSS; • **Multiple stressors:** Models able to tackle multiple stressors in the assessment of countermeasure strategies and in relation to malicious dispersion (CBRNE); • Process based models (extension to non-common radionuclides)	Projects: PREPARE HARMONE TERRITORIES CONFIDENCE Platforms: ALLIANCE

[1] FDMT software : Food Chain and Dose Module for Terrestrial Pathways

Key topic 2. Improved monitoring

Objective: Improve monitoring capabilities and efficiency in emergency and post-emergency/existing situations

Expected results:

- Optimized monitoring and monitoring strategies;
- Improved link between modelling efforts and monitoring efforts.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and current running projects and other SRA's
Monitoring techniques & strategies	• **The further development and integration of novel techniques and methods** for the measurement of radiation and radioactivity, such as drones, small detector devices and smartphone apps, retrospective dosimetry, etc. will become very important in the next decades in nuclear and radiological emergencies; • **The further development and integration of existing techniques** of key importance for the monitoring of persons, such as whole body, thyroid, lung counting; • **Improved assessment of measurement uncertainties in the field during emergency monitoring;** • **Development of improved measurements strategies supporting and tailored to decisions;** • **Optimised use of monitoring resources**, including mobile units and trans-border issues. Use of new monitoring technologies; • **Development of processes and tools for integrating the monitoring results** from experts and lay people into a common operational picture (monitoring crowdsourcing) Information fusion (radiological and non-radiological);	Platforms: EURADOS
Data collection	• **Data collection for model validation:** Availability of data are crucial for validating models, such as for example a program for resuming measurements of Chernobyl contaminants on different surfaces (and if possible Fukushima-measurements). Other data from routine releases, small incidents or obtained by controlled experiments (e.g.; RDD's) for model validations. Implementation of new experimental campaigns; • Establish an **overview** of / **guidance** on which data should be collected **for recovery operations** to be considered; • **New meteorological data:** optimised use of new meteorological instruments (E.g.; Lidar, ..) with evaluation of application to improve modelling.	Projects: HARMONE, SHAMISEN-SINGS

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and current running projects and other SRA's
Optimisation	• **Optimized use of specific monitoring resources** for nuclear and radiological emergencies (early warning networks, mobile teams, laboratories, …), in function of protective actions and decision support; • **Optimization of early warning networks and other monitoring resources**, including aerial surveys taking into account new technologies, such as the potential use of drones.	Projects: DETECT

Key topic 3. Data assimilation

Objective: Source term estimation based on monitoring and inverse modelling, combining monitoring and modelling effort to decrease uncertainty on impact assessments.

Expected results: better source term reconstruction and operational data assimilation techniques, reduced uncertainty allowing improved protective actions and countermeasure strategies.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Improved source term estimation	• **Rapid analytical tools:** Development of rapid analytical tools in combination with mobile and automated equipment to assess source terms and contamination levels in a short time frame; • **Advanced source term estimation methods:** Further development of advanced operational source term estimation computational methods – including unknown source location - combining inverse modelling with data assimilation of observations. Of special interest are operational data assimilation methods for estimation of unknown source location and strength in urban (i.e., complex) environments. Research is needed on the effects of modelling and measurement uncertainties that enter in the data assimilation methods; • **Combined ensemble dispersion modelling with data assimilation.**	Projects: PREPARE
Improved impact assessment	• **Combining different types of measurements in the data assimilation for improved assessment of impact or estimation of source term –** ranking types of measurements, including the uncertainty of measurement results and phase of accident; • **Data assimilation models:** Development of operational data assimilation methods and models for doses and concentrations (aiming at "correcting" parameters other than source term). In particular for areas without dense monitoring and in the time when monitoring is still limited: quantification of uncertainties in the assessed concentrations and doses depending on the amount and quality of available observations; integration of such methods in DSS.	Projects: CONFIDENCE
Big data, data fusion	• **Employment of advanced Information Technology instruments** to develop computational structures (e.g., platforms, aggregators) that would allow storing, processing and combining large volumes of heterogeneous and of different origins data (modelling, observational) for purposes like unknown source term estimation, radiological impacts assessment, etc. • **Further development of platforms and protocols for sharing and exchange of data, taking into account different existing data formats such as EURDEP/IRIX**	Projects: SHAMISEN-SINGS

Research Area 2. Challenges in countermeasures and countermeasure strategies in emergency & recovery, decision support & disaster informatics

The following key topics and subtopics are defined:

Area 2. Key topics	Sub-topics
Key topic 4. Countermeasures and countermeasure strategies	Countermeasures/management options
	Implementation and monitoring of countermeasures, including lifting of countermeasures
	Consequence assessment, justification and optimisation of countermeasure strategies
Key topic 5. Formal decision support	Decision making, methods and tools
	Decisions under high uncertainty
Key topic 6. Disaster informatics	Analytical platform
	Knowledge database
	DSS interface, output and coupling
	Serious gaming

Key topic 4. Countermeasures and countermeasure strategies

Objective: Development of flexible and user friendly simulation models that allow the definition of sensible countermeasure strategies by combining individual management options. In addition improvement of understanding of processes related to countermeasures (e.g. movement of contamination, parameter selection for different environment). Models have to be improved to allow also for estimation of termination of countermeasures based on criteria that have to be defined. Identification, characterisation and assessment of the response of the actions (management options) and strategies to mitigate the consequences of a radiological or nuclear event. Analyses of behavioural aspects, such as self-evacuation, self-initiated protective actions on countermeasure effectiveness

Expected results: Improved countermeasure models fit for purpose.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Countermeasures & countermeasure strategies	• **Revision of the European handbooks:** Generic revision and revision of European handbook sections (creation of addendum) for consideration of malicious dispersion scenario's; • **Countermeasure strategy preparedness:** Development of sustainable preparedness strategy at local, national and European level, based on the analyses of countermeasures for relevant accident scenarios, ensuring that parameters governing the radiological consequences can be identified in time to enable optimized remediation; • **More detailed studies and evaluations of countermeasure effectiveness,** especially if several countermeasures are combined, or impact from other environmental and external conditions	Projects: PREPARE, CONFIDENCE Platforms: ALLIANCE
Implementation and monitoring of countermeasures, including lifting of countermeasures	• **Development of tools for the usage at the local level:** Analyse the need of the local actors in respect to local-national interaction, for implementation of mitigating actions in response and recovery phases. Compatibility of local and national tools. • **Timeline of implementation;** • **Termination and withdrawal of protective measures**: Development of framework and guidance for setting up criteria to lift in particular early phase countermeasures. This includes guidelines for returning people but also compensations schemes. • **Feedback on decision / action effectiveness:** Feedback on the use of methods and tools to monitoring of situation and evaluate the effectiveness of protective actions. Simple measurement strategies are needed to secure that CM's implementation is optimised in practice. If this is not done, a 'paper-optimised' strategy may well fail completely in practice;	Projects: NERIS-TP, PREPARE, CONFIDENCE

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Consequence assessment and optimisation of countermeasure strategies	• **Consequence assessment:** Establishment of evaluation criteria and their metrics to estimate the consequences of the action alternatives; qualitative and quantitative methods; consideration of the uncertainty; • **Optimisation:** Development and application of criteria, indicators and methods to optimise the management options and/or the protective strategies.	Projects: NERIS-TP, PREPARE, CONFIDENCE, TERRITORIES

Key topic 5. Formal decision support

Objective: Improvement of the decision making process by using tools to structure the process and support the selection of appropriate options.

Expected results: new methods and tools that can be used by decision makers at all levels of the decision making process.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Decision-making, methods and tools	• Structuring the decision processes at national, regional and local levels with the help of formal decision aid tools, such as multi-criteria analysis; • Development of guidance on the use of DSS based on feedback from stakeholder processes and from Fukushima experience in emergency response and recovery; • Development of Machine Learning techniques for decision making.	Projects: PREPARE, CONFIDENCE, TERRITORIES
Decision under high uncertainty	• **Assessment and communication of uncertainties:** Investigation of data uncertainties (model or monitoring results), how they are transferred in chains of successive models and how they can be communicated or presented, e.g. in model results and in DSS to help decision-makers to understand the radiological situation; • This also includes work on model sensitivity, validity of model results and inter-comparisons of models and measurements • How uncertainties influence optimization process	Projects: CONFIDENCE

Key topic 6. Disaster informatics

Description: Study of the use of information and technology, including artificial intelligence, in the preparation, mitigation, response and recovery phases of disasters and other emergencies.

Objective: Development of databases and methods to support decision making when little information is given and assessments with simulation models are very uncertain. This should be based on historic experience and/or scenarios that can be processed by DSS. Further to this, a coupling of the strategic tools (e.g. DSS) with tools from first responders (e.g. Command and Control) that have to carry out recommendations is of interest. Use of Artificial Intelligence methods.

Expected results: Knowledge databases and tools that use existing knowledge to support decision making when little information is available and also supports the first responder in considering resources when recommending countermeasures.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Analytical platform	• **Access/exchange platform** collecting and distributing results from governmental and non-governmental organisations;	Projects: PREPARE
Knowledge database	• **Development of a knowledge database** with scenarios and response, including lessons learned from historic events and decision support tools developed in international handbooks such as the European handbooks; • **Development of information material** of general nature on radiation emergencies, countermeasures and recovery based on lessons learnt from past events.	Projects: PREPARE
DSS interface, output and coupling	• **Tailor the output of DSS's to the user's needs:** Modification of existing interface of DSS's to allow easy selection of specific output in particular calculation points and export of results to other formats; • **Coupling** of the existing strategic DSS such as ARGOS and RODOS **to Command and Control (C2) systems.** • **Study on optimising exchange of information:** covering all aspects of data exchange throughout emergency response and recovery.	Projects: BOOSTER
Serious gaming	• **Development of virtual and augmented reality to train the emergency response actors** (first responders, competent authorities, decision makers…); • **Other types of serious gaming for exercise/training support.**	Projects: TERRITORIES

Research area 3. Challenges in setting-up a trans-disciplinary and inclusive framework for preparedness for emergency response and recovery

The following key topics and subtopics are defined:

Area 3. Key topics	Sub-topics
Key topic 7. Emergency response and recovery framework, including reference levels	Implementation of BSS including reference levels and relation with operational levels
	Governance of preparedness
	Long term management
	Contaminated goods
	Integration in all-hazard approach
	Exercises and drills
Key topic 8. Stakeholder engagement, involvement of the public & communication	Stakeholder engagement processes including the public
	Communication
	Citizen Science
Key topic 9. Integrated emergency management – non-radiological aspects (health surveillance, ethical aspects, economic issues, etc.)	Health Surveillance
	Ethical aspects
	Socio-economic aspects
	Integrated surveillance and monitoring
	Accident waste management
	Radiological protection culture
Key topic 10. Uncertainty and incomplete information handling	Deal with, manage and address uncertainties in the decision making process
	Communication of decisions under uncertainty
	Train decision makers to better deal with uncertainties

Key topic 7. Emergency response and recovery framework, including reference levels

Objective: Development of radiological decision criteria and implementation frameworks to improve and ensure the sustainability of emergency response and recovery management, addressing societal and ethical issues.

Expected results: Operational radiological decision criteria and guidance for implementation taking into account societal and ethical issues, and management framework for improve sustainable emergency response and recovery.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Implementation of BSS including reference levels and relation with operational levels	• Development of socially and scientifically robust Operational Intervention Levels (OILs) and radiological decision criteria for the transition and longer-term management; • Investigate the potential of simulation models to set up possible radiological decision criteria and reference levels early in the emergency to support decisions such as temporary or permanent relocation; • Development of methodology and tools to better address actual and future risks and vulnerabilities and their management in the implementation of countermeasures; • Adapt decision support systems to implement results from the screening of reference levels; • Development of governance approaches at local, national and international levels to better integrate radiation protection into a broader environmental protection framework; • Development of stakeholder engagement approaches in context of BSS implementation; • Study on which factors can influence and enhance the coordination and harmonization in emergency preparedness, response and recovery in neighbouring countries and at the European and international level in general; • Study on good indicators for nuclear preparedness in different countries including cross-border aspects.	Organizations: HERCA Projects: ENGAGE

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's

Governance of preparedness	• Development of processes, methodologies and tools to support sustainable strategies of preparedness of European member states to the occurrence of nuclear events including relevant stakeholders:
	  ○ Identifying the specificities of respectively preparedness to emergency response and preparedness to recovery process and corresponding knowledge, skills and culture;
	  ○ Roadmaps for the development of RP culture during the preparedness phase;
	  ○ Clarifying the respective role of the different concerned categories of stakeholders in the preparedness process (considering the option of incremental in time engagement of stakeholder categories), notably local communities;
	  ○ Articulating with existing CBRN capacities and drawing lessons from preparedness processes in other fields such as Chemicals, Biological, Natural events;
	• Investigating the conditions for Human resilience at individual and community levels and possible preparedness strategies for increasing resilience;
	• Defining strategies for reviewing preparatory processes over time, overcoming the turnover of qualified actors while articulating with rolling stewardship of society;
	• Experimenting and testing the developed preparedness methodologies at national level while supporting diffusion and coordination of preparedness processes at EU level.
		Platform:
		Jointly with SHARE

Long term management	• Develop long term, sustainable communication models and stakeholder engagement frameworks to improve public health and well-being ; • Development of decision criteria for lifting of countermeasures and transition from emergency to existing exposure situations; • Test the guidance on communication and participatory processes in stakeholder groups and improve the framework.	Projects: CONFIDENCE TERRITORIES ENGAGE SHAMISEN-SINGS Platforms: SHARE ALLIANCE

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Contaminated goods	• Further analysis on the implications of trade and use of goods from contaminated territories in the perspective of a sustainable recovery, including the management of business activities; • Development of simulation models that allows the quantification of potential doses from usage of contaminated goods; • Development of guidance on management strategies for goods, addressing health, societal, economic and ethical issues.	Projects: PREPARE CONFIDENCE
Integration in all-hazard approach	• Nuclear and/or radiological emergencies can be part of a larger natural or man-made hazard, development of approaches to optimize emergency preparedness response and recovery in such scenarios, including the stress test of the nuclear emergency plan.	
Exercises, drills	• Emergency exercises and drills are the key moments to practise nuclear and radiological emergency preparedness and response: research related to the methodological and practical/technical development of emergency exercises and on the return-of-experience from exercises.	Projects: ENGAGE CONFIDENCE

Key topic 8. Stakeholder engagement, involvement of the public & communication

Objective: Improve the efficiency and social robustness of emergency response. Ensure that stakeholders are involved in decisions that impact their lives.

Expected results:

- Maintain the inclusion of social aspects of emergency response and stakeholder engagement;
- Greater recognition of the importance of stakeholder and public engagement;
- Improve understanding of the factors and criteria for successful stakeholder engagement;
- Improved preparedness for media and social media communication.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Stakeholder engagement processes including the public	• **Defining stakeholders and framing problems:** Identifying roles, constraints, responsibilities and cooperation among European/national/regional/local levels in order to improve the Preparedness Plans for each phase of the emergency and post-accident • **Stakeholder engagement database:** Database on experiences of stakeholder engagement in preparedness and response highlighting lessons learned and guidance for best practice, taking into account the national context; • **Public participation and dialogue:** Develop guidance on information and participation of population, increasing effectiveness if multiple sources of information may compete or conflict; • **Analysis of societal needs for an evaluation of legal instruments and governance frameworks** supporting access to information, public participation and access to justice in relation with RP issues; • **Examination, assessment and design of stakeholder and public participation tools and methodologies** for emergency and post-accident emergency situations. Roles and rules of stakeholders in the engagement process. Motivational factors (including motivations for dis-engagement), ethics and link between theory and practice. Impact of engagement processes and update of their outcome; • Preservation of knowledge and experience of local stakeholders' (e.g.; local community, schools, citizens) involvement and participation. Community research and tracing for development of participation culture in relation to different exposure situations.	Projects: ENGAGE NERIS-TP PREPARE CONFIDENCE TERRITORIES SHAMISEN-SINGS Platforms: SHARE

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's

Communication	• **Assessment of the mechanisms by which the public gains information:** Investigate the conditions and means for pertinent, reliable and trustworthy information to be made available to the public in due time according to its needs in the course of nuclear emergency and post-emergency contexts;
	• **Trustworthiness of information: Development and usage of social media and other information sources in emergency response:** how social media can be used to improve emergency response and better communicate and cooperate with the public;
	• **Role of social media link:** Links between perception of radiological risk and radiation protection behaviour, or individual strategies to cope with perceived risk in relation to radiation exposure, using both cross-sectional and longitudinal studies focusing on one or more of these aspects:
	    ○ different exposure context (workers, population living in areas affected by radiological contamination);
	    ○ different time scales (e.g.; different generations);
	    ○ cultural context;
	    ○ socio-economic issues of behaviour change;.
	    ○ Social and traditional media impact on perception of radiological risk and general well-being linked to radiation exposures. This includes the influence of citizen journalism on radiation protection behaviour in different exposure situations and developing models for integrating scientific journalism in radiation protection?
	• Developing long term communication models to improve radiation protection culture and public well-being in long term exposure situations;
	• Use and perception of technical information and risk estimates in communication with various publics (lay people, experts, informed civil society):
	    ○ Media communication about ionizing radiation, in particular low radiation doses and related uncertainties in the field of radiological protection including inter-media agenda setting in different exposure situations;
		Projects:
		PREPARE,
		CONFIDENCE,
		ENGAGE,
		SHAMISEN,
		SHAMISEN SINGS
		Platforms:
		SHARE

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Citizen Science	• Potential and pitfalls of citizens involvement in knowledge production for radiological risk governance; • Authorities versus citizen measurements/science: integration, interpretation, stakeholder involvement, interaction between different partners, assessment of technical aspects on reliability, … • Mutual influence of citizen science and radiation protection culture.	Projects: ENGAGE, TERRITORIES, SHAMISEN-SINGS, CONFIDENCE Platforms: SHARE, EURADOS

Key topic 9. Integrated emergency management, including non-radiological aspects (health surveillance, ethical aspects, economic issues,…)

Objective: Better addressing non-radiological aspects for developing guidance and framework in an integrated way to improve emergency response and recovery management, covering many disciplines including the non-radiological aspects.

Expected results: Improved knowledge on the role of non-radiological aspects in emergency response and recovery, and procedures and guidance for the development of an integrated approach.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Health Surveillance	• Development of procedures for health surveillance including monitoring of population and dose reconstruction and involvement of stakeholders; • Socio-psychological and economic aspects of medical follow-up after accidental or other exposures.	Projects: SHAMISEN, SHAMISEN SINGS, ENGAGE Platforms: MELODI, SHARE
Ethical aspects	• Ethical aspects of crisis situations, particularly ethical questions of evacuation, and post-accident management ("emergency ethics" vs. "normal ethics"), the transition from emergency to existing radiation exposure situations; • Practical implications for emergency and recovery preparedness; • **Compensation:** Ethical perspective of compensation for damage incurred due to various situations of radiation exposure and differences among countries; • Ethical basis and values underpinning risk communication about ionizing radiation exposures.	Projects: ENGAGE, SHAMISEN Platforms: SHARE

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Socio-economic aspects	• **Public behaviour response analyses:** Understand how the population reacts and which information related to the behaviour of the population can be used by local-national tools to improve the response – research on gap knowledge and behaviour (knowledge – action gap); • **Assessment of factors important for social trust in emergency situations and recovery:** Development of methods and procedures for analysing the information flow related to social trust including traditional information sources as well as social media and modern IT-based structures; • Comprehensive approaches studying the perception of radiological risk and environmental remediation actions in post-accident and existing exposure situations; • The interplay of psychological aspects associated with radioactivity, social environment and radiation protection behaviours; • Perception of radiological risks from low doses of radiation, accounting for cultural differences in routine, emergency and other exposure situations; • Development of socio-economic valuation and multi-criteria decision aid methods to formally structure the evaluation and integration of radiological and non-radiological factors for different ionising radiation exposure situations; • Studying compensation schemes.	Projects: CONFIDENCE, TERRITORIES, SHAMISEN, ENGAGE Platforms: SHARE
Integrated surveillance and monitoring	• Investigate connections between issues of health surveillance, human dose assessment, environmental monitoring and food monitoring from the point of view of institutions and local populations in the emergency response and transition phases; • Investigate connections between these different dimensions of surveillance, healthcare and the development of radiation protection culture; • Develop guidance on the way to set up comprehensive surveillance and monitoring systems articulating health, body, environment and food surveillance and healthcare, taking into account the potential of citizen-based monitoring; • Test the guidance with local and national stakeholders on the way to set up comprehensive surveillance and monitoring systems articulating health, body, environment and food surveillance and healthcare, taking into account the potential of citizen-based monitoring.	Projects: ENGAGE, SHAMISEN, SHAMISEN SINGS, TERRITORIES, CONFIDENCE Platforms: SHARE, EURADOS

Sub-topic	Description and current research challenges within this (sub)topic	Relation with recent and running projects and other SRA's
Accident waste management	• Analyses of environmental and socio-economic aspects of waste management after an accident	Projects: CONFIDENCE

Radiological protection culture	• Awareness on radiation;
	• The role of RP culture, in particular:
	  o The contribution of RP culture in the implementation and improvement of the protection "system";
	  o How RP culture can improve health and well-being of populations?
	Practical achievements from developing / building a RP culture (impact on level of exposure, protective actions, decision making processes,…).
	• Development of tools, methods, processes to build, maintain and transmit RP culture:
	  o Needs and concerns of stakeholders regarding RP culture, with attention to the development of participatory tools and low dose exposure situations;
	  o Development of tools / methods / processes to enhance RP culture in specific fields: emergency and late phase nuclear accident preparedness, NORM activities, Radon exposure, paediatric imaging;
	  o Processes to maintain/ transfer RP culture through generations;
	  o Guidance for enhancing RP culture for specific publics (communities around nuclear installations, schools, patients, pregnant women, medical doctors).
		Projects:
		ENGAGE,
		SHAMISEN,
		SHAMISEN-SINGS
		Platforms:
		SHARE

Key topic 10. Uncertainty in the decision making processes

Objective: Improve the capabilities to perform sensible and robust decisions at all levels under high uncertainty. (This includes communication and visualisation of uncertainties in model results but also the consideration of how uncertainties are used when making decisions).

Expected results: Improved (communication) tools to present uncertainties in model results and tools and methods to include this information in the decision making process.

Sub-topic	Description and current research challenges within this (sub)topic	Relation with current projects and other SRA's
Deal with, manage and address uncertainties in the decision making process	• Identify key information that should be considered for decision-making in the various phases of an emergency and develop indicators that indicate the usefulness of model results for decisions in the different phases, e.g. robustness or quality indicators; • Based on the needs for decision making initiate studies on model sensitivity, validity of model results and inter-comparisons of models with measurements to better judge the quality of model results for decision-making; • Investigating overall uncertainties and how uncertain model results can be better integrated into decision support systems to help decision makers to fully assess the radiological situation; • Investigate how uncertainties influence optimization process of management strategies, • Further develop formal decision aiding tools such as Multi Criteria Decision Analysis to integrate uncertain information from model result and uncertain preferences of decision makers; • Explore agent based simulation systems to systematically study the decision making process under different aspects such as composition of team, preference settings, constraints, and blockage of consensus seeking. • Investigate how local actors and non-institutional stakeholders make sense of uncertainty in their own decision-making processes and what governance mechanisms can facilitate these processes.	Projects: CONFIDENCE, TERRITORIES

Sub-topic	Description and current research challenges within this (sub)topic	Relation with current projects and other SRA's
Communication of decisions under uncertainty	• Investigate how decisions taken under high uncertainty can be communicated to media and general public; • Investigate media communication about ionizing radiation, in particular low radiation doses and related uncertainties in the field of radiological protection including inter-media agenda setting in different exposure situations; • Develop tools and methods for a two-way communication of uncertain information between experts and non-experts; • Review the developments from the first decade and develop further needs for improved communication of uncertainties; • Investigate to which extent serious gaming can be used in communication of uncertainties.	Projects: CONFIDENCE, TERRITORIES
Train decision makers to better deal with uncertainties	• Develop education and training material for decision makers on uncertainty management; • Investigate to which extent serious gaming or other modern IT-tools can be used for training of first responders and decision makers.	Projects: CONFIDENCE

5. CROSS-CUTTING TOPICS

5.1. Education and training

Education and training is an essential part of any Strategic Research Agenda both for guaranteeing high level research in the field as well as for transfer of knowledge gained through research and development towards the operational field of nuclear and radiological emergency preparedness and other stakeholders. Maintenance of the range of expertise vital to keep up competence and run an effective Programme of research into radiation protection in general and specifically in nuclear and radiological emergency preparedness, response and recovery has been identified to be critical. Specific Programmes aiming at knowledge management across generations are designed in order to achieve sustainable continuity and development. The NERIS supported early and late phase emergency courses (organized respectively by the SCK•CEN Academy and CEPN) described in Annex 3 and organized since many years in different frameworks are essential parts of such a Programme. In addition to this basic courses in nuclear emergency, preparedness and recovery specific courses, organized within the E&T activities under the CONCERT umbrella, are important. Especially the "Assessment of long-term radiological risks from environmental releases" organised by the Technical University of Denmark and the travel grants for participation of young scientists in workshops and conferences in the field, such as the yearly NERIS workshop and the European radiation Protection Week.

The initiative was taken to organize during the yearly NERIS workshop a young scientist award with the goal to promote presentations by and participation of young scientist in the Workshop.

The ARGOS and RODOS user groups, described in Annex 4, offer also good training opportunities in the technical aspects of both decision support system, crucial to get started with the use of these systems.

5.2. Safety and security related activities

Radiation and nuclear safety and (radiation and nuclear) security have a common goal — the protection of people, society and the environment. In both cases (safety and security), such protection is achieved by preventing a large release of radioactive material. Many of the principles to ensure protection are common, although their implementation may differ. Moreover, many elements or actions serve to enhance both safety and security simultaneously. For example, the containment structure at a nuclear power plant serves to prevent a significant release of radioactive material to the environment in the event of an accident, while simultaneously providing a robust structure that protects the reactor from a terrorist attack. Similarly, controls to limit access to vital areas not only serve a safety function by preventing or limiting exposures of workers and controlling access for maintenance to qualified personnel, but also serve a security purpose by inhibiting unauthorized access by intruders.

The IAEA defines safety and security in the following way (IAEA 2007):

- **(Nuclear) safety:** "The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.";
- **(Nuclear) security:** "The prevention and detection of, and response to, theft, sabotage, unauthorized access, illegal transfer or other malicious acts involving nuclear material, other radioactive substances or their associated facilities."

Stemming from their different historical roots, the areas of safety and security have long been treated within separate research communities with their own terminologies and methods. But since almost all systems today are connected to global networks, safety and security have become very much interdependent, meaning that safe systems also need to be secure and vice versa. Recent terrorist events have served as a catalyst for the development of an array of new nuclear security arrangements. Although concern about malicious acts involving nuclear installations is not new, recent terrorist events have demonstrated that an attack on a nuclear facility might be attempted and that terrorists have formidable capabilities and dedication. This has led to an increased focus on defences against terrorists at nuclear facilities, as well as at other critical infrastructures. The development of revised security arrangements arises at a time when the public expects high standards of nuclear safety and security to be met. The challenge in meeting these expectations is predicted to grow in light of the interest in the new construction of nuclear power plants. In the Seventh Framework Programme (FP7) of the European Commission, security related research is centred in the Security Programme and radiation and nuclear safety research in the Euratom Programme (http://cordis.europa.eu/fp7/home_en.html).

As noted above, the fundamental goal of safety and security actions is the same — the protection of people, society and the environment. The acceptable risk is presumptively the same whether the initiating cause is a safety or a security event. Moreover, the philosophy that is applied to achieve this fundamental objective is similar. Both safety and security typically follow the strategy of defence in depth — that is, the employment of layers of protection. The fundamental nature of the layers is similar. Priority is given to prevention. Second, abnormal situations need to be detected early and acted on promptly to avoid consequent damage. Mitigation is the third part of an effective strategy. Finally, extensive emergency planning should be in place in the event of the failure of prevention, protection and mitigation systems. The steps taken to provide protection against malicious acts incorporate specific features to ensure physical protection, but also rely on provisions that may have been installed for safety reasons.

NERIS Platform follows and recommends the R&D activities both in the safety and security areas and encourages scientists in these areas to collaborate with each other to achieve the best possible impact of research in nuclear and radiological emergency management.

5.3. Collaboration with other platforms

The NERIS Platform creates close co-operation relationships with other research platforms in the areas of radiological protection and nuclear safety in Europe. It is of special importance to follow R&D and collaborate in the areas of radioecology, biological effects of exposure to ionizing radiation and epidemiology, and dosimetry and medical issues. This is guaranteed by the integration and active involvement of NERIS in the 'CONCERT-European Joint Programme for the Integration of Radiation Protection Research' under Horizon 2020. NERIS also signed in 2013, a Memorandum of Understanding with the European research platforms in the domain of radiation protection (MELODI, ALLIANCE and EURADOS). In addition, for developing and implementing its SRA, NERIS has established interactions with different European and International organisations involved in radiation protection. The main research platforms and organisations interacting with NERIS are the following:

European Radioecology Alliance, (http://er-alliance.eu/) was founded in 2009 to strengthen European R&D in the area of radioecology. Radioecological studies are of special importance to assessment and management of nuclear or radiological emergency response and recovery, notably for developing Decision Support Systems (DSS) and addressing scientific issues associated with environmental contamination and countermeasure strategies. Reliability of environmental models used in emergency and recovery depends on radioecological parameters incorporated in the models. The Radioecology Alliance focuses not only on radiological protection of humans, but also on protection on wildlife. This aspect has to be taken into account in nuclear and radiological emergencies.

MELODI (Multidisciplinary European Low Dose Initiative, http://www.melodi-online.eu/) is an European Platform dedicated to low dose radiation risk research, founded in 2010 as a registered association with currently 30 members. MELODI aims at identifying R&D priorities for Europe in its field of competence and seeking the views of stakeholders on the priorities for research, keeping them informed on progress made, and contributing to the dissemination of knowledge. Since MELODI focuses on better understanding the health effects of exposure to low dose ionising radiation, its work is directly linked with the work of NERIS when protective measures in response to and recovery from nuclear and radiological emergencies are discussed. NERIS closely follows the work of MELODI and investigates how new findings of MELODI could be implemented in the European emergency management procedures.

EURADOS (European Radiation Dosimetry Group, http://www.eurados.org) is a network of more than 60 institutions and more than 500 scientists from the European Union, Switzerland, Eastern and Central Europe. It serves the promotion of research and development and European cooperation in the field of the dosimetry of ionizing radiation. The scope of EURADOS includes the fields of radiation protection, retrospective dosimetry, environmental radiation monitoring, radiobiology, radiation therapy, diagnostic and interventional radiology. Its activities promote technical development and its implementation into routine and contribute to compatibility within Europe and conformance with international practices. Dosimetry and monitoring issues are part of the management of emergency and recovery. NERIS follows the current developments in this field to improve preparedness.

EURAMED (European Alliance for Medical Radiation Protection Research), created in 2015, represents a consortium of associations involved in the application of ionising radiation in medicine, with the goal of jointly improving medical care and its radiation protection issues through sustainable research efforts. The main objective of this collaboration is improve the application of ionising radiation in medical care by developing and exploring common research strategies and by actively promoting the translation of results into clinical practice. Several topics have to be considered with EURAMED for better addressing medical issues in the case of a nuclear accident. NERIS is currently engaging a discussion with EURAMED in this perspective.

SHARE (Social Sciences and Humanities in Ionising Radiation Research) Building a more robust role for SSH in Ionising Radiation (IR) is imperative. This would open vital opportunities for multiple research communities to integrate social and ethical considerations into IR research, thereby expanding research options, clarifying values, and fostering collaborative approaches to research and innovation. The Platform will ensure that: i/existing and future research, policy and practice, in all areas relating to IR, can better take into account the concerns, values and needs of a wider range of stakeholders, including citizens and communities; ii/ the findings of social sciences and humanities (SSH) research can be better co-ordinated and also be better integrated in European research and development on IR; iii/research relating to IR will be conceived as transdisciplinary and inclusive, integrating technical and non-technical inputs from the start.

5.4. Collaboration with European and International Organizations

HERCA (association of the Heads of European Radiological protection Competent Authorities, http://www.herca.org/) is a collaboration forum of the European radiation protection authorities, founded in 2007. HERCA has recognized the need for a more harmonised approach with regard to the management of nuclear and radiological emergency situations as a top priority. HERCA has also recognised that the events at the Fukushima Daiichi NPP in March 2011 dramatically illustrate that similar needs for a common understanding and, whenever possible, a common approach in the field of nuclear emergency response also exist for accidents happening even at great distance from Europe. National radiation protection authorities are the key players in nuclear and radiological emergencies and therefore the objectives of HERCA and NERIS are common. NERIS is the forum where new methods and tools are developed and the radiation protection authorities, among the others, take care of implementing them. Therefore it is of primary importance that these two forums work closely together.

ICRP (International Commission on Radiological Protection, http://www.icrp.org), created in 1928, helps to prevent cancer and other diseases and effects associated with exposure to ionising radiation, and to protect the environment. ICRP is an independent, international organisation with more than two hundred volunteer members from approximately thirty countries across six continents. These members represent the leading scientists and policy makers in the field of radiological protection. ICRP has developed, maintained, and elaborated the International System of Radiological Protection used world-wide as the common basis for radiological protection standards, legislation, guidelines, programmes, and practice. NERIS is recognised as liaison organisation by ICRP and participates each year to the exchange meetings to identify the main challenges for the application of the radiological protection system in emergency and recovery situations.

IAEA (International Atomic Energy Agency, https://www.iaea.org) was created in 1957 in response to the deep fears and expectations generated by the discoveries and diverse uses of nuclear technology. Widely known as the world's “Atoms for Peace” organization within the United Nations family, the IAEA is the international centre for cooperation in the nuclear field. The Agency works with its Member States and multiple partners worldwide to promote the safe, secure and peaceful use of nuclear technologies. Specific developments have been made following the Chernobyl and Fukushima accidents and regular meetings are organised, leading to publications and recommendations for the management of emergency and recovery. NERIS interacts regularly with IAEA to exchange information and identify areas where NERIS researches can be disseminated.

IRPA (International Radiation Protection Association, http://www.irpa.net) is the international association of the national societies of radiation protection. It aims to provide a medium whereby those engaged in radiation protection activities in all countries may communicate more readily with each other and through this process advance radiation protection in many parts of the world. NERIS interacts more specifically at the occasion of the international and regional congresses, providing an opportunity to present and discuss the results of research developments among the community of radiation protection experts.

NEA (The Nuclear Energy Agency) is an intergovernmental agency that facilitates co-operation among countries with advanced nuclear technology infrastructures to seek excellence in nuclear safety, technology, science, environment and law. The NEA, which is under the framework of the Organisation for Economic Co-operation and Development, is headquartered in Paris, France.

WHO (World health Organization) The WHO is building a better, healthier future for people all over the world. Working with 194 Member States, across six regions, and from more than 150 offices, WHO staff are united in a shared commitment to achieve better health for everyone, everywhere. Together we strive to combat diseases – communicable diseases like influenza and HIV, and noncommunicable diseases like cancer and heart disease. We help mothers and children survive and thrive so they can look forward to a healthy old age. We ensure the safety of the air people breathe, the food they eat, the water they drink – and the medicines and vaccines they need.

NUGENIA (NUclear GENeration II & III Association). Established in 2011, **NUGENIA is an international non-profit-making association** according to the Belgian law of 1921, headquartered in Brussels. Today, **we gather more than 100 members worldwide** to advance the research and development of nuclear fission technologies, in particular for Generation II and III nuclear plants. The association aims to be an integrated framework for R&D to **ensure safe, reliable and competitive Gen II & III fission technologies** by: i/ Fostering collaboration between industry, SMEs, research organisations, academia and technical safety organisations; ii/ Building knowledge and expertise and iii/ Generating R&D results with added value for the nuclear community

EC-DG-JRC (European Commission - Directorate General - Joint Research Centre). The Joint Research Centre is the Commission's science and knowledge service. The JRC employs scientists to carry out research in order to provide independent scientific advice and support to EU policy.

EC-DG-ENER (European Commission - Directorate General – Energy) This Commission department is responsible for the EU's energy policy: secure, sustainable, and competitively priced energy for Europe.

6. WAY FORWARD

The vision of the NERIS Platform is that all European organizations being involved in nuclear emergency management and recovery are sharing common views and common approaches as well as, developing and using state-of-the-art compatible technology and methods for consequence management of the emergencies. This vision presumes commitment of all key players in a joint European approach and existence of necessary technology and methods to be applied in response to and recovery from an emergency situation. Mission of the NERIS Platform is to encourage European, national, regional and local authorities, technical support organisations (TSOs) and other players to co-operate to achieve this vision. The aim is to get national players in different European countries to act in a coherent way in order to avoid confusion and to enhance confidence among the population. Role of the European Commission and other bodies having a mandate to establish binding arrangements in management of nuclear and radiological emergencies and recovery have a central role in achieving more coherent European approach.

The NERIS Platform itself shall have a clear vision of what development is needed to achieve a functioning European emergency response and recovery arrangements. The Strategic Research Agenda should include these needs. The SRA is a living document. This is the third update and the platform shall always update it at more or less regular intervals. The Key Topics in the future research and development are identified in this SRA and the Platform will go all out for getting these topics in the appropriate European research programmes in the coming years. Of course, engagement of the European Commission in the process is extremely important.

7. CONCLUSION

A NERIS SRA defines ten key topics in three research areas. The three areas are seen as equally important to achieve the overall goals in nuclear emergency preparedness, response and recovery. All defined key topics require further R&D. Specific challenges are largely based on the previous versions of the NERIS SRA, but substantial changes were made to take into account the progress made in the different R&D projects currently running and that have recently been concluded. Priorities are not defined in this document and all challenges are identified as important. Further prioritization has been done in NERIS statements, in the context of CONCERT or in the NERIS roadmap. The relation with other European radiation protection platforms (MELODI, ALLIANCE, EURADOS, EURAMED and SHARE) and EU projects addressing part of the topics have also been indicated.

8. REFERENCES

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7. Proceedings of the 3rd NERIS Workshop in Lisbon - State of the art and Needs for further research for emergency and recovery preparedness and response (ISBN - 978-2-9552982-1-3), 2017.
8. Proceedings of the 4th NERIS Workshop in Dublin - Adapting nuclear and radiological emergency preparedness, response and recovery to a changing world (ISBN - 978-2-9552982-2-0), 2018.

9. ANNEX 1. Previous SRA versions

Three previous versions of the NERIS SRA has been published on the NERIS website:

- Strategic Research Agenda of the NERIS Platform, SRA-Report-v2.pdf, published on 30 March 2012
- Strategic Research Agenda of the NERIS Platform - v2, NERIS_SRA_version4_22122017.pdf, Published on 22 April 2014
- Updated version of the NERIS SRA - December 2017, NERIS Roadmap_20_november_2017.pdf, Published on 09 January 2018

10. ANNEX 2. NERIS RELATED RESEARCH PROJECTS

NERIS-TP

The NERIS- TP Project (2011-2014) aimed on the one hand to keep the momentum gained through the European Project EURANOS in establishing a platform where the operational and research community can meet and discuss with all the relevant stakeholders the topics related to emergency response and recovery preparedness and on the other hand to tackle urgent research topics in the area of nuclear emergency response and recovery preparedness. Through a collaboration of industry, research and governmental organisations in Europe, methodological aspects and computational models have been developed to be consistent with recommendations from international bodies such as the ICRP (International Commission for Radiological Protection) and improve Europe's response by coupling decision support systems with an emergency information system such as the European wide information system ECURIE. Within this project, the NERIS platform was established as a unique place for combined meeting of the research and the operational community.

FP7-project PREPARE (Innovative integrative tools and platforms to be prepared for radiological emergencies and post-accident response in Europe) - Finished

The European research project PREPARE ended in January 2016 and brought together 46 partners from Europe and Japan. The objective was to close gaps identified after the Fukushima accident. The following results have been obtained:

- Atmospheric modelling:
  - First prototype of inverse source term estimation modules (released activities, isotopic composition, height) through data assimilation of near or far field measurements;
  - Improvements in the speed of calculation allowing to use them for long lasting releases;
  - Improved deposition modelling of particles with spectrum of different sizes and densities.
- Aquatic modelling:
  - Improved models for coastal areas;
  - Improved run-off modelling, however still very limited;
- Data mining, information gathering and providing information to stakeholders and mass media:
  - Analytical Platform for data exchange;
  - Knowledge data base – so far limited to the early phase, but work in HARMONE will deal with the later phase;
  - Trustworthiness of information.
- Stakeholder engagement and dialogue:
  - Contaminated goods.
- Social media/networking technology:
  - Public behaviour;
  - How the public obtains information;
  - Factors important for trust.

OPERRA-project CATHyMara (Child and Adult Thyroid Monitoring after Reactor Accident) - Finished

The Cathymara project aims at setting-up guidance for monitoring the internal contamination in the case of a large scale nuclear accident, with a focus on the measurement of I-131 content in the thyroid, especially for children and included:

- Evaluation of existing response capabilities for thyroid monitoring in Europe in case of a large scale accident;
- Harmonization of measurement practices and establishment of a robust protocol in case of the need to monitor children;
- Setting-up the basis for a sustainable network of responders, including trained but non-specialized operators;
- Studying to what extent the total committed effective dose (internal dose) can be evaluated from I-131 measurements and the development of emergency oriented dose assessments methods;
- Developing the optimal monitoring strategy, including guidelines and recommendations.

OPERRA-project HARMONE (Harmonising Modelling Strategies of European Decision Support Systems for Nuclear Emergencies) - Finished

The HARMONE project started December 1, 2015 and aimed to reduce scientific, methodological and operational gaps identified in the strategic research agendas of the four European Platforms in the area of radiation protection and issued as TOPIC 2 of the OPERRA-2014 Call: "Spatial and temporal environmental modelling and human dose assessment after a nuclear accident". This included the following work activities:

- Development of a knowledge data base and guidance that allows, according to the first event description, to propose a first management strategy to reduce doses and highlights potential issues for the dose assessment;
- Refinement of simulation models for all exposure pathways to obtain a better assessment of the total dose. This would include also a methodology for the regionalisation of the model to have assessments on all relevant scales;
- Development of guidelines for dose monitoring to back-up the first two steps and facilitate the refinement of the simulations.

OPERRA-project SHAMISEN (Nuclear energy situations – Improvement of medical health surveillance) - Finished

The aim of the project is to build upon the experience and feedback from Chernobyl, Fukushima and other emergency situations to develop recommendations for health surveillance and medical follow-up of affected populations for:

1. Dose assessment in support of emergency response, clinical decision-making in the aftermath of a radiation accident, and long-term follow-up of exposed populations;
2. Improvement of living conditions of affected populations, responding to their needs, and engaging them in surveillance programmes without generating unnecessary anxiety; and
3. Improvement of population estimates of radiation-induced risk both for radiation protection and for communication with affected populations, if and where feasible.

Five complementary subtasks (ST) have been executed: ST1 focuses on learning from radiation accidents; ST2 looks at the needs of populations by way of case-studies; ST3 will develop recommendations for health surveillance aimed at improving living conditions of affected populations and knowledge on health effects; ST4 focuses on cross-cutting issues (stakeholder engagement, ethics, and economics of health surveillance); and ST5 is dedicated to efficient project management.

BOOSTER (BiO-dOSimetric Tools for triagE to Responders)

The BOOSTER project, gathering seven partners from five different countries, addressed the effective management of an event involving the exposure of numerous people to radioactive material, whether accidental of following malevolent act, requiring a mechanism for rapid triage of exposed individuals. A unique toolbox was developed that allowed to quickly assess the radiological situation in the field and to provide fast and reliable biodosimetric tools to Triage Teams to evaluate the radiological dose received by each victim. This allows to speed up the categorisation of the triage and provided material for any potential further follow-up.

The BOOSTER System architecture was designed to fit the current procedures for radiological crisis management, generally based on the definition of different areas around the scene. An exclusion area and a controlled area are defined based on radioactivity levels measured in these zones. The equipment used in the controlled area allows the cartography of the radiological situation and therefore the real-time assessment of the dose received. In the Decontamination area, victims are controlled for contamination and a decontamination process is applied if necessary. Several measurement devices are deployed to assess the level and position of external contamination on individuals

When affected people arrive to the Support area, a deeper analysis is performed for radiological triage. A complete kit for a first determination of the dose received by internal contamination and irradiation is installed in the Support area: Low-Background Spectroscopy on biological samples and environment samples, portable LIBS analysis of biological samples, retrospective dosimetry using environment samples and SMD resistors from cell phones, biodosimetry using γH2AX quantification. All results, obtained in less than 20 min, are linked with the victim ID and stored in a database processed by Decision Support System for triage instructions and medical care.

As supporting tools two easily deployable DSS systems consisting in rugged laptop with SIMACOP and RODOS applications are available for crisis managers and authorities, to show all information from the Controlled area as well as second level information from the Support area.

The BOOSTER equipment was demonstrated at Budapest on May 16, 2013, to present all the techniques developed during BOOSTER project and their final integration.

CONFIDENCE COping with uNcertainties For Improved modelling and DEcision making in Nuclear emergenCiEs

The H2020 CONFIDENCE Project aims to address existing gaps in several areas of emergency management and long-term rehabilitation. It concentrates on the early and transition phases of an emergency, but considers also longer-term decisions made during these phases. The work-programme of CONFIDENCE aims to understand and, if possible with the given resources, to reduce and cope with the uncertainty of meteorological and radiological data and their further propagation in decision support systems, including atmospheric dispersion, dose estimation, foodchain modelling and countermeasure simulations models. Consideration of social, ethical and communication aspects related to uncertainties is also considered. First attempts will be made to combine simulation with monitoring to help gaining a more comprehensive picture of the radiological situation. Decision making principles and methods will be investigated to understand the need for uncertainty handling in the decision making process. A comprehensive education and training programme is linked with the research activities.

TERRITORIES To Enhance unceRtainties Reduction and stakeholders Involvement TOwards integrated and graded Risk management of humans and wildlife In long-lasting radiological Exposure Situations

The TERRITORIES project targets an integrated and graded management of contaminated territories characterised by long-lasting environmental radioactivity, filling in the needs emerged after the recent post-Fukushima experience and the publication of International and European Basic Safety Standards. A graded approach, for assessing doses to humans and wildlife and managing long-lasting exposure situations (where radiation protection is mainly managed as existing situations), will be developed through reducing uncertainties to a level that can be considered fit-for-purpose. The overall outcome will be a first attempt to provide an umbrella framework, that will constitute the basis to produce, and disseminate, novel guidance documents for dose assessment, risk management, and remediation of NORM and radioactively contaminated sites as the consequence of an accident, with due consideration of uncertainties and stakeholder involvement in the decision making process.

ENGAGE: ENhancinG stAkeholder participation in the GovernancE of radiological risks for improved radiation protection and informed decision-making

ENGAGE seeks to identify and address key difficulties and opportunities for stakeholder engagement in three fields of exposure to ionising radiation: i/ medical use of ionising radiation, ii/ post-accident exposures, and iii/ exposure to indoor radon. The ENGAGE project is part of CONCERT European Joint Programme for the Integration of Radiation Protection Research' under Horizon 2020.

SHAMISEN SINGS project - Stakeholder INvolvement in Generating Science after Nuclear Emergencies

SHAMISEN-SINGS, building on the recommendations of the EC-OPERRA funded SHAMISEN project, aims to enhance Citizen Participation in preparedness for and recovery from a possible radiation accident through the evaluation and development of novel tools and APPs to support data collection on radiation measurements, health and well-being indicators.

The project's goals:

- Interaction with stakeholders to assess their needs and interest in contributing to dose and health assessment through the use of new technologies, for example, mobile applications (APPs);
- Review of existing APPs for citizen-based dose measurements and for health monitoring, establishing minimum standards of quality. Develop a core protocol for a possible citizen-based study on health, social, and psychological consequences in the case of a radiation accident;
- Develop the concept/guidelines for one or more APPs that could be used to monitor one's radiation dose (possibly contributing to radiation exposure assessment after an accident including visualisation of real-time radiation conditions), and log behavioural and health information. In addition to contributing to citizen science studies, these Apps would be designed to provide a channel for practical information, professional support and dialogue, as needed by stakeholders.
- Address ethical issues related to the use of these Apps through a consensus workshop.

11. ANNEX 3. NERIS supported training courses

Preparedness and response for nuclear and radiological emergencies

The course on "Preparedness and response for nuclear and radiological emergencies" addresses the state of the art in nuclear and radiological emergency management including the latest international recommendations, the lessons learned from the Fukushima accident and the challenges we still face. The main objective is to provide fundamental knowledge and practical advice to all actors involved in emergency planning and response. Main topics in the course are the principles of intervention; radiological evaluations; decision-support tools; different aspects of planning and organization in off-site emergency response; economic, social and psychological impact; European Community legislation; and international data and information exchange. The course is organized by the SCK•CEN Academy for Nuclear Science and Technology, in collaboration with the main European emergency management actors and the European platform NERIS (Preparedness for Nuclear and Radiological Emergency Response and Recovery). It is building on over 20 years of organizing this international course in different frameworks and it is organised on a yearly basis: see https://academy.sckcen.be/en/Customised_trainings/Open_courses/Open_emergency

Late Phase Nuclear Accident Preparedness and Management

The Training Course on "Late Phase Nuclear Accident Preparedness and Management" is organised by the Nuclear Protection Evaluation Center (CEPN - France) and the Institute of Radiology (RIR - Belarus) in cooperation with the European platform NERIS on emergency and post-accident preparedness and response. The training course is co-funded by the European Joint Program for the integration of radiation protection research CONCERT. The main objective of the course for late phase nuclear accident preparedness and management is to provide principles and practical guidance for the key players involved in the preparedness and recovery of living conditions in contaminated areas in the aftermath of a nuclear/radiological accident.

The course offers a comprehensive overview of the various dimensions and challenges of the long-term rehabilitation. It includes also practical elements for the implementation of countermeasures for managing long-term contaminated rural and urban environments, notably through the planning of direct meetings and dialogue with local stakeholders (inhabitants, pupils, local authorities, etc.) living in the areas affected by the Chernobyl accident.

The course is based on international recommendations and on the material produced and developed in several European and international projects: ETHOS, SAGE, FARMING, CORE, EURANOS, NERIS TP, etc. as well as the first results obtained under PREPARE and SHAMISEN programs. The course is made of lectures, practical working sessions, technical visits and discussions. It strongly relies on the practical experience of Belarussian organisations in the management of the Chernobyl consequences as well as on the first lessons from the management of the consequences of the Fukushima accident.

12. ANNEX 4. User groups - Decision Support Systems

The ARGOS Consortium

PDC (Prolog Development Centre) and DEMA (Danish Emergency Management Agency) originally developed the ARGOS system to be used for CBRN(E) Emergency Preparedness and Response. In 2001 the ARGOS Consortium was founded to give other organizations the possibility to use ARGOS and participate in the further development. The purpose and mission of the ARGOS Consortium is to establish a forum for exchanging knowledge and ideas about the use of ARGOS, and to further develop the system to become the best possible tool for emergency preparedness and response. The Consortium arranges annual meetings where all members have the opportunity to influence the development of the system. New ideas and cases are discussed and the members decide on which new facilities to develop, which new models to include, etc. This way, the ARGOS Consortium ensures a user driven development of ARGOS. New members can enter the Consortium and get access to ARGOS license free - but there is an annual member fee that covers future developments and maintenance. ARGOS integrates and relies heavily on models from several Consortium Partners. ARGOS supports emergency management organizations in 13 countries covering more than 400 million people worldwide.

The RODOS user group

The RODOS Users Group (RUG) has the following objectives

- To provide a platform through which the members of the RUG can communicate their views, needs and comments and exchange their experience related with all elements of the RODOS system and its use, in particular provide response and guidance on refinements to make the system more user friendly and for any future developments of RODOS.
- To share experience gained while integrating RODOS in the national emergency management arrangements, and to enable RUG members to enhance their own arrangements.
- To identify best practices, to share technical know-how and organisational solutions, software developments and data bases and their implementation, and to provide mutual support, particularly on a regional basis.
- To share practice and solutions related with use of RODOS for training and in exercises.
- To provide a forum through which the members of the RUG can network with each other, independent of the RUG’s activities.
- To establish contacts to the User Groups of other decision support systems within Europe (e.g. ARGOS) and overseas.
- Strive at reaching compatibility of the RODOS system with other decision support systems.
- To ensure sustainability of the RODOS decision support system through the establishment of maintenance procedures and sustainable arrangements between the users and the developers.
- Promote the use of RODOS in Europe.

RODOS user group meetings are organized on a yearly basis and last in general for 2 days. In general a European RODOS user hosts the meeting.

Strategic Research Agenda for Radioecology

3rd version

30/11/2019

European Radioecology Alliance
http://www.er-alliance.eu/

IRSN – 31, Avenue de la Division Leclerc - BP 17
F-92265 Fontenay aux Roses Cedex

Abstract

…

The European Radioecology Alliance

The member organisations of the European Radioecology Alliance (ALLIANCE)[1] bring together parts of their respective research and development programmes into an integrated programme that addresses scientific and educational challenges in assessing the impact of radioactive substances on humans and the environment and that maintains and enhances radioecological competences and experimental infrastructures. This integration is important and required to enable tackle complex radioecological challenges that could not be dealt with by one organisation alone.

To address emerging issues in radioecology within Europe, eight founding organisations signed a Memorandum of Understanding (MoU) in 2009 that formed the ALLIANCE. The MoU states the intentions of ALLIANCE members to integrate a portion of their respective R&D efforts into a trans-national programme that will enhance and sustain European radioecological competences and experimental infrastructures. The MoU asserts that ALLIANCE members will jointly address scientific and educational challenges related to assessing the impacts of radioactive substances on humans and the environment.

The ALLIANCE members, at present incorporating an expanding number of organisations, recognise that their shared radioecological research can be enhanced by efficiently pooling resources among its partner organizations and prioritising group efforts along common themes of mutual interest. A major step in this prioritisation process was to develop a Strategic Research Agenda (SRA). This is one of the tasks of the SRA Working Group of the ALLIANCE.

The ALLIANCE is an Association open to other organisations with similar interests in promoting radioecology, both within and outside of Europe. Thus, although the development of the SRA was largely a European effort, the hope is that it will stimulate an open dialogue within the international radioecology community.

The list of the ALLIANCE members at the date of the 2019 General Assembly is given below.

[1] European Radioecology Alliance http://www.er-ALLIANCE.org/, the association created by 8 founding organizations in Europe to integrate radioecological research in a sustainable way; also referred to the Radioecology Alliance.

Table 1 – List of the ALLIANCE member organisations and representative persons in Working Groups

ALLIANCE members *year subscription and representative persons (**ALLIANCE contact** in bold)*	**EJP CONCERT Working Groups**				**Topical Roadmaps Working Groups**				
	SRA & Roadmap	**Education & Training**	**Infrastructures & Sustainability**	**Stakeholders**	**Human food chain modelling**	**NORMs**	**Marine radioecology**	**Atmospheric transfer**	**Transgeneration. & radioSensitivity**
SCK.CEN - Nuclear Research Center - Belgium (founding member - 2012)									
Hildegarde Vandenhove	x		x			x			
Nele Horemans	x		x						**x lead**
Jordi Vives i Batlle	x	x					**x lead**		
Lieve Sweeck	x				x	x			
Nathalie Vanhoudt					x	x			
Talal Al Mahaini					x	x			
DSA - Radiation and Nuclear Safety Authority - Norway (formerly NRPA - founding member, 2012)									
Jelena Mrdakovic Popic	x			x		x			
Anne Liv Rudjord			x						
Justin Brown					x				
Mikhail Iosjpe							x		
Bredo Moller								x	
Dag Brede									x
IRSN - Institute for Radiological Protection and Nuclear Safety - France (founding member, 2012)									
Rodolphe Gilbin	**x lead**	x							x
Celine Duffa	x						**x lead**		
Olivier Masson	x							**x lead**	
Laureline Fevrier			x			x			
Marie Simon-Cornu					x				
Sylvain Bassot						x			
Chartlotte Cazala						x			
Rodolfo Gurriaran								x	
NERC-CEH - Centre for Ecology & Hydrology - UK (founding member, 2012)									
Nick Beresford	x	**x lead**			**x lead**	x	x		x
Catherine Barnett		-			**x lead**				
Dave Spurgeon		-			-				x
STUK - Radiation and Nuclear Safety Authority - Finland (founding member, 2012)									
Sisko Salomaa				-	-	-	-	-	-
Maarit Muikku	x		x						
Pia Vesterbacka			x			x			
Tuomas Peltonen					x				
Juhani Lahtinen					x				
Antti Kallio						x			
SSM - Radiation Safety Authority - Sweden (founding member, 2012)									
Karolina Stark	x				x				x
CIEMAT - Center for Energy, Environmental and Technological Research - Spain (founding member, 2012)									
Almudena Real	x	x	**x lead**			x		x	
Danyl Perez-Sanchez			-		x				
Juan Carlos Mora			-			x	x		
Catalina Gascó			-					x	
MªAntonia Simón			-					x	

Table 1 *(cont'd.)*

ALLIANCE members **Table 1** *(cont'd.)*	**EJP CONCERT Working Groups**				**Topical Roadmaps Working Groups**				
	SRA	**E&T**	**Infra**	**Stkhlds**	**Food Chain**	**NORM**	**Marine**	**Atmo**	**TESS**
BfS - Federal Office For Radiation Protection - Germany (founding member, 2012)									
Martin Steiner	x		x	**x lead**	x	x	x		
Bernd Hoffmann				-	x	x			
Jacqueline Bieringer				-				x	
Christopher Strobl				-				x	
CEA - Alternative Energies and Atomic Energy Commission - France (2014)									
Laure Sabatier									
Catherine Berthomieu	x					X			
Virginie Chapon						x			
Jacques Bourguignon					x	x			
Olivier Evrard							x		
Dominique Calmet								x	
NNCRK - National Nuclear Centre of the Republic of Kazakhstan (2014)									
Sergey Lukashenko									
Zhanat Baigazinov					x				
HMGU - Helmholtz Zentrum München - Germany (2014)									
Jochen Tschiersch	x							**x lead**	
Jan Christian Kaiser									
HZDR - Helmholtz-Zentrum Dresden-Rossendorf - Germany (2014)									
Thuro Arnold	x					**x lead**			
Susanne Sachs	x					**x lead**			
Karim Fahmy									x
EPA - Environmental Protection Agency - Ireland (2014)									
Simon O'Toole	x						x		
GIG - Central Mining Institute - Poland(2015)									
Boguslaw Michalik	x	x	x		x	x			x
Malgorzata Wysocka									
Krystian Skubacz								x	
Izabela Chmielewska									x
IST - Technical University of Lisbon - Portugal (2015)									
Maria José Madruga	x				x	x			
Isabel Paiva		x				x			
José Corisco			x		x	x			
Mário Reis				x	x	x			
NMBU-CERAD - Center for Environmental Radioactivity - Norway (2015)									
Brit Salbu	x							x	x
Lindis Skipperud		x				x			
Ole Christian Lind			x					x	
Hans Christian Teien			x				x		
Deborah Oughton				x	x				
Yevgenia Tomkiv				x					
IMROH - Institute for Medical Research and Occupational Health - Croatia (2015)									
Ivica Prlić						x			

Table 1 *(cont'd.)*

ALLIANCE members	EJP CONCERT Working Groups				Topical Roadmaps Working Groups				
Table 1 *(cont'd.)*	**SRA**	**E&T**	**Infra**	**Stkhlds**	**Food Chain**	**NORM**	**Marine**	**Atmo**	**TESS**
Marin Mladinic						x			
NCSR Demokritos - Institute of Nuclear and Particle Physics - Greece (2016)									
Kostas Eleftheriadis								x	
Eleni Florou					x				
CLOR - Central Laboratory for Radiological Protection - Poland (2016)									
Paweł Krajewski	x		x			x			
Krzysztof Ciupek		x							
UB - University of Barcelona - Spain (2016)									
Miquel Vidal	x	x	x		x	x			
Anna Rigol					x				
LARUEX - Environmental Radioactivity Laboratory of the University of Extremadura - Spain (2017)									
Francisco Jav. Guillén Gerada		x	x		x	x	x	x	
UPV-EHU - University of the Basque Country - Spain (2017)									
Fernando Legarda	x				x				
Margarita Herranz		x				x			
Raquel Idoeta			x			x			
Saroa Rozas					x				
UGR - University of Granada - Spain (2017)									
Mohamed L. Merroun	x	x				x			
Thünen Institute (2017)									
Marc-Oliver Aust									
Pedro Nogueira	x				x		x		x
University of Porto - Portugal (2018)									
Ruth Pereira						x			x
University of Aveiro - Portuga (2018)									
Sonia Mendo						x			x
Joana Lourenço						x			x
Leibniz Universität Hannover - Germany (2019)									
Georg Steinhauser		x			x			x	
Clemens Walther		x			x				
NRG – Consultancy & Services - Netherlands (2019)									
Govert de With	x				x	x	x		
CNRS-IN2P3 - National Institute of Nuclear Physics and Particle Physics - France (2019)									
Gilles Montavon						x			
IER - Institute of Environmental Radioactivity at Fukushima University - Japan (2019)									
Hirofumi Tsukada									

Preface and Executive Summary

The ALLIANCE Strategic Research Agenda (SRA) devoted to radioecology is a living document that defines a long-term vision (20 years) of the needs for, and implementation of, research in radioecology in Europe. Initiated by the STAR[2] Network of Excellence (Hinton et al., 2013), the current reference document is the third version of our SRA. It integrates the update of the research strategy implemented under the EU funded COMET[3] project (Garnier-Laplace et al., 2018). The CONCERT European Joint Program (EJP) extended the opportunity for **integration at the European level in a synchronised manner for all the platforms for research in radiation protection** by coordinating the release of a joint research roadmap for all platforms, planned in December 2019. This reference document, shared by stakeholders and researchers, will serve as an input to those responsible for defining EU research call topics.

This updated version of the SRA constitutes the ALLIANCE contribution to the CONCERT WP2 task for the development of SRA, roadmap and priorities for research on radioecology. A first activity was to make sure that recent scientific knowledge from radioecology (research outputs from the EC-funded projects (STAR, COMET and CONCERT funded projects: CONFIDENCE, TERRITORIES), main research advances from the ALLIANCE members and relevant international research outputs was integrated. Thus, it considers the state of radioecology and the stakeholders views, the interests of ALLIANCE member organisations, the research needs, data gaps and recommendations for the future of radioecology, and its sister science of ecotoxicology.

Research in radioecology and related sciences is justified by **drivers of various types**, such as policy changes, scientific advances and knowledge gaps, radiological risk perception by the public, integration of research infrastructures, education and training to serve recruitment, lessons learned from the Fukushima disaster and a growing awareness of interconnections between human and ecosystem health. This version of the SRA is formulated by considering several aspects related to these drivers.

Furthermore, it explores how **social and human sciences**, including ethical developments and communication issues, could contribute to the consolidation of European radiation protection culture, bringing together human perceptions and behaviour with science and technology. Research and innovation supporting the implementation of the revised European Basic Safety Standards is also considered.

The strategy underlying the SRA development and its implementation within a roadmap is driven by the need for **improvement of mechanistic understanding across radioecology, such that we can provide fit-for-purpose human and environmental impact/risk assessments in support of protection of man and the environment, in interaction with society and for the three exposure situations defined by the International Commission on Radiological Protection**, ICRP (i.e., planned, existing and emergency).

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[2] https://radioecology-exchange.org/content/star

[3] https://radioecology-exchange.org/content/comet

Adequate research **infrastructures and capabilities** (facilities, equipment, methods, databases and models) are a necessary resource for state-of-the-art radioecological research. Ideas about how to study and evaluate the behaviour and impacts of radiation and radionuclides on the living world are changing. Consequently the required infrastructure and capabilities are also changing. Therefore, the updated version of the SRA specifically addresses the research infrastructures and capabilities needs in this SRA.

Implementation of the SRA and the future of radioecology will depend on scientists and professionals being trained with skills relevant to industry and the needs of other stakeholders. It is critical for a vibrant science to continually attract and recruit bright, young talents into the discipline. Thus, the updated version of the SRA also includes a section on **education and training challenges in radioecology**, the associated vision and key action lines.

The SRA prioritises **three important scientific challenges** that radioecology needs to address. Each of these scientific challenges includes a vision statement of what should be accomplished over the next 20 years, followed by key research lines required to accomplish the vision. Addressing these challenges is important to the future of radioecology to enable the science to provide adequate scientific knowledge and tools to decision makers and the public. Other European platforms, among MELODI (Low-dose health effects), NERIS (Emergency preparedness and post-emergency management), EURADOS (Dosimetry of ionising radiation), have expressed common interests for some of the research lines.

The three scientific challenges presented below, with their **14 associated research lines**, are a strategic vision of what radioecology could achieve in the future through a directed effort and collaboration by many organisations. It is a vision in which the participants were asked to think creatively and without boundaries as they imagine the results that could most shape the future of radioecology and benefit stakeholders.

Challenge one: **To Predict Human and Wildlife Exposure in a Robust Way by Quantifying Key Processes that Influence Radionuclide Transfers and Exposure**

Our strategic vision is that over the next 20 years, radioecology will have achieved a thorough mechanistic conceptualisation of radionuclide transfer processes within major ecosystems (terrestrial, aquatic, urban), and be able to accurately predict exposure to humans and wildlife by incorporating a more profound understanding of environmental processes.

Research Lines:

1. Identify and mathematically represent key processes that make significant contributions to the environmental transfers of radionuclides and resultant exposures of humans and wildlife
2. Acquire the data necessary for parameterisation of the key processes controlling the transfer of radionuclides
3. Develop process-based transfer and exposure models that incorporate physical, chemical and biological interactions and associated kinetics, and enable predictions to be made *spatially and temporally*
4. Represent radionuclide transfer and exposure at a landscape or large geographic scale with an indication of the associated uncertainty

Challenge two: **To Determine Ecological Consequences under Realistic Exposure Conditions**

Our strategic vision is that over the next 20 years radioecology will have gained a thorough mechanistic understanding of the processes inducing radiation effects at different levels of biological organisation, including the consequences on ecosystem integrity, and be able to accurately predict effects under realistic exposure conditions.

Research Lines:

1. Mechanistically understand how processes link radiation induced effects in wildlife from molecular to individual levels of biological complexity
2. Understand what causes intra-species and inter-species differences in radiosensitivity (i.e. among cell types, tissues, life stages, among contrasted life histories, influence of ecological characteristics including habitats, behaviour, feeding regime...)
3. In a broader exposure context, understand the interactions between ionising radiation effects and other co-stressors
4. In a broader ecological context, understand the mechanisms underlying multi-generational responses to long-term ecologically relevant exposures (e.g., maternal effects, hereditary effects, adaptive responses, genomic instability, and epigenetic processes).
5. Understand how radiation effects combine in a broader ecological context at higher levels of biological organisation (population dynamics, trophic interactions, indirect effects at the community level, and consequences for ecosystem functioning)

Challenge three: **To Improve Human and Environmental Protection by Integrating Radioecology**

Our strategic vision is that over the next 20 years radioecology will develop the scientific foundation for the holistic integration of human and environmental protection, as well as their associated management systems.

Research Lines:

1. Integrate uncertainty and variability from transfer modelling, exposure assessment, and effects characterisation into risk characterisation
2. Integrate human and environmental protection frameworks
3. Integrate the risk assessment frameworks for ionising radiation and chemicals
4. Provide a multi-criteria perspective including decision support systems for an optimised decision-making
5. Towards better interaction and integration of radioecology with other disciplines, including social sciences and humanities (SSH)

The reality is that the SRA will require considerable resources and time to bring to fruition. The "how", "means" and "practicality" of accomplishing the research items presented in the SRA are being developed in **topical roadmaps** that have been initiated by the COMET project, with the help and endorsement of the ALLIANCE Working Groups (WGs), on five priority subjects:

1. Marine Radioecology.
2. Human food chain.
3. Naturally Occurring Radioactive Materials (NORM).
4. Atmospheric Radionuclides in Transfer Processes.
5. Transgenerational Effects and Species Radiosensitivity.

The topical roadmap WGs regularly reviews the various roadmaps at a higher level to ensure that they are being consistent and complementary, without substantial overlaps, and without significant gaps. Their inputs were considered in this version of the SRA. Furthermore, a constant effort is to ensure that the roadmaps are translated effectively into adequately funded research programs, with funding at intra-national, national and international levels.

The vision statements of our strategic agenda concentrate on the research aspects of radioecology. The Strategic Agenda also includes plans for other equally important aspects of our science (i.e. maintaining crucial radioecological infrastructures and knowledge management).

Thanks to this work, the ALLIANCE has now the constituents to build a global roadmap with other research platforms in Radiation Protection. This will be the main output from the WP3 of the CONCERT EJP. This global roadmap will help in giving visibility to priority research to be implemented consistently with stakeholders' needs and request for associated funds. Based on building blocks constituted by topical roadmaps, the ALLIANCE roadmap will be established and viewed as a global picture of the main achievements planned for the next 15 to 20 years.

For society to obtain a significant contribution from the radioecology of the future, a long-term, multidisciplinary approach is needed that goes beyond national boundaries. It is our hope that a Strategic Research Agenda for radioecology will focus and priorities our collective efforts, resulting in increased value and more rapid advancement in our understanding of environmental radioactivity.

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1. Introduction to the Strategic Research Agenda

Radioecology is a branch of environmental science devoted to a specific category of stressor: radioactive substances. The science includes key issues common with other groups of pollutants, particularly metals (e.g., environmental transport, speciation, bioavailability, and effects at various levels of biological organisation), as well as aspects specific to radionuclides (e.g., specialised source terms including radioactive particles, external irradiation pathway, radiation dosimetry, radioactive decay, and unique aspects of very low level measurements). Radioecology emerged as a science in the late 1940s and 50s in response to concerns about releases from nuclear weapons production facilities and radioactive fallout from nuclear weapons tests. Scientific studies of several subsequent accidents at nuclear facilities enhanced knowledge about radioecology; however, much of the early data was classified and not publicly available until the cold war ended in the late 1980s (Iiyin and Gubanov, 2004).

Radioecological expertise is needed whenever ionizing radiation within the environment is of potential concern. The CONCERT First Joint Roadmap Draft (Impens et al., 2017) grouped four contexts, from which three of them result from environmental release (or remobilisation) of radionuclides:

- **Human activities related to the nuclear energy cycle and other industrial applications** of ionising radiation not related to medical applications: Installations from the nuclear fuel cycle (from uranium mining through deposition of radioactive wastes); Industrial and scientific applications of ionising radiation; Military (former nuclear bomb testing sites, weapons fallout, nuclear-powered vessels.
- **Human activities related to the use of natural resources, containing naturally occurring radionuclides (NORM/ TENORM)**: Mining, processing, waste management of natural resources containing natural radionuclides (e.g. oil and gas extraction, NOR-rich ore mining); use, processing, recycling and waste management of technologically enhanced naturally-occurring radionuclides, including decommissioning of NORM affected industrial facilities; NORM contaminated legacy sites.
- **Natural radiation as source of ionising radiation**: terrestrial and cosmogenic radiation, natural events leading to radionuclide releases: High natural radiation background areas, potentially resulting in radon and thoron in indoor and outdoor air/ or in natural nuclides present in water/food; exposure to cosmic radiation at high-altitude or in space.

Seven exposure scenarios related those contexts have been identified and grouped according to the ICRP classification in planned, existing and emergency exposure situations. Five of these scenarios covers environmental exposure of the public and the ecosystems (two scenarios are not related to environmental exposures, i.e. patient exposure regarding medical applications and exposure of workers).

- Exposure of the general public, workers and the environment as a consequence of **industrial applications** of ionising radiation and the use of NORM in normal operation conditions.
- Exposure of the general public and the environment with regard to nuclear **legacy.**
- Exposure of the public and the environment to the **natural radiation** environment.
- Exposure of the general public, workers and the environment following a **major nuclear or radiological accident or incident** including long term consequences.

- Radiation protection of the public, workers and environment as a consequence of a **malevolent nuclear or radiological act** including long term consequences.

Following the Chernobyl accident, European research in radioecology excelled such that Europe's foremost expertise was widely recognised. Radioecology was faced with a substantial decrease in funding in the beginning of the 21st century leading to a decline of expertise. One major reason for the decline is that research efforts that were intensive during the years following the Chernobyl accident have substantially decreased. FUTURAE (2008), a Euratom Coordinated Action within the European Commission's 6th framework, surveyed the state of radioecology in Europe and found deficiencies in research, as well as in education, funding and infrastructure support. Following FUTURAE but also following the Fukushima disaster, where a call for radiological expertise from various embassies in Japan, alerted several government agencies to the scarcity of qualified personnel (e.g., U.S. case[4]). Since then there has been a small but steady European funding but also the responsible authorities in the different European member states invested again in radiation protection research.

This Strategic Research Agenda is a suggested prioritisation of research topics in radioecology, with a goal of improving research efficiency and more rapidly advancing the science. It responds to the question: "What topics, if critically addressed over the next 20 years, would significantly advance radioecology?"

The ALLIANCE is an Association open to other organisations with similar interests in promoting radioecology, both within and outside of Europe. Thus, although the development of the SRA has largely been a European effort, the hope is that it will stimulate an open dialogue within the international radioecology community:

- other pan-European platforms with research topics that require radioecology [Multidisciplinary European Low Dose Initiative (MELODI); European Platform on Preparedness for Nuclear and Radiological Emergency Response and Recovery (NERIS); Implementing Geological Disposal of Radioactive Waste Technology Platform (IGD-TP)];
- other radioecology networks around the world [e.g., National Centre for Radioecology (NCoRE), within the United States];
- the International Union of Radioecology (IUR);
- international organisations [e.g., World Health Organization (WHO); United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR); International Commission on Radiological Protection (ICRP), International Atomic Energy Agency (IAEA)];
- regulators;
- industry; and
- other interested stakeholders.

The original SRA was distilled from several evaluations on the state of radioecology, including input from stakeholders (FUTURAE 2008), the interests of ALLIANCE member organisations, the IUR[5], lists of research needs, identification of data gaps and recommendations for the future of radioecology, or its

[4] Information from presentation made by representatives of the U.S. Centers for Disease Control and Prevention during the annual meeting of the National Council on Radiation Protection (Washington, D.C.; 13 March 2012; see pages 13-14 of the 48th Annual MeetingReport):
http://www.ncrponline.org/Annual Mtgs/2012 Ann Mtg/Electronic NCRP 2012 Annual Mtg Program.pdf

[5] www.iur-uir.org/en/

sister science of ecotoxicology (Whicker *et al.* 1999; Hinton 2000; Brechignac *et al.* 2003; Calow and Forbes 2003; Brown *et al.* 2004; Eggen *et al.* 2004; Garnier-Laplace *et al.* 2004; Shaw 2005; Alexakhin 2006; OECD-NEA 2007; Brechignac *et al.* 2008; Larsson 2009; Pentreath 2009; Salbu 2009a; Repussard 2011; Artigas *et al.* 2012; Garnier-Laplace et al. 2018).

The updated SRA was formulated by considering a number of different drivers (Garnier-Laplace et al., 2018):

- *Credibility concerns*: Uncertainties and lack of predictive power in risk assessments are major contributors to the public's reduced credibility of the radiological sciences, and thus a major driver for additional research to enhance knowledge. Credibility of assessment models is particularly important because their predictions are often key constituents in decisions made about emergency response, waste management, environmental remediation, and mitigation (Whicker *et al.* 1999). Some of these uncertainties originate from the exposure assessment, which is largely dependent on knowledge of the environmental behaviour of radionuclides.
- *Generating trust*: The general public needs to have the necessary confidence in decision makers to be able to trust their judgements, advice and recommendations. The increasing environmental awareness of the public reinforces the need for clarity and transparency within the scientific community relative to the long-term ecological consequences of any nuclear accident or chronic exposure situation. For example, the divergent scientific opinions on the effects on human health and wildlife in the Chernobyl exclusion zone do little for public confidence. This means that multidisciplinary opinions, either consensual or divergent, have to be shared and used to revisit evidence and related actions. Even more, as it has been demonstrated in the event of a nuclear accident, scientific consensus does not always translate into consensus of action by authorities (e.g., Oughton 2011; Hasegawa 2012; Beresford et al 2016).
- *New paradigms and scientific advancements*: Recent changes relevant to radiation effects on humans are also relevant to radioecology, and go beyond the previous dogma of single target theory for cell survival as the only mode of action for cell death. New ideas are being incorporated into the science, such as epigenetics, bystander effects, genomic instability and population consequences from multigenerational exposures. Radioecology also must capitalize on the rapid advances in the "-omic" and AOP sciences to help develop mechanistic explanations and early warning biomarkers.
- *Changing policy*: The present framework of radiological protection is moving towards the need to demonstrate the protection of the environment explicitly as opposed to an assumption of protection. For example, this is seen in the revised versions of the international Basic Safety Standards (BSS) (IAEA 2011) and to a lesser extent, in the Euratom BSS (European Commission 2013) in their interim or draft status at the time of the SRA inception.
- *Integration issues:* Recognition that radioecology's future success, such as for example, meeting stakeholder needs, will require integration into the whole system of radiological protection. The recent ICRP rearrangement of its Committees to address protection of people and the environment in an integrated manner is a further indication of the recognition of this need.
- *Potential risks:* The lessons learned following the accidents at Three Mile Island (USA, 1979), Chernobyl (Ukraine, 1986) and Fukushima (Japan, 2011) demonstrate a number of knowledge gaps, with excessively large uncertainties associated with a number of environmental

processes governing the fate and effect of radionuclides within ecosystems. Future events (e.g. misuse of nuclear weapons, attack on nuclear installations, or use of dirty bombs containing many poorly researched radionuclides) may release radionuclides to the environment that are different from those for which we now have the most knowledge. This situation results in uncertainties in human and wildlife dose assessments, making it difficult to robustly support the decision-making process.

- *Impact of controversial findings:* In the context of ecological consequences of nuclear accidents, the growing number of peer-reviewed publications alleging ecosystem damage from radiation doses at the level of natural background (and sometimes even below) undermine credibility in radioecology. If such findings evidencing the biological effects of ionising radiation at very low dose rates are correct, both the systems for environmental protection and protection of humans from ionising radiation will be questioned.
- *The growing awareness by the public* of the importance of the global quality of environmental resources and biodiversity, with many examples of national regulations directed to the protection of the environment as a whole (e.g., nature conservation, uses of environmental resources, air, soil, water quality). Even more significantly, human and ecosystem health are now recognised as strongly interconnected as evidenced, for example, by several principles and goals for sustainable development recently agreed upon in the 2030 development agenda of the United Nations (2015).
- *The need for an integrated approach in order to improve the degree of realism in dose assessments* (and therefore in evaluations of the associated impacts or risks) either for the public or wildlife for a wide range of exposure situations. Going towards more site specific, individual (for humans) dose assessments to enhance realism imply a need to improve risk communication among stakeholders as to the most significant uncertainties.
- The need to develop applied research activities in order to *solve several statements of the new Euratom BSS* that are related to radioecology. These needs are urgent since the BSS are already being translated into corresponding national laws.

Based on consideration of the items above, the SRA prioritises three major **scientific challenges** facing radioecology. Each of these scientific challenges is developed as a separate section of the SRA and includes a **vision statement** of what should be accomplished over the next 20 years in that area of radioecology. The **Strategic Research Agenda** includes key research lines deemed necessary to accomplish the vision.

The three scientific challenges presented below, with their 14 associated research lines, are a strategic vision of what radioecology can achieve in the future through a directed effort and collaboration by many organisations. It is a vision in which the participants were asked to think creatively and without bounds as they imagine the results that could most shape the future of radioecology and benefit stakeholders. Implementation of the SRA and the future of radioecology will depend both on (1) adequate research infrastructures and capabilities (facilities, equipment, methods, databases and models) and (2) scientists and professionals being trained with relevant skills for industry and the needs of other stakeholders. It is critical for a vibrant science to continually attract and recruit bright, young talent into the discipline. Thus, the updated version of the SRA also includes a section on Infrastructures and Capabilities and on Education and Training challenges in radioecology, the associated vision and key action lines. Those sections includes inputs from the CONCERT WP6 (access to infrastructures) and WP7 (Education and Training).

2. Three Scientific Challenges in Radioecology

2.1. Challenge One: To Predict Human and Wildlife Exposure in a Robust Way by Quantifying Key Processes that Influence Radionuclide Transfers and Exposure

One of the fundamental goals of radioecology is to understand and predict the transfers of radionuclides and consequent exposure of humans and wildlife. This is needed for a wide range of sources and release scenarios, exposure situations and assessment contexts in atmospheric, terrestrial (agricultural, semi-natural, natural, urban) and aquatic (marine, freshwater, estuaries) environments. The problem is that the key processes that govern radionuclide behaviour, associated transfers among environmental compartments and resulting exposures are not always well understood, leading to models that have an incomplete (or even inaccurate) representation of the processes, i.e. model conceptual uncertainty. Scientific knowledge is gradually being accrued through on-going improvements in our understanding of these underlying processes. Hence in recent years, a number of research programmes have contributed to challenge 1 including EU-funded projects such as STAR, COMET with two associated COMET-FRAME and COMET-RATE projects, HARMONE associated to OPERRA, CONFIDENCE and TERRITORIES associated to CONCERT or national funded projects such as the French-funded projects (AMORAD) and the UK-funded RATE. The major achievements of these programmes can be summarised as follows:

- Improvement of **wildlife dose assessment** by initiating alternative models to the concentration ratio (CR) approach (Beresford et al. 2013, 2016, STAR) and exploring the application of Bayesian approaches (Hosseini *et al.,* 2013) and allometric models for wildlife (Beresford and Vives i Batlle, 2013, STAR).
- Assessments of **animal-environment interactions** were performed with the view of determining if current assessment models are fit for purpose (Aramrun et al., 2019; Hinton et al., 2015, 2019) and from these recommendations for improved field dose assessments (Beaugelin-Seiller et al. in-press, on-line) (STAR/COMET).
- **Regionalisation of radioecological food chain models** (Brown et al. 2018) and development of **taxonomy based models** for freshwater (Cs) and terrestrial wildlife species (Cs, Pb, Se, Sr and U) (Beresford et al. 2013; Beresford & Willey 2019; Søvik et al. 2017, COMET and OPERRA-HARMONE). Evaluation of these led to the recommendations that they need to bef urther parametrised for the edible portions of plants (currently the models are parameterised using green shoots only) (Beresford et al. 2019, CONCERT-CONFIDENCE).
- Development of **process-based soil-plant transfer models** (Almahayni et al., 2019, CONCERT-CONFIDENCE and Shaw et al. 2019, UK-funded RATE) and addition of a process-based sub-model in to an existing human food chain model (Almahayni et al., 2019, CONCERT-CONFIDENCE).
- For **NORM**, identification of the key processes for safety assessment studies using an FEP approach (Features, Events and Processes) to highlight future research priorities (COMET), but no EC-funded project
- For **marine radioecology**, a dynamic transfer model for biota was applied to the Fukushima environment (Vives i Batlle et al., 2016, COMET-FRAME), dynamic transfer modelling was further integrated with emergency methodologies (OPERRA-HARMONE) and different levels of complexity

of marine models were compared to simulate the West Cumbrian beaches, contaminated by releases from the Sellafield reprocessing facility (CONCERT-TERRITORIES).

- For **forest modelling** a handbook giving practical guidance on the need and applicability of process-based modelling in conjunction with other approaches from simple to complex, for modelling contamination in forests (Diener et al., 2017, COMET) and further in CONCERT-TERRITORIES to produce guidance in forest modelling. ECOFOR SVAT (a soil vegetation atmosphere transfer model), was fully developed and parametrized under controlled conditions at the Belgian NORM-contaminated forest Observatory (ECOFOR, Vives i Batlle et al., 2019), whereas another one was based on meta-analysis of Japanese data (Gonze & Calmon, 2017). A major achievement of these is including of incorporation as one of the key processes in cycling process-based models (Gonze & Calmon, 2017).
- For **radioactive particles**, progress was made in quantifying the processes of their transformation in the environment and associated radionuclide leaching and to assess their ecosystem transfer (Salbu et al., 2018, COMET-RATE). The CONFIDENCE project has for the first time begun to assess the relevance of particles when modelling human food chain transfer (Lind et al., 2019).
- Finally in the **aftermath of the Fukushima accident** a number of projects have studied the applicability of different models dynamic transfer models for marine biota to the Fukushima scenario. In this respect also the early stage dynamics of radiocesium in forest ecosystems, mainly driven by the rates of canopies depuration (returns to forest floor processes/fluxes) were investigated within several Japan-funded and a French-funded projects (AMORAD) for various species (Loffredo et al., 2015 ; Kato et al., 2019). Additionally translocation of forest contamination to other environmental compartments (rivers, watersheds), with potential entry into the food chain was investigated by Japanese colleagues ter (Laceby et al., 2016; Naulier et al., 2017).
  Within this context, some innovative methods for removing radionuclides from contaminated solid and liquid matrices were also developed and proposed as part of the « post-accidental » management of contaminated territories (eg. DEMETERRES project- Chagvardieff et al., 2017).

The challenge faced by radioecologists to date is to further incorporate this knowledge into models capable of realistically representing the behaviour of the radionuclides, ideally considering the different levels of organisation present in the environment, from small to large scales (i.e., from molecules to environmental compartments and global ecosystems). By making the models more realistic and process-based, we expect: (i) a significant reduction in model uncertainty; (ii) a better quantification of environmental variability; (iii) identification of the most influential parameters; and of parameters/factors contributing the most to the overall uncertainties, (iv) improved modelling tools capable of predicting radionuclide migration overtime and subsequent exposure to humans and wildlife under a variety of conditions, thereby enhancing predictive power and the robustness of both human and wildlife assessments of exposure to ionising radiation, and; (v) to be able to provide scientifically justified safety assessments for hypothetical future situations that need to take into account biogeochemical cycling of radionuclides over large time scales, changing climate conditions, and changing landscapes (Figure 1).

The input data and models needed for assessing the radiological environmental and human impacts differ depending on the source term, release conditions (aquatic versus atmospheric, routine versus accidental), assessment endpoints and the type of space- and time-dependency (dynamics and speciation) of the problem. The simplest is a static scenario in which the radionuclides are released in a continuous and uniform way which is in balance with physical decay, chemical and microbiologically influenced reactions and dispersion into the wider environment. This assumes the radionuclides to be in a "constant" equilibrium and is a reasonable (i.e. fit-for-purpose) approximation for most routine release and existing exposure situations. However, the approach has limitations for releases occurring on short time scales such as a planned series of rapid pulsed releases, accidental situations or simply when processes are influenced by dial and seasonal variations. In such events, a simplistic, empirical ratio approach is no longer valid and a dynamic, process-oriented modelling approach is required. **Fundamental research is hence needed to better understand and model the key dynamic processes, such that powerful dynamic process-based radioecological models can be parameterised and populated.** However, from recent consultation with industrial and regulatory end-users (Almahayni et al., 2019) a need to more clearly communicate the need and benefits for process-based models was demonstrated. This will include a need for validation of the models and an opportunity for the ALLIANCE (and other relevant platforms) to collaborate with the International Atomic Energy Agency within their model orientated programmes (e.g. EMRAS, MODARIA[6]).

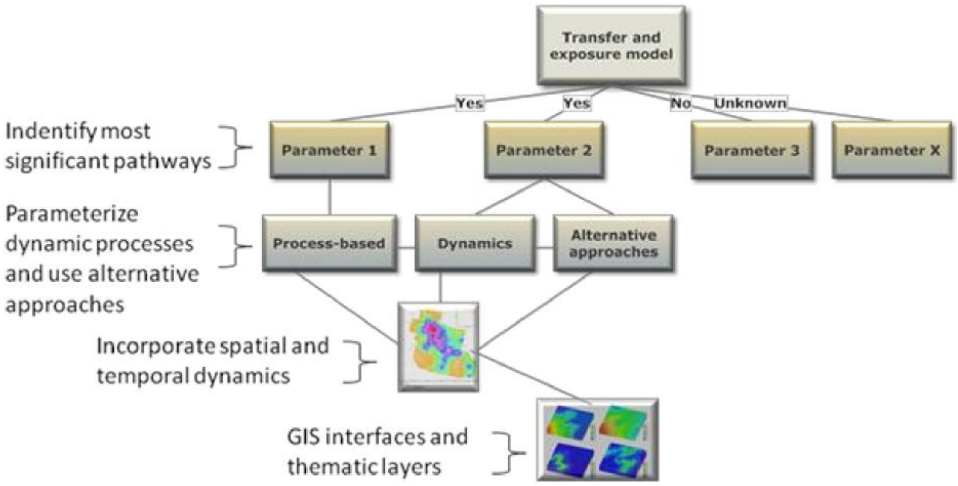

Figure 1. Scheme of key aspects to challenge one: To Predict Human and Wildlife Exposure More Robustly by Quantifying Key Processes that Influence Radionuclide Transfers, and Incorporate the Knowledge into New Dynamic process-based Models.

S**the description and assessment of the source term and its evolution**. For numerous elements soil-to-plant transfer factors were available for only 10 % of the plant and soil group combinations or were derived from only a single generic value estimated by expert judgment, or derived by analogy to a chemically similar element (IAEA 2009). The scarcity of data also increases with trophic level and stages in the human food chain. For approximately 50 % of the listed radionuclide-animal product combinations, no transfer coefficient data were available. The wildlife empirical ratios compiled by IAEA (2014) also have substantial data gaps and many of the values are based on few data (345 of 946 values for the generic wildlife groups are derived from less than 3 observations). The STAR-COMET-

[6]https://www-ns.iaea.org/projects/modaria/modaria2.asp?s=8&l=129

CONCERT-CONFIDENCE EURATOM funded projects and the UK sponsored TREE project[7] have advance extrapolation approaches (e.g. Beresford et al, 2016). However for a range of radionuclides assessments is still needed (Beresford et al. 2019x). These include radionuclides released by medical facilities (e.g. radioisotopes of Cr, F, Fe, Ga, Ho, In, La, P, Re, Sm, Tc, etc.); associated with the decommissioning of nuclear licenced sites (including, $^{108,108m}Ag$, ^{243}Am, ^{10}Be, ^{41}Ca, $^{152,154,155}Eu$, $^{55,59}Fe$, ^{203}Hg, ^{93}Mo, ^{22}Na, ^{93m}Nb, ^{147}Nd, ^{93m}Nb, ^{193}Pt, ^{46}Sc, ^{151}Sm and ^{182}Ta); relevant to fusion reactors (including activation products such as Fe, Ni, Mn); long-lived radionuclides associated with geological disposal facility assessments. For some of these radionuclides there are no existing data for either human or wildlife assessment, and no guidance on how to conduct an assessment given this lack of data.

Uncertainty also arrives from **the use of simple empirical ratios** in radiological assessment models (Ng, 1982; IAEA, 2009) as to represent the transfer between environmental media means aggregating many physical, chemical and biological processes into one parameter, and this is an implicit weakness of the approach leading to the observed variability and uncertainty in model predictions. For example, 'distribution coefficients' (K_d's) defined as a simple solid/water activity concentration ratio, assuming equilibrium conditions have been shown to vary by orders of magnitude under changing geochemical conditions. Therefore process-based dynamic models not relying on K_d's are supposed to describe the situation more realistically (Børretzen and Salbu, 2002). A major improvement here is to further develop the “smart Kd” concept (Stockmann et al., 2017) that relies on data bases of surface complexation constants which are combined with information from the respective field sample. Additionally, the large variation in soil-to-plant transfer factors for e.g., Cs among agricultural crops (IAEA, 2009) is mainly because soil processes affecting radiocaesium fluxes are not adequately captured by empirical ratios, even when grouped by soil texture classes. Alternatively, the semi-mechanistic model of Absalom et al. (1999) explained 60 to 90 % of the observed variability in Cs uptake by plants by including soil contamination level, clay content of the soil and the soil exchangeable K status. Further understanding of the chemical speciation of radionuclides in different soils, as well as the influence of microbiological processes, is crucial to understand and be able to describe the transport of radionuclides through the environment and the manner in which humans and other organisms are exposed to radiation. Improving our understanding and developing process-based approach should result in models which are globally applicable and potentially able to model the impact of soil-based countermeasures (e.g. Cox et al., 2005).

The environmental behaviour of radionuclides is controlled by **complex biological, chemical and physical processes** and may vary (1) spatially - due to differences in water chemistry, sedimentary dynamics, soil type, land use management, and diversity of biological assemblages and communities; (2) temporally - due to time after release, organism’s life stage, climatic stressors such as floods, storms, water cascading, biologically-driven processes, landscape evolution and scenarios of global change; and (3) with source term - due to history of the releases, physico-chemical forms (speciation), and presence of co-contaminants. Unfortunately, although these factors are acknowledged to be important and have been the focus of considerable research (*e.g.,* Salbu, 2009b; Vandenhove et al., 2007; Eyrolle *et al.*, 2009), they are still poorly developed in radionuclide transfer and exposure models. Spatially implemented process-based soil-crop models have previously been developed and incorporated into decision support systems (Gillett et al., 2001; Cox et al., 2005). However, such models have not been widely adopted likely because of poor communication of their benefits and lack of

[7]https://tree.ceh.ac.uk/

confidence by end-users as they are perceived to be too complicated (Almahayni et al., 2019). With respect to predicting the exposure of wildlife the potential importance of considering the extent to which spatial variability may need to be considered has been highlighted in studies which have attached dosimeters and GPS collars to animals in contaminated environments (Aramrun et al., 2019; Hinton et al., 2019 Jones et al., 2019, CONCERT TERRITORIES). Work in CONCERT-CONFIDENCE has begun to address the lack of data for Mediterranean food production systems (Guillén et al. 2019); similarly data have recently been provided for Mediterranean wildlife in collaboration with the COMET project (Guillén et al. 2018).

A gap generally exists between the **measurement scale typically used in research studies and the scale needed in management decisions and regulatory measures**. One of the reasons for this gap is that the understanding of radionuclide interactions in the environment is often based on small-scale observations or experiments, and it is not known how such processes or changes may affect key processes and functioning of environmental systems at larger scales. Therefore, understanding of spatial scales between and within environmental compartments and the impact from global circulation patterns needs to be expanded to provide improved assessment and management strategies for radionuclides released into the environment. This is particularly important in atmospheric and marine modelling as highlighted by the findings of COMET project FRAME regarding radionuclide transport processes in marine ecosystem near Fukushima (such as, for example, groundwater infiltration to sea) and of the IAEA MODARIA working group on marine dispersion modelling, also in Fukushima.

Process based models have **varying degrees of complexity** that depend on the situation modelled. Yet a process based model is not necessarily always too complex and may be easier to explain to the public than a 'black-box' model based on ratios and rate constants. The observation that the model complexity may change depending upon need has led to the suggestion that it would be useful to have one modelling package where different components are modularly assembled. The implementation of the FDMT food chain model, the 'Absalom' model and a sub-model for particle source terms into the EGOLEGO package within CONCERT-CONFIDENCE (Brown et al., 2018; Lind et al., 2019) are a good demonstration of how we could develop models in the future.

In summary, the priority given in this SRA to process-based modelling is based on sound science, the ability of such models to reduce modelling uncertainty, increased predictive power, their ability to treat dynamic situations, potential to model soil-based countermeasures and their higher transferability compared with empirical models. There is however, as already noted, a lack of uptake of the previously developed process-based models by end-users and we need good communication, training and the ability to demonstrate validation to improve this in the future.

2.1.1. Strategic vision for research

Our strategic vision is that over the next 20 years radioecology will have achieved a thorough mechanistic conceptualisation of radionuclide transfer processes within major ecosystems (terrestrial, aquatic, urban) for a wide range of source terms, release and migration scenarios and exposure situations, where relevant and needed, and be able to accurately predict exposure to humans and wildlife by incorporating a more profound understanding of environmental processes and assure that fit-for-purpose process-based models based on scientific modelling of the radioecological mechanisms will have found a way into future assessment tools.

2.1.2. Strategic agenda

The major aim of challenge one is to develop process based models of environmental transfer and exposure to substantially improve human and environmental dose and impact assessment. Research should be focussed on those factors contributing the most to uncertainties in exposure assessments. The developed process-based models will begin to form part of the next generation of assessment tools. They should also contribute to addressing the need for an integrated approach to human and wildlife exposure assessment.

The approach can be applied (with an appropriate level of complexity) to a wide range of sources encompassing existing (e.g. uranium mining and milling sites, NORM sites, post-accident situations), planned (*e.g.,* new build, (geological) waste disposal, NORM involving industries, medical radio-isotope and radiopharmaceuticals production facilities) and emergency (accident, incident, malevolent acts) exposure situations. Emergency situations are the focus of the SRA of NERIS so the radioecological related aspects will be researched and developed in close collaboration with NERIS); aspects of source-term characterisation, distribution and migration through food chains, development of countermeasures and remediation strategies are within the remit of Challenge 1 of the ALLIANCE's SRA. Related to (high-level) waste disposal our SRA will concentrate on the biosphere and geosphere/biosphere interaction zone, linking to networks such as BIOPROTA[8], IGD-TP[9] and EURADScience[10] as well as the IAEA MODARIA successor projects. Environments other than temperate ecosystems will be considered.

The mechanistic, process-based, approach should

- Enhance scientific knowledge about environmental processes and their mutual interactions. Radionuclides then become tracers to understand local and large scale processes, which in turn can help inform other disciplines (such as ecology, geochemistry and toxicology);
- Enable long-term forecasts and the influence of climate and landscape changes on the environmental transfers of radionuclides;
- Assist in the development of tools for response, remediation, and restoration; and
- Support multi-criteria analysis and hence decision making.

Validation of developed models will be important to ensure end-user uptake; there is potential for a strong collaboration with IAEA programmes in model validation.

2.1.2.1. Identify and mathematically represent key processes that make significant contributions to the environmental transfers of radionuclides and resultant exposures of humans and wildlife

A challenge for radioecologists over the next two decades is to develop a profound understanding of environmental transfers and exposure processes that permit observations to be explained and robust predictions to be made. The main aspects will be (i) identifying processes, parameters or factors that

[8] http://www.bioprota.org/
[9] http://www.igdtp.eu/
[10] http://hal.in2p3.fr/in2p3-02169313

contributes the most to the overall uncertainties, (ii) determine the level of model complexity needed for specific exposure scenarios and (iii) justifying the additional research required for data generation and to parameterise dynamic-mechanistic models.

Criteria will be developed to identify key processes that have a significant impact on radionuclide transfers in atmospheric, terrestrial, aquatic and built-up (e.g. urban) environments. For example through process sensitivity analysis developed in geological disposal safety assessment (Features, Events and Processes - FEP) where processes rather than parameters are varied/added/removed to test the optimum process representation in a radioecological model; this approach was applied by the COMET project and further refined by CONCERT-TERRITORIES. Amongst the model features considered will be source-term-specific release scenarios (including physico-chemical forms), spatial and temporal dynamics in source term–environment interfaces (dispersion and dilution, changes in radionuclide speciation due to physical, chemical and biological interactions), migration and cycling pathways in specific ecosystems, and radionuclide uptake, accumulation, redistribution and depuration by organisms. Once the key processes have been identified, equations will be derived that capture their temporal and spatial kinetics. Criteria to identify the relevant factors and processes could be inferred from the variability observed in aggregated parameters and the associated uncertainties in transfers, as shown by scatter plots of empirical transfer factor values and associated cumulative distribution functions. A classification based on key environmental characteristics, taxonomy, source term, etc. along with a scientific understanding of radioecological mechanisms, should help unravel and classify the processes underlying the aggregated parameters.

One of the goals of this research line is to identify the key processes, based on fundamental physical, biogeochemical and ecological principles that govern the transfer of radionuclides within major ecosystems types (*e.g.,* agricultural, grasslands, coniferous forests, freshwater lakes and rivers, marine systems, urban environments) or contexts (e.g. nuclear or NORM related industrial environments, waste disposal environments). Some elements of this knowledge may exist in other fields (e.g. soil scientists). This goal can be realised by the development of conceptual and mathematical test models allowing the identification and ranking of key processes in a quantitative, but also in a qualitative manner using expert judgement. Systematic model reduction can be applied to test the utility of the model components (e.g. Tarsitano et al., 2011). For the future, the verification of model predictions could better benefit from a comparison with observatory data.

Within this research line, we intend to progress further towards process-based dynamic models. Process-based modelling is essential to demonstrate that scientifically justified impact and safety assessments can be made for future situations. The various empirically-based model parameters will be replaced by mathematical equations that describe the key physical, chemical and biological processes that govern radionuclide transfers. Properties specific to radionuclides and the biotic and abiotic components of each environment will be incorporated. A key issue is then to validate the model outcome in the field. Examples include:

- relating the environmental mobility of radionuclides to their speciation resulting from the oxidising/reducing properties, pH, redox potentials, salinity, DOC, mineralogy, general chemical composition of environmental media or biological actors (e.g. microbial activity, presence of mycorrhiza);
- advection-dispersion equations for describing flow kinetics in aquatic environments;

- simulating rates of water movement in porous media; and
- metabolic theory for describing the biokinetics/toxicokinetics of contaminants in living organisms.

In all cases, the objective will be to produce a set of physically and dimensionally consistent primary differential equations that represent the temporal and spatial dynamics of processes governing radionuclide transfers. The equations will, to the extent possible, incorporate the material properties of the radionuclides and environments and, ultimately, the basic laws of nature. Knowledge on associated processes has advanced for post-accident situations (Cs, Sr, I) but is generally deficient for other exposure situations and contexts (unforeseen events, decommissioning of nuclear facilities, urban context, industrial environment) and the majority of other radionuclides. For some recently emerging radionuclides such as medical radioisotopes, data are missing but scoping calculations related to potential dose contribution are required before setting of too complex modelling.

It is important that the knowledge gained from the various research activities is rapidly assimilated and made available to the wider community. This is likely to require the development of flexible and open databases that do not 'force' the information into an over-constrained conceptual model framework, together with a platform (or platforms) for the modular development of mathematical models (as exemplified by recent work in the CONCERT-CONFIDENCE project (Brown et al., 2018; Lind et al., 2019).

2.1.2.2. Acquire the data necessary for parameterisation of the key processes controlling the transfer of radionuclides

Major data collection activities (such the IAEA handbooks of radioecological transfer parameters) have identified significant data gaps and limitations for many of the empirical parameters which underpin dose assessment models for humans and wildlife. The wide range of radionuclides, human foodstuffs and species of wildlife means that, pragmatically, we may never be in the position of having empirical data for everything.

There is a need to consider alternative approaches to address this lack of data for model parameterisation in the most robust manner possible (rather than relying on highly conservative judgment to avoid analysing the problem in more depth, as is often the case currently). Extrapolating across the periodic table using chemical analogues is such an approach. For example, in the context of the Fukushima accident, it was proposed that estuarine reactivity of short-lived radioactive tellurium could be assessed based on the behaviour of its stable analogue. Other approaches, such as Bayesian statistics, allow a low number of empirical observations to be supported by inferences from more comprehensive, larger datasets (this approach has been used in the parameterisation of the ERICA Tool (Brown et al., 2016)). Some approaches to extrapolate data have been suggested for application across species (wildlife species or human food chain species) such as phylogeny (*i.e.* using 'common ancestry' to categorise transfer) and allometric (mass dependent) relationships. These approaches have started to be advanced by activities in the STAR, COMET, CONCERT-CONFIDENCE and TREE projects (see above).

The data for model parameterisation will require focused laboratory-based work and field studies, as well as on-going reviews of published information from the wider scientific community (both at suitably-designated "observatory sites" and more generally from environmental monitoring). For example, a preliminary inventory of databases acquired from observatories and monitoring sites at the European scale by the various STAR partners highlighted the richness of environmental data, especially their temporal and spatial distributions, even though heterogeneity and data gaps were identified. The Belgian NORM site (Alliance observatory intensely investigated in CONCERT- TERRITORIES) proved the benefit of establishing mechanistic investigations in controlled conditions to scientifically explore process-based models (Vives I Battle, 2019). The Upper Silesia Coal Basin (another European radioecological observatory) was also investigated in CONCERT-TERRITORIES in order to explore the conceptual scheme of processes occurring in a Polish lake displaying NORM, including the occurrence of early diagenesis process (Mora et al., 2019). Even if less exhaustively informative, long-term data series obtained along routine surveillance programs can also provide information for transfer modelling (Brimo *et al*., 2019).

Some of the data gaps are expected to be filled by innovative analytical tool developments in both radioactive and non-radioactive metrology. For example, difficulties persist in quantifying the various radioactive decay products from the natural U-Th decay chains within the same sample at a given time. In this context, ICP-MS and AMS analyses offer potentially exciting solutions.

To maximise opportunities for data acquisition whilst minimising the environmental impacts of our science, a strategic focus should be placed on the development and adoption of non-lethal methodologies (which do not require animals to be killed) for use in radioecological research.

The ALLIANCE have highlighted the need for experimentalists and modellers to work together from project outset, in order to obtain the correct match and compatibility of models and the data necessary to parameterise them.

2.1.2.3. Develop process-based transfer and exposure models that incorporate physical, chemical and biological interactions and associated kinetics, and enable predictions to be made spatially and temporally

Accurate, process-based radioecological modelling reduces model conceptual uncertainty and can reduce the uncertainty of model predictions, leading to a greater confidence in the results. For example, the consideration of chemical and physical speciation of radionuclides and their effect on subsequent environmental transfer (*e.g.,* Salbu, 2009b; Salbu et al., 2018; Mitchell *et al.*, 1995) reduces the 1-order of magnitude discrepancy between the near-field and far-field K_d's in the assessment of plutonium releases from Sellafield. Likewise, assessments of the globally-circulating radionuclides ^{14}C and ^{3}H have been greatly improved by including the influence of stable carbon, nitrogen and hydrogen cycles in radionuclide transfers (*e.g.,* Schell et al., 1974). Knowing the early dynamics of radionuclide distributions following atmospheric deposition and marine releases has already played a major part in understanding the consequences of the nuclear accident at Fukushima. These developments are also crucial in context of site and environmental remediation. Hence, process-based and mechanistic models are also expected to advance countermeasure strategies and optimize site remediation and restoration.

The transfer models developed should be able to integrate radioactive contaminants into the general dynamics of ecological systems. An example is using pollutant-coupled soil-vegetation-atmosphere transport (SVAT) models to investigate the wider, long-term circulation patterns of radionuclides in the geosphere-biosphere interface (e.g. ECOFOR forest modelling as used in CONCERT-TERRITORIES), taking into account the biogeochemical (re)cycling of radionuclides over very long time-scales, changing climate conditions and evolving ecosystems or the coupling of radionuclide transfer biokinetic modelling with short-range, (e.g. coastal) dispersion with long-range movement of water and sediment dynamics to identify the ultimate fate of radionuclides in the aquatic environment (see COMET-FRAME). Ahead in the future lies the further coupling of such modelling with the climate-induced ocean global circulation patterns but also to include speciation in these dynamic models. Other understanding that should be improved includes the behaviour of radionuclides at interfaces (*e.g.*, atmosphere-water surfaces, land-coastal, watershed-freshwater courses, saline-freshwater, geosphere-biosphere, oxic-anoxic, air and water and built environment) and the influence of co-contaminants on radionuclide behaviour. Furthermore, progress is awaited on representing the redox behaviour in soil, influence of soil organisms on mobility and uptake by plants and other organisms in an integrated way, improving semi-mechanistic models such as the Absalom model. In addition, drivers of global change, such as climate variation and evolving hydrological and land use changes, will influence the transport, fate and effects of radionuclides in the environment, and therefore need to be considered. Ultimately, by using dispersion, transport and kinetic exchange equations and well-defined boundary conditions, a dynamic, process-based understanding can be incorporated into our models, especially for systems which are outside their biogeochemical equilibrium, fundamental for the understanding of accidental situations and incidents but also in the context of NORM (decay chains seldom in equilibrium). An analysis that relates to fundamental processes becomes conceptually simpler. Moreover, it facilitates performing the necessary abstractions and simplifications *a posteriori* (by way of a simplified description of less important sub-processes) rather than *a priori* (by way of insufficiently justified transfer parameters). In addition, as stated previously, it should be more feasible to communicate, to the public, a process-based model than an empirical model based on aggregated parameters which contain a lot of implicit assumptions.

Radioecology is particularly under-developed in analysing the interactions of substances with living organisms at the cell membrane level, as well as in considering the biokinetics of internally incorporated substances leading to their time-dependent distribution, assimilation and elimination. An expectation is that it will be possible to combine circulation, metabolism and elimination processes with toxicokinetics and consequently gain an understanding of the effects of internally deposited radionuclides (links with Challenge 2).

There is a need to assess wildlife exposure more realistically by considering spatial as well as temporal variability in for instance, habitat utilisation, contaminant densities and interactions between organisms, all of which impact animal movement and hence exposure in heterogeneously contaminated environments. During various life stages, dynamic processes may change many characteristics of an individual organism, such as weight, food intake, metabolism, internal contaminant concentration and the habitat in which they reside. These factors all influence the amount of contaminant intake and/or external irradiation levels. By modelling exposure dynamically and mechanistically, these changes can be taken into account. By introducing spatial heterogeneity models, it will be possible to take into account the organism's movements (*e.g.,* foraging behaviour, migration, burrowing or nesting in function of life history stages). An organism’s mobility in a heterogeneously contaminated area will contribute significantly to the variation in exposure observed between individuals. Recent studies in which GPS units and dosimeters were attached to free ranging animals show the potential impact of not taking these factors into account in assessments (Aramrun et al., 2019; Hinton et al., 2019). Advances in this area would have synergies with population modelling (Alonzo et al., 2016; Vives i Batlle et al., 2012) approaches being developed to better predict ecosystem level effects (links with Challenge 2). Animal mobility can be predicted using random or quasi-random walk models (Loos *et al.*, 2006). A particular potential of this approach is its ability to determine what individuals or populations of a particular species are more at risk, rather than treating all the individuals of a species in a given ecosystem as having received the same exposure. In present exposure models, these aspects are not yet considered though the use of agent based random walk models and mass-balance food-web approaches is currently being assessed[11].

Wildlife dosimetry is also in need of some advancements (e.g. Stark et al., 2017). Current wildlife dosimetry models are simplistic and generally describe organisms as single ellipsoid forms that are homogeneous in composition and contamination. We should evaluate, in connection with challenge 2 on effects assessment, how important it is to incorporate radionuclide-specific heterogeneous distributions within the body and microdosimetry measurement to be able to account for differences in sensitivity among various organs and to better assess the dose-response relationships in particular situations for improved future predictions. Initial simplistic investigations on this topic were carried out during the FASSET and ERICA EURATOM projects whilst other work has explored the use of voxel phantoms (e.g. Ruedig et al., 2015). Comparison of voxel phantoms (detailed three dimensional models which represent individual organs/tissues and can cope with heterogeneous distribution) with the simplistic ellipsoid used in assessment models have tended to demonstrate that for regulatory assessment the ellipsoid approach is generally sufficient (Ruedig et al., 2015). Where voxel phantoms will be of value is in the analyses of effects data, perhaps most especially from contaminated field sites with a mixed radionuclide profile (e.g. the Chernobyl Exclusion Zone). Skewed dose distributions from internally incorporated radionuclides (macro-distribution of radionuclides within organisms, but also the micro-distribution within specific organs and tissues, especially for alpha or beta emitters and for radioactive particles) also represent a challenge as it can significantly influence radiotoxicity. Studies in this field should involve collaboration with EURADOS on advanced dose assessment techniques and dose monitoring tools (e.g. the notable developments in microdosimetry). However, more basic improvement is also needed to reduce the uncertainties in environmental dosimetry, notably geometries used for plant are currently poor and do not necessarily consider the most exposed or sensitive plant parts (e.g. the geometry for a tree is represented by a section of trunk).

The Observatory Sites initiated under COMET and continued to be assessed under CONCERT-TERRITORIES (cf. 2.1.2.2) and with continued support of the ALLIANCE are excellent large-scale field laboratories with spatial variability. These site allow for multidisciplinary studies (radioecology, dosimetry, toxicology, hydrogeology, ecosystem approaches, etc.), long-term investigation of environmental processes, parameter value generation, modelling tool testing and validation within real systems. Observatory sites have been established in Chernobyl and Fukushima but also NORM contaminated sites are established. The Observatory Sites will be receiving due attention and further development as an essential radioecological 'infrastructure' (see also section §4 - Strategic Agenda for Infrastructures).

[11] https://gnssn.iaea.org/RTWS/modaria/Shared%20Documents/MODARIA%20II/3rd%20MODARIA%20II%20Technical%20Meeting/25th%20October%202018%20-%20TM%20Closing%20Plenary%20Presentations/06%20-%20WG5%20TM3%20Closing%20Presentation%20(Beresford+Vives).pdf

2.1.2.4. Represent radionuclide transfer and exposure at a landscape or large geographic scale with an indication of the associated uncertainty

The objective of this research line is to improve the current status by mapping radionuclide transfer and exposure at the European or global scale based on thematic maps, including spatial and temporal variability, using the newly developed process-based models. Since geographical distributions of radionuclides tend to be highly heterogeneous (Van der Perk *et al.*, 1998), a detailed understanding is needed of radionuclide transfer processes at multiple scales. Within this research line we intend to design and implement a user-friendly, state-of-the-art GIS interface with the developed models, facilitating mapping of radionuclide transfer and exposure at a landscape level to identify sensitive environmental compartments/areas. An added benefit of such development could be the integration of knowledge at the European level (interaction with challenge 3). Improvements in spatial dimensioning are still needed by incorporating better process-based approaches. Such an approach was proposed by Gonze et al. (2016) who modelled at the landscape level air dose rates with a process-based dynamic approach. This priority should be further developed in collaboration with NERIS), as they are of specific interest for post-accident situations.

An important task here will be to bridge the previously-mentioned difference between the small scales at which radionuclide behaviour and transport are often studied and the larger scales often relevant for management decisions, also in context of site and environmental remediation. A GIS interface could include reference values (geochemical or anthropogenic backgrounds) and thus provide useful means to evaluate the level of exposure. The changing exposure conditions experienced by wildlife animals as they traverse and utilise various habitats with heterogeneous contamination could also be incorporated and visualised to improve our understanding of the exposure conditions and, as result, reduce uncertainties in the environmental assessment. Thematic maps of different terrestrial variables such as land use, soil type, leaf area index and crop coefficient, local climate, etc. will be linked to the radionuclide transport datasets. Such a system will enable robust environmental exposure predictions at various scales, allowing advanced visualisation of the complex interactions between radionuclides and the various environmental properties and processes. It would also enable the modelling (if appropriately parameterised) of countermeasures (as exemplified by Cox et al., 2005).

2.2. Challenge Two: To Determine Ecological Consequences under Realistic Exposure Conditions

There is a growing awareness by the public of the importance of the global quality of environmental resources and biodiversity, with many examples of national regulations directed to the protection of the environment as a whole (e.g., nature conservation, uses of environmental resources, air, soil, and water quality). Even more significantly, human and ecosystem health are now recognised as strongly interconnected as evidenced, for example, by several principles and goals for sustainable development recently agreed upon in the 2030 development agenda of the United Nations (2015).

This challenge is of high priority regarding new regulatory requirements for the radioprotection of the environment which has shifted during the last decade from an implicit to an explicit environmental protection. The IAEA's Fundamental Safety Principles (IAEA, 2006), revised ICRP Recommendations (ICRP, 2007), the revised versions of the international Basic Safety Standards (BSS) (IAEA, 2011) and to a lesser extent, the Euratom BSS (European Commission 2013) promote developing guidance on wildlife radiological risk assessments and, as a consequence, espouse the need for ecological protection criteria of radioactively contaminated environments. Acquiring new scientific results on which decisions can be based is key to answering social concerns about (eco)toxic effects from ionising radiation and its ecological consequences.

Over the last 20 years, international efforts have focused on new strategies for protecting the environment from radioactive substances e.g. by setting up an effects database for non-human species (FREDERICA) (Copplestone et al., 2008) and producing screening ecological benchmarks needed to implement a tiered Ecological Risk Assessment approach (ERA) [(FASSET (Williams, 2004), ERICA (Larsson, 2008), PROTECT (Howard et al., 2010)]. Whilst the ERA-type approach is a substantial advancement in radioecology, a lack of sufficient data prevents current ERA analyses from fully accounting for the realistic environmental conditions that organisms are actually exposed and ecological processes that are actually affected.

Data are still insufficient to take into account low dose effects, variable dose rate regime, dose deposit heterogeneity (from molecular targets up to individuals and ecosystems), multi-contaminant scenarios (including the different exposures from external irradiation and internal contamination), species variation in radiation sensitivity due to life-history traits, community or ecosystem level effects. Such knowledge gaps are accounted for via extrapolation and the use of assessment factors (or safety factors) that add conservatism and increase uncertainties in predictive risk assessments. The vision of this SRA is to address such deficiencies (Figure 2).

There exists still considerable scientific disagreement on the actual extent of the radiation effects on wildlife in contaminated areas. Many studies have reported no significant effects of radiation on wildlife (e.g. in the Chernobyl and Fukushima exclusion zones), whereas others reported significant radiation effects on different wildlife groups at very low dose rates (below natural background exposure) (Beresford et al., 2016; Chesser and Baker, 2006; Moller and Mousseau, 2009, 2016; Beresford et al., 2019; Fuller et al., 2019). This controversy challenges the ecological protection criteria published by research groups, as well as international organisations that issue guidance for radiological exposures. Several protection criteria with different ways of derivation and different protection purposes are established (UNSCEAR, 2008; ICRP, 2008; Anderson et al., 2009; Garnier-Laplace et al., 2010); ICRP, 2014).

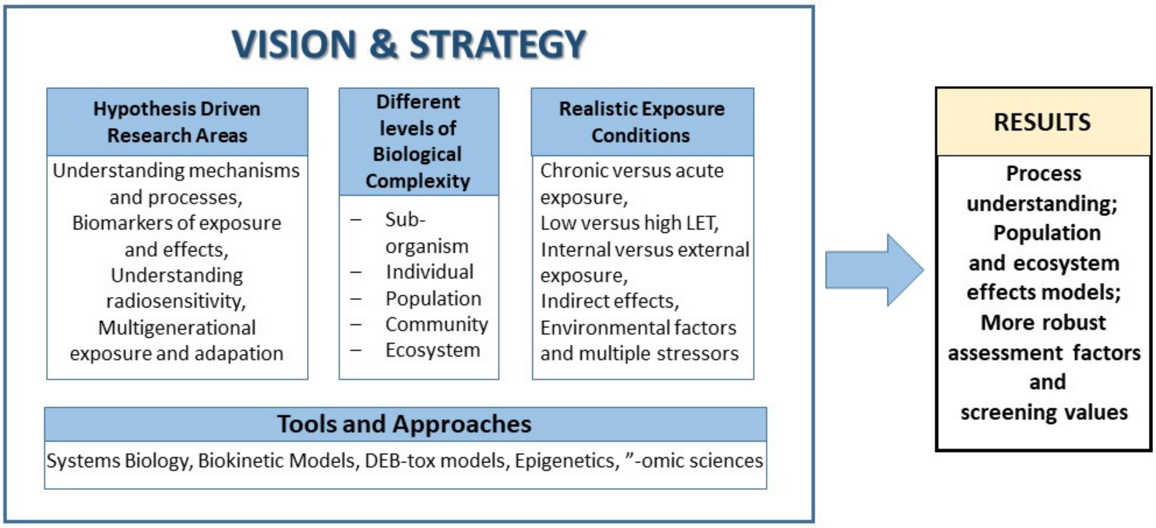

Figure 2. Schematic of the components and anticipated results of the Strategic Research Agenda concerned with challenge two: To Determine Ecological Consequences under the Realistic Conditions that Organisms are Actually Exposed.

In the last decade the STAR, COMET and TREE programmes were large multi-institute programmes, in part designed to address these identified priorities. Whereas STAR initiated research on multiple stressors, the COMET project focussed on understanding the role of epigenetic processes in the trans-generational effects of radiation (Saenen et al., 2017; Horemans et al., 2019; Beresford et al., 2019). The need to further resolve this important low dose rate controversy at Chernobyl (to understand the phenomenon, and in doing so enhance public confidence) was an important consideration in developing this SRA.

In order to build new environmental radiation protection approaches and to understand and assess the effects of radiation on wildlife, radioecology will need to benefit and collaborate across different disciplines such as environmental sciences including ecology and ecotoxicology of chemical substances, stress ecology (Van Straalen, 2003) and other European research platforms such as MELODI with which it shares a number of challenges (e.g., for extrapolating from acute to chronic ecotoxicity, laboratory to field, one species to another, individual to populations) as well as methods, concepts, models, and tools. New approaches adopted by environmental sciences in general, and ecotoxicology and ecology in particular, emphasize that to properly determine the effects from any contaminant we must address the realistic environmental conditions in which organisms are actually exposed, including the consequences to ecosystem integrity (i.e. structure, composition, function). Realistic environmental conditions incorporate natural abiotic factors (e.g., climate change, temperature, flooding events, snow and ice) as well as biotic factors (e.g., physiological and life-history status of organisms; ecological processes such as competition, predation, and food availability). Adding this realism will aid at developing integrated exposure assessment approaches (including the development of proper tools for the dose calculation for wildlife species) that encompass the dynamics over time and space during the entire life cycle of organisms (links with Challenge 1). One operational outcome from this challenge, directly relevant to radioprotection of flora and fauna, is to establish sound-science protection criteria for ecosystems and their sub-organisational levels following exposure to radioactive substances, whatever the source term and the environmental situation.

2.2.1. Strategic vision for research

Our strategic vision is that over the next 20 years radioecology will have gained a thorough mechanistic understanding of the processes inducing radiation effects at different levels of biological organisation, including the consequences on ecosystem integrity, and be able to accurately describe and predict effects under the realistic conditions in which organisms are actually exposed.

2.2.2. Strategic agenda

Similarly to Challenge one, the key research lines developed below are intended to be applied for all exposure situations, as described by the CONCERT Joint Roadmap scenarios: planned exposures situations under normal operation conditions (scenarios 2), existing environmental exposure scenarios with regard to legacy (scenario 4) and natural radiation (scenario 5), as well as long term exposures after accidents (scenario 6) and malevolent acts (scenario 7). To address these, studies will have to include an appropriate combination of laboratory studies conducted under controlled conditions and field studies and statistical data treatment and/or mathematical modelling. In connection with challenge one, common to all five research lines outlined below, is a crucial need for an improved dosimetric assessment to reduce uncertainty and enhance robustness of dose estimates and for the establishment of dose-response relationships, whatever the model used (e.g., logistic, hormetic, linear non threshold). Such response relationships constitute the basis for any predictive risk assessment. Specifically, the following five research lines will need to be addressed to achieve the vision.

2.2.2.1. Mechanistically understand how processes link radiation induced effects in wildlife from molecular to individual levels of biological complexity

This research line aims at identifying key molecular/cellular and individual characteristics driving radiation induced effects at the individual level. The use of advanced analytical methods from molecular biology including high-throughput screening technologies and computational models to extrapolate data at different levels of biological complexity, holds great promise for enhancing our mechanistic understanding of radiation induced responses at the sub-cellular levels and their consequences to individuals and is shared between human and other organisms (Mothersill et al., 2018). One way of describing the links between molecular initiation of the response and the observed adverse effects is through the formulation of an Adverse Outcome Pathway (AOP) (Ankley et al., 2010; Groh et al.,., 2015). The formulation of a radiation specific AOP will form a framework within which data and knowledge coming from different organisms, different levels of biological complexity and even multiple stressors are synthesised in a way that is useful for risk assessment. The key molecular events (which may include epigenetic change) of an AOP might serve as a potential biomarker, once their response sensitivity and natural variability in populations are characterised. With validated biomarkers under field conditions and populations of native or non-native species (e.g., using caged animals in the environment), innovative biomonitoring in the field should be developed, with a preference to non-lethal methods and tools where possible. Field studies will be required to test the detectability of radiation induced changes used as biomarkers within complex realistic exposure situations (e.g., confounding factors such as seasonal variations, other contaminants, changes in habitats). A radiation-related AOP for different organisms together with specific biomarkers could potentially be used in a regulatory setting to verify the results of impact assessments for operational facilities.

In addition, coupled Biokinetics/Dynamic Energy Budget (DEB) approaches can aid in understanding the metabolic mode of actions at the individual level following radiological exposures. DEB theory (Kooijman, 2000) offers a single consistent framework to understand effects of stressors on growth, reproduction and survival in an integrated way.

Examples of key issues are given to illustrate this research line:

- How does the oxidative status of the cells (or tissue/organisms) modulate the responses?
- How may those elementary mechanisms result in adverse outcomes at the cellular and individual levels (immune and neurological systems integrity, general metabolism, reproduction, growth, survival, behaviour, susceptibility to diseases)?
- How do radiation type (α, β, γ), exposure duration (acute, chronic), pathways (external vs. internal irradiation) and cellular/biological characteristics modulate the quality and quantity of damages? Are those damages reversible?
- Do specific modes of action or master genes exist for different types of radiation, and can they be used to develop specific biomarkers or biosensors or AOPs?

2.2.2.2. Understand what causes intra-species and inter-species differences in radiosensitivity (i.e. among cell types, tissues, life stages, among contrasted life histories, influence of ecological characteristics including habitats, behaviour, feeding regime...)

Even though the fundamental mechanisms that cause radiation damage seem universal, individual responses to radiation exposure vary tremendously, depending on factors such as type of radiation (variation up to ca. x50); acute versus chronic exposure (variation ca. 1-2 orders of magnitude); cell type; biological endpoint (e.g., reproduction versus mortality); life stage (embryos, larvae, and juveniles stages are the most sensitive); species (variation ca. 6 orders of magnitude); and level of biological organisation; simple laboratory experiments versus complex ecosystems (UNSCEAR, 2008). Some recent research suggests that current international protection benchmarks may not be protective of all organism groups (Raines, 2018). Some general parameters known to determine the sensitivity of an organism to radiation are: the DNA content (i.e. mean chromosome volume) of the cell; the efficiency and types of DNA repair/pathways; the cell repopulation capacity; and the ability of tissue and organs to regenerate (reviewed in Harrison and Anderson, 1996 and Adam-Guillermin et al.,., 2017).Differences in sensitivity between species also lie behind overall effects at higher levels (community, ecosystem). Understanding the mechanisms of inter-species radiation sensitivity may also help us understand mechanisms behind intra-species variation (Beresford et al., 2019).

This research line will be strongly combined with the first one. It will highlight the key drivers for intra- and inter-species radiosensitivity differences. A combination with phylogeny/homology concepts as it exists in comparative toxicology could help to support inter-species extrapolation. This research line requires a long-term commitment and comprises fundamental key issues such as:

- How do differences in DNA damage between different species, or the potential for DNA repair, explain the inter- intra-species differences in radiosensitivity?

- For internal contamination, how does uneven internal distribution of radionuclides and the subsequent dose heterogeneity in the cell/tissue/organ influence the biological response?
- What is the variability in sensitivity / response between life stages and between species?
- How do those findings, combined with a phylogeny/homology-type approach, support inter-species extrapolation?
- How do occupied habitats, organism behaviour and feeding regimes contribute to determining potentially exposed/critically sensitive life stages and species?

2.2.2.3. In a broader exposure context, understand the interactions between ionising radiation effects and other co-stressors

Exposure to multiple stressors may directly or indirectly modulate radiation effects. The environment is contaminated with low concentrations of complex mixtures (e.g., radionuclides, metals, pesticides, fire retardants and endocrine disruptors) and non-optimal or adverse environmental conditions (e.g. heat, drought) (Vanhoudt et al., 2012; Vandenhove et al., 2012; Mothersill et al., 2019). Studying a contaminant in isolation is necessary and provides critical information on the underlying mechanism resulting in detectable effects and can be used to test the specificity of biomarkers but cannot predict possible interactions among the many stressors to which organisms are exposed. Interactions can provide protective effects and reduce overall damage, or augment effects in negative, synergistic ways (SCHER, SCCS, SCENIHR, 2012).

Modifying effects of multiple stressors can be the consequence of altering the bioaccumulation characteristics of radionuclides, or influencing the radiosensitivity of the species (e.g., Au et al., 1994; Sugg et al., 1996). Radiosensitivity is affected by exposure to other contaminants and a combination of stressors reduces the physiological fitness of organisms. Multiple stressors are included within our SRA because of the need to understand the potential for mixtures to cause antagonistic or synergistic interactions with radiation.

Some research projects, including the EU funded STAR project, have been trying to answer the question of multi-contaminant/stressors (Gilbin et al., 2015; Gagnaire et al., 2017). While studies of stressor interactions are common in ecotoxicology, it has been difficult to derive general rules by which to predict how different species may be effected by a given combined stressor exposure (additive, greater than additive, less than additive) (Holmstrup et al., 2010; Vanhoudt et al., 2012). For many species, the limits of tolerance for some types of stressors (e.g. soil pH, temperature ranges) are known. Measurements of potential stressors along with radioecological measurements may identify those cases in which radionuclide exposures coincide with other stressful conditions helping to identify when multiple stressor effects may need to be taken in to account (Beresford et al., 2019.).).

Research should be developed to understand radiation effects in the context of contaminant mixtures and multiple stressors. Emphasis will be placed on identifying combinations of mixtures and stressors that interact such that super-additive and sub-additive effects are likely to occur with radiation. The potential for interactions among stressors will be based on their modes of action and their cellular targets at the molecular level (e.g., oxidative stress, genotoxicity). This will also contribute to the understanding of radiotoxicity and chemotoxicity, and their delineation when it is relevant. Because of the multitude of potential stressors that exists in real exposure conditions, early research efforts will develop a scheme to prioritise hypotheses and maximise research efficacy (Escher et al., 2017).

Examples of key questions addressed in this research line are:

- What are the combinations of mixtures situations or co-contaminants that are likely to show interacting effects with radiation?
- What are the mechanisms underlying interacting effects of different co-contaminants and radiation or radionuclides?
- At what level does interaction take place: for example at the exposure, uptake, internal redistribution of the radionuclides, at the site of damage or in regulation and signal transduction of the response of the organism towards radiation effects?

2.2.2.4. In a broader ecological context, understand the mechanisms underlying multi-generational responses to long-term ecologically relevant exposures (e.g., maternal effects, hereditary effects, adaptive responses, genomic instability, and epigenetic processes).

A strong connection with evolutionary ecology is needed to study adaptive responses and modulation of effects at a multi-generation scale following exposures to radiation. Understanding long-term effects of radiation on the phenotypic and genetic characteristics of the population is crucial to assess the risk of population extinction and its consequence for the maintenance of both genetic biodiversity and species biodiversity. This is true whatever the radiation type and exposure pathways.

The mechanisms involved in organism responses to chronic radiation exposure, both within and between generations, are the subject of an active debate in the scientific literature (e.g. Boubriak et al., 2016; Carroll et al., 2007; Goodman et al., 2019; Horemans et al., 2019). Whilst adaptation of organisms to radiation within the Chernobyl Exclusion Zone (CEZ) has been suggested (Møller and Mousseau, 2016; Boubriak et al., 2008), it has not yet been the focus of any comprehensive research programme. If it does occur, adaptation of specific populations could lead to adaptation of the ecosystem over time (e.g. the plant biome is thought to help plants cope with abiotic stress such as drought or salinity (Dodd and Pérez-Alfocea, 2012; Liu and Zhang, 2015)). If adaptation to chronic radiation exposure exists in the CEZ, it will have implications for the interpretation of studies comparing current effect and exposure levels.

Radiation can directly affect DNA by ionisation of the molecules that form the double helix indirectly through formation of Reactive Oxygen Species (ROS) leading to molecular lesions (e.g., base degradation or deletion, single- or double-strand breaks, protein-DNA cross link). Indirect effects of oxidative stress can also alter protein, enzyme and lipid structure or function, resulting in disruption of general metabolism. Other alterations of the cellular genome can be induced by ionising radiation through changes in epigenetic mechanisms that cause changes in cell signalling processes [e.g., genomic instability (genomic damage expressed post-irradiation, after many cell cycles), bystander effects (where non-irradiated cells in proximity to irradiated cells exhibit effects similar to those that received the radiation), and reduced repair efficiency (e.g., Morgan, 2003; Mothersill et al., 2009].

Knowledge about genomic instability incorporating changes in the epigenetics and in the DNA sequence due to mutations and repaired double strand breaks should be improved to support the understanding and prediction of the evolutionary response of populations chronically exposed to ionising radiation (Horemans et al,., 2019). One novelty could be to associate an experimental approach (lab and field) with quantitative genetic methods to study the evolutionary response of a natural population to a rapid change in its environment.

Some of the major elementary key questions are:

- What are the biological and evolutionary significance of genomic and epigenetic changes due to exposure to ionising radiation? How much do they contribute to transmission of genomic damage to offspring, through successive generations?
- What is the influence of ionising radiation exposure on epigenetic changes in comparison with other environmental factors?
- To what extent does multigenerational exposure make the consequences worse (or better)? Are populations that are exposed for several generations to ionising radiation more (or less) resistant to new environmental changes? What is the molecular basis of resistance (or vulnerability) in comparison to non-exposed populations? What is the impact of previous 'acute' radiation exposure on organisms in contaminated environments now?

2.2.2.5. Understand how radiation effects combine in a broader ecological context at higher levels of biological organisation (population dynamics, trophic interactions, indirect effects at the community level, and consequences for ecosystem functioning)

Regardless of the stressor or type of contaminant, the vast majority of ecotoxicological data describe effects on individual traits of organisms at the cellular, tissue or individual levels. As demonstrated for chemicals, effects observed at these levels may propagate such that they have consequences at higher levels of biological organisation (population, community, ecosystem; e.g., Forbes and Calow, 2002a; Forbes et al., 2011). Our knowledge of radiation effects (and radiation protection) is based almost entirely on single species experiments, while in reality species are exposed as part of a multi-species assemblage. In radioecology, the importance of an ecosystem approach has been emphasised many times over the last decade. Several publications and international workshops have led to a number of recommendations and consensus statements (Bradshaw et al., 2014; Bréchignac et al., 2016; Mothersill et al., 2018, 2019).

In the wild, species within the same environment are differentially exposed to radioactivity due to their specific habitat, behaviour, and feeding regime. Species also have different sensitivities to radiation. In an ecosystem, this means that the various responses of species to radiation will also alter the interactions between species and may affect aspects such as competition, predator-prey or parasite-host interactions. This may lead to secondary effects that change community structure, composition and function. These secondary, indirect effects may impact a population to a larger extent than the direct effects of radiation. Such issues have been poorly addressed in radioecology and, for that matter in ecotoxicology, partly due to the complexity of studying multi-species assemblages in the laboratory or unravelling complexity in field situations. Recently, a literature review assessing the design and properties of multispecies effect-study experiments and their suitability for radioecology is currently in review (Haanes et al, submitted). A few experiments using microcosms (multispecies experiments) have clearly demonstrated such indirect effects (e.g., Doi et al., 2005; Fuma et al., 2010) at quite high doses. A recent microcosm study performed at dose rates similar to those at contaminated field sites (Hevrøy et al., 2019) allowed to isolate specific relationships between interacting species in an ecosystem and test the direct and indirect effects. Studies have investigated the effects of ionising radiation on wildlife from subcellular to community levels in the CEZ (e.g. Beresford et al., 2019) and increasingly in the Fukushima region. However, the consequences of increased ionising radiation levels on key ecosystem processes such as plant production, the degradation of dead organic matter, and elemental cycling have received little attention.

However, very few studies have actually measured effects at the higher levels. A few have attempted to extrapolate effects observed in individuals to what might occur in the population by using population dynamic models. Modelling the propagation of ionising radiation effects from individuals to populations has been addressed theoretically (Woodhead, 2003; Vives i Batlle et al., 2010), and based on experimental data, such as those acquired within the ERICA project by chronically exposing earthworms and daphnids (Alonzo et al., 2008) or more recently using available radiation effect data available in the FREDERICA database (Lance et al., 2012; Alonzo et al., 2016). Such models are a valuable, under-utilised method for predicting effects from environmental stressors, and thus are included within this SRA as they need to be further explored in radioecology. However, all models need to be tested in realistic systems (e.g., complex laboratory studies or in the natural environment) before accepting them as predictive tools.

The propagation of effects from individuals to population depends on the characteristics of specific life histories. Understanding and accounting for the differences in life history traits among species will likely reduce our current uncertainties in predicting effects to populations of wildlife exposed to radiation. Recognising the importance of life history strategies is not unique to radioecology; Forbes and Calow (2002b) suggested that it was not feasible to identify a priori among growth, mortality and reproduction, the best predictors of population growth rate. This underlines the necessity for adequate experimental development to address the following questions for radioactive substances: (i) How sensitive is the population growth rate to changes in each of the life-history traits? Which life-history stage(s) is sufficiently sensitive to influence the population growth; (ii) To what extent do effects on life-history traits influence population growth rate?

To extrapolate even further to communities or ecosystems, concerted collaborative effort is needed to carry out both controlled laboratory experiments on simple predator-prey relationships and more complex multi-species microcosms and field investigations/experiments, with a focus on ecosystem-relevant endpoints covering both ecosystem structure and function. In addition, development of population and ecosystem models capable of integrating radiation effects with population dynamics would substantially advance the field. Assessing the consequences of radioactive substances on ecological integrity (i.e., structure, composition and function) is essential to optimize management of ecosystems resources (water, forest, agriculture...), as well as other natural goods and services provided to society. For example, recent studies (ALLIANCE, 2018) demonstrate shifts in developmental and reproductive endpoints (e.g. flowering time or sexual maturity) due to radiation exposure, that may be significant for ecological functioning (e.g., delayed production of pollinators and earlier flowering may mean no floral resources are available for pollinators). Key issues would include:

- How does radiation affect food availability and quality (taxonomic composition, nutritional value) for predatory species?
- How do radiation effects modulate under changing food conditions and varying environmental constraints such as predation, migration and natural mortality?
- How do radiation effects alter trophic interactions such as competition, parasite/host relationships?

- How do radiation effects ultimately lead to changes in taxonomic composition, biological diversity and complexity, including delayed effects after multiple generations particularly in populations already subjected to environmental stress?
- How does ionising radiation affect the ecological integrity (structure, composition) key ecosystem processes (function)?
- How does ionising radiation affect the provision of goods and services provided by the environment of importance to humans (e.g. how species lifecycle dynamics may become uncoupled from the resources (e.g. food supply, nest sites, pollinators) on which they rely)?

2.3. Challenge Three: To Improve Human and Environmental Protection by Integrating Radioecology

The risks posed by the presence of radionuclides in the environment require an efficient, balanced and adaptable assessment for protecting and managing exposed humans and environments. The individual contaminant-medium-pathway paradigm is changing towards a more integrated view of the environment as a whole. Radioecology's position relative to this paradigm shift can be best maintained by embracing the concept of integration – integration of the underlying systems and methods of human and environmental protection, and integration of radioecology with other scientific disciplines, including social sciences and humanities (SSH) to provide necessary scientific basis for system and practice of radiation protection and to ensure proper answers on societal questions and challenges in different exposure situations. Thus, radioecology's future success, broadly defined as meeting stakeholder needs, will require integration in several ways and from several different perspectives. This portion of the SRA identifies several integration challenges (Figure 3), as well as highlights the advantages gained by the science of radioecology in meeting the integration challenges:

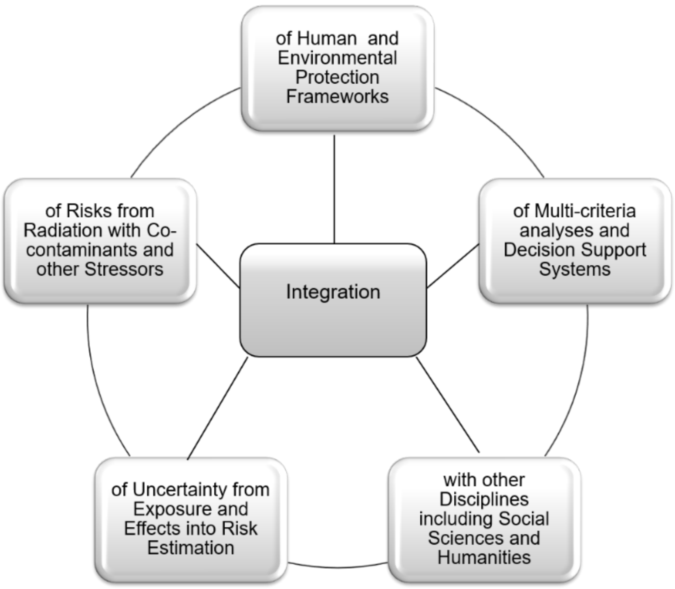

Figure 3. Five areas in challenge 3: To Improve Human and Environmental Protection by Integrating Radioecology.

During the last decades, the need was recognised for explicit demonstration of the protection of the whole environment from the effects of radioactive contaminants, which also resulted in changes to international policy (ICRP, 2007; EU Directive 2013/59; ICRP, 2014). Significant effort has been expended in that regard and a system of environmental protection is emerging, along with the tools required to estimate exposure, evaluate risk and demonstrate protection (Larsson, 2008; Brechignac et al., 2016). In some important areas, however, the methodologies for human and environmental assessments still differ. This problem is exacerbated because human and environmental assessments are not complementary in terms of how they are conducted. The differences can cause difficulties for operators, stakeholders and regulators. An integration of the two radiation protection systems – both in terms of the underlying philosophy and the practical application via appropriate tools and systems - offers significant benefits on many levels.

Additionally, radionuclides and the risks posed by them to humans and the environment typically occur as part of a complex suite of co-contaminants and other stressors that may act as confounding variables, as exemplified by waste streams from nuclear and non-nuclear industries, complex legacy contamination and releases as a result of accidents. There is a clear and long-standing gap in our understanding of contaminant mixtures that include radioactive materials. Radioecological research integrated with other disciplines and directed towards better understanding of mixture effects, as well as adapted risk assessment methods, will make it possible to determine whether radiation protection criteria are robust in a multiple contaminant context.

Radioactive contamination can occur as a result of a range of different scenarios, disparate in character and often specific in their actual or potential impacts, but often of great concern to the public. Societal perception of the technical capacity and resources required to prevent, mitigate or remediate impacts and ensure recovery of any contaminated area after a release should take into account the disparities and specificities inherent in the exposure scenarios, as they play a significant role in the assessment of consequences – in terms of economic considerations and from a societal perspective. A continuum of effects includes societal concerns, varying degrees of economic impact or loss of societal benefit, administrative disruption, health impacts or loss of life and impact on ecosystem services. In addition to these impacts, the measures taken to address them may, in turn, incur societal and environmental side effects. This complex interplay has been well demonstrated in the aftermaths of both the Chernobyl and Fukushima accidents and has been taken into consideration when developing the Joint Roadmap of radiation research platforms in 2017.

Management approaches in planned, existing and emergency exposure situations can range from the minimal through ascending levels of complexity and detail. Although a significant amount of valuable knowledge exists for a wide range of exposure situations, it is fragmentary with respect to constituting an integrated strategy sufficient to deal with complex, dynamically changing conditions. In dealing with a range of actual or potential exposure situations, a gradient of integrated management approaches based on multi-criteria decision analyses (MCDA) and the means of creatively implementing them are required. The development of appropriate tools – Decision Support Systems (DSSs) – for best implementing such approaches must occur in tandem with the development of management objectives to ensure that maximum benefit is derived. The need for integrated, graded management approaches and the tools to implement them in handling the entire spectrum of possible effects of exposure and ensuring the productivity and societal benefit of impacted areas will be a primary driver for radioecological research in the coming decades. The recent events at Fukushima in Japan exemplify these problems and the existing challenges. Intrinsically bound to this need is the requirement for sound, fundamental and progressive science to underpin and derive maximum benefit from these efforts.

2.3.1. Strategic vision for research

Our strategic vision is that over the next 20 years radioecological research will develop the scientific foundation for the holistic integration of human and environmental protection, as well as their associated management systems.

2.3.2. Strategic agenda

The following five research and integration lines will need to be addressed to achieve the vision.

2.3.2.1. Integrate uncertainty and variability from transfer modelling, exposure assessment, and effects characterisation into risk characterisation

Risk characterisation is the final step of risk assessment that integrates information from exposure assessment and effects characterization.

Challenge 1 of this SRA identified that transfers and exposure have to be assessed at multiple spatial scales, from an emitting source to the landscape or even global scale. Challenge 2 emphasised that effects have to be characterised not only at the individual level, but also at higher levels of biological organisation (population, community, and ecosystem). This means that any risk assessment at such integrated scales should simultaneously take into account: (i) variability of doses, depending on spatial variability of radionuclide transfers, as well as behavioural heterogeneity among exposed species, (ii) and variability in radiosensitivity among species, including gender- and life stage-dependencies. Improvements in risk assessments, and the increased confidence in their results, require challenge 3 to integrate all these sources of variability into a single calculation.

In parallel, the temporal variability characterising transfers and exposure (cf. challenge 1) as well as effects, from age-dependent differences to multi-generational responses (cf. challenge 2) need to be integrated over the period of interest for risk assessment, depending on the context, from weeks in an emergency situation to thousands of years for radioactive waste repositories.

Lastly, due to its inherent integrative power, risk characterisation is the ad hoc step to fully characterise the global uncertainty of a risk assessment, by incorporating uncertainty from exposure assessment and effects characterisation. Considering the multiple sources of uncertainty, including those mentioned in challenges 1 and 2, this final stage is the key to a real integrated ecological risk assessment.

Some recent advances have been made in relation to characterising uncertainty and variability in transfer modelling and exposure assessment within EJP-CONCERT funded projects. From the CONCERT-TERRITORIES project, Urso et al. (2019) provide guidance for carrying out uncertainty analysis with experts' knowledge specifically in the field of radioecology. Structured information about parameter uncertainty, conceptual model uncertainty, scenario uncertainty as well as role of variability are presented together with analytical, probabilistic and Bayesian approaches and methodologies to quantify and (where possible) to reduce these uncertainties. From the CONCERT-CONFIDENCE project, Brown et al. (2018) explore how information on parameter uncertainty can be used in the agricultural food-chain models commonly implemented within European post radiological emergency decision support systems, the aforementioned ARGOS and RODOS systems. These new developments provide initial steps towards fulfilling the objectives of this research line. Integrating the mentioned uncertainties and variability into the overall risk assessment would contribute to better reliability of dose assessments in general (this being one of the ICRP's (2017) identified areas for which research is needed in order to support the system of radiological protection).

Nonetheless, the requirement still remains to reduce uncertainties so that risks to biota and humans can be better quantified, whatever the situation (low, as well as high risk situations; planned, existing and emergency situations). Most of the research lines described in Challenges 1 and 2, as well as research lines described in related SRAs from other platforms), identify research that could contribute to improved risk quantification. The strong links which are already being built between the ALLIANCE and existing radiation protection research platforms will help facilitate integration and reduce uncertainties

2.3.2.2. Integrate human and environmental protection frameworks

Risk assessments for ionizing radiation have historically been exclusively focussed on human risk but have expanded to gradually include ecological risk. This shift is reflected in recent high-level policy changes. It is recognised that the present framework of radiological protection should be changed to explicitly demonstrate rather than assume the protection of the environment, as stated in the general recommendations of the International Commission on Radiological Protection (ICRP, 2007), international Atomic Energy Agency (IAEA, 2014) and in the EURATOM (EC, 2013) Basic Safety Standards.

Over the last decade, new drivers for integration of human and environmental protection frameworks have emerged, such as the increasing interest from society in environmental issues, requests to demonstrate the overall protection of the environment and aspirations to build public confidence through information and transparency. Human and ecosystem health are now recognized as strongly interconnected as evidenced, for example, by a number of principles and goals for sustainable development recently agreed in the 2030 development agenda of the United Nations (UN, 2015). Furthermore, according to the ICRP's and IUR's recommendations about the integration issue, more focus should be put on the development of an integrated view of all benefits and impacts that includes consideration of protection of people and ecosystems (Brechignac et al., 2016; Garnier-Laplace et al., 2017). Moreover, integrating environmental protection and human protection under one generalised system for radioprotection, would enhance efficiency and would be of great interest to regulators, industry and the public (Salomaa and Impens, 2016).

. Some initial steps with regards to exploring the issue of integration were taken in the radiological sciences through the application of case studies (Copplestone et al., 2010). A step forward has been made by the development of a combined screening model for both human and non-human biota in the form of the CROMERICA tool (Mora et al., 2015).) Although, this integrated assessment platform provides alignment with respect to the advection and dispersion models used in modelling the behaviour and fate of radionuclides, the tool falls short of providing a satisfactory amalgamation of all methodologies employed. More recently, Copplestone et al. (2018) has explored how an integrated approach might be applied in planned, existing and emergency situations. This was achieved by, for example, showing how simplified numeric criteria may be used in planned exposure situations that are protective of both the public and non-human biota.

Nonetheless, these deliberations still fall some way short of being considered a full framework for integration of human and ecological risk assessments for radionuclides. Therefore, further consideration of the acceptable or optimal level of integration for assessment approaches is still needed. . Valuable insights for future research actions can be gained by recent developments that have occurred for the risk assessment of chemicals (Wilks et al., 2015; Ciffroy et al., 2016). Building of common exposure scenarios based on a tiered approach using cautious assumptions and simple deterministic models, developing tools to support the harmonization, sharing of human and environmental exposure data and sampling designs are seen as further steps to be done through multidisciplinary research in order to develop an integrated system.

The ALLIANCE is convinced that the scientific and pragmatic (application via appropriate tools) foundation for a holistic integration of human and environmental assessment should be addressed (Vandenhove et al., 2017). Further development, in the radiological sciences, of integrated methodologies for transfer, exposure and risk assessment, and the production of tools incorporating those methodologies for existing, emergency and planned exposure situations, remain a major step forward in ensuring efficient, adequate, demonstrable protection for both humans and the environment. Areas where active research towards integration is required include transfer/exposure and dosimetry. Currently, transfer/exposure studies for humans and biota are conducted separately using two dissimilar methodologies. It is evident that progress is still needed to gain fundamental knowledge (on underlying processes), validate tools and methods for performing realistic, integrated and graded impact and risk assessments for both humans and wildlife, across all ecosystems and exposure scenarios (Salomaa and Impens, 2016).

This challenge, incorporating the knowledge generated in other strands of activity within the SRA, will focus on the scientific and practical integration of human and environmental transfer and exposure methodologies. By determining where harmonisation of approaches for humans and environment is justifiable and beneficial, the challenge will focus on developing integrated methods for assessment in the areas of transfer, exposure, dosimetry and risk. Future research initiatives in this area need to continue good links with MELODI and the work being carried out by the ICRP.

2.3.2.3. Integrate the risk assessment frameworks for ionising radiation and chemicals

Both human populations and wildlife in polluted environments of radiological concern may be exposed to a complex mixture of radioactive and chemical substances and various confounding factors; such combined exposure may sometimes cause adverse effects. The need to account for multiple stressors in experimental set-ups, effect analysis and risk assessment has been recognized and addressed in the SRA through several research lines, among others, by integration of the risk assessment frameworks for ionizing radiation and chemicals.

Recently, new drivers that additionally implied the need for further development of integrated risk assessment frameworks emerged, such as the increased awareness by the public of the simultaneous presence of chemicals and ionizing radiation in the environment, their importance for ecological quality of environmental resources and for biodiversity, practical issues of assessors, operators and regulators related to the existence of separated approaches. Integration of environmental exposure assessment for ionizing radiation and other stressors and optimization of radiological protection have been identified as a common challenge and knowledge gap in the Joint Roadmap of the international radiation research platforms (MELODI, NERIS, EURAMED, ALLIANCE) (Impens, 2017; Vanhavere, 2018).

The issue of multiple stressors in the risk assessment framework has recently been considered by studying the factors affecting the impact assessment of mixed waste disposal in the context of achieving an optimized waste management (BIOPROTA forum (2013, 2015); Thorne and Kautsky (2016;);); Thorne and Wilson (2015)). Although constraints such as missing data on stressors and endangered biota as well as the general complexity and diversity of existing mixed exposure scenarios, have been identified, steps for future alignment of the approaches by focussing on a relatively limited set of hazardous components (such as U, Pb, Cd, Cr and asbestos) have been proposed.

Furthermore, development of integrated multiple stressors risk assessment using species sensitivity distribution (SSD) in combination with mixture models (CA, RA, IA) allowed the derivation of an integrated proxy of ecological impact of radionuclide and stable stressors (msPAF, multisubstances potentially affected fraction of species) (Beaumelle et al., 2017; Beaugelin-Seiller et al., 2019).

One of the recommendations from the CONCERT-TERRITORIES project, aimed to regulatory authorities, focuses on establishing and implementing an integrative approach in decision making under exposure situations involving multiple stressors and including NORM.

In perspective, to meet the challenge of integration of risk assessment frameworks, the development process will require missing data collation, incorporation of overall uncertainty, sensitivity analysis, meta-analysis and integration of long time scales within the proposed tiered approach.

2.3.2.4. Provide a multi-criteria perspective including decision support systems for an optimised decision-making

In handling of existing, planned and emergency exposures, a gradient of integrated management approaches is required as well as the means of creatively planning environmental management (including waste disposal options, remediation and decommissioning strategies) and assessing their effectiveness prior to implementing them. Although the primary driver in choosing management options for radiation exposure situations will always be the reduction or prevention of dose, the problem is inherently multi-factorial and will involve many stakeholders. There are significant needs in other sectors - economic, infrastructural, social services, production – that should be considered when selecting management options. Thus, there is a need to transparent communication to optimise management approaches for radioactive contamination that go beyond the simple consideration of radiation dose vs. economic cost. Optimisation requires expertise in areas such as radioecology, urban planning, social and economic sciences, information technology, waste handling, environmental and agricultural sciences, and risk perception and communication. From a practical viewpoint, the optimisation process could be based on the integration of decision support systems (DSSs) associated with radiological sciences with knowledge data-bases and other decision-aid tools from different disciplines (e.g., urban planning, economics, sociology) so that contaminated environments are managed in a holistic way to the maximum benefit for society. Concerning DSSs, the following aspects of how integration will be of benefit for decision making are apparent: (i) integration of available radioecological DSSs, (ii) development of DSSs for integrated assessment and (iii) integrating DSSs for existing and planned with those for emergency exposures.

As discussed above, integration of human and environmental protection systems and methodologies is a challenge for radioecology (and MELODI) with the potential for significant benefits which can only be fully realised if the means of efficiently implementing such systems are available to stakeholders, regulators and operators. The development of DSSs for integrated assessments of both man and environment is necessary in ensuring demonstrable protection in a manner accessible to stakeholders. Moving towards this goal serves to generate maximum benefit from the research and ensures an important feedback mechanism between radioecology research and stakeholders. In situations requiring decisions to be taken dealing with radioactive contamination, it is almost never the case that one criterion can be used in isolation when determining the actions to be taken. The results of joint European research projects clearly showed that apart from the radiological effectiveness and technical feasibility of the various management options, the acceptance of stakeholders and the public at large is at least as important. Multi-criteria analysis (Linkov and Moberg, 2012) provides a suitable theoretical framework that can be used to combine quantitative and qualitative factors and to guide the decision process towards a satisfactory solution (since no global optimum exists in the presence of multiple, often conflicting criteria).

Multi-Criteria Decision Analysis is often employed for the analysis of complex problems involving non-commensurable, conflicting criteria that form the basis within which alternative decisions are assessed. This methodology promotes "a good decision-making process" (Keeney and Raiffa, 1972; Linkov and Moberg, 2012) by a clearer illustration of the different types of data and information items that go into decision-support, being able to deal in a structured and transparent way with multiple, conflicting objectives and value systems. At the same time, multi-criteria decision aid methods overcome the shortcomings of traditional decision support tools used in economy, such as Cost – Benefit Analysis, especially when dealing with values that cannot be easily quantified (e.g., environmental issues), or translated in monetary terms due to their intangible nature (e.g., social, cultural or psychological issues).

Proper site characterization, human and environmental exposure and impact assessments, safety assessments and evaluation of remediation and waste disposal options (in terms of technical performance, associated exposure reduction and social impact), constitute the basis for decision making and need to be underpinned by robust scientific and technological developments. At the same time, societal uncertainties and ethical implications must be seen as a constitutional part, of high importance, in every regulatory decision-making process.

The integrative and participatory process between the research community and relevant stakeholders has been recently established in EJP CONCERT to provide a range of benefits and optimized decision making based on (i) better definition of radiation protection objectives, (ii) improvement of existing knowledge and (iii) support in challenges of regulatory authorities and TSO to (IV) choice of relevant measures, proper risk and uncertainty communication. Beyond EJP CONCERT, collaborative actions on I-IV as well as on further integration work on DSS and definition and development of multi-criteria for better decision making are foreseen as necessary.

2.3.2.5. Towards better interaction and integration of radioecology with other disciplines, including social sciences and humanities (SSH)

The system of radiological protection is underpinned by advanced research in numerous scientific disciplines including radioecology. At the European scale, efforts have been made in the last decade to establish and bring together European platforms for radiation protection research, namely MELODI, EURADOS, NERIS, ALLIANCE, EURAMED, as well as social sciences and humanities (SSH) researchers. A European Joint Programme for Radiation Protection Research CONCERT was organized (2015-2020) with the main objective being implementation of a joint activities in radiation protection research (ranging from organising open research calls to coordination and networking activities, including training, research infrastructure development and stakeholder involvement) (Impens et al., 2017).

Main results of joint activities targeted current system and practice of radiation protection by giving the contribution to questions of general importance. Furthermore, improved answers to societal needs and challenges have been provided, as well as sharing and better use of state-of-the art- research infrastructure.

Growing public awareness of the importance of the global quality of environmental resources and biodiversity nowadays covers various philosophical perspectives such as anthropocentrism (protection of resources), biocentrism (intrinsic value of organisms) and ecocentrism (intrinsic value on all living organisms and their natural environment). In these terms, integration of radioecology with other disciplines, especially SSH, would help in mutual understanding, generation of trust and improvement of credibility by better linking scientific findings with different stakeholders and general public needs.

Benefits from better integration of the fields of radioecology and SSH are numerous (Perko et al. 2019, CONCERT-TERRITORIES Deliverable 9.72) and can be of more general (1-3), but also of more specific nature (4-8). Some more prominent examples of future actions and related benefits could be as following:

- bridging the gaps and/or improvement of the links and development of the tools for mediation between radioecology research and stakeholders, at more levels - from local, national to international;
- collaboration for research prioritization; getting the scrutiny into radioecology research and assessment methodologies;
- collaboration to develop the holistic approach for the governance of radiation risks;
- collaboration to develop integrated assessment framework for multiple hazards and integrated protection frameworks for man and biota;
- clarification of the stakeholders' viewpoints on various issues (e.g. integration of risk assessment approaches for chemicals and radioactive substances, different factors in multi-criteria decision making);
- improved social understanding of the uncertainties related to exposure characterization and risk assessments in different exposure situations;
- better risk communication on different levels (e.g., from better communication of modelled risk to better communication of knowledge-based intervention levels, remediation actions, etc. in relation to predicted but also perceived risk);
- identification of social constraints related to decision making based on impact and risk assessments (such as remediation and decommissioning).

Further close communication and collaboration between radioecology and related research disciplines, including social sciences concerned with issues of radiological protection, are foreseen as necessary to achieve the goals set in this SRA challenges 1, 2 and previously given lines in challenge 3. Regular dissemination and update of research achievements should also be planned as beneficial for future beyond EJP CONCERT.

3. Strategic Agenda for Education and Training

Scientific research in radioecology and application of that knowledge in the radiation protection of man and the environment requires scientists and workers with adequate competence, appropriate skills. Research-based education and training depends on access to relevant infrastructures and facilities. The EC EURAC project (2005) and the Radioecology Master Programme at the Norwegian University of Life Sciences (2007) have been important steps in promoting environmental radioactivity as an academic discipline under the Bologna Model. This work continued in the Network of Excellence STAR, with increased participation of STAR network scientists as teachers, international students and professionals taking course modules, an increase in the number of radioecology graduates as well as interaction and joint courses with DoReMi (low-dose research) and CINCH (radiochemistry). STAR also solicited stakeholder engagement (industry, regulators, academics, educators, etc) in the development of a strategic agenda through supply and demand workshops linked to education and training (STAR Deliverable 6.1 Oughton et al., 2012).

To secure the sustainability of education and training in radioecology internationally, potential funding mechanisms need to be discussed with the ALLIANCE, the Internal Union of Radioecology (IUR) and other relevant organizations, to maintain the Education and Training Platform developed in STAR and further developed under COMET/ OPERRA as well as under CONCERT-TERRITORIES.

3.1. Challenge: To maintain and develop a skilled workforce in Europe and world-wide, through university candidates and professionals trained within radioecology.

3.1.1. Strategic vision for Education and Training

The strategic vision is to secure and further develop a sustainable, integrated European training and education platform in radioecology that attracts top-level graduates and provides a workforce that has the necessary skills to meet future scientific, economic and societal needs within radioecology and other nuclear and environmental sciences.

3.1.2. Strategic agenda

The following action lines will need to be addressed to achieve the vision.

- Increasing student and teacher/researcher mobility requires sustainable funding mechanisms within radioecology. Actions such as travel grants for students and guest lecturer fees have a relatively low cost, but need to be maintained. The ALLIANCE will foster attendance of students at international radioecology conferences by offering small supportive grants.
- Inclusion of bespoke E&T work packages in EU (and other large) funded projects with wide reaching outreach activities to deliver training across all levels from the public to researchers.

- Attachment of PhD, post doc or young researcher positions to EU (and other large) funded projects is encouraged.
- Exploring joint EU MSc opportunities through the Erasmus Mundus programme and other activities under Horizon 2020 and Horizon Europe. This would include mechanisms to increase the number of ECTS courses in radioecology that are given by European Universities as well as to stimulate integration within the ALLIANCE.
- Fostering links with other E&T programmes in nuclear and environmental sciences (e.g., radiation protection, emergency management, radiochemistry, ecology, environmental chemistry) to maximize use of infrastructure and human resources by ensuring courses are compatible between different disciplines. Links with environmental sciences (e.g. via lectures on courses) should be made at all educational levels, from schools to post graduate.
- Providing joint courses for students and professionals with both ECTS (academic credits) and ECVET (vocational credits) or equivalents. This will ensure student merits, efficient use of resources and offer important networking opportunities for students, both across countries and disciplines, as well as with potential employees.
- Increasing stakeholder and employer involvement in education and training through student placements, sponsored courses or university positions, and development of specialized intensive courses to meet stakeholder needs. For professional training courses, particular focus will be placed on access to state-of-the-art methods and models.
- Development of distance learning courses (including webinars) where applicable (e.g. modelling, impact and risk assessment), to increase the recruitment of students.
- Development of novel educational materials and approaches, and promoting participation in science festivals to bring radioecology to the wider public.
- Offering refresher courses and seminars at relevant regional and international conferences.
- Organising summer schools and field training courses.

4. Strategic Agenda for Infrastructures

Adequate infrastructures and capabilities are a necessary resource for state-of-the-art and excellence radioecological research, as well as for education and training activities in radioecology. Infrastructures and capabilities encompass the facilities, equipment, methods, databases and models, and also the expertise required to perform radioecological research.

In the recent past, several EURATOM funded projects have performed activities to drive the improvement of the knowledge and use of radioecology infrastructures in Europe. Thus, in the Network of Excellence on Radioecology STAR an inventory of infrastructure, including databases and sample archives, available in the member organizations was created (STAR Deliverable 2.2). Also during the STAR project, with the subsequent support of COMET and the ALLIANCE, a virtual laboratory was developed to contribute to the harmonization of practices and protocols between the different radioecological facilities.

The establishment of Radioecological Observatory sites[12] was proposed as a tool for innovative research, research integration and sustainability (Initiated in STAR and fostered in COMET and CONCERT-TERRITORIES[13] European projects, with the support of the ALLIANCE).

Within the EJP-CONCERT the work package 6 is devoted to increase visibility of radiation protection infrastructures. To do so, a database (AIR^2D^2) and a bulletin (AIR^2), on infrastructures have been created[14].

The approaches used to study and evaluate the behaviour and impacts of radiation and radionuclides on the living world are changing. Consequently the required infrastructures and capabilities are also changing. A robust long-term vision is essential to successfully and sustainably develop, construct and operate radioecological (and radiation protection) infrastructures and capabilities. Thus, a network of collaborations between organizations would allow advanced platforms to be utilized within the consortium, within Europe or internationally.

12 Radioecological Observatory sites are contaminated field sites that provide a focus for long-term joint field investigations. The development of a pooled, consolidated effort maximises the sharing of data and resources. The Observatories also provide excellent training and educational sites.

13 https://territories.eu/

14 https://www.concert-h2020.eu/en/Concert_info/Access_Infrastructures

4.1. Challenge: To maintain and acquire the infrastructures and capabilities needed to accomplish the three scientific challenges, as well as to support the education and training challenge, of the SRA.

4.1.1. Strategic vision for Infrastructures

The strategic vision for the next 20 years is that radioecology will develop a sustainable, integrated network of infrastructures and capabilities, to best meet the needs of the radioecology community, both in research and in education and training activities.

4.1.2. Strategic agenda

The following four action lines will need to be addressed to achieve the vision.

- Identify the requirements for infrastructures and capabilities and create the partnerships of excellence that bring together these required infrastructure and tools.
- Maintain and keep up to date a web-based catalogue on physical infrastructures, e-infrastructures and capabilities to ensure an efficient and effective sustainable integration of resources and capacities at a European level and to show stakeholders the radioecology capabilities available.
- Further development of the Radioecological Observatory Sites (ROS). The ROS are considered as field laboratories where experiments are conducted that support greater understanding of radioecological processes, enables model development, validations and improvement and forecasting of future radioecological conditions. The data collected at the ROS and the models developed will be made available and may be combined with other datasets or data collected in other studies to support the three challenges of the SRA. ROS are a unique tool for integration among different disciplines through common studies, shared data, and E&T activities. Actually the ALLIANCE exploits ROS in the Chernobyl Exclusion Zone, the Fukushima Exclusion Zone and NORM-impacted sites in Belgium, Poland and France.
- Promote the visibility and joint use of existing infrastructures. Encourage wider collaboration, not only in the field of radioecology, but also in the broader area of radiation protection and with other related disciplines, leading to a better use and development of infrastructures.

5. Value of a Strategic Research Agenda

The acquisition of new scientific knowledge through research in radioecology is a crucial element in safeguarding humans and the environment against harmful consequences, as well as responding to stakeholders concerns regarding the presence of radionuclides in the environment. Such studies are important to society because over-estimation of exposures or effects could lead to unnecessary and costly restrictions; alternatively, under-estimation of the risks will result in injury to humans and the environment.

The three scientific challenges presented above, with their 14 associated research lines, are incompletely studied because they are complex and complicated. Attempts to address them have been piecemeal. The only way to provide rapid and efficient solutions to these difficult problems is a focused, hypothesis-driven research program with clear common goals and resources shared among the international radioecology community. For society to obtain a significant contribution from the radioecology of the future, a long-term, multidisciplinary approach is needed that goes beyond national boundaries.

Additionally, this updated version of the SRA contains important sections on education and training of radioecology and infrastructure for our research. Sustaining knowledge and educating new scientists is critical to the viability of radioecology and was a concern expressed by several stakeholders.

It is our hope that a science-based SRA for radioecology will focus and prioritise our collective efforts, resulting in increased value and more rapid advancement in our understanding of environmental radioactivity, as well as an improved ability to predict its effects on humans and the environment. It is expected that further integration within the global radiation protection community and consideration of stakeholders will push towards maximal efficiency, completeness and societal relevancy.

6. Acknowledgements

This Strategic Research Agenda was first developed under the European Commission's 7th Framework (STAR, Contract Number: Fission-2010-3.5.1-269672). Its 2019 update was made possible through funding from the European Joint Programme for the Integration of Radiation Protection Research (CONCERT, Contract Number: H2020 – 662287) with the participation of ALLIANCE members.

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Journal of Radiological Protection

Official journal of the Society for Radiological Protection

PAPER • OPEN ACCESS

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To cite this article: Tanja Perko *et al* 2019 *J. Radiol. Prot.* **39** 766

OPEN ACCESS
IOP Publishing | Society for Radiological Protection Journal of Radiological Protection
J. Radiol. Prot. 39 (2019) 766–782 (17pp) https://doi.org/10.1088/1361-6498/ab0f89

Towards a strategic research agenda for social sciences and humanities in radiological protection

Tanja Perko[1,17], **Michiel Van Oudheusden**[1], **Catrinel Turcanu**[1], **Christiane Pölzl-Viol**[2], **Deborah Oughton**[3], **Caroline Schieber**[4], **Thierry Schneider**[5], **Friedo Zölzer**[6], **Claire Mays**[7], **Meritxell Martell**[8], **Stéphane Baudé**[9], **Ilma Choffel de Witte**[10], **Ivica Prlic**[11], **Marie Claire Cantone**[12], **Sisko Salomaa**[13], **Tatiana Duranova**[14], **Sotiris Economides**[15] and **Susan Molyneux-Hodgson**[16]

[1] Belgian Nuclear Research Centre SCK.CEN, Boeretang 200 2400 Mol, Mol, Belgium
[2] Bundesamt fur Strahlenschutz Neuherberg – AG-SGIngolstaeder Landstrasse 1, Neuherberg 85764, Germany
[3] CERAD – IMV, Norwegian University of Life Sciences, Aas 1432, Norway
[4] CEPN Fontenay-aux-Roses, Île-de-France, France
[5] Centre d'étude sur l'Evaluation de la Protection dans le domaine Nucléaire (CEPN), Fontenay-aux-Roses, France
[6] University of South Bohemia – Radiology, Toxicology, and Civil Protection Emy Destinové 46, České Budějovice 37011, Czech Republic
[7] Institut Symlog, 262 rue Saint Jacques, Paris 75005, France
[8] Merience Scpolerdola, Spain
[9] Mutadis5, rue d'Alsace, Paris 75010, France
[10] Institut de Radioprotection et de Sûreté Nucléaire IRSN, Fontenay-aux-Roses, France
[11] Institut za medicinska istrazivanja i medicinu rada Zagreb, Croatia
[12] University of Milan, Milan, Italy
[13] Radiation and Nuclear Safety Authority – STUK – Research and Environmental Surveillance, Helsinki, Finland
[14] Vujeas, Trnava, Slovakia
[15] Greek Atomic Energy Commission, Athens, Greece
[16] University of Exeter, Exeter, Devon, United Kingdom

E-mail: tperko@sckcen.be

Received 17 December 2018, revised 11 March 2019
Accepted for publication 13 March 2019
Published 25 June 2019

[17] Author to whom any correspondence should be addressed.

0952-4746/19/030766+17$33.00 Printed in the UK

Abstract

Reflecting a change in funding strategies for European research projects, and a commitment to the idea of responsible research and innovation in radiological protection (RP), a collective of research institutes and universities have developed a prospective Strategic Research Agenda (SRA) for Social Sciences and Humanities (SSH) in radiological protection. This is the first time such a research agenda has been proposed. This paper identifies six research lines of interest and concern: (1) Effects of social, psychological and economic aspects on RP behaviour; (2) Holistic approaches to the governance of radiological risks; (3) Responsible research and innovation in RP; (4) Stakeholder engagement and participatory processes in RP research, development, policy and practice; (5) Risk communication; and (6) RP cultures. These topics were developed through broad stakeholder consultation, in conjunction with activities carried out in the framework of various projects and initiatives (EU H2020 CONCERT programme, the EU FP7 projects OPERRA, PREPARE and EAGLE, the 2015–2018 RICOMET series of conferences, and the 2014 and 2016 International Symposia on Ethics of Environmental Health); as well as through dialogues with members of the European radiation protection research communities. The six research lines open opportunities to integrate a range of key social and ethical considerations into RP, thereby expanding research opportunities and programmes and fostering collaborative approaches to research and innovation.

Keywords: radiological protection, social sciences and humanities, ethics, strategic research agenda, responsible research and innovation

1. Introduction

In this article, we present the contours of a Strategic Research Agenda (SRA) for the Social Sciences and Humanities (SSH) in radiological protection (RP). Despite an increased institutional recognition of the need for SSH research in radiological protection, SSH involvement in the field remains fleeting and dispersed (Van Oudheusden *et al* 2018). Building a more robust role for SSH in RP would open opportunities for scientific research communities (e.g. experts in radiobiology, dosimetry, radioecology) to integrate societal and ethical considerations into radiological protection work. Moreover, this would lead to expanding research options and the fostering of collaborative and co-creative approaches to research and innovation.

In recent decades, SSH researchers in Europe and beyond have demonstrated how social studies can fruitfully inform risk governance and clarify the societal understanding of radiological protection issues, for instance in relation to public response to and engagement in radioactive waste management (Jenkins-Smith *et al* 2011, Perko *et al* 2012, Dubreuil, Baudé, and Mays 2013, Bergmans *et al* 2014, Schröder *et al* 2015). Other studies shed light on public risk perception of industrial uses of ionising radiation, such as food sterilisation (Turcanu and Perko 2014); identify societal constraints related to environmental remediation and decommissioning processes (Perko *et al* 2017a); and raise public awareness about radon (Hevey 2017, Lofstedt 2018). Research has been undertaken to stimulate mutual learning and contribute to radiation safety and security by identifying and addressing mismatches between emergency management plans and practice (Malesic *et al* 2015, Liland and Raskob 2016, Prezelj *et al* 2016, Schneider *et al* 2016); pinpoint new security challenges (Becker 2004); and to propose novel ways to manage informed consent in the medical field (Friedrich-Nel and Munro 2015). Social studies—often in a comparative perspective across risky objects or technologies, and/or cultural contexts—also clarify how people interpret and take decisions in the presence of radiation related risks. This work highlights, for instance, factors influencing public concern about ionising radiation (Železnik *et al* 2016), such as the perception of uncontrollability, involuntariness, invisibility and having potentially catastrophic consequences (Slovic *et al* 2000). The direct contribution of SSH practitioners has been recognised to be valuable in the societal and scientific governance of contentious issues related to radiation risks to human populations and the environment, including in post-accidental exposure situations (OECD-NEA, CRPPH 2003, OECD/NEA 2011, Bréchignac *et al* 2016).

These research studies 'open up' (Stirling 2008a) radiological protection to society by questioning RP concepts, programmes and policies, and by incorporating social needs and considerations into science, technology and innovation (Felt and Wynne 2007, Stirling 2008b). More than simply a critique of radiological protection, social studies are an invitation to develop avenues for systematic collaboration between natural scientists and social scientists, and between technical and non-technical communities. The potential contribution of SSH is acknowledged by the existing European RP research and technical platforms[18], by various projects in the radiological protection field, for instance RISKEDU[19] (Wojcik *et al* 2018), and by CONCERT—the European Joint Programme for the Integration of Radiological Protection Research. As stated in the Public Declaration following the RICOMET 2016[20] Conference, '*[m]any radiological protection fields could profit from social science and humanities input, which could help cover knowledge gaps in complex radiological issues. The practical role of ethics, education and economics in decision making also needs further elaboration.*'[20]

The aim of the SRA, therefore, is to contribute to the improvement of the radiological protection system by coordinating SSH research in radiological protection; supporting education and training; building stakeholder involvement, knowledge management and sharing; and identifying SSH state of the art across disciplines. Enabling SSH research to play a fuller and stronger role in RP through a coordinated SRA mechanism will ensure that societal perspectives on research, policy and practice related to RP will be acknowledged and accounted for.

The members of the collective which has authored the SRA (see appendix) share a commitment to the ideals of *Science with and for society* and to *Responsible Research and Innovation*, both of which emphasise the need for collective, inclusive and system-wide governance involving all relevant stakeholders (Owen *et al* 2012). This development coincides with increasing interest in the ethical aspects of radiological protection as reflected, for instance, in the most recent publications of the International Commission on Radiological Protection (ICRP 2018).

[18] Multidisciplinary European Low Dose Initiative (MELODI), European Radioecology (ALLIANCE), European Platform on Preparedness for Nuclear and Radiological Emergency Response and Recovery (NERIS), European Radiation Dosimetry Group (EURADOS) and European Alliance for Medical Radiation Protection Research (EURAMED), European radon association (ERA), The European NORM Association (ENA).

[19] RISKEDU : How can teachers support the development of scientific literacy through teaching about risk and risk-assessment; http://riskedu.se.

[20] RICOMET : Conference on Risk Perception, Communication and Ethics of Exposures to Ionising Radiation http://ricomet2019.sckcen.be/.

The underlying principles that inform the SRA are that:

- SSH can support existing and future research, policy and practice, in all areas relating to radiological protection, to better take into account the concerns, values and needs of a wider range of stakeholders, including citizens;
- SSH research should be coordinated, shared and integrated into existing research and development (R&D) on radiological protection; hence, collaboration with the European radiological protection platforms and associations must be an integral component of the agenda;
- Research relating to RP should be conceived of as transdisciplinary and inclusive, integrating citizen, science and stakeholder input into research and innovation from the start.

With these principles in mind, the SSH SRA identifies priorities for future European Commission-supported SSH research, and beyond, in the field of radiological protection. The SRA is structured along six research lines addressing issues that are relevant for all existing European radiation protection research platforms (MELODI, ALLIANCE, NERIS, EURADOS and EURAMED), as well as topics of wider interest in the radiological protection area.

The SRA and will be regularly updated in light of changing stakeholder needs, as identified by research performed by the collective's members, under other platforms or in the international research community. Effective adaptation will therefore require continuous engagement of the SSH community in RP and ongoing interactions with all concerned parties, particularly the technical and research platforms.

In the following sections, we outline the state of the art of SSH research on RP, briefly describe the process of SRA development, and then present the scope and topics of the SRA, subsequently identifying the initial top priorities. We conclude by emphasising the need for ongoing and integrated SSH research on RP, for the benefit of society.

2. Current status of social sciences and humanities in radiological protection research

The field of radiological protection is challenged by particularities of ionising radiation (e.g. scientific and societal uncertainties, different perceptions of risks, societal trust issues) and the evolving societal landscape (e.g. rise in social media, active citizenship). The assessment of health effects from low radiation doses is confronted with the complexity of assessing causal and temporal relationships, alongside sources of uncertainty. This is not only due to limits of the models and data, but also to the inherent boundaries of radiation protection knowledge (Renn 2008).

While SSH research has been conducted for many years on multiple aspects of radiological risk, this research is fragmented and often circumscribed by input from actors beyond the SSH community (Lazo *et al* 2016). Therefore, SSH research has addressed in depth only some areas of relevance, directly or indirectly, related to radiological protection, whereas many areas have remained largely unexplored. Understanding how societies have engaged (or not) with nuclear energy and radioactive waste management has been the object of several studies (Bergmans *et al* 2014). Recently the relationships between societies and actors in the nuclear energy sector, and how these have changed over the course of the past 60 years, have been investigated from historical and sociological perspectives (HONEST[21]). Linguistic and discursive analyses have been conducted mainly in relation to nuclear emergencies (PREPARE[22]), while research on techno-cultural questions on the preservation of records, knowledge and memory of nuclear

[21] HONEST: History of nuclear energy and society, http://honest2020.eu.

[22] PREPARE: Enhanced emergency preparedness and response for nuclear and radiological incidents https://eu-neris.net/projects/prepare.html.

waste across generations has been undertaken by the OECD Nuclear Energy Agency (RK&M[23]). Extensive literature has addressed the perception of radiological risk and its influence on trust, attitudes, or governance of ionising radiation applications and their life cycle (Sjoberg 2004, Slovic 2012, Visschers and Siegrist 2013, Perko 2014, Perko *et al* 2015a, 2015b). However, there is a dearth of studies addressing these factors in specific long-term exposure situations such as those relating to Naturally Occurring Radioactive Material (NORM), radon in homes, legacy sites, or recent applications of ionising radiation in the context of food sterilisation or security threats. In sum, while different SSH disciplines have addressed some areas of RP to varying levels of detail, there remain large gaps in the knowledge base and a lack of integration of knowledge across domains.

A gap is also observed between state-of-the-art SSH concepts, theories and outcomes and their rate or rigor of application in the radiological protection field. Although a number of national and international recommendations and legal requirements for stakeholder engagement in radiological protection have been developed (e.g. Basic Safety Standards, Aarhus Convention, IRPA guiding principles), there remain gaps between those policies and actual practice, as highlighted for instance by the 'Aarhus Convention in Nuclear' initiative conducted by ANCCLI[24] and European Commission DG-ENER from 2009 to 2012 (UNECE 2013), and the FP7 European projects EAGLE[25] and PREPARE (Perko *et al* 2016c).

From a methodological perspective, there is insufficient dissemination of reliable and validated quantitative measurement scales for concepts relating to radiological protection. There is a need to harmonise qualitative research protocols and disseminate already existing, systematic, and transparent protocols for qualitative research. Such research protocols may concern, for instance, media studies, living-laboratory observations, and 'social laboratory workshops'. Currently, there are no publicly accessible databases of methods or tools for SSH research on radiological protection. Hence, there is methodological development yet to be undertaken.

Social sciences and humanities can lend insight and method to bridge gaps between technical experts and wider society in complex radiological issues (Perko 2014). SSH can also facilitate the development of RP research programmes that take into account: responsible research and innovation imperatives; citizen-centered RP governance (e.g. citizen science, environmental citizenship); vulnerability and resilience of societies and individuals; and cultural perspectives on technical solutions for radiological protection. The SSH SRA presented in section 4 addresses these and other areas and proposes new research lines and topics with a view to improving the radiological protection of individuals and society.

3. Development of the SRA

The research topics to be included in the SRA were collected through several activities carried out in the framework of the H2020 CONCERT project (http://concert-h2020.eu, specifically WP 2.6) and the FP7 projects OPERRA[26] (Perko *et al* 2015a), PLATENSO[27] (Meskens 2016), PREPARE (Schneider *et al* 2017), and EAGLE (Perko *et al* 2016b). The topics

[23] RK&M: Preservation of Records, Knowledge and Memory across Generations https://oecd-nea.org/rwm/rkm/.
[24] ANCCLI: The Association Nationale des Comités et Commissions Locales d'Information; http://www.anccli.org/.
[25] EAGLE: ENhancinG stAkeholder participation in the GovernancE of radiological risks for improved radiation protection and informed decision-making; http://eagle.sckcen.be.
[26] OPERRA: Open project for the European radiation research area; https://cordis.europa.eu/project/rcn/109481/en.
[27] PLATENSO: Building a platform for enhanced societal research related to nuclear energy in Central and Eastern Europe; http://www.merience.eu/en/ortfolio-items/platenso-2013-2016.

were further developed using a stakeholder consultation and dialogue approach. This process was initiated by social scientists at the annual RICOMET conferences (2015, 2016, 2017 and 2018), and the International Symposia on Ethics of Environmental Health (2014 and 2016) and included also other dialogues with members of the radiological protection research platforms. The first meeting of the persons engaged in the SRA collective took place in June 2016 at the RICOMET conference in Bucharest and an outline SRA was produced. The refinement of research topics identified through a series of dialogues was further discussed at the September 2016 Radiation Protection Week in Oxford with members of the CONCERT task group, SSH community and technical platforms, and resulted in an early draft of the SRA document. Following these interactions, a consensus was formed through discussion as to the most urgent topics for SSH research and the principles that would underlie the SRA work.

A systematic verification of the research priorities was conducted in June 2017 through an email-based consultation of 1400 individuals from the RP field. Respondents were asked to share their opinions, remarks and advice on the existing version of the SRA. They were, moreover, invited to participate live or online in a dedicated discussion and debate at the 2017 RICOMET conference in Vienna. At that session, the collected comments and the existing SRA version were discussed by 130 physically present delegates, and live streamed from the IAEA venue using technology that allowed distance-attendees to submit further input in real time.

Toward the end of 2017, the first steps to build a joint roadmap for radiological protection research were taken by the scientific platforms (Impens *et al* 2017). At this time, a specific challenge for SSH was identified and integrated into the draft Joint Roadmap for Radiation Protection Research: 'Enhancing integration of radiation protection science with society' (Salomaa *et al* 2017).

By using a range of events and processes for engaging the SSH community and stakeholders, a robust SRA has been developed. In the following section, we present the key features of this Strategic Research Agenda, as agreed upon by the aforementioned contributors and based on the priorities identified in the consultations.

4. Strategic research agenda (SRA) for social sciences and humanities (SSH) in the radiological protection field (RP)

The SRA aligns with recent calls for more open and responsive modes of research and science policy-making, and attends to four challenges put forward in contemporary EU-wide policy discourses on *Science with and for society* and *Responsible Research and Innovation* (EC 2018): health and wellbeing; secure, safe and resilient societies; communication, collaboration and citizenship; and integration, impact and reflexivity.

Firstly, *health and wellbeing* comprise the social, mental and physical health of individuals, as well as social factors such as the strength and diversity of social bonds within a community and its capacity for autonomy within a healthy environment. Research in the field of SSH can explicitly address these aspects in connection to radiological exposure situations, with the aim of ensuring a good quality of life for all. Achieving health and wellbeing requires investments on behalf of decision makers and research communities at a time of economic restraint and the aging of populations across Europe and the world.

Secondly, on the topic of *secure, safe and resilient societies*, European nations face major natural hazards and human-induced threats. SSH research seeks to make significant contributions towards enhancing societal resilience and preparedness in the face of these threats by examining contemporary approaches to safety and security, and by opening a broader societal debate on the kinds of resilience that can, and should, be achieved.

Thirdly, SSH research on *communication, collaboration and citizenship* advances our understanding of how individuals and communities are included and excluded, and how processes such as communication and collaboration foster novel forms of identity, sense making and belonging. It does so with the aim of creating societies in which citizens thrive, feel confident to express themselves and empowered to take decisions concerning radiological risks and connected issues.

Finally, SSH research on *integration, impact and reflexivity* assesses the impact of research activities on the values and choices made by researchers in their communities. This includes giving due consideration to the societal and ethical implications of scientific research agendas, processes, and outputs.

The SRA has six research lines that reflect areas for which the need for a concerted effort has been identified as a prerequisite to addressing the contemporary societal challenges outlined above. Each of these research lines includes a number of specific research topics relevant to the future European research agenda in the field of radiological protection. Indeed, we anticipate that the relevance extends beyond Europe. Exchanging views on these joint challenges will be an integral part of developing and improving the SRA further, setting priorities and initiating research projects.

4.1. Research line 1: effects of social, psychological and economic aspects on radiological protection behaviour and actors' choices

Research line 1 is geared towards understanding behavioural aspects related to radiological risks, including the interrelation between behaviour, perception of risks, economic aspects, knowledge, culture, historical memory and other factors.

Relevant topics include:

- Links between perception of radiological risk and radiological protection behaviour, or individual strategies to cope with perceived risk in relation to radiological exposure. Using cross-sectional and longitudinal studies, multiple aspects will be brought into focus:

different exposure contexts (e.g. workers, populations living in areas affected by radiological contamination).
different time scales (e.g. different generations).
cultural contexts,
socio-economic issues.

Perceptions of radiological risk and environmental remediation actions in post-accident and existing exposure situations (e.g. human ecology, psychology, epidemiology).

Media impacts (social media, traditional media) on perception of radiological risk and ideas of well-being linked to radiological exposures. This includes the influence of citizen journalism on radiological protection behaviour in different exposure situations and examining if, and how, citizen science journalism can be integrated into RP.

The interplay of individual differences, such as psychological aspects associated with radioactivity, social environment and radiological protection behaviour.

Capturing different understandings of ionising radiation concepts, risks and uncertainty as byr stakeholder group (e.g. practitioners, patients, local population) and the respective amplification or

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attenuation of radiological risks. Contexts are medical exposures, industrial applications, natural radiation and nuclear or radiological accidents.
Perception of radiological risks by individuals and groups when exposed to low radiation doses, accounting for cultural differences in routine, emergency and other exposure situations.
Socio-psychological and economic aspects of medical follow-up after accidental or other exposures. Societal approaches to dealing with uncertainties and the potential for bridging the gap between different concepts of uncertainty.

4.2. Research line 2: Holistic approaches to governance of radiological risks

The aim of this research line is to develop inclusive approaches for the governance of radiological risk situations by integrating technical assessments and social assessments, raising public awareness on the social scientific aspects and integrating these into knowledge building, framing of issues and the decision-making process together with technical assessments. Evaluation of radiological and non-radiological aspects by the various stakeholders should serve as inputs for decision-making. Stakeholders comprise formal institutions, as well as actors without a predefined institutional role that have to manage their own decision-making processes, stakes, and expectations. A core emphasis here is on providing insights and guidance on multi-dimensional, multi-actor and multi-institutional decision-making and policy-making and on resolving emerging trade-offs in radiological protection. As radiological protection is a burgeoning multidisciplinary field, special attention will be devoted to the added value of SSH in relation to contributions from other fields and sciences.

Relevant topics include:

Assessment of the radiological and non-radiological effects of radiological accidents through transdisciplinary research, for instance in the case of a medical overexposure or in industrial radiology.
Holistic approaches to accident preparedness, management and recovery, taking into account multiple risks, social, economic and psychological factors. These approaches should account for the development of psychological support for evacuees as part of preparedness policies; socio-economic aspects of preventive distribution of iodine tablets in different EU countries; and psychological consequences of emergency management decisions. Inappropriate responses of individuals and groups (e.g. voluntary evacuation when sheltering is advised) and how to avoid such responses is also important.
Social, ethical and psychological issues related to preparedness and response to nuclear and radiological terrorism and other criminal behaviour.
Ethical aspects of crisis situations, particularly ethical questions around evacuation, post-accident management, and the transition from emergency to recovery radiological exposure situations.
Development of socio-economic valuation and multi-criteria decision methods as one approach to formally structure the evaluation and integration of radiological and non-radiological factors for different ionising radiation exposure situations.

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Decision making mechanisms in post-accident situations, with emphasis on local knowledge, values and decision-making.
Analysis of existing policy and regulatory influence on the radiological protection field.
The development of joint actions with institutional and non-institutional actors in radiological protection governance.
Analysis of the values and principles that inform radiological protection programmes and practices in the medical field.
Assessment of how uncertainties are identified and managed in different professions, for instance general practitioners, surgeons, food scientists, environmental scientists, publics.
The ethics of compensation for radiological risks in different countries.
Assessing values and expectations that come with the integration of SSH in radiological protection.

4.3. Research line 3: Responsible Research and Innovation in Radiological Protection

Research line 3 aims at assessing how radiological protection research, development and innovation is conducted, with the aim of inciting more socially responsive and ethically sound processes and outcomes. The design of transdisciplinary activities is emphasised in this research line, for example through co-creation agenda setting-processes that engage technical and social scientists alongside publics.

Relevant topics include:

Enhancing the reflexive awareness of actors involved in technical R&D about the societal implications of nuclear technology applications and radiological exposure situations that require radiological protection research.
Examining the social, cultural, and historical context of radiological protection research; the rationales, possibilities, and limitations of research approaches and methods; the social relevance of research hypotheses.
Ascertaining conflicts of interest in radiological protection research and finding ways to manage such conflicts.
Identifying and developing sound ethical principles and approaches to guide radiological protection research in a socially responsive, inlcusive and responsible manner.
Operationalising, as well as problematising and developing, principles such as trans-disciplinarity, which sustain the integration of SSH into radiological protection research.
Evaluating the institutional uptake of research projects and findings.

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Determining how to make SSH integration meaningful and effective for all stakeholders.
Developing methodologies and tools for the dynamic mapping of stakeholders' concerns, views and needs to identify R&D priorities in the radiological protection field.

4.4. Research line 4: stakeholder engagement in radiological protection research and development, policy and practice

Research line 4 aims at fostering stakeholder engagement in radiological protection research, policy and practice in ways that enhance responsiveness to societal needs and concerns. By 'stakeholder' we denote anyone who has a stake in radiological protection research, its development or applications and/or is potentially affected by radiological protection R&D and the outcomes it generates.

Relevant topics include:

Mediation and facilitation between authorities, scientists, publics and other stakeholders for different exposure situations and nuclear applications, research and development. This implies giving due attention to issues of representation and lessons learned.
Establishment of a collaborative framework for stakeholder engagement in radiological protection research, policy and practice in ways that enhance responsiveness to societal needs and concerns.
Analysis and evaluation of societal needs to shape the legal requirements and governance frameworks in ways that support access to information, public participation and access to justice.
Assessment and development of stakeholder and public participation tools and methodologies for different radiological exposure situations; including roles, rules and responsibilities of stakeholders in the engagement process, motivations, values and links between theory and practice.
Potential and limitations of involving citizens in the production of knowledge for radiological protection. Examples include citizen science, citizen journalism, and partnerships with local communities.
Preservation of knowledge and experience of local stakeholders' (e.g. local community, schools, citizens) involvement and participation. Community research and tracing of the development of a participation culture in relation to different exposure situations.

4.5. Research line 5: risk communication

This area covers issues related to communication of risk, how affect and trust influence risk perception and behaviour, and how exchange or sharing of risk-related data, information and knowledge between and among different parties (such as regulators, experts, consumers, media, general public) can be provided. Research line 5 aims at developing research to support communication about ionising radiation between different stakeholders and citizen-centred risk communication, in order to clarify choices and options in a variety of exposure situations. It also seeks to empower citizens and other stakeholders to make more informed decisions.

Relevant topics include:

Risk communication about radioactivity and radiological protection principles in medical applications of ionising radiation, and the impact of communication on the radiological protection behaviour of practitioners.
Improving decision-making through informed consent of patients for medical procedures involving ionising radiation; by empowering patients in decision making; ethical issues and communication about uncertainties; informed consent versus the right not to know.
Developing long-term communication models to improve radiological protection culture and public well-being in long-term existing exposure situations.
Use and perception of technical information and risk estimates in communication with various publics (lay people, experts, informed civil society).
Media communication about ionising radiation, in particular low radiation doses and related uncertainties in the field of radiological protection including inter-media agenda setting in different exposure situations.
Ethical basis and values underpinning risk communication about ionising radiation exposures.
Risk communication and stakeholder involvement in post-accident recovery in order to support decision-making process related to daily life and improving public health.
Developing risk communication about low doses: Use of state of the art knowledge from socio-psychological research with focus on low doses of ionising radiation and related uncertainties.
Ethical principles guiding deliberative processes on questions that cannot be decided by radiological specialist alone: role of uninformed risk perceptions, applicability of informed consent, appropriateness of risk comparisons, dealing with refusal to communicate.
Perception and communication related to radiosensitivity and radiosusceptibility including mental maps, ethical aspects.

4.6. Research line 6: radiological protection culture

Research line 6 involves research concerning the assessment and development of a radiological protection culture among all RP stakeholders, in various exposure situations (planned, existing and emergency), and for different categories of exposure (occupational, patient, general public). The aim of this research line is to increase the understanding and application of radiological protection principles, norms and standards; to enhance the decision-making processes concerning the management of radiological exposure situations, and the identification and implementation of RP actions. At the same time, it aims to enable individuals and collectivities to reflect on their own protection and/or that of others; to consider consciously radiological protection aspects in their activities or decisions; to make their own decisions with regard to their own protection against ionising radiations; to participate in decision-making processes related to the management of exposure situations. By enabling the dialogue between professionals in the RP field and other stakeholders, Research line 6, contributes to enhancing the efficiency and reliability of the radiological protection system and its capacity to effectively address the concerns of all stakeholders.

Relevant topics include:

- Characterisation of RP culture, including

Specificities associated with exposure situations;
Organisational, social, political, economic, cultural and psychological aspects influencing RP culture or RP behaviour;
Ethical frameworks and value judgments underlying RP cultures;
Interactions between the RP culture at the level of an organisation or community, and at individual or sub-group level;
Impact of evolving RP technologies, knowledge, information, and communication technologies on RP culture;
Relationships between RP culture and safety or security culture.
Analysis of processes of RP knowledge production, values and expectations.

Qualitative and quantitative evaluation of RP culture, at group and or individual level.

The role of RP culture for the implementation and improvement of the RP system; and the health and well-being of populations.

Development of tools, methods, processes and guidelines to build, maintain, enhance and transmit RP culture, taking into account the needs and concerns of various stakeholders regarding RP culture, including future generations, and the specificities of RP fields (e.g. emergency and recovery preparedness, NORM activities, radon exposures, paediatric imaging).
Social, psychological and economic aspects of radiological protection choices by different actors.

5. Research needs in short-term and medium-term

Social and ethical aspects in radiological protection research, policy and practice involves research that must be addressed to numerous fields related to ionising radiation and its applications, for example: medical exposures to ionising radiation, naturally occurring radioactive materials, nuclear waste management, environmental remediation, emergency and recovery management, and decommissioning. On the one hand, the Social Sciences and Humanities community encourages multi-disciplinary approaches that ensure attention to social and ethical considerations. On the other hand, the SSH community has its own SSH SRA dedicated research priorities, which are not currently addressed by the research agendas for RP produced by other, non-SSH disciplines.

A gap analysis was carried out in order to identify the top SSH research priorities to be addressed by projects responding to the EURATOM NFRP[28] 2018 calls (Vanhavere 2018). The gap analysis considered topics included in the SSH SRA (Perko *et al* 2016a, Perko *et al* 2017b) and/or defined as priorities by radiological protection stakeholders (Impens *et al* 2017). The analysis highlighted key topics that have been addressed to only a limited extent in recent or ongoing EU projects, namely:

- Risk communication in medical exposures; impact of communication on RP behaviors of practitioners.
- Risk communication on low doses and related uncertainties.

[28] NFRP: Nuclear fission and radiation protection research.

- Ethical basis and values underpinning risk communication exposures to ionising radiation.
- The understanding of ionising radiation concepts, risks and uncertainties by different stakeholders in the context of planned, existing and emergency exposure situations.
- The interplay of psychological aspects associated with radioactivity, social environment and radiological protection behaviour.
- Potential and pitfalls of citizen involvement in knowledge production for radiological risk governance.
- Socio-economic valuation and multi-criteria decision-aiding methods to formally structure the evaluation and integration of radiological and non-radiological factors.
- Enhancing the reflexive awareness of actors involved in radiological protection R&D as to the societal implications of research.
- Democratic culture in RP in order to construct joint actions with institutional and non-institutional actors.
- Mediation, facilitation and representation on the triangle scientists, public and other stakeholders for different exposure situations.
- Collaborative framework for stakeholder engagement in RP research, policy and practice in ways that enhance responsiveness to societal needs and concerns.
- Societal needs for and evaluation of legal instruments and governance frameworks supporting access to information, public participation and access to justice in relation to RP issues.
- Stakeholder and public participation tools and methodologies for different exposure situations. Roles and rules for stakeholders in the engagement process. Motivational factors, ethics, and links between theory and practice.
- Characterisation of RP culture.
- The role of RP culture in the implementation and improvement of the protection system.

The SSH community encourages multi-disciplinary approaches that address one or more of the above topics and facilitate the integration of social and ethical considerations into radiological protection agendas and programmes at an early stage. This vision of priorities will guide further development of the SRA with a view towards enhancing the role of SSH research in RP for the mutual benefit of science and society.

6. Conclusions

In this article, we outlined a prospective Strategic Research Agenda for the Social Sciences and Humanities in radiological protection. The SRA represents the views and commitments of a wide range of stakeholders in the RP arena (researchers, policy makers, implementers, authorities, and members of technical and research platforms). In line with European science policy appeals to responsible research and innovation, the proposed SRA seeks to facilitate more socially responsive science and technology processes by systematically integrating social and ethical considerations into RP research programmes and policies. It extends, unifies and builds on previous European efforts to integrate SSH into radiological protection research in fields such as medicine, radio-ecology, energy, dosimetry, and waste, with due consideration to the social, political, ethical, cultural and historical factors that shape research. Among the benefits of conducting scientific intra-, inter-, multi- and trans-disciplinary research in radiological protection may be the fostering of user-friendly technologies for radiological protection, helping citizens make informed decisions, and improving radiological risk governance. As evidenced by numerous studies, SSH researchers can fruitfully inform RP research and decision-making in these and related areas.

Far from a conclusive declaration, the SRA is intended as a dynamic document to encourage debate on what are SSH research priorities in RP; provide guidance on what subjects could and should be covered in new research programmes on radiological protection research (for example through PhD and postdoctoral programmes); and offer a list of key SSH topics for research programmes on specific radiological protection subjects. The SRA will be adapted in view of changing stakeholder needs, through ongoing interactions with all concerned parties, including the technical and research platforms.

We anticipate that the SSH SRA presented here will have significant scientific and policy impact in the intermediate and long run, as social scientists and humanities scholars increasingly engage with RP stakeholders, policies and practices. These engagements open up new possibilities to embed social and ethical considerations in RP research and development, thereby expanding research options, addressing stakeholder needs and values, and fostering forms of inter- and transdisciplinary research collaboration.

Now is the time for European research institutions, as well as national and international authorities, including the European Commission, to invest resources in the identified research lines and topics. This will facilitate the further development of SSH research, under a broad, engaged, and reflexive agenda, whose effect will be to promote responsible RP practices and benefits for both science and society.

Acknowledgments

The authors are grateful to the many people who have provided comments and suggestions on earlier versions of the SSH SRA, and to the reviewers who provided thoughtful advice on this article. This endeavour has received funding from the CONCERT project, within the EURATOM research and training programme 2014–2018 under grant agreement No 662287.

Appendix

Direct Contributors to the SRA of Social Sciences and Humanities in radiological protection (alphabetical order by institutions).

Name	Institution/Affiliation
Vasiliki Tafili	Atomic Energy Commission, EEAE (Greece)
Gaston Meskens Tanja Perko Michiel Van Oudheusden Catrinel Turcanu	Belgian Nuclear Research Centre, SCK · CEN (Belgium)
Mélanie Maître	Centre d'étude sur l'Evaluation de la Protection dans le domaine Nucléaire, CEPN (France)
Katarzyna Iwińska	Collegium Civitas (Poland)
Penelope Allisy –Roberts	Editorial Board member, Journal of Radiological Protection (United Kingdom)
Nadja Zeleznik	Elektroinštitut Milan Vidmar (Slovenia)
Christiane Pölzl-Viol	Feral Office for Radiation Protection, BfS (Germany)
Sotiris Economides	Greek Atomic Energy Commission, EEAE (Greece)
Genevieve Baumont, Eloise Luçotte, Sylvie Charron Ilma-Choffel de Witte	Institut de Radioprotection et de Sûreté Nucléaire, IRSN (France)
Claire Mays	Institut Symlog de France , SYMLOG (France)

(Continued.)

Name	Institution/Affiliation
Piet Sellke	Institute for cooperation and communication research, DIALOGIK (Germany)
Maria Suric Mihic, Ivica Prlic	Institute for Medical Research and Occupational Health, IMROH (Croatia)
Daniela Diaconu, Marin Constantin	Institute for Nuclear Research (Romania)
Grazyna Zakrzewska	Institute of Nuclear Chemistry and Technology, ICHTJ (Poland)
Caroline Schieber, Thierry Schneider	Le Centre d'étude sur l'Evaluation de la Protection dans le domaine Nucléaire, CEPN (France)
Mihok Peter	Matej Bel University (Slovakia)
Meritxell Martell	Merience (Spain)
Gilles Heriard Dubreuil, Stéphane Baudé	MUTADIS (France)
Paola Fattibene, Sara Della Monaca	National Health Institute, ISS (Italy)
Clara Carpeggiani	National Research Council, CNR (Italy)
Lavrans Skuterud	Norwegian Radiation Protection Authority, NRPA (Norway)
Deborah H Oughton, Yevgeniya Tomkiv	Norwegian University of Life Sciences, NMBU (Norway)
Edward Lazo	OECD- NEA
Eeva Salminen	Radiation and Nuclear Safety Authority of Finland, STUK (Finland)
Jim Malone	Trinity College Dublin (Ireland)
Susan Molyneux-Hodgson	University Exeter, (United Kingdom)
Peter Thijssen	University of Antwerp (Belgium)
Peter Simmons	University of East Anglia (United Kingdom)
Sisko Salomaa	University of Eastern Finland, UEF and Radiation and Nuclear Safety Authority , STUK (Finland)
Ana Delicado	University of Lisbon (Portugal)
Iztok Prezelj, Drago Kos, Marko Polic	University of Ljubljana (Slovenia)
Marie Claire Cantone	University of Milano, UMIL (Italy)
Friedo Zölzer	University of South Bohemia in České Budějovice, USB (Czech Republic)
Ortwin Renn	University of Stuttgart (Germany)
Tatiana Duranova	VUJE (Slovakia)

ORCID iDs

Tanja Perko https://orcid.org/0000-0001-8405-6631

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