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D2.6 Regulators' needs and expectations relevant to medical radiation protection research

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1. Introduction

The panel of task 2.6 is made up of representatives of regulatory agencies from 6 European countries and additional experts from universities and clinics. Echoing the need for better integration of radiation protection organisations with other EU bodies in healthcare and research, the members include representatives of the Heads of the European radiological protection competent authorities (HERCA), European Society of Radiology (ESR), European Society of Cardiology (ESC), EUROSAFE, European Trade Association (COCIR) and international Committee for Radiation Protection (ICRP). After a total of 12 meetings we reached a consensus on eight topics that comprise the current research needs and expectations of regulators for medical applications of ionising radiation.

These research needs and expectations of regulators have been structured in two big groups, according to the initial proposal of the EURAMED rocc-n-roll project: subjects related to quality assurance (A); and subjects related to screening and individual health assessment (B). Eight different research topics have been identified and presented in approximately one page (each one describing the legal requirement, research needs and indicative research topics). A summary of two pages including the main research needs from these topics can be found at the end of this deliverable. These two pages will be part of the EURAMED strategic research agenda.

2. Identified research needs

A. Research needed for quality assurance

A.1.1. Research needed for quality assurance of new artificial intelligence (AI) technologies for medical applications of ionising radiation to diagnostics

LEGAL REQUIREMENT:

Article 60 of the European BSS ("equipment") [BSS 2013] requires that "all medical radiological equipment in use is ***kept under strict surveillance*** regarding radiation protection" and more precisely that "performance testing is carried out thereafter on a regular basis, and after any maintenance procedure ***liable to affect the performance***".

PRACTICAL IMPLEMENTATION NEEDS:

To this date, performance testing (as well as acceptance testing) has been performed by imaging **physical phantoms** that contain relatively simple structures (circles, bars, spikes, rings…). An underlying assumption is that the imaging chain (image acquisition and image processing) does not distinguish between a patient and a phantom. Therefore, the image quality measured with the phantoms (noise, resolution, contrast) has been assumed to be the image quality provided when imaging patients.

However, algorithms using machine learning (ML), such as modern CT-reconstruction algorithms [Singh 2021], can easily **recognise and enhance the simple structures in the phantoms**. This is possible because the phantoms exhibit simple structures in comparison to the high variability of structures in actual patients (vessels, bones, organs…). In addition, these ML algorithms can be taught to update themselves continuously ("unsupervised learning"), so that, although this is not likely to happen in the near future, the **image processing and the resulting image quality can be somewhat different in two consecutive examinations**.

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This new situation is not compatible with the traditional assumption above, and thus would benefit from an updated paradigm for performance testing of image quality.

INDICATIVE RESEARCH TOPICS:

The following indications can help to define research projects:

Find tools and practical methodologies to **guarantee** "**strict surveillance**" of adequate image quality when dealing with AI products (such as new reconstruction algorithms for tomosynthesis or CT). Examples: properly simulating **human variability**, evaluating **patient images** directly [Gong 2019], performing evaluations **after every examination with an automated software**.

Design strategies to accurately define a "maintenance procedure **liable to affect the performance**" when dealing with AI methods. Example: find **constancy tests** in the case of algorithms "improving" themselves continuously.

A.1.2. Research needed for quality assurance of new artificial intelligence (AI) technologies for medical applications of ionising radiation to radiotherapy

LEGAL REQUIREMENT:

In the European BSS [Council directive 2013], the importance of quality assurance is raised in several articles.

First, in **Article 4 - definition (70)** it states: *"quality assurance" means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;*

Then the following articles require that:

Article 56 Optimisation

*4. Member States shall ensure that the **optimisation includes** the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, **quality assurance**, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.*

Article 60 Equipment

1. Member States shall ensure that:

*(c) **appropriate quality assurance programmes** and assessment of dose or verification of administered activity **are implemented by the undertaking**;*

Article 61 Special practices

1. Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure:

(a) of children;

(b) as part of a health screening programme;

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(c) ***involving high doses to the patient****, which may be the case in interventional radiology,* ***nuclear medicine****, computed tomography or* ***radiotherapy****.*

Special attention shall be given to quality assurance programmes *and the assessment of dose or verification of administered activity for these practices.*

Article 63 Accidental and unintended exposures

Member States shall ensure that:

(b) ***for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures****;*

RESEARCH NEEDS:

In radiation therapy, several applications of AI based software can be identified to date [Vandewinckele 2020]:

- Automatic tumour and organ-at-risk segmentation
- Synthetic computed tomography (sCT) (based on MRI or CBCT images)
- Automated treatment planning and adaption (adaptive EBRT)
- Automated quality assurance models (for patient specific treatment verification and machine QA) (at early stages of development)

Quality assurance concerns:

- the commissioning phase of the AI-based application,
- the clinical implementation phase,
- the daily use of the AI model.

For QA tools to operate with similar effectiveness in different clinics and translate across practice sites, it will be of great importance to develop standards and formalisms [Kalet 2019].

To date, the difficulty for regulators is to ensure that the appropriate quality assurance programs are in place i.e. if the planned and systematic actions necessary are in place to provide adequate assurance that AI based software will perform satisfactorily in compliance with agreed standards. Methodologies, metrics and acceptance criteria should be developed and agreed to define a common set of references.
This work will need a concerted effort of the stakeholders, including vendors and national professional societies in radiation therapy.

INDICATIVE RESEARCH TOPICS:

Studies should be conducted to develop standards, formalisms, metrics and criteria to define common quality assurance programs and to evaluate/audit the application of AI based software.

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A.1.3. Research needed to develop (AI)-tools for inspection and surveillance of medical applications of ionising radiation

LEGAL REQUIREMENT:

Section 7 (System of enforcement) of the European BSS [BSS 2013] includes article 104 ("Inspections"), which requires that "Member States shall establish a system or **systems of inspection** to enforce the provisions adopted pursuant to this Directive and to **initiate surveillance and corrective action** where necessary". The following paragraphs require all or parts of this information to be available "to the undertaking concerned" and to the **public**, as well as a "**timely dissemination** to relevant parties" […] "of information concerning significant lessons learned".

RESEARCH NEEDS:

The inspection and surveillance duty of regulators can be facilitated by AI-tools. AI algorithms can be used to find **patterns within large amounts of data**. These patterns can serve to **identify facilities** with especially efficient protocols, **trigger alerts** for authorities and users in case of inefficient protocols or **predict potential incidents**. These tools and algorithms could enable **timely dissemination** of (anonymous) surveillance information.

Research is needed to harmonise **automatic collection and transmission** to national dose/data repositories, which is essential to make an effective use of AI-algorithms. This need is stressed in topic 2.2 regarding the need to update diagnostic reference levels with nearly real-time data. These repositories will collect and contain large amounts of **exposure and other kinds of related data** that can be considered "**big data**". Because of data protection issues, the data collected locally in facilities needs to be anonymised before it is sent to a national repository [Cybernetica 2022].

AI algorithms can also be used to **analyse data for and from inspections in a larger and/or faster scale**. This could serve to establish a system of inspection that can **initiate surveillance and corrective action** where necessary. A certain percentage of inspected facilities could be selected by an AI-algorithm and the rest by a random procedure within the authorities (The same could be helpful to feed data for clinical audits but this is not the responsibility of regulatory authorities).

If DICOM-images are added to this data set, AI-algorithms could **relate the exposure parameters with image quality indicators** defined by the authorities and scientific societies. This could serve to alert the facilities (and/or the authorities) in case of **deviation from expected practice**, but also guarantee that all facilities are **inspected under the same conditions**.

AI algorithms could also help to improve or standardise dosimetry of "problematic" technologies such as cone-beam CT.

INDICATIVE RESEARCH TOPICS:

How can AI or other tools **harmonise and analyse** the (national and international) data? How can this data be made available to relevant partners and the public?

How can AI or other tools **assist in the prediction of incidents**? How can AI help to **improve inspections**? Can we develop a platform for on-line AI-assisted inspections?

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How can AI or other tools **check previously defined image quality parameters** in clinical images? As an example: how to define objective criteria for medical (anatomical) features and/or physical thresholds? How can AI predict dosimetry values from any x-ray modality? Can AI help to find easier methods for dosimetry?

A.1.4. Research needed for quality control of new technologies (not AI) for medical applications of ionising radiation (diagnostics and therapy)

LEGAL REQUIREMENT:

The BSS Directive [BSS 2013] mandates the implementation of appropriate quality assurance programmes. A quality assurance programme, which includes quality controls (QC), is intended to provide adequate guarantee that the performance of a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards.

According to BSS Article 60.1 "*Member States shall ensure that […] appropriate quality assurance programmes and assessment of dose or verification of administered activity are implemented by the undertaking;*"

The MDR Regulation, published in 2017 and entered into force in 2021, requires, at Annex I, article 16.1.b [MDR 2017] requires that "*The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified*."

RESEARCH NEEDS:

Manufacturers can provide, according to MDR, information regarding acceptance and performance criteria, etc. It can be expected however that such protocols, due to the novelty of the technology, would be different between manufacturers. Initial protocols may even require sophisticated tools not always immediately available or intensive use of resources and time. Research is needed to refine QC protocols with time and experience both by manufacturers and users.

The role of standardization bodies and professional societies is crucial in the further phase of harmonization and improvement of QC efficiency, as a few recent examples show: IEC Committee TC62 is updating a range of international standards IEC 61223 on the "Evaluation and routine testing in medical imaging departments"; COCIR and EFOMP recently started a series of webinars on the importance of cooperating with industry; and EFOMP consulted COCIR on the draft of their recent QC protocol for PEC/CT and PET/MRI. However, research is needed to avoid or reduce the lack of harmonization in Europe, as well as to design strategies that can help national authorities towards a better alignment.

INDICATIVE RESEARCH TOPICS:

Research and cooperation within all stakeholders are needed to avoid difficulties that may be encountered to design specific quality control for the diagnostic fields of monochromatic x-rays, dark-field imaging, phase-contrast imaging, x-ray fluorescence and molecular imaging.

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Within therapy research is needed to develop methodologies that may enable a future harmonisation of quality assurance in the fields of FLASH therapy (proton, electron), heavy ions, ZAP-X, micro and nanobeam therapy.

A.2.1. Research needed to improve diagnostic reference levels and achievable levels for medical applications of ionising radiation

LEGAL REQUIREMENT:

Article 56 of the European BSS ("optimization") [BSS 2013] requires that "*Member States shall ensure the* ***establishment, regular review and use of diagnostic reference levels*** *for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose. […] Member States shall ensure that the optimisation includes* ***the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes****, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.*"

RESEARCH NEEDS:

The diagnostic reference levels (DRLs) are designed to provide an indication whether a radiological procedure is carried out in an appropriate manner. Comparison of patient dose indicator to corresponding DRL gives a rough indication whether the procedure is adequately optimized. However, the DRL is calculated for average patient material and it does not consider individual patient properties such as size, age or sex, all of which may be important for optimizing the exposure. Moreover, DRLs are often established via extensive data collection and the update process can be very long (3 or more years). Technological developments are fast and DRLs do not necessarily follow this evolution. The use of DRLs in interventional radiology has challenges because of large variations in technical factors in carrying out the procedure as well as complexity of the procedure for instance.

Research is needed to provide more **flexible and tailored DRLs** and to adapt to fast technological developments. Automatic utilisation of data repositories in establishing (nearly real time) DRLs should be investigated in more detail. The concept of DRL itself is simple and easy to adapt to clinical use, but the use of more detailed statistical description of dose distributions should be investigated to further help in optimization process. Earlier studies have shown that large variations exist in DRLs between different clinics, hospitals, and countries. This could be assessed with more detailed information on dose distributions and related influencing factors (e.g., procedure complexity).

Currently, the majority of DRLs are defined per anatomical location (thorax, brain etc) and then for a same localization, one DRL can include several kinds of examinations (for instance low dose lung CT and high dose thorax CT depending on the clinical goal). The development and harmonisation of clinical DRL (identified by clinical indication instead of anatomical part) is necessary as recommended in the EUCLID project. The reasons why this recommendation is not being followed yet should be investigated.

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Additionally, a proper use of DRL implies to keep an image quality adapted to the clinical need (see also topic 1.3).

INDICATIVE RESEARCH TOPICS:
Identified research questions are: How can we harmonize data collection along Europe? In other words, how can we setup national repositories with reliable data? How can we update the information online as fast as possible? Can we construct a platform for (AI-)assisted update of DRLs? See also related questions in topic 1.3.
To continue the work on clinical DRL initiated by the EUCLID project developing the concept of DRLs, to set efficient national and local DRLs. For example:
To include image quality indicators in the lists of DRL and/or define indicators which consider both dose (DRL) and image quality (see also topic 1.3) and their connection
More efficient use of patient exposure data to foster optimization (consider possible use of artificial intelligence and machine learning for automated analysis of these big data)

A.2.2. Research needed for medical applications of ionising radiation for new isotopes in nuclear medicine therapies: patient dose optimisation

LEGAL REQUIREMENT:

Article 56.1 of the European BSS ("equipment") [BSS 2013] requires that:

"Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure."

RESEARCH NEEDS:

The European Commission organises every year, in cooperation with the Group of Experts referred to in Article 31 of the Euratom Treaty, a Scientific Seminar on emerging issues in Radiation Protection – generally addressing new research findings with potential policy and/or regulatory implications. In November 2019, an EU Scientific Seminar covered the issue Developments in nuclear medicine – new radioisotopes in use and associated challenges.

During this Seminar, a list of challenges and solutions concerning dosimetry guided radionuclide therapy were raised (see table 1 below).

Challenges	Solutions
Time and resource consuming	Reimbursement for dosimetry studies
Inconvenient for the patient	Keep it practical and relevant
On-site expertise needed	Medical physics expert support mandatory

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No established dosimetry method	Benchmark for dosimetry software
Unclear dose-response models	Focussed radiobiology research in MRT
Large uncertainties in absorbed dose	Improve accuracy in dosimetry process
Safe activity from clinical trials /experience	Dose response model guided clinical trials
"One size fits all" is more convenient	Sub-optimal patient care in not acceptable

Table 1: Challenges to dosimetry guided radionuclide therapy and possible solutions (adapted from RP Nr. 194 [EC 2020])

Among this list, the following 4 topics especially require research work:

1. to foster radiobiology research in MRT (molecular radiation therapy)
2. to improve accuracy in dosimetry process
3. to develop a common methodology for dosimetry for MRT
4. to conduct a benchmark of the different dosimetry software

INDICATIVE RESEARCH TOPICS:

The following indications can help in the implementation of patient dose optimisation in MRT according to Article 56.1:

Studies should be conducted to benchmark the different dosimetry software and to develop a common methodology for dosimetry

Improvement of the knowledge in radiobiology is needed. To this end, the research should be intensified to improve the knowledge regarding the relation between dose and effects both for organs at risk and tumor targets, specific to MRT. In particular for new isotopes like Ac-225, trans-uranes, Ho-166, Lu-177.

A.2.3 Research needed for personalized dosimetry of patients and carers for medical applications of ionising radiation: patient dose optimisation (Diagnosis)

LEGAL REQUIREMENT:

Article 5 of the European BSS ("General principles of radiation protection") [BSS 2013] requires that "*Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations, reflect a system of radiation protection based on the principles of justification, optimisation and dose limitation " and in particular for diagnostic procedures in Article 56 it is stated that "Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors*".

Article 58.b states that "*Member States shall ensure that […] information relating to patient exposure forms part of the report of the medical radiological procedure*", but this poses certain problems regarding the quality and the quantity of delivered information.

Article 64 requires that „*Estimates of population doses Member States shall ensure that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined, taking into consideration where appropriate the distribution by age and gender of the exposed.*"

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RESEARCH NEEDS:

The rise of personalized medicine and the increase of risk awareness of the society has led to the situation where doses to individual patients need to be better estimated, adapted to the real variation in individual patient anatomy and physiology, to perform dose (risk) assessment and optimization of exposure. In particular, the dosimetry methods in imaging procedures need to be improved. Real time methods using Monte Carlo computations and/or machine learning (artificial intelligence) must be improved.

In order to deliver proper information, uncertainties and traceability in these estimates need to be considered explicitly. Methods to assess cumulative doses from subsequent x-ray examinations also need to be developed.

RELATED RESEARCH TOPICS:

Development of methods (including AI alternatives) to estimate individual patient doses

Development of software for standard reporting of individual patient doses and related quantities

Development of interfaces with picture archiving and communication system (PACS), Radiology Information System (RIS), and electronic health record (eHR), for example using dose management systems to harmonise and automatise the collection of exposure data and their analysis.

If (many) member countries did not implement some BSS articles, where are the obstacles?

B. Research needed for screening and individual health assessment for medical applications of ionising radiation

LEGAL REQUIREMENT:

Article 55 of the BSS "Justification" [BSS 2013] paragraph f requires that "***specific justification for medical radiological procedures to be performed as part of a health screening*** *programme are carried out by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies*" and paragraph h requires that "***any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening programme****, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by point (d) of Article 57(1)*".

PRACTICAL IMPLEMENTATION NEEDS:

Screening is a significant departure from the clinical model of healthcare, because apparently healthy individuals (asymptomatic persons) are offered a radiological procedure [HERCA 2012]. An effective screening procedure detects either pathology demonstrating risk factors for developing a disease, or the disease itself at an early stage where treatment can improve clinical outcome. The aim is to identify those individuals who are more likely to be helped than harmed by further diagnostic procedures or treatment. When apparently healthy individuals are offered a radiological procedure which is not part of a formal screening programme then

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this scenario is denoted as "Individual health assessment". In this scenario, there is potential for a large number of individuals receiving more harm than good, particularly if the individual examination used carries a higher risk and the false positive rate from the examination is high.

INDICATIVE RESEARCH TOPICS:

Tools and practical methodology for the justification of radiological procedures to be performed as part of a health screening programme. For example: justification of Digital Breast Tomosynthesis for breast cancer screening [EHU 2019, EC 2019].

Tools, practical methodology and guidelines for screening programmes to be performed for the early detection of disease through the use of radiological procedures and also in the perspective of the development of personalised medicine.

. For example: Lung cancer screening, bowel cancer screening, screening for Osteoporosis and, possibly, neurodegenerative diseases.

Tools and practical methodology for the evaluation and re-evaluation of existing screening programmes for a range of resource settings.

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Annex

Summary: Two pages for the EURAMED strategic research agenda

Introduction / regulatory requirements

The evaluation of regulators´ needs and expectations relevant to medical radiation research has been based on the European basic safety standards (BSS) of the Council Directive 2013/59/Euratom. In particular, the content of the following articles requires active participation of the research community: articles 5, 55 and 56 related to the concepts of justification and optimisation; articles 57(1) and 58.b (together with article 16.1.b of Annex I in the medical device regulation) related to the provision of information regarding medical exposure; article 60 "equipment" (in particular 60.1 related to quality assurance programmes); article 61 "Special practices"; article 63 "Accidental and unintended exposures"; Article 64 related to estimation of collective doses and article 104 "Inspections". A general challenge for regulators is the different adoption of the BSS by the member states.

The needs of regulators have been structured in three fields: 1. quality assurance regarding artificial intelligence (AI), 2. quality assurance regarding other technologies (non-AI) and 3. screening and individual health assessment.

1. Research needs regarding artificial intelligence

Research needs to regulate the use of AI systems

Many of the urgent needs of regulators arise from the recent applications of AI, in particular machine learning algorithms. The difficulty for regulators is to ensure that planned and systematic actions are in place to ensure that AI-enabled software will perform satisfactorily in compliance with agreed standards over its lifetime. Methodologies, metrics and acceptance criteria need to be developed and agreed to define a common set of references. This work needs a concerted effort of all stakeholders, including vendors and national professional societies. Specific research questions relevant to regulators involve the following topics (non-exhaustive list):

- Diagnostic radiology procedures: evaluation of algorithms for justification, optimisation, image processing and deep-learning-based dose modulation; identification of dose reduction systems in a holistic way;
- Nuclear medicine reconstruction algorithms in PET-CT;
- Radiation therapy: synthetic computed tomography, automatic segmentation, treatment planning systems; adaptive external beam radiation therapy or automated quality assurance models.

Associated technical topics are also being explored in task 4.2 (section XXX); social and ethical issues are explored in more detail in task 4.3 (section XX).

Research needs on AI-enabled tools that may help regulators

Applications of AI also include potential benefits for the work of regulators. Current and future repositories can collect large amounts of patient and worker exposure data that can be considered "big data". Research is needed to harmonise this automatic collection and transmission (for example using dose management systems), as well to make adequate information available (to regulators, researchers and the public) and to manage data protection issues. AI algorithms are needed to find patterns within these data. These patterns can serve to identify facilities with especially efficient protocols (e.g., regarding dose and image quality), alert authorities and users in case of inefficient results or potential incidents. AI algorithms

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could also help to define a fair system of inspections/audits, as well as to improve or standardise dosimetry reporting.

2. Research needs on quality control regarding other technologies

Regarding non-AI technologies, the medical RP community has identified a need for research towards personalised dose assessment for patients and towards harmonisation of methodologies, which in turn require the proper set-up of shared data repositories. Further, the current science behind communication of individual patient dose and risk assessment is a critical role for all RP workers to understand, including the regulator. The following research needs were identified specifically for diagnostic and therapy

In **diagnostic radiology**, the on-line availability of harmonised exposure data (including among others, information about patient size, age at exposure, sex, image quality and procedure complexity after interventions) could help to upgrade the concept of diagnostic reference levels and to adapt the dosimetry methods to real patient anatomy (rather than standard phantoms), both contributing to optimisation and personalised risk assessment. Uncertainties and traceability to primary standards in the dose estimates and risks need to be more carefully addressed, in particular for cumulative doses from subsequent examinations. Research to harmonise quality assurance methods should include emerging technologies such as photon counting CT, monochromatic x-rays, dark-field imaging and phase-contrast imaging.

In **molecular radiation therapy** there is a need to benchmark different dosimetry software packages, develop common, more accurate methodologies for dosimetry and foster focused radiobiology research in molecular radiation therapy (in particular for new isotopes like Ac-225, trans-uranes, Ho-166, Lu-177). Research is also needed to harmonise quality assurance in the fields of FLASH therapy (proton, electron), heavy ions and stereotactic radiosurgery (e.g. ZAP-X).

3. Research needs regarding screening and individual health assessment:

Radiological procedures forming part of a screening program have to be justified in advance before being implemented by national health ministries following a cost-effective analysis or technical assessment where appropriate. When healthy individuals are offered a radiological procedure that is not part of a formally approved screening programme, then this scenario is denoted as "Individual health assessment" (IHA). In this scenario, imaging is not justified and there is potential for a large number of individuals receiving more harm than good, particularly if the individual examination used carries a higher risk and the false positive rate from the examination is high. However, the development of personalised medicine could be a breakthrough and should be considered in the justification of IHA.

Research is needed to develop and evaluate tools and practical methodologies for the justification of radiological procedures to be performed as part of an existing health screening programme (for example justification of digital breast tomosynthesis for breast cancer screening). In addition, harmonised guidelines are required to define new screening programmes for the early detection of disease through the use of radiological procedures, such as for lung cancer screening, bowel cancer screening, screening for osteoporosis and, possibly, for some neurodegenerative diseases as treatments become more available.

Finally, other tools and practical methodologies are required to evaluate existing screening programmes taking into consideration the situation in different European member states. Research is required to investigate which existing guidelines are being followed locally and why, in order to ensure proper understanding and harmonisation (NCRP Commentary 13).

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