MEDIRAD

RECOMMENDATION 3

FURTHER OPTIMISATION OF RADIATION PROTECTION FOR PATIENTS AND MEDICAL WORKERS

PROJECT TITLE

Implications of Medical Low Dose Radiation Exposure

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About MEDIRAD Recommendations

MEDIRAD is a research project funded by EURATOM under Horizon 2020 Programme (2016/ 2022). Bringing together radiological and clinical research teams from several European countries, it aimed to enhance the scientific basis and clinical practice of radiation protection in the medical field, in particular by better understanding and evaluating the health effects of exposure to low doses of ionising radiation resulting from diagnostic and therapeutic applications. MEDIRAD was designed to have direct implications for the radiological safety of European patients undergoing medical imaging and therapy procedures involving ionising radiation, and of exposed medical professionals. For this purpose, one of the goals of MEDIRAD was to establish evidence-based consensus policy recommendations for enhancing the effective protection of patients and medical professionals, as well as for identifying further research priorities.

The scientific basis for the following recommendation stems from the research developed in the course of the MEDIRAD project. In order to achieve a sufficient degree of consensus, MEDIRAD engaged in a substantial dialogue with relevant stakeholders in Europe and internationally. The MEDIRAD Stakeholder Forum, which underpinned this dialogue, included representatives from 86 organisations who were invited to express their views on issues to be considered as priority, and to comment on the draft formulation of MEDIRAD recommendations.

MEDIRAD Recommendations are made publicly available under the sole authority of the MEDIRAD Consortium. More information on MEDIRAD is available in Annex 3.

Competent international organisations, public authorities at European and national level, and organisations such as European research platforms and professional or patient associations, are invited to consider these recommendations and engage or support actions towards their implementation as they see fit, taking the opportunity of initiatives such as the SAMIRA (Strategic Agenda for Medical Ionising radiation Applications) European Action plan.

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Introduction

MEDIRAD research has addressed the following three key aspects for the radiation protection of patients and of medical workers.

1. Setting up optimised systems for quantitative imaging of radiopharmaceuticals

This recommendation addresses the growing field of molecular radiotherapy (MRT) in nuclear medicine, focusing on improved radiation protection of patients through personalised treatment. The individual patient determination of pharmacokinetics and radiation dosimetry of established and innovative radiopharmaceuticals, greatly depends on the data provided by quantitative nuclear medicine imaging through gamma cameras, for which standardised protocols and performance are currently lacking. Characterisation of gamma camera performance for high activity quantitative imaging enables personalised treatment planning in MRT. It also enables standardised collation of quantitative image data and absorbed dose calculations to facilitate multi-national, multi-centre, clinical studies and to allow accurate absorbed dose estimations.

To achieve this, a number of challenges need to be addressed:

- Variability in methodologies to set up imaging systems for quantitative imaging and obtain calibration factors such as system volume sensitivity, partial volume recovery factors, and dead-time factors.
- Lack of guidance documents for quantitative imaging for different radionuclides.
- Lack of in-built capability and/or significant associated costs for additional software packages to allow for quantitative imaging.
- Lack of standardisation of imaging systems of different manufacturers.

To allow for quantitative imaging of radiopharmaceuticals and absorbed dose calculations, standardised protocols must be established, and this MEDIRAD recommendation proposes a way toward this goal.

2. Bridging medical communities

MEDIRAD research has highlighted how a closer cooperation between medical professionals can benefit the patient's radiation protection. Patients undergoing diagnostic and therapeutic procedures involving ionising radiation should receive care and follow-up from a multidisciplinary group of relevant specialists; especially in the case of adverse tissue reactions due to the radiation treatment. The multidisciplinary consortium of experts brought together by the MEDIRAD project, in radiology, radiotherapy and nuclear medicine, as well as in nuclear and radiation protection research has identified several avenues to ensure adequate and improved radiation protection of patients and medical personnel.

3. Radiation protection of medical workers in the field of interventional radiology

MEDIRAD research has focused on one of the exposure situations that accounts for a significant part of the collective dose received by medical professionals in European hospitals: the conduct of fluoroscopically-guided procedures in interventional radiology. Staff performing these procedures can be exposed to low doses of ionising radiations on a daily basis, eventually resulting in high doses throughout a complete career. The radiation field to which staff are exposed is highly heterogeneous, resulting in some body parts being more exposed than others. In general, workers wear at least a lead apron that partially protects most organs in the trunk, but other parts of the body can be unprotected, such as the skin of the hand and fingers which are usually close to the X-ray beam during most procedures.

Additionally, there has been increasing concern in recent years regarding exposure of the eye lens and brain, highlighting the need for optimising staff protection. Innovative protection devices have appeared on the market but the current European regulation does not provide practical criteria to support medical physicists and radiation protection experts in the selection of these devices. The EURATOM 2013 European directive simply states the need for providing, testing and checking "appropriate personal protective equipment", while the regulation on personal protective equipment underlines the selection of "the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use", "without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement". Further, the general requirements in the international standards on, among others, the properties of the materials and the equipment themselves, are not sufficient to ensure effectiveness in clinical practice.

As a result, the use of such protective equipment is not as common as it should ideally be. MEDIRAD research identified that increased independent testing of such equipment, with reference to typical and realistic conditions of use, would be an effective way to promote better radiaiton protection practice for the medical workers concerned.

1

Setting up optimised systems for quantitative imaging of radiopharmaceuticals.

Overall recommendation

Optimise systems for quantitative imaging irrespective of camera make or model.

» **Specific recommendations:**

1. Establish a roadmap to enable personalised treatment planning on any imaging system and to benchmark quantitative imaging capabilities across centres.
2. Provide necessary funding and medical physics support to allow for quantitative imaging and radiation dosimetry in all clinical centres offering molecular radiotherapy.
3. Establish a dialogue between competent authorities, manufacturers and medical physics experts to ensure imaging systems can be effectively enabled for quantitative imaging.
4. Enable smaller centres to participate in multi-centre dosimetry trials by providing funding for support from medical physics experts.
5. Ensure that radionuclide calibrators used for molecular radiotherapy (MRT) are traceable to an appropriate national primary standard.

1.1. Justification

The science-based policy recommendations above were developed to advocate and facilitate the further development of European-level protocols for quantitative imaging of radiopharmaceuticals, including site set-up measurements, and imaging protocols, for the improvement of patient radiation protection.

The recommendations are based on work with [^{131}I]NaI, the most widely used radiopharmaceutical in molecular radiotherapy, but could easily be amended for other radiopharmaceuticals.

These recommendations, which aim to answer the expectations of MEDIRAD Stakeholders, are based on the research results and experience gathered in the MEDIRAD project.
They are intended for policy makers, public health authorities, medical professional organisations, as well as medical personnel involved in the imaging and absorbed dose calculations in MRT. They are designed to facilitate the widespread roll-out of quantitative imaging in nuclear medicine and MRT in order to allow for absorbed dose calculations, as required under Council Directive 2013/59/Euratom.

1.2. Implementation

1. Establish a roadmap to enable personalised treatment planning on any imaging system and to benchmark quantitative imaging capabilities across centres.

While standardised protocols are the first step towards quantitative imaging at centres, their implementation can be perceived by some centres as a time-consuming and challenging process due to differences in imaging systems and software packages used for the absorbed dose calculations. To allow for standardised quantitative imaging and absorbed dose calculations in MRT, a roadmap should be developed by public health authorities, medical professional organisations, and the scientific community, involving the manufacturers of imaging systems, to enable personalised treatment planning on any imaging system.

Further, as is standard practice for external beam radiotherapy, support for medical physics experts, and reimbursement for routine clinical dosimetry calculations, is needed for personalised treatment planning including dosimetry. Furthermore, work performed by MEDIRAD suggests that global calibration factors may be used for the same manufacturer and model of a gamma camera if standardised image acquisition and reconstrunction protocols are employed.

» Target audience: health authorities, medical professional organisations, scientific communities, manufacturers.

2. Provide necessary funding, and medical physics support, to allow for quantitative imaging and radiation dosimetry in all clinical centres offering molecular radiotherapy.

Participation in multi-centre, multi-national, clinical studies in MRT with a dosimetry component necessitates standardisation of quantitative imaging in each centre. Currently, there is a lack of positions for experts in medical physics who are essential for performing dosimetry estimations. Therefore, a pipeline supply of suitably qualified medical physicists, with a comparable level of training throughout Europe, is required.

The protocols developed within MEDIRAD will allow centres to be enabled for [131I]NaI quantitative imaging, and may be adapted to other radiopharmaceuticals.

» Target audience: medical professional organisations, medical practitioners, scientific communities, health authorities.

3. Establish a dialogue between competent authorities, manufacturers, and medical physics experts to ensure imaging systems can be effectively enabled for quantitative imaging.

MEDIRAD has shown that the set up of imaging systems for multi-centre, multi-national, studies is possible, but that measurements remain complicated and time consuming due to different national/local radiation protection regulations and differences in gamma cameras depending on the manufacturer. Further coordination between competent authorities, manufacturers, medical physics experts, and radiation protection experts is needed to ensure a standardised set up of systems across Europe to allow large-scale, multi-centre, multi-national, clinical studies in molecular radiotherapy to be conducted.

» Target audience: competent authorities, manufacturers, medical radiation protection experts.

4. Smaller centres should be enabled to participate in multi-centre dosimetry trials by providing funding for medical physics expert support.

Medical physics support at each centre is crucial to allow for the set up of centres and their imaging systems for quantitative imaging. Centres with limited medical physics support may, potentially, be curently unable to participate in clinical studies that require quantitative imaging due to the significant efforts required to set up imaging systems. Furthermore, EC Directive 2013/59/Euratom article 56 states that exposures of target volumes in nuclear medicine treatments shall be individually planned and their delivery appropriately verified. Only centres with sufficient medical physics support are able to adhere to this directive. Funding should be made available for centres to have access to sufficient medical physics expert support to enable quantitative imaging and absorbed dose calculations.

» Target audience: policy makers, scientific communities.

5. Ensure that radionuclide calibrators used for MRT are traceable to an appropriate national primary standard.

Traceable image quantification is an essential requirement for multi-centre clinical studies and is necessary to make quantitative imaging and radiation dosimetry results comparable between centres. Furthermore, if results of multi-centre MRT clinical studies are to be adopted for routine clinical practice, each centre must ensure that image quantification is performed in a comparable and traceable manner.

The site set up measurements of [^{131}I]NaI in the multi-centre clinical study performed by MEDIRAD have shown that traceability to a national primary standard was not always easily achievable: dose calibrators in that study were either traceable to a national standard or had calibration certificates from an accredited laboratory. In one centre the accuracy of the dose calibrator was assessed with respect to a local standard.

» Target audience: policy makers, scientific communities, competent authorities, medical radiation protection experts.

1.3. MEDIRAD scientific achievements supporting the above recommendations

- Developed standard operating procedures for the set up of centres for quantitative imaging of radioiodine.
- Successfully set up and conducted a multi-national, multi-centre, study involving dosimetry in molecular radiotherapy.
- Set up of the first European network for quantitative imaging of radioiodine.
- Results suggest that gamma cameras of the same make and model show very similar response to radioiodine and that the set up process can be simplified.
- Developed a dose data repository for the transfer of molecular radiotherapy imaging and dosimetry data.
- Identified a lack of traceability across Europe which will impact the accuracy and comparability of results.

2

Bridge medical communities to improve radiation protection.

Overall recommendation

Encourage harmonisation of practices through active engagement between health professionals, researchers, health authorities, and patients.

» **Specific recommendations:**

1. Establish multidisciplinary protocols of care for high risk procedures, including guidance on pre-procedure planning, intra-procedure strategies, and post-procedure follow-up, and integrate into quality management systems.
2. Draft and implement guidance documents on justification of diagnostic / interventional / therapeutic procedures to facilitate effective, and streamlined, communication between the disciplines involved in patient care and follow-up.
3. Encourage the development of Artificial Intelligence (AI) applications, to integrate multidisciplinary information and facilitate patient's follow-up.
4. Provide tailored and standardised continuous education and training for medical professionals on radiation protection and optimisation.
5. Engage with the public, and patients in particular, by informing, listening and developing a robust communication strategy and educational materials developed in consultation with patient associations.

2.1. Justification

The scope of this recommendation is to enhance awareness among medical professionals (including those outside the radiology, nuclear medicine, and radiotherapy professions) and scientific communities of the importance of interdisciplinary connections for optimising radiation protection and to promote efforts which facilitate this new way of conducting medical research.

Specifically, the recommendations herein aim to overcome current barriers to transdisciplinary optimisation of radiation protection and propose ways in which to bridge medical communities for the improved protection of patients and workers. Such cooperation and engagement can be facilitated by joint programming and calls for research focused on radiation protection implementation in clinical practice.

2.2. Implementation

1. Multidisciplinary protocols for high risk patient procedures should be established. The protocols should provide guidance for pre-procedure planning, intra-procedure strategies, and post-procedure follow-up, and should be integrated into quality systems.

Attention has to be paid to minimise patient exposure. The complexity of procedures requires a multidisciplinary approach that involves the specialist doctor, the specialist in medical physics, the radiographer, and the nurse. Collectively these professionals form a team committed to optimising the radiological technique, the clinical procedure, and the performance of the radiological equipment. If needed, this should also include medical professionals outside traditional radiology groups, e.g. dermatology, primary care physicians, etc.
This is in compliance with ethical principles but also Euratom Directive 2013/59 which requires that, without prejudice to competences and responsibilities of the various professional figures, the exposure of the patient is optimised and as minor as possible while remaining compatible with the achievement of the diagnostic or therapeutic purpose in case of procedures requiring radiological imaging guidance. Multidisciplinary protocols should be set up for high risk patient procedures and they should mainly deal with:

- Informed consent and information to the patient with reference to medical ionising radiation exposure and, for repeated and complex procedures, the potential risks of skin damage.
- Patient exposure monitoring, dose assessment methods to organs, methods of skin exposure monitoring, and patient follow-up after complex high-dose procedures.
- Exposure optimisation methods, description of the technical parameters that influence the dose to the patient, optimisation of the clinical protocol, discussion of the complexity of the procedures, and the periodic monitoring of exposure methodology through the comparison with relevant diagnostic reference levels (DRLs).
- Management of equipment: description of the salient features, methods and contents of a quality assurance programme, including quality controls, which are necessary to guarantee the maintenance of system performance over time.

Performance against these protocols should be incorporated into organisational quality management systems.

» Target audience: practitioners, medical professional organsations, research community.

2 Implement / draft guidance documents on the justification of diagnostic / interventional / therapeutic procedures to facilitate effective, and streamlined, communication among the various disciplines involved in patient care and follow-up.

It has been foreseen by the MEDIRAD Consortium and Stakeholder Forum, and witnessed through various European-level research initiatives, that a standardised approach to clinical practice and quality assurance must be implemented for effective and efficient interdisciplinary communication. The need to improve compliance to the principle of justification arises directly from the changing patterns of practice in diagnostic radiology, particularly the routine introduction of relatively high-dose techniques. It is recommended that medical professionals and the research community develop procedure-specific guidance documents for the justification of diagnostic / interventional / therapeutic techniques and patient pathways.

In this way, clinical practice and workflow can be better harmonised for ease of collaboration and best practices for the protection of patients and workers maintained. Development and implementation of common guidance documents on the principle of justification would be facilitated by raising awareness through communication and consent, by sharing appropriateness criteria as referral / acceptability guidelines, and by implementing clinical audits on justification. Harmonisation of guidance documents could avoid divergent interpretations and risk of duplication.

» Target audience: practitioners, medical professional organisations, research community.

3. Encourage the development of Artificial Intelligence (AI) applications to enhance radiation protection by means of bridging multidisciplinary information and facilitating patient follow-up.

AI could help manage, predict, and even reduce patient exposure to ionising radiation. Every field within the scope of medical ionising radiation is looking at the opportunities offered by AI to advance imaging and radiotherapy's contributions to healthcare. AI applications are suitable for diagnosis, treatment planning, and follow-up analysis, with strong potential impact on personalised medicine. AI could also be used to predict, rather than measure, dose during an intervention, which would improve the safety of said intervention.

AI could represent a bridge between medical communities, as well as benefit from the data and multidisciplinary expertise of the different disciplines. In fact, the intent of this "bridging" is to proactively identify, monitor, and improve a range of medical, environmental, and social factors relevant to the health of communities. These efforts show a significant growth in a range of population health-centric information exchange and analytics activities. Improvement in diagnostic image quality (for a given dose) can be achieved, for example, by the use of AI processing models combined with the definition and implementation of AI trained task-specific observers which provide quality information beyond the conventional quality indices. The overall system requires a strong collaboration between algorithm developers, medical physicists, radiologists, and radiographers.

AI applications in medical imaging, nuclear medicine, or radiation oncology, require close interaction among medical physicists, radiologists, nuclear medicine physicians, cardiologists, radiation oncologists, and radiographers. They should set up a national network among health research structures and scientific societies to share standardised collected data, to extract the informative content of the data, through the use of dedicated algorithms. Sharing can be performed at different levels; edge computing and federated learning platforms are gaining interest in terms of sustainability and sensitive data protection requirements. A promising domain for AI applications in radiation protection deals with scatter reduction, denoising, and image reconstruction methods. Another attractive option is to exploit AI-based approaches in order to improve managing, and adjusting, dose to individual patients: it can be anticipated that it will be possible in the near future to quantify image acquisition parameters and optimise procedures before or during each examination, evaluating image quality in real-time for a given patient.

» Target audience: practitioners, medical professional organisations, research community.

4. Tailored and standardised continuing professional development of supported and resourced education and training programmes for medical professionals on radiation protection and optimisation, should be foreseen.

Aligned with Article 18 of Council Directive 2013/59/Euratom, it is critical that all practitioners and clinical research staff involved in any practical aspect of medical ionising radiation undertake continuous education and training on radiation protection aspects relevant to their specific area of work. European core curricula should be tailored for all professionals involved in radiation sciences, while promoting interdisciplinary collaboration.

Additionally, these curricula must undergo regular review to stay up to date with ongoing advancements in technology, techniques, and best clinical practices. It is recommended that the Council of the European Union, and relevant policy makers, provide detailed guidance documents regarding implementation and regular revision of continuing professional development (CPD) programmes in radiation protection to best ensure frequent, robust, and standardised education and training for all those involved in the medical use of ionising radiation. It is essential that such systems are supported and resourced at a national level.

» Target audience: policy maker, regulatory authorities, medical professionals, research community.

5. Education and training of the public, and in particular patients, to make them fully informed, and their opinion taken into account, by way of robust communication strategies and educational materials developed in consultation with patient associations is needed.

It is important to bridge the gap between patients and care providers and it has become widely accepted that patient understanding and consent around medical treatment are critical for the protection of public health and well-being, including radiation protection. Yet recent research has demonstrated a notable lack of public knowledge and proper informed consent formulation in the medical ionising radiation sector.

The development of education and training for the general public should take into account previous research and have regard for existing organisations dedicated to improving public knowledge.
Medical professional organisations and practitioners, in collaboration with patient associations, are encouraged to further develop communication strategies and patient-centred educational material (e.g. leaflets, posters, short videos, analogies, etc.) regarding the equipment/technology, justification, benefits and risks of ionising radiation. Additionally, the research community should look to disseminate research findings via communication channels with a strong patient interface, similar to what MEDIRAD has worked to achieve through collaboration with EuroSafe Imaging. All essential best practice elements (e.g. benefit-risk communication, risk management, etc.) need to be integrated.

» Target audience: medical professional organisations, practitioners, patient associations, research community.

2.3. MEDIRAD achievements supporting recommendations

- MEDIRAD brought together a multidisciplinary research group from different areas of medical research and clinical practice to achieve project objectives.
- A Stakeholder Forum (SF) was set up which facilitated regular consultation with an inter-disciplinary group of healthcare professionals, medical professionals, scientists, policy-makers, industry partners, and competent authorities. Consultation took place throughout both project development and execution.
- Linking medical professionals from relevant disciplines was identified by the SF as a key factor for the optimisation of patient follow-up.
- The SF highlighted a lack of education and training, in some subject areas, related to radiation protection optimisation for some professional groups.
- Through discussions with the SF and project leaders, the need for greater patient/patient association engagement in radiation protection research was highlighted along with the need to make patients and the general public more aware of the benefits and risks of ionising radiation and the importance of patient involvement in research. .
- Project leaders identified the need to create guidance documents on the justification of diagnostic/interventional procedures along with patient/pathology-tailored protocols for high risk procedures.
- MEDIRAD has provided valuable resources to support and inform the development of such guidance documents or protocols. Resources include: risk models; standardised protocols; Image and Radiation Dose Biobank (IRDBB); software tool (CT-IQURAD) modules on image quality and radiation dose.

3

Optimisation of radiation protection of medical workers.

Overall recommendation

Optimise the use of protective equipment to improve radiation protection of medical workers in interventional settings.

» **Specific recommendations:**

1. Support the development of appropriate guidance at European-level in order to facilitate reduction of staff exposure through good practise.
2. Encourage continuous education of medical professionals, including appropriate information related to radiation shielding equipment.
3. Encourage independent testing of equipment performance in typical conditions of use.
4. Support the use of protective equipment in daily clinical practise.

3.1. Justification

MEDIRAD explored the performances of shielding protective equipment selected for their novelty, their widespread use, and/or their potential for dose reduction in the context of interventional radiological procedures for workers. The research confirmed that, in many exposure conditions, the use of such equipment may contribute significantly to improved protection whereas other equipment could become nearly ineffective in other exposure conditions.
These contrasting results underline the need to carefully select the protective devices and consider the actual conditions of use. This could most effectively be implemented through existing, and future, standards, and through professional guidance.

In particular, the effectiveness of following equipment was investigated:

- Lead and lead-free caps
- Leaded masks
- Lead and lead-free drapes
- Light lead and lead-free aprons
- Zero-gravity suspended system

Detailed recommendations and supporting results are available in Annex 2. To complete the recommendations, literature data were gathered for:

- Ceiling-suspended screens
- Lead glasses

Their effectiveness was investigated by combining three complementary methods: Monte Carlo (MC) simulations, measurements on staff, and measurements on anthropomorphic phantoms. Particular attention was given to potential dose reduction to the eyes and the brain due to the current International Commission on Radiological Protection (ICRP) thresholds for tissue reactions. Although the equipment effectiveness was investigated for procedures and configurations frequently used in interventional cardiology practice, the results should apply to other specialities provided the configurations and irradiation conditions are similar.

3.2. Implementation

1. Support the development of appropriate guidance at the European-level to reduce staff exposure through good practise.

As the actual contribution of shielding equipment to the dose reduction to workers might strongly depend on factors related to their conditions of use, appropriate guidance should be produced at the European-level in order to facilitate the exposure optimisation through good practise. Such guidance could be produced in cooperation between end-user professionals, radiation protection experts, and equipment manufacturers.

» Target audience: policy makers, regulatory authorities, research community, professional societies, practitioners, hospital managers.

2. Encourage continuing education of medical professionals, including appropriate information related to radiation shielding equipment.

Training curricula should be organised for the education of medical professionals, as per the European Commission guidelines. These curricula should include up to date and appropriate information related to available, and technically-proven, shielding equipment. The habits of the medical professionals regarding the use of radiation protection equipment in daily clinical practice, and how it affects shielding effectiveness, should also be reviewed.

» Target audience: policy makers, regulatory authorities, research community, professional societies, practitioners, hospital managers.

3. Encourage independent testing of equipment performance in typical conditions of use.

Independent testing of radiation shielding equipment shows that the effective performances in typical conditions of use are usually lower than could be assumed from the material properties as observed in lab conditions. This is very dependent on how the protective equipment is used and on the specifics of the procedure. Also, the attenuation characteristics as stated on the equipment label are indicative of the lead equivalence of the material or the resulting X-ray attenuation in a direct X-ray beam with a specific energy spectrum, which might not be representative of the dose reduction to any specific organ. In addition, the availability of the composition of lead-free material would help to estimate their performance in different exposure conditions.

For the optimised protection of medical professionals, independent testing of the key performance characteristics of shielding equipment, including their ease of use, should be encouraged, in line with the EURATOM Directive requirements. In particular, collaboration between professional societies as well as medical professionals is desirable since independent testing can be very demanding in terms of time, knowledge, and equipment. An update of standards related to such equipment might be necessary, to reflect that specific requirements of current standards and certifications are not sufficient to ensure practical effectiveness.

» Target audience: policy makers, regulatory authorities, research community, practitioners, hospital managers.

4. Support the use of protective equipment in daily clinical practise.

For optimal radiation protection, protective equipment should be readily available to the medical professionals in daily clinical practise. They should also receive adequate support to ensure that the radiation protection equipment is optimally used in practise.

» Target audience: practitioners, hospital managers.

3.3. MEDIRAD scientific achievements supporting recommendations

- Evaluation of effectiveness of five pieces of protective equipment by means of computer-aided simulations.
- Validation of simulation results by means of clinical measurements on staff and on phantoms.
- Results confirmed that: (i) the tested equipment may significantly improve staff protection in many exposure conditions, but (ii) could become ineffective in adverse conditions.
- Results underline the need for careful selection of the equipment taking into account the actual conditions of use.
- Identification of the inadequacy of lab measurements to predict the effectiveness of protective equipment in clinical conditions.

4

Annex 1
Supporting evidence from MEDIRAD research.

RECOMMENDATION 3.1

Protocols to set up optimised imaging systems for quantitative imaging of [^{131}I]NaI irrespective of camera make or model

MEDIRAD Scientific Goals and Research Results

Within the scope of the MEDIRAD a multi-national multi-centre clinical study was set-up including quantitative imaging of radioiodine [^{131}I]NaI. This was a proof-of-concept study to highlight that multi-national multi-centre studies including a dosimetry component are feasible in molecular radiotherapy (MRT). The developed protocols can be used for future studies to allow for quantitative imaging of high-activity radioiodine.
Protocols were published by Taprogge et al (1). The results of MEDIRAD have been published as publicly available documents on the MEDIRAD webpage as part of deliverables D3.1, D3.2, D3.3, D3.6, D3.8. Detailed guidelines and recommendations for quantitative [^{131}I]NaI imaging and dosimetry were provided in D3.8.

Setup of a European imaging network for quantitative [^{131}I]NaI

A network of centres for standardised quantitative imaging of radioiodine was set-up comprising of four centres in three countries (UKW, UMR, IUCT-O and RMH). Five SPECT(/CT) systems at the four centres were calibrated with respect to their system volume sensitivity, recovery coefficients and dead-time. All results have been published by Taprogge et al. (1) including details of the proposed site set up protocol for quantitative imaging of [^{131}I]NaI. Further details of the developed protocols as part of MEDIRAD can be found in the publicly available deliverable 3.8 “Guidelines and recommendations for quantitative [^{131}I]NaI imaging and dosimetry”.

The site set-up protocol developed for quantitative imaging of [^{131}I]NaI is presented in "Annex 1 - Protocol for the set-up of a European imaging network for quantitative [^{131}I]NaI".

Methodologies for standardised pre-study gamma camera set-up and calibration measurements were in part defined by restrictions based on the local interpretation of radiation protection laws in different countries, which for example prevented the use of large quantities of liquid [^{131}I]NaI. Site set-up measurements were performed according to National Electrical Manufacturers Association (NEMA) standards wherever possible (3). Accuracy of ancillary equipment in the quantification chain was also assessed as part of the process including clock synchronisation, traceability of radionuclide calibrators and accuracy of weighing scales. Radionuclide calibrators used must be traceable to an appropriate national primary standard. (4)
Results of the MEDIRAD site set-up measurements in conjunction with results published by Gregory et al. (5) indicate that the use of global calibration parameters for cameras of the same make and model may be justified. This will facilitate the extension of the imaging network for further dosimetry-based studies.

References

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Protocol for the setup of a European imaging network for quantitative ^{131}I Preparing for the Setup Visit

The pre-study site setup measurement will consist of calibration measurements of the gamma cameras at each site. The aim is to optimise and standardise image data collected from each participating centre.

In preparation for the setup visit please ensure the following checks have been made.

Table 1
PRE-CALIBRATION QUALITY ASSURANCE TESTS

Test	Within preceding	Limits
Photopeak position	Month	Centred within peak energy window defined in Table 2
^{131}I intrinsic (20 Mcount) uniformity	Month (allow time to correct artefacts where necessary)	Integral CFOV ≤ 4% Differential ≤ 3% NO MAJOR TUBE ARTEFACTS
^{131}I intrinsic (20 Mcount) uniformity at high count rates (~100 kcps)		
^{99m}Tc intrinsic (20 Mcounts) uniformity		
Centre of rotation for High-Energy General Purpose (HEGP) collimators	Month	Within local limits
SPECT/CT system alignment, if applicable	Month	
Extrinsic HEGP flood	Month	
QC of weighing scales used in these measurements	Year	
QC of dose calibrators used in these measurements	Day	

Please note:
Before making these calibrations all centres need to check with the camera manufacturers that their system are set-up to acquire at high count rates of ^{131}I.

SPECT Acquisition Protocols

Please save the patient imaging protocols on the gamma camera with the parameters given in Table 2. These will be used for the following calibration measurements and patient scans. It is important that the parameters used to acquire patient data match those used for these calibration measurements.

Angular sampling at 6°, with 60 projections, has been chosen to achieve better statistical quality projections and reduce the noise introduced by triple-energy window (TEW) scatter correction. Noisy, low count rate projections can lead to biases in quantification due to the non-negativity constraint of Ordered-Subset Expectation-Maximisation (OSEM).

Preliminary measurements have been made to ensure that this makes negligible difference to the spatial resolution or visualisation of the smallest (1 cm diameter) calibration sphere, compared to 3° angular sampling.

Table 2
^{131}I PATIENT SCANNING PARAMETERS

Parameter	Suitable for ^{131}I
Collimator	HEGP
Photopeak energy window (20%)	364 keV ± 10%
Low scatter energy window (6%)	318 keV ± 3%
High scatter energy window (6%)	413 keV ± 3%
WB planar	
Acquisition mode	Continuous
Speed	20 cm/min*
SPECT(/CT)	
Matrix	128×128
SPECT movement	Body contour (or radius as close to phantom as possible)
Projections	60 (6° projection)
Time per projection	60 s*
CT	Standard low-dose protocol

* Acquisition duration will be adjusted according to the count rate.

Table 3
EXAMPLE SPECT IMAGE RECONSTRUCTION PARAMETERS

Parameter	Suitable for ^{131}I
Reconstruction	OSEM
Attenuation correction (AC)	CTAC if available, otherwise Chang (0.11 cm^{-1} @ 364 keV)
Scatter correction	Triple-energy window (TEW)
Iterations and subsets	4 iterations, 10 subsets
Post-reconstruction filtering	None
Resolution recovery	No

This number of iterations has been shown to reach convergence of the smallest sphere for Hermes Monte Carlo based scatter correction reconstructions. This may need further optimisation at each centre depending on acquisition hardware and reconstruction software. For Siemens Symbia based reconstructions make sure that the 'Preserve Low Count Data' option is NOT checked, as this, and the resolution recovery feature multiplies the counts up by an arbitrary value.

Suggested Site Visit Plan

The initial site set-up measurements could be performed over a single day; a total of 4 hours system time per gamma camera is needed to perform these measurements. Additional scanning of the DT phantom every 24–192 h for eight weeks will be required. Checking protocols and preparing phantoms will take an additional couple of hours. The phantoms filled with liquid ^{131}I will need to be stored on-site whilst their activity decays. Please ensure that there are appropriate storage facilities for the phantom used to determine system volume sensitivity for at least six weeks, and that the phantom

will not be required for anything else in that time. The spheres and lesions used in the recovery coefficient measurement and validation will also need to be stored for at least nine weeks before they can be emptied and sent to the next centre as exempt packages.

^{131}I SPECT Calibration Factor Measurement

Calibration factors are needed to correct for partial volume and resolution effects on the activity concentration measured in the reconstructed SPECT images. This is necessary to ensure quantitative accuracy of the images used for dosimetry. It is important to measure the activity concentrations of the spheres imaged in this calibration as accurately as possible.
These measurements should be performed only after recent intrinsic uniformity, peak checks, centre of rotation and SPECT/CT alignment checks. Extrinsic 57Co floods should have been acquired recently to ensure the collimator integrity.

Prepare Solution

Equipment:

- 150 MBq liquid ^{131}I
- Radionuclide calibrator with factors for ^{131}I traceable to the national primary standard
- 1 g potassium iodine and 1 g sodium thiosulphate
- Perspex shell of IEC head phantom
- Custom lid with 3D printed sphere inserts
- Large gauge spinal needle
- Bench cote / inco pad & micropore
- Approximately 1 h scan time

Table 4
SPHERE INSERT DIAMETERS AND VOLUMES

Internal diameter (cm)	Volume (ml)
1.0	0.524
1.7	2.57
2.8	11.5
3.7	26.5
5.0	65.4
6.5	144

Procedure:

1. Zero the scales and weigh the empty 500 ml bottle (with lid).
2. Weigh 300 ml of water into the bottle and add the potassium iodine and sodium thiosulphate and agitate.
3. Weigh empty vial.
4. Dispense 150 MBq into the vial and top-up volume to 4 ml.
5. Weigh full vial.
6. Measure the vial activity in the calibrator using the correct factor.
7. Draw up and wash out the contents of the vial into the bottle.
8. Reweigh the full bottle (with lid).
9. Measure the residual vial and syringe activity in the calibrator. The residual activities should be negligible.

Prepare the Phantom

Procedure:

1. Attach the spheres to the modified IEC phantom lid in the configuration shown in Figure 1 below.
2. Fill the phantom with water and secure lid.
3. Fill the 1.0, 1.7 and 2.8 cm diameter spheres with the ^{131}I solution, avoiding air bubbles.

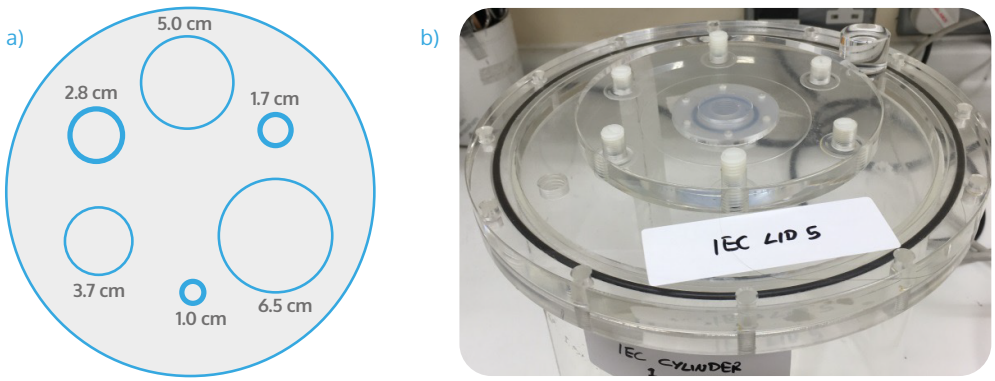

Figure 1
a) sphere positions within the IEC head phantom
b) modified IEC head phantom lid depicting filling holes for phantom background and spheres.

4. Fit the HEGP collimators to the camera.
5. Tape bench cote / inco pad securely to the camera couch.
6. Position the phantom on its side in the centre of the field of view ensuring the symmetry axis is coincident with the axis of rotation of the SPECT system. Mark the position of the phantom on the inco pad.
7. Acquire a SPECT/CT scan with the protocol detailed in Table 2 acquiring for 60 seconds per projection.
8. Remove phantom from scanner bed.
9. Fill the 3.7, 5.0 and 6.5 cm diameter spheres with the solution, avoiding air bubbles.
10. Return the phantom to the scanner bed and place in same position as for the previous acquisition.
11. Acquire a SPECT/CT scan with the protocol detailed in Table 2 with 60 s per projection.

Recovery Factor Creation

Procedure:

1. Reconstruct the images using the parameters listed in Table 3.
2. Define a spherical volume of interest (VOI) on the CT matching the dimensions of each sphere.
3. Calculate the mean counts per second for each sphere.
4. Divide this by the known activity concentration of the counts in each sphere, decay corrected to the acquisition time.
5. Plot these factors against the known volumes of the spheres, listed in Table 4.
6. Fit the following curve to the points:

$$RC_{fit} = \frac{\alpha}{1 + (\delta / x)^{\beta}}$$

Where x is the sphere volume, α, β and δ are the coefficients of fit.

In this way a recovery coefficient can be derived based on the CT defined volume of the lesion. These curves will be dependent on the method used to outline the lesions, the acquisition and reconstruction protocols. They may need further modification as the protocols are further optimised.

System Volume Sensitivity Measurement

The system volume sensitivity characterises the system's response to a uniform concentration of activity. The phantom will need to be stored at each site for at least five weeks following these measurements.

Prepare the Phantom

Equipment:

- 40 MBq liquid ^{131}I
- 1 g potassium iodine and 1 g sodium thiosulphate
- Hollow phantom with fillable volume greater than 6 l
- Radionuclide calibrator with factors for ^{131}I traceable to the national primary standard
- Approximately 90 minutes scan time

Procedure:

1. Determine the volume of the empty phantom by measuring the weight of water needed to completely fill it.
2. Add potassium iodine and sodium thiosulphate, agitate the solution, and secure lid.
3. Draw up 10 ml of background water from the phantom.
4. Draw up 40±2 MBq ^{131}I into syringe.
5. Assay syringe with appropriate calibration factor and note syringe activity and assay time.
6. Dispense contents of syringe into phantom. Redraw the solution within the phantom up into the syringe several times to wash the syringe contents into the phantom.
7. Measure and note the syringe activity with the cap on, this should be negligible.
8. Agitate the phantom to mix.
9. Remove any remaining air bubbles with the solution drawn from the phantom in step 1.

Sensitivity Factor Creation

Procedure:

1. Fit the HEGP collimators to the camera.
2. Tape bench cote / inco pad securely to the camera couch.
3. Position the phantom on its side in the centre of the field of view ensuring the symmetry axis is coincident with the axis of rotation of the SPECT system.
4. Perform a 100 kcount/projection SPECT scan utilising the settings in Table 2.
5. Note the scan start time and count rate.

6. Reconstruct the projections using the reconstruction parameters listed in Table 3.
7. Calculate the average counts per minute for the SPECT acquisition, A, by dividing the total counts imaged by the total elapsed time.
8. Calculate the source activity concentration (decay corrected activity in the phantom / phantom volume), B_c, at time T, halfway through the acquisition.
9. Calculate the system sensitivity factor as A/B_c.

Dead-Time Characterisation

Dead-time factors are to be used to correct the acquired image counts for counts lost due to detector paralysis. This procedure checks that the system correctly handles high activities of 131I and identifies artefacts that may occur at high count rates.
Before making this calibration all centres need to check with the manufacturers that their systems are set-up to acquire at high count rates of ^{131}I. This may be verified by acquiring a check image of the vial before commencing the following measurements.

Dead-Time Measurement

Equipment:

- 3700 MBq capsule of ^{131}I
- Scatter phantom

Procedure:

1. Assay the capsule with the calibration factor appropriate for ^{131}I capsules.
2. Fit the HEGP collimators to the camera.
3. Position the flat end of the phantom on the couch so that the top is level horizontally.
4. Ensure that the phantom is positioned in the centre of the detector field of view.
5. Position one detector level with and as close as possible to the phantom's upper flat surface and the other detector as close as possible to the underside of the couch.
6. Note:

Table height	_____
Table position	_____
Detector radius (1)	_____
(2)	_____

7. Acquire a 10 minute static planar scan with the energy window settings given in Table 2.
8. Position capsule in the scatter phantom and acquire a 100 kcount static planar scan with the energy window settings in Table 2.
9. Note the scan start time and count rate.
10. Repeat the background and capsule scan according to the scanning schedule listed in Table 5 recording the scan date, start time and count rate for each acquisition.

Table 5
SCANNING SCHEDULE FOR DEAD TIME MEASUREMENT USING DECAY METHOD

Nominal A(MBq)	Nominal day	Scan date & start time	Count rate (kcps)	
			Background	Capsule
3700	0			
3113	2			
2402	5			
2020	7			
1700	9			
1430	11			
1203	13			
1012	15			
716	19			
391	26			
196	34			
90	43			
58	48			
41	52			
21	60			

Dead-time Factor Creation

1. Check each image for artefacts and note the activity at which any begin to occur.
2. Determine the activity of the phantom at each time point, decay correcting for acquisition time.
3. Check the total peak window counts acquired at each time point and divide by the acquisition length to find the count rate at each activity for each detector, m.
4. Plot the count rate against phantom activity.
5. Linear fit the points up to 100 MBq and extrapolate to 3700 MBq, to show the expected true counts, n.
6. Calculate the correction factor at each activity level as n/m.
7. Correct each image using TEW correction and then check the corrected count rate in each image.
8. Plot these against activity and calculate the correction factors required for TEW correction.

^{131}I WB Planar Calibration Factor Measurement

The scans acquired in section Error! Reference source not found. can be utilised in the count-rate dependent calibration factors for planar scanning.

Procedure:

1. Calculate the average counts per minute, A, by dividing the total counts imaged in a ROI encompassing the majority of the counts by the total elapsed time.
2. Calculate the source activity, B, at time T, halfway through the acquisition.
3. Calculate the system sensitivity factor as A/B for each activity.
4. Plot system sensitivity factor against count rate.

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RECOMMENDATION 3.2

Optimisation of radiation protection of medical workers

MEDIRAD Scientific Goals and Research Results

The advice and figures of RP efficiency in the present recommendations are reported as (MC), (ST), (PH) depending whether they were produced using results from Monte Carlo simulations, staff measurements or phantom measurements, respectively. Where necessary, literature data (LI) were also used for completing the recommendations.

Caps

- PRO: potential for dose decrease to the brain in specific conditions

(MC) Results of MC simulations showed a dose reduction of 35% averaged over several configurations. (PH) Phantom measurements showed a considerably lower average reduction (7%), indicating the great influence of the irradiation conditions.

- PRO: protection comparable for lead and lead-free caps

(MC) Results of MC simulations showed comparable reduction of the brain dose, ranging from 10% to 43% depending on the configuration.

- PRO: more comfortable than the lead mask

In general, a lead cap is considerably lighter than a mask (e.g., 3 times lower weight for a lead cap) and does not impair vision. However, the protection level is lower than for the masks investigated.

- PRO / CON: efficiency strongly depends on staff position and head orientation

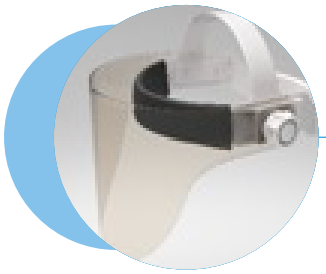
(MC) The closer the staff member is to the centre of the incident X-ray field, the smaller the dose reduction. Indeed, when the staff member is close to the beam, the backscattered X-rays can reach the brain through regions not covered by the cap. When the staff member is further away from the beam, a higher proportion of X-rays are intercepted by the cap. For instance, when the staff position was modelled at 40 cm from the field with the head perpendicular to the patient, the average reduction was only about 13%, whereas at 70 cm it was 37%. The height of the staff (and of the table) has logically an influence too.

- CON: dose reduction to the brain is not the attenuation characteristics of the device

(MC and PH) The lead equivalence of the cap and the resulting X-ray attenuation in a direct X-ray beam stated by the manufacturer are not representative of the dose reduction to the brain. Indeed, the scattered X-rays reaching the staff brain mostly come obliquely from below, through lower head regions not covered by the cap (LI: as much as 85% from MC simulations in a specific configuration [7]).

- CON: only limited parts of the brain are protected

(MC & PH) MC simulations and phantom measurements have shown that only some upper regions of the brain were protected. Dose reduction was lower for all regions when the physician was close to the primary beam; further away from the beam, protection of the hippocampus and the right side of the white matter was low whereas frontal and parietal lobes were more protected.



Masks

- PRO: potential for dose decrease to the eyes and brain

(MC) MC simulations indicated that the best mask model offered an average dose reduction of 53% and 62% to the eyes and the brain, respectively. (PH) Phantom measurements indicated dose reduction to the eye and the brain up to 10% and 17%, respectively. The mask was the most effective to protect the brain for left lateral projection which delivers the highest exposure to the physician when standing on the patients right hand side.

- PRO: More efficient than a lead cap for protecting the brain

(MC & PH) Both simulations and measurements showed that a mask was more efficient than a cap to protect the brain.

- PRO / CON: efficiency strongly affected by design

(MC) From three mask models investigated , the length of the mask and the lateral protections had a strong effect on the efficiency. Different designs could result in an additional 50% reduction in specific configurations. Long and enveloping masks offer better protection.

- PRO / CON: efficiency is strongly affected by staff position and head orientation

(MC) The staff distance from the X-ray beam entrance on the patient and the orientation of the staff head with respect to the beam could have a strong influence on the mask efficiency. For instance, the dose reduction to the brain and the left eye were very limited close to the beam (on average, 12.5% and 0.5%, respectively), further away from the beam, the reduction improved (on average, 43% and 4.1 %, respectively). (PH) The mask may not be effective in the frequently used PA projection in case it cannot be adjusted close enough to the physician's face.

- CON: heavier than lead-free cap

A mask can weigh about 400 g, while a lead-free cap can be three to four times lighter.

- CON: some parts of the brain are less protected than others

(MC & PH) Results from both simulations and measurements showed that the protection might be very heterogeneous and only limited regions, closer to the skull, might be protected. For instance, (MC) dose reduction for the left side of the white matter could be twice as much as for the right side. However, when no shielding was used, the right side was exposed to lower absolute doses than the left side.

[1]Two masks commercially available (VIS400 face mask (manufacturer unknown) and Full face style mask (Philips Safety products, USA)) and a third mask combining the characteristics of the previous masks.

Drapes

- PRO: significant dose decrease to hands, fingers and whole body dosimeter

(ST) Clinical measurements showed considerable dose reduction to the hand and fingers (20–40%) and to WB dosimeter (30–50%). (MC) Although MC simulations supported the decrease to the hands, no effect was observed on the WB dosimeter.

- PRO: no significant effect on patient dose

(MC) MC simulations have shown no significant effect on patient dose if the drape stays outside the primary beam.

- PRO /CON: influence of the positioning

(MC and PH) The drape efficiency increases when it is placed closer to the primary beam and when it covers the patient side closer to the cardiologist without gap at the level of the table. In addition, the drape protects better the organs in its direct vicinity such as the hands and the forearms.

- CON: limited effect on eyes and brain

(ST) Measurements on staff showed dose reduction up to 50% to eye lens; however, this was not observed in all participating hospitals, possibly indicating a strong influence of local practice. (MC and PH) Besides, MC simulations showed very limited dose reduction to eye lens and brain, between 0 to 13%.

- CON: risk to increase the dose if in the beam

(LI) If the drape is positioned partially in the primary beam, it will interfere with the automatic exposure system, which will increase the delivered dose.

Light lead and lead-free aprons

- PRO: protection comparable to that of conventional lead aprons for covered organs

(MC) For two models of lead-free and one model of lead apron, results of MC simulations showed comparable reduction of the effective dose E, ranging from 71% to 94%. (ST) From routine dosimetry measurements, no significant dose increase under the apron was observed for staff who changed a conventional lead apron for a light lead or a lead-free apron.

- PRO: potentially lower weight than conventional aprons

(LI) Lead aprons have been known to cause back pain [8]. Lead-free aprons can be lighter (up to 25% [9]).

- CON: Lead-equivalence claimed by manufacturers might not be met

(LI) Studies reported many cases of lead equivalence thicknesses being smaller than the values claimed by the manufacturers [10].

- CON: Dose enhancement for superficial organs with lead-free aprons

(LI) Dose enhancement reported in the literature for superficial organs (breast for instance) with lead-free apron [11] has to be further investigated in realistic clinical conditions as a possibly increased risk for cancer induction cannot be fully excluded.

Zero-Gravity suspended system (ZG)

- PRO: protection comparable to that of conventional lead aprons for covered organs

(PH & ST) For the regions normally covered by the lead apron, including the WB dosimeter, no meaningful difference could be observed during measurements. (MC) Simulations have shown a potential for dose reduction to organs normally covered by the lead apron.

- PRO: significant dose decrease to the eyes and brain

(ST) In clinical practice, 75% and 90% reduction to the eyes and the whole body dose were observed, respectively, when compared to ceiling suspended shield only. (MC) MC simulations delivered comparable reduction magnitude when comparing the device to a configuration with only a lead apron.

- PRO: lower weight on the operator than lead apron

(ST) Thanks to the suspending system, none of the weight of the ZG lies on the operator.

- CON: limited visibility of pedals

(ST) Due to the design of the ZG and its front lead glass, the operator cannot see the pedals of the X-ray system.

- CON: big investment

Compared to the price of conventional protective equipment, the price of the ZG is considerably higher and might not be accessible to all medical centres.

Ceiling-suspended screen

- PRO: potential for dose decrease to the eyes and the brain

(LI) The ceiling-suspended screen showed potential for significant dose reduction to the eye lens and the brain. Results of MC simulations indicated dose reduction to the eye closest to the beam (often the left eye) from 46% up to more than 92% [12], and reduction to the brain from 74% up to 94% [7]. Measurements on staff showed that the median eye dose was 40% lower for specific cardiac procedures but could be up to 90% lower for some radiology procedures [13].

- PRO: potential for dose decrease to the hands and the chest

(LI) A well-positioned screen can also protect the hands and the chest. Results of MC simulations showed dose reductions to the left hand by 21% to 68% [12].

- CON: efficiency strongly affected by screen position

(LI) The closer the ceiling-suspended screen is placed to the patient, the greater the efficiency. For instance, results of MC simulations showed that when the screen was positioned 15 cm above the patient the dose reduction to the white matter could be as low as 27%, while it was at least 74% when positioned 1 cm above the patient [7]. Flexible lead stripes attached to the bottom of the screen are therefore advised [12].

Lead glasses

- PRO: potential for dose decrease to the eyes

(LI) The lead glasses have a potential for significantly reducing the dose to the eyes, particularly to the eye closer to the X ray field (often the left eye). For instance, MC simulations of a wrap-around glass model lead to an average dose reduction as high as 74% to the left eye [14]. Phantom measurements showed similar potential with dose reductions up to 88% to the left eye [15].

- PRO: potential for dose decrease to the brain

(LI) The lead glasses can also offer limited protection to the brain. Results of MC simulations showed a dose reduction between 10% and 17% to the brain [7]. However, only few configurations were investigated, and the dose decrease is very dependent on the configuration and type of lead glasses.

- CON: efficiency strongly affected by design and operator position

(LI) MC simulations showed that glass design, in particular the shape and the air gap (distance between glasses and face), operator position with respect to the X ray beam and the head orientation have a significant effect on the efficiency. For instance, a factor two was calculated between the efficiency of two models simulated using MC software [14]. Phantom measurements confirmed these effects with the efficiency of five models tested in various conditions varying between 9% and 88% for the left eye and between 0% and 57% for the right eye [15].

- CON: dose decrease to eye-lens dosimeter is not representative of eye lens dose decrease

(LI) MC simulation [16] and phantom studies [17] have shown that a dedicated eye-lens dosimeter can severely under- or over-estimate the actual dose to the eye lens when lead glasses are worn. Ideally, an eye lens dosimeter should be positioned close to the eyes and under the glasses so that it would receive the same protection level as the eyes. However, this is rarely feasible in practice because the dosimeters are too big and/or uncomfortable to be put under the glasses.

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Annex 2

Supporting evidence resulting from the stakeholder consultation process.

MEDIRAD stakeholder forum outcomes

At the onset of the MEDIRAD project a stakeholder forum (SF) was established as a means of engaging in meaningful dialogue with a multidisciplinary group of representatives from the field of medical ionising radiation and associated protection research. The SF was consulted via a comprehensive questionnaire which aimed at ranking various broad-ranging approaches for optimisation of exposure to ionising radiation of patients and medical professionals and prioritise technical topics for inclusion in the current MEDIRAD recommendations.

Of the 86 SF members, there were 85 respondents to the questionnaire offering an interdisciplinary perspective from 69 nationals within Europe and 16 international representatives.

MEDIRAD stakeholder forum expectations

Table 1
EUROPEAN STAKEHOLDERS' EXPECTATIONS: HIGH PRIORITY TECHNICAL TOPICS

Rank	Topics
1	Optimising image quality / dose during CT scans, including multimodality imaging procedures (e.g. SPECT-CT and PET-CT-scans).
2	Improved protocols aimed at reducing exposure whilst preserving or improving diagnostic quality/ therapeutic benefits (e.g. better accounting of potential secondary or late effects of healthy tissue exposure).
3	Optimising patient follow-up care after radiation therapy and collecting valuable epidemiological data through a better linkage of medical professionals from relevant disciplines.
4	Increasing education and training of medical professionals on radiation protection optimisation.

Table 2
EUROPEAN STAKEHOLDERS' EXPECTATIONS: INTERMEDIATE PRIORITY TECHNICAL TOPICS

Rank	Topics
5	Promoting individualised patient care in nuclear medicine. Procedure for evaluating patient-specific doses deliver to volumes and organs through activity uptake.
6	Improvement of target definition by better delineation of the target volume, better margins definition and better definition of the heterogeneity and of the biological volumes of the tumour at the voxel scale.
7	Modelling of patient dosimetry at the voxel scale. It is necessary to move from planned dose maps to delivered dose maps. (Treatment planning improvement, doses delivered during diagnostic and positioning imaging procedures, modelling simulations, clinical Decision Support System, Data standardisation and machine learning data base...).
8	Predicting quickly and accurately the response of tumours and normal tissues to ionising radiation using new multimodal and functional imaging and/or new biological and molecular surrogates. The development and validation of novel biomarkers will be required in order to develop treatment personalisation approaches.
9	Development of European registries of patient dose/imaging with recommended appropriate quantities (effective dose, organ dose) for radiological examinations.
10	Developing and validating operational biomarkers predictive of patient exposure – side or late adverse effects - following repeated radiological examinations, or radiotherapy protocols.
11	Optimising medical staff protection during interventional radiological procedures by ensuring proper availability and use of shielding equipment, while at the same time considering their actual effectiveness and efficacy.

Table 3
EUROPEAN STAKEHOLDERS' EXPECTATIONS: LOW PRIORITY TECHNICAL TOPICS

Rank	Topics
12	Technology development.
13	Future radiation protection research for radiation-oncology: Normal tissue response.
14	Development of European patient registries of dose/image/clinical diagnosis and patient follow-up, for the purpose of clinical procedure standardisation and radiation protection optimisation (European radio-vigilance).
15	Future radiation protection research for radiation-oncology: Combined treatment.
16	Modelling of patient dosimetry on an individual basis by highlighting the range of absorbed doses delivered from fixed administrations of activity, in order to evaluate the range of possible secondary effects, including long-term risks of secondary malignancies.
17	Future radiation protection research for radiation-oncology: Medical countermeasure.

Table 4
EUROPEAN STAKEHOLDERS' EXPECTATIONS: LOW INTEREST TECHNICAL TOPICS

Rank	Topics
18	Facilitating the development of large-scale multinational epidemiological studies by proposing guidelines to help European countries to implement at the national level European regulatory requirements on ethics (including compliance with GDPR directive).
19	Development of personalised protocols that factor in individual patient radiation sensitivity (e.g. via biomarkers of radiation sensitivity).
20	Exploring of the potential of patient-specific radiobiology tests to assess individual radio-sensitivity, in order to personalise treatment protocols.
21	Protocols to set up optimised imaging systems for quantitative imaging of I-131 irrespective of camera make or model.
22	Outlining a plan for a large-scale and multi-site epidemiological study to evaluate the effects of low absorbed doses of radiation as a result of nuclear medicine imaging procedures in a population with an expected normal life expectancy.
23	Consideration of individual bio-kinetics in patients with residual thyroid tissue or adjuvant disease, rather than reliance on models and values established for a healthy population.
24	Reinforcing regulations (e.g. by extending the scope of Diagnostic Reference Levels (DRLs) at the European level), and regulatory oversight (e.g. radiation protection experts, inspections).
25	Web/smartphone application for adverse effects.

For more information on the stakeholder consultation process and outcomes, see: M. Benderitter, E. Herrera Reyes, M.A. Benadjaoud, F. Vanhavere, N. Impens, U. Mayerhofer-Sebera, M. Hierath, J.R. Jourdain, G. Frija and J. Repussard. MEDIRAD formulation of science-based recommendations for medical radiation protection: a stakeholder forum survey. Radioprotection. 2021. 56(4), 275–285. doi: 10.1051/radiopro/2021030.

Annex 3

Stakeholder involvement in the development and implementation of Recommendations.

MEDIRAD Recommendations were elaborated on the basis of scientific findings from the research developed during the project, in consultation with stakeholder organisations which were invited to take part in the MEDIRAD Stakeholder Forum. This consultation process included an enquiry, based on on-line questionnaires aiming to identify priority concerns among stakeholder organisations, in the field of MEDIRAD scientific investigations, and a review of draft recommendations which were presented on-line to Forum members, and discussed at two workshops organised by MEDIRAD.

The list of MEDIRAD Stakeholder Forum members is provided hereafter. The publication of this list does not imply that the contents of MEDIRAD Recommendations are formally endorsed by these organisations. MEDIRAD Stakeholder organisations are invited to contribute to the dissemination and implementation of Recommendations or parts thereof, as they see fit within the limits of their missions and attributions.

MEDIRAD Stakeholder Forum Members, in alphabetical order:

· Associação Portuguesa dos Técnicos de Radiologia, Radioterapia e Medicina Nuclear
· Associazione Italiana di Radioprotezione Medica
· Associazione Italiana di Radioterapia Oncologica
· Associazione Italiana Medicina Nucleare
· Belgian SocieTy for Radiotherapy & Oncology
· Belgian Society of Radiology
· Biobank of Eastern Finland and University of Eastern Finland
· Bulgarian Society of Biomedical Physics and Engineering
· Bundesamt für Strahlenschutz (Federal Office for Radiation Protection)
· Cardiovascular and Interventional Radiological Society of Europe
· Commissariat à l'Energie Atomique et aux Energies Renouvelables
· Croatian Society of Radiology
· Czech Association of Medical Physicists
· Danish Health Authority, Radiation Protection
· Danish Society for Medical Physics
· Deutsche Gesellschaft für Biologische Strahlenforschung
· EFRS Educational Wing
· ESR EuroSafe Imaging
· ESR Patient Advisory Group
· European Network for Training and Education of Medical Physics Experts
· European Nuclear Education Network Association
· European Nuclear Education Network Association +project
· European Organisation for Research and Treatment of Cancer
· European Society for Vascular Surgery

· European Society of Medical Imaging Informatics
· European Society of Paediatric Radiology
· Federal Agency of Nuclear Control
· Federazione nazionale Ordini dei Tecnici di radiologia e delle professioni sanitarie tecniche, della riabilitazione e della prevenzione
· Finnish Advisory Committee for clinical audit
· Food and Drug Organization
· German Commission on Radiological Protection
· German Roentgen Society
· Greek Atomic Energy Commission
· Heads of the European Radiological Protection Competent Authorities
· Hellenic Society of Gastroenterology
· Hungarian Society for Medical Physics
· Institut National du Cancer
· International Agency for Research on Cancer, Section of Environment and Radiation
· International Atomic Energy Agency - Radiation Protection of Patients Unit
· International Commission on Radiological Protection
· International Organization for Medical Physics
· International Radiation Protection Association
· International Society of Radiographers and Radiological Technologists
· International Society of Radiology
· Irish Institute of Radiography and Radiation Therapy
· Irridium Network
· Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro the National Institute for Insurance against Accidents at Work
· Italian Association for radiation Protection
· Italian Association of Medical Physics
· Kuopio University Hospital, Cancer Centre
· Lithuanian Association of Medical Physics and Engineering
· National Professional Association of Italian Qualified Experts
· Nordic Association of clinical Physics
· Nordic Working Group on Medical Applications
· Österreichische Röntgengesellschaft (Austrian Soicety of Radiation Protection)
· Plataforma Nacional de I+D en Protección Radiológica
· Quality Assurance Group in Radiotherapy
· Radiation Protection Association of Serbia and Montenegro
· Radiation Protection Officers working group on the West Coast of Norway
· Radiotherapy Translational and Preclinical Research network
· Romanian College of Medical Physicists
· Sociedad Española de Oncologia Radioterapica
· Società Italiana di Cardiologia
· Società Italiana di Cardiologia pediatrica e di cardiopatie congenite
· Società Italiana per la Radiologia Medica
· Societatea Română de Medicină Nucleară și Imagistică
· Société Française de Physique Médicale
· Société Française de Radiologie
· Société Française de Radiothérapie Onocologie
· Society and College of Radiographers
· St. James's University Hospital
· Superior Health Council
· Swedish Society for Medical Physics
· Swedish Society of Medicine
· Swiss Society of Radiobiology and Medical Physics
· University Hospital Leuven
· University of Arkansas
· University of California
· University of Eastern Finland
· University of Ghent
· University of Malta
· WHO network of Patients for Patient Safety

Annex 4

The MEDIRAD Project

Implications of Medical Low Dose Radiation Exposure.

A European multi-disciplinary project to enhance the scientific bases and practice of radiation protection in the medical field.

Coordinator	**European Institute for Biomedical Imaging Research (EIBIR), AT** **Coordinator contact: Monika Hierath, mhierath@eibir.org**
Scientific Coordination	**Prof. Elisabeth Cardis** **Barcelona Institute for Global Health (ISGlobal), ES**
Clinical Coordination	**Prof. Guy Frija** **Paris Descartes University, FR**
Duration	**1 June 2017 – 28 February 2022 (57 months)**
Total max EU Funding	**€9,995,145.75**
Website	**www.medirad-project.eu**

Ambition

MEDIRAD is a multi-disciplinary, cross-cutting project that aims to enhance the scientific bases and clinical practice of radiation protection in the medical field. MEDIRAD addresses the need to better understand and evaluate the health effects of low-dose ionising radiation exposure from diagnostic and therapeutic imaging and from off-target effects in radiotherapy. The MEDIRAD key research objectives are summarised in three pillars:

- **Pillar 1:** Development of innovative tools to increase the efficiency of future radiation protection research activities and support good clinical practice.
- **Pillar 2:** Improvement of the understanding of low-dose ionising radiation risks associated with major medical radiation procedures.
- **Pillar 3:** Development of recommendations based on research results and establishment of information exchange infrastructure to facilitate consensus.

Work plan

The MEDIRAD Project consisted of six interdependent and complimentary work packages (WP).

- **WP1:** Project management and dissemination: Scientific and clinical coordination, ethics management, knowledge management and exploitation, internal and external communication.
- **WP2:** Dose evaluation and optimisation in medical imaging: Optimisation of chest CT, interventional procedures and multimodality imaging, and development of imaging and radiation dose biobank.
- **WP3:** Impact of low-dose radiation exposure: Standardisation, biokinetic modelling and treatment planning, dosimetry, biomarkers of absorbed doses, protocol for epidemiological study.
- **WP4:** Breast radiotherapy and secondary cardiovascular risks: Epidemiological study on cardiovascular changes after radiotherapy, measuring markers of exposure and risk modelling.
- **WP5:** Possible health impact of paediatric scanning: Epidemiological study of paediatric CTs and cancer, including (epi)genetic biomarkers of possible sensitivity, dosimetry and statistical analyses.
- **WP6:** Bringing together medical & nuclear scientific communities: Formulation of science-based policy recommendations, consultation of stakeholders, organisation of dissemination seminars.

Impact

MEDIRAD will achieve significant progress in the interaction between the radiation protection and medical scientific communities at EU level, leading to cross-fertilisation of research efforts and the provision of more consolidated and robust science-based policy recommendations to decision makers in the respective sectors.

MEDIRAD will allow a better evaluation of the risks from radiation and better quantification of the necessary precautionary measures, leading to a more robust system of protection of patients, workers and the general public, whilst not unduly penalising activities through unnecessary and costly measures.

MEDIRAD will endeavor to positively modify the public perception of risks associated with ionising radiation thanks to the results of such combined nuclear and medical research.

MEDIRAD's long-term impacts are additional and improved practical measures for the effective protection of people in the medical and nuclear sectors.

Consortium

The multi-disciplinary consortium combines the expertise of 34 partners from 14 European countries. It includes major universities and research institutes as well as clinical partners.

· European Institute for Biomedical Imaging Research, AT
· Belgian Nuclear Research Centre, BE
· Ghent University, BE
· University of Geneva, CH
· Otto von Guericke University Magdeburg, DE
· University Medical Center of the Johannes Gutenberg University Mainz, DE
· Helmholtz Zentrum München German Research Center for Environmental Health, DE
· University Hospital of Würzburg, DE
· Philipps University of Marburg, DE
· University Hospital rechts der Isar of the Technical University Munich, DE
· Brandenburg Medical School, DE
· Barcelona Institute for Global Health, ES
· Polytechnic University of Catalonia, ES
· Autonomous University of Barcelona, ES
· Catalan Institute of Oncology, ES
· Paris Descartes University, FR
· Institute for Radiological Protection and Nuclear Safety, FR
· B-COM, FR
· French National Institute of Health and Medical Research FR
· Claudius Regaud Institute FR
· University of Crete GR
· University College Dublin, National University of Ireland, IE
· Sapienza University of Rome, IT
· Italian National Institute of Health, IT
· University Medical Center Groningen, NL
· VU University Medical Center, NL
· Netherlands Cancer Institute, NL
· Nofer Institute of Occupational Medicine, PL
· Polytechnic Institute of Coimbra, PT
· Cardiovascular Centre of the University of Lisbon, PT
· Region Västra Götaland, SE
· The Royal Marsden National Health Service Trust, UK
· University of Newcastle upon Tyne ,UK
· Imperial College London, UK

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