

Chapter 2

How Radiation Protection Influences Quality in Radiology

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Abstract Radiation safety is a key quality element in medical imaging and interventional radiology. Radiologists, referrers and other practitioners involved in the use of radiation medicine must be properly trained in radiation protection (RP) to ensure quality care and patient safety. Workforce shortage, workload increase, workplace changes, and budget challenges are emerging issues around the world, which could place quality at risk. Selecting the right procedure by justification, using the right dose and choosing adequate imaging data by optimization, and preventing errors along the patient journey must be considered and applied in practice. This chapter describes the positive impact of RP to quality in imaging and intervention through justification and optimization actions, including the use of Diagnostic Reference Levels (DRL) and individual patient dose recording and tracking. The relevant International Commission on Radiological Protection (ICRP) recommendations are highlighted together with a discussion on a wider cooperation between relevant professional groups, industry and other stakeholders. A set of actions to improve RP in quality programs for medical imaging and interventional radiology is suggested. It is concluded that RP and radiation management are integral elements for quality in imaging and intervention. Radiation safety topics should be covered in education and training programs and research projects in radiation medicine. While an individual action addresses a certain aspect of RP, collectively these actions will improve quality in medical imaging and

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interventional radiology. Leadership and on-going collaboration by developing and implementing innovative actions will ensure RP and quality objectives are attained in the not too distant future.

Keywords Diagnostic reference levels (DRL) • Optimization of protection • Procedure justification • Quality improvement • Quality program • Quality radiology • Radiation protection • Radiation safety • Radiology errors

1 Introduction

1.1 *Quality and Safety*

Quality medical imaging has been defined as ‘a timely access to and delivery of integrated and appropriate procedures, in a safe and responsive practice, and a prompt delivery of an accurately interpreted report by capable personnel in an efficient, effective, and sustainable manner’ [28]. Radiation safety is a key quality element when ionizing radiation is used in imaging and intervention. Medical imaging and interventional radiology save lives, are indispensable in healthcare, and their use has greatly expanded worldwide. Radiologists and other eligible operators of radiological equipment, simple or sophisticated, must be properly trained in radiation safety and RP to ensure quality care and patient safety. Budget constraint is a critical issue that may influence the level of quality and impact on basic radiation safety. Sometimes, new medical imaging technology is introduced without due consideration for the economic and human resources required to ensure adequate staff training, including RP, or to implement a basic quality control program, including patient dosimetry.

1.2 *Issues*

Workforce shortage, workload increase, workplace changes, and budget challenges are emerging issues around the world, which could place quality medical imaging and intervention radiology at risk [28]. It is important for the stakeholders to collaborate and jointly address these issues in order to ensure patient safety and improve the quality of care. Several strategies have been proposed to improve quality medical imaging by conducting research, promoting awareness, providing education and training, strengthening infrastructure, and implementing policies. In practice, these actions will result in selecting the right procedure (justification), using the right dose (optimization), and preventing errors along the patient journey [29].

The growth in medical imaging and interventional radiology over the past two decades has yielded undisputable benefits to patients in terms of better quality of life and longer expectancy. This growth reflects new technologies and applications,

including new imaging modalities. However, part of this growth can be attributed to overutilization. In 2009, the American Board of Radiology Foundation hosted a summit to discuss the causes and effects of overutilization of medical imaging [11]. The key elements contributing to overutilization were: payment mechanisms and financial incentives; practice behavior of some referring physicians; self-referral, including referral for additional medical imaging procedures; defensive medicine; missed educational opportunities when inappropriate procedures were requested; patient expectation; and duplicating procedures. A range of actions to reduce overutilization was proposed: national collaboration to develop evidence-based appropriateness criteria; wider use of practice guidelines in the request and delivery of procedures; decision support at the point of care; education of referring physicians, patients, and the public; accreditation of facilities; management of self-referral and defensive medicine; and payment reform.

A quality program for medical imaging and interventional radiology should maximize the benefits and minimize the risks of radiation exposure. Radiation risk should be considered and quantified by regular systematic radiation dose audits. The increased use of high dose procedures, e.g. CT and interventional procedures; the duplication or repeat of these procedures in certain group of patients; and the age of some patients, i.e. paediatric and young adults, could substantially increase radiation risk.

1.3 Principles

The driving principles of a quality system for medical imaging and interventional radiology are procedure justification and optimization of diagnostic information, including image quality. When ionizing radiation is used in imaging and intervention, the proper management of radiation exposure for the patients and staff has to be considered. Of course, optimization should include error prevention, covering unintended or over exposures.

In relation to the management of radiation exposure, it is helpful to use the term ‘diagnostic information’ instead of ‘image quality’ because the new imaging modalities can combine several acquisition modes, e.g. fluoroscopy, cine, digital subtraction, rotational acquisition, cone beam CT, etc., and can result in differences in exposure and image quality. Sometimes, ‘noisy images’ may be acceptable and diagnostic if the saving in radiation dose is significant. The objective is to obtain ‘adequate diagnostic information’ for the clinical task, rather than ‘best image quality’ especially if the latter could involve much higher exposure.

Sometimes quality medical imaging is judged only by the accuracy and timeliness of a report, especially in clinical teleradiology, without radiation risk being taken into account [56]. Consistent with conventional practice, providers of clinical teleradiology are encouraged to apply good practice principles and guidelines to underpin quality practice and radiation safety [24, 25, 27]. With digital imaging, it is possible to obtain good or even excellent image quality and at times too much

diagnostic information while the patient could be inadvertently over-irradiated. Therefore, a good and timely report is not necessarily a guarantee that the procedure has been carried out with the most optimal radiation dose management.

The successful development and implementation of quality system in medical imaging and interventional radiology requires leadership and collaboration between radiologists, other clinicians, radiographers, medical physicists, and nursing professionals. Active participation of and good communication between the referrers and other healthcare managers at all levels are essential to ensure coordinated and continuity of care and the requested procedures are justified and not duplicated. Patient information on the benefits and risks of procedures should be available to facilitate informed decision-making and patient satisfaction. For example, some procedures are not recommended if and when the benefits do not outweigh the radiation risks, as the case for some paediatric CT procedures.

Interventional radiology is an area in which a quality program, including radiation safety, has been developed including considerations for the pre-procedural, procedural and post-procedural steps along the patient journey [30–32]. The aim is to prevent radiation-induced injuries relating to these complex procedures and to address the deficiencies due to the absence of a proper radiation management program.

1.4 Individual Exposure Recording and Monitoring

Reiner suggested the elements for consideration when quantifying radiation safety and quality in medical imaging [36]. These included an automated recording, tracking, and analysis of quality data. Very few data on radiation dose are being prospectively collected, tracked, or analyzed. These individual patient dose and image quality data can be used for education and training, certification, research, practice guidelines development, and new technology development.

In 2012, an international collaboration on patient radiation safety has led to the publication of a ‘Joint position statement on the IAEA patient radiation exposure tracking’ [13], supported by the Conference of Radiation Control Program Directors USA (CRCPD), European Society of Radiology (ESR), Food and Drug Administration USA (FDA), IAEA, International Organization for Medical Physics (IOMP), International Society of Radiographers and Radiological Technologists (ISRRT) and World Health Organization (WHO). The scope includes the recording, reporting and tracking of radiation doses of all imaging and interventional procedures employing ionizing radiation, including radiography, fluoroscopy, CT and nuclear medicine procedures.

This chapter focuses on the impact of RP on quality in medical imaging and interventional radiology and describes the role of RP by justification through referral criteria and guidelines and by optimization of procedures. The relevant recommendations of the ICRP are highlighted. There is a need to improve the

participation of and the wider cooperation between all stakeholders, e.g. radiologists, other clinicians, radiographers, medical physicists and other stakeholders to advance and strengthen radiation safety programs including those dealing with RP training and patient dose recording and tracking.

2 Justification and Referral Guidance

All medical imaging and interventional radiology procedures must be justified for a good clinical reason and the radiation dose involved in some of these procedures should also be considered. If available and when appropriate, imaging or intervention by other modalities not using ionizing radiation should be selected.

2.1 *Referral Guidelines and Radiation Protection*

Some international organizations and national professional societies have published and promoted referral guidelines [2, 6, 44, 55]. For these guidelines to remain relevant and to reflect rapid technological advances and changing practice, timely updates are needed, requiring both human and financial resources. In Europe, the Council Directive on Medical Exposures stated in one of its articles: ‘Member States of the European Union shall ensure that recommendations concerning referral criteria for medical exposure, including radiation doses, are available to the prescribers of medical exposure’ [3]. In addition to the existing national guidelines, the European Commission published ‘Radiation Protection 118. Referral guidelines for imaging’ in 2000. This document included discussions on RP and provided a list of the typical radiation dose of the different radiological procedures [6]. However, the majority of the content was not related to RP. Due to limited resources these European guidelines have not been updated regularly, but it is important to recognize the initial RP recommendations are still currently valid. Further, an update of the typical radiation doses for diagnostic radiological and nuclear medicine procedures have been published as part of the DOSE DATAMED and SENTINEL programs [7, 8]. Currently, a new version of DOSE DATAMED (DOSE DATAMED 2) is being implemented [10].

2.2 *Means to Improve Care and Minimize Exposure*

The following is an extract from the European Guidelines [6] highlighting the scenarios where inappropriate use could be avoided and RP enhanced:

1. Repeating investigations which have already been done e.g. at another hospital, in an outpatient department, or in the accident and emergency department. HAS

IT BEEN DONE ALREADY? Every attempt should be made to get the previous films (images). The transfer of digital data through electronic links may assist in the future.

2. Investigation when results are unlikely to affect patient management, e.g. when the anticipated 'positive' finding is usually irrelevant, e.g. degenerative spinal disease (as 'normal' as hair turning grey with age) or because a positive finding is so unlikely. DO I NEED IT?
3. Investigating too often, i.e. before the disease could have progressed or resolved or before the results could influence treatment. DO I NEED IT NOW?
4. Doing the wrong investigation. Imaging techniques are developing rapidly. It is often helpful to discuss an investigation with a specialist in clinical radiology or nuclear medicine before it is requested. IS THIS THE BEST INVESTIGATION?
5. Failing to provide appropriate clinical information and questions that the imaging investigation should answer. Deficiencies here may lead to the wrong technique being used, e.g. the omission of an essential view. HAVE I EXPLAINED THE PROBLEM?
6. Over-investigating. Some clinicians tend to rely on investigations more than others. Some patients take comfort in being investigated. ARE TOO MANY INVESTIGATIONS BEING PERFORMED?

The typical effective dose for some common diagnostic radiology procedures can vary by a factor of 1,000, e.g. from the equivalent of 1 or 2 days of natural background radiation (0.02 mSv for a chest radiograph) to 4.5 years (for a CT of the abdomen). However, there is a substantial variation in the level of background radiation between and within countries. These general recommendations should be applied and other specific advice should also be considered, e.g. when transitioning from conventional film-screen to digital imaging [16, 35].

These six basic and clear advices on RP published in the 2000 EC guidelines are still valid today and probably will be in the coming years. A regular update of referral criteria should be made by the professional organizations after taking into account of RP issues and having RP specialists participating in the working groups. Amongst other updates, this process enables the incorporation of radiation dose for the various procedures as reported in the most recent literature. It is important to recognize that while a certain procedure is generally justified for a particular condition, its appropriate use for a certain patient requires a careful consideration of an individual's specific circumstances.

2.3 *An ICRP Perspective*

Justification, as stated by the ICRP, shall be applied at three levels [18]. In principle, the decision to adopt or continue an activity involves a consideration of the benefits and risks of the available options. In medical imaging and interventional radiology, this consideration usually leads to a number of alternatives that will do more good than harm. The decision process could be complex but is necessary. The harm, more

strictly speaking the detriment, is not confined to radiation but includes others as well as economic and societal costs. Often, radiation risk is only a small part of the total consideration.

For these reasons, the Commission uses the term ‘justification’ to the first of the three levels, i.e. it only requires that the net benefit for the procedure be positive. Selection of the best available option is usually a task beyond the responsibility of RP organizations.

In some healthcare systems, commercial interest may encourage more referrals to medical imaging, since these procedures may be a major source of income to the parties concern. This reason, with or without utilization-based incentives, could lead to increased use of procedures well beyond the norm for good medical practice. The Commission disapproves referrals that confer unjustified risk to patients, and that are inconsistent with medical ethics and the principles of RP.

The three levels of justification of a radiological practice in medicine are:

- The first and most general, the proper use of radiation in medicine is accepted as doing more good than harm to society. This general level of justification is now taken for granted and is not discussed further.
- The second level, a specified procedure with a specified objective is defined and justified, e.g. a chest x-ray for a patient with relevant symptom(s), or a group of individuals at risk for a condition that can be detected and treated. The aim of this second level of justification is to determine whether the radiological procedure will improve the diagnosis, or will provide necessary information about the exposed individuals. The justification of a radiological procedure at this level is a matter for national and international professional bodies, in conjunction with national health and radiological protection authorities, and the corresponding international organisations. The total benefits from a procedure include not only the direct health benefits to the patient, but also the benefits to the patient’s family and to society. Justification at this level should be reviewed from time to time, as more information becomes available about the risks and effectiveness of the existing procedure and the availability of new procedures.
- The third level, the application of a procedure to an individual patient should be justified, i.e. the particular application should be judged to do more good than harm to an individual patient. Hence all individual medical exposures should be justified in advance, taking into account of the specific objectives of the exposure and the characteristics of the individual involved. Justification of individual exposures should include checking that the required information is not already available. For high-dose procedures, such as complex diagnostic and interventional procedures, individual justification by the practitioner is particularly important and should take account of all the available information. It is often possible to speed up the procedure by defining referral criteria and patient categories in advance.

Although the principal aim of medical exposures is to do more good than harm to an individual patient, the Commission recommends consideration of radiation exposure to staff and other individuals should be part of this justification process.

2.4 *How Optimization Affects Justification*

Justification and optimization are closely linked and these two principles should be considered jointly in some cases. For example, due to technological advance but limited by resources, between and within countries, a procedure such as paediatric CT could not be justified in a facility without a paediatric radiologist or experience in paediatric low dose protocols, but could be the first option in another facilities where these conditions are met. The availability of better infrastructure such as experienced paediatric radiologist, CT scanner with dose reduction technology, and good quality program enables a facility to offer CT as the first choice for some conditions.

Therefore, if and when RP is fully optimized, certain procedures could be justified and appropriate even though these are usually not when such provisos are not met. A similar consideration could be extended to some adult procedures. The choice between invasive cardiac catheterization and CT coronary angiography is a good example illustrating how local experience and expertise, equipment availability, and use of dose reduction strategies could influence the selection of an imaging modality [39, 40].

3 Optimization of Radiation Protection and Data

3.1 *Diagnostic Reference Levels*

To improve the optimization of RP of patient in diagnostic procedures, the ICRP recommends the use of Diagnostic Reference Levels (DRLs) to compare procedures, which is applicable to groups of similar patients rather than individuals. DRLs are used to ensure the doses do not deviate significantly from those achieved at peer departments for that procedure unless there is a known, relevant, and acceptable reason for this deviation [18].

However, the DRL concept is not well understood by many practitioners and referrers. The following provides some helpful hints relating to the use of DRLs [49]:

- DRLs are not dose limits, they should be used as investigation levels;
- DRLs are not applicable to individual patients;
- Comparison with DRLs shall be made using mean or median values of a sample of patient doses;
- Quantities used as DRLs should be easily measured;
- The use of DRLs should be made in conjunction with the evaluation of image quality or diagnostic information;
- DRLs should be applied with certain flexibility, i.e. allowing tolerances for patient size, condition, etc.;

- DRLs are not differentiators for good or bad practice;
- Values that are UNDER the DRLs may not necessarily be optimised values;
- Values that are OVER the DRLs should require an investigation and optimization of the x-ray system or operational protocols;
- DRLs should be used in a dynamic and continuous process of optimization;
- The goal in using DRLs is not to reduce patient doses if image quality or diagnostic information is compromised; and
- Compliance or faults with DRLs should be discussed with the staff of the imaging department.

Optimization could be a challenge when introducing new imaging modalities and acquisition protocols. However, equipment manufacturers have significantly improved the hardware and post-processing tools in recent years, especially for interventional procedures and CT. The end-users contribute by undertaking clinical evaluation of these systems and acquisition protocols. The combined efforts have resulted in the successful use of dose-saving strategies, e.g. substantial patient doses reduction in CT coronary angiography [37].

3.2 Patient Dosimetry

In the past, patient dosimetry in interventional radiology was made over a small sample of procedures to calculate the mean or median values as part of clinical audits and in the use of DRLs. With the introduction of digital systems, it is possible to easily collect and archive dosimetric and demographic data for these procedures together with images, as part of the Digital Imaging and Communication in Medicine (DICOM) header or other DICOM services, e.g. Modality Performed Procedure Step (MPPS) or Radiation Dose Structured Reports (RDSR), and to manage an individual patient's dose data [51, 52].

The analysis of this data is subjected to quality control and should include: (a) a periodic calibration of patient dose quantities as reported by the x-ray system, (b) an automatic detection and identification of high individual dose values, (c) a periodic statistical analysis of the local DRLs and comparison with national or regional DRLs, and (d) corrective actions when indicated to meet the requirements of quality assurance and clinical audit programs.

An example of an automatic patient dosimetry management system is the 'Dose on Line for Interventional Radiology (DOLIR)' used to analyze, monitor, audit and archive individual patient dosimetry for fluoroscopy-guided cardiology and interventional radiology procedures in seven catheterization laboratories at the San Carlos Hospital, Madrid [42]. Figure 2.1 shows the data in Dose Area Product (DAP) and Fig. 2.2 in cumulative air kerma. Comparative benchmarks such as median value, local reference level and trigger level could be individually or collectively selected and displayed. Programs such as this enable a ready identification of those procedures associated with high exposure and alert prompt intervention to those with potential radiation-induced skin injuries.

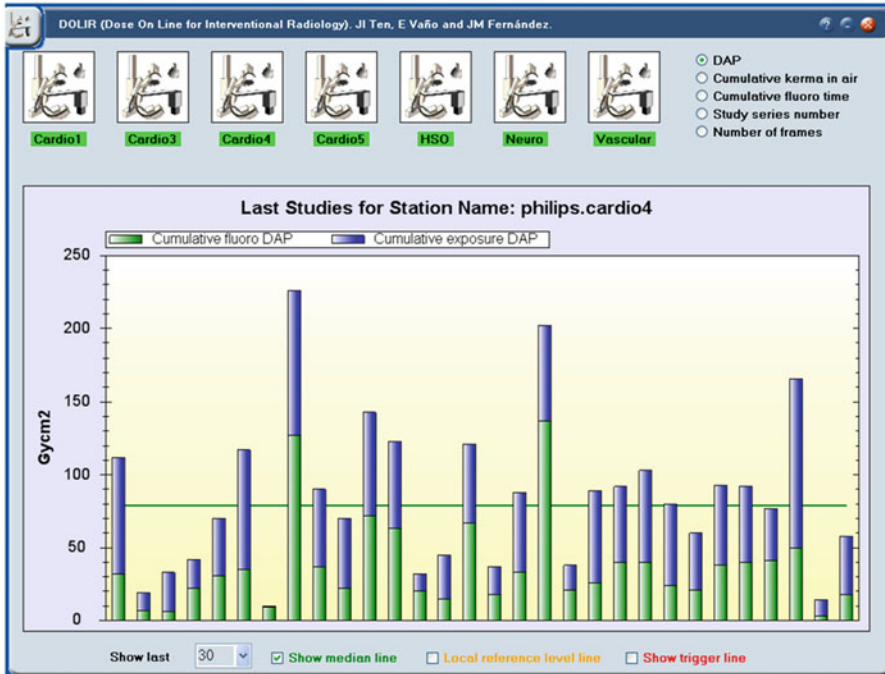


Fig. 2.1 The Dose On Line for Interventional Radiology (*DOLIR*) Program displaying Dose Area Product (*DAP*) values. This example shows the exposures for the last 30 patients (*far left of lower screen*) in *DAP* (*right of upper screen*) expressed in $Gy\ cm^2$ including a breakdown of the fluoroscopic and cine acquisition exposures. The median *DAP* was chosen (*centre left of lower screen*) and represented by the *green horizontal line*. This program enables the operators to readily identify those procedures with higher exposure

The North American based Society of Interventional Radiology (SIR) Standards of Practice Committee has recently published a document on ‘Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures’ [30]. This document stated that ideally all available patient radiation dose data should be recorded. The society also recognizes that this may become mandatory in the future, as the FDA has already expressed an intention to establish requirements for CT and fluoroscopic devices to provide radiation dose data for incorporation into an individual’s medical record or a radiation dose registry. The guidelines suggested an adequate recording of the different dose metrics, including skin dose mapping, for all fluoroscopy-guided interventional procedures is needed. The establishment of threshold levels to enable prompt analysis was also suggested.

3.3 Radiation Protection for Patients and Staff

The most important changes introduced by the ICRP in 2007 concerning the optimization of diagnostic imaging, were the application of DRLs for interventional

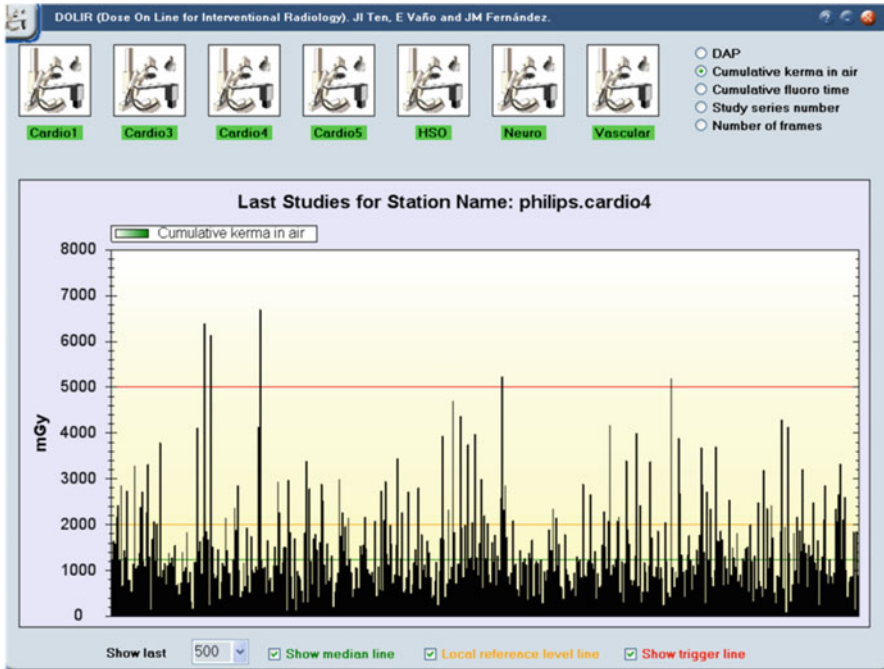


Fig. 2.2 Another example of the DOLIR Program displaying exposures in cumulative air kerma. The parameter chosen here (*right of upper screen*) was cumulative air kerma at the entrance reference point given in mGy for the last 500 cardiology procedures (*far left of lower screen*). The reference benchmarks selected (*centre of lower screen*) were: median value (*green line*, at approximately 1,200 mGy for this laboratory), local reference level (*orange line*, at 2,000 mGy) and trigger level (*red line*, at 5,000 mGy). The DOLIR Program enables ready identification of those procedures resulted in high exposure and prompt action on those with potential radiation-induced skin injuries

procedures [15, 18] and to consider the exposure to staff as part of optimization [17, 18]. The latter is particularly relevant to staff involved in fluoroscopy-guided interventional radiology procedures, especially in the context of the ICRP Statement on tissue reactions (deterministic effects), and the recommended changes to the occupational dose limits for the lens of the eye and the need to improve optimization for some high dose procedures [21].

The Commission drew attention to recent epidemiological evidence, which suggested that tissue reactions could occur when the threshold doses are at or might be lower than previously considered, i.e. 0.5 Gy for the lens of the eyes (radiation induced opacities) and 0.5 Gy for circulatory disease to the heart or brain. Doses of this magnitude to staff (lens of the eyes) and to patients could be reached in some complex interventional procedures and the Commission recommended particular emphasis on optimisation in these circumstances. Therefore, when discussing optimization, it is important to consider the RP of patients and staff

together. The Commission has recommended the reduction of the dose limit to the lens of the eyes from 150 to 20 mSv/yr.

Other medical specialties in addition to radiology and cardiology also use fluoroscopy-guided interventional procedures as alternative to surgery, especially in some elderly patients unsuitable for general anesthesia or due to other clinical constraints. The increasing interest in these minimally invasive techniques together with the updated international recommendations on radiation safety, have promoted several international research projects in patient and staff dosimetry that should help to improve radiation safety and quality when performing these procedures.

The Commission's recommendations and other improvements in the pending European regulation [9] will encourage the radiology community and users to develop strategies and software programs to improve dosimetric data processing, individual dose evaluation, automated result analysis, and data transfer to patient record and dose tracking system.

3.4 Education, Training and Optimization Strategies

Education and training in RP by focusing on the need and means to apply appropriate exposure in radiation procedures is a key component to reduce dose to patients and staff. The Commission published a set of recommendations on 'Education and training in radiological protection for diagnostic and interventional procedures' [19].

In recent years several scientific and professional societies have produced guidelines on radiation safety, including patient dosimetry for interventional radiology. Some of these guidelines have been adopted simultaneously by the American and European societies of interventional radiology [4, 30, 32]. Other recommendations have been produced by expert groups and later endorsed by the professional societies [5]. The role of the European Commission in the publication of guidelines and reports [7, 8] is particularly important in the optimization of interventional procedures.

DRLs are still a challenge especially for interventional radiology. The Commission proposed their application to interventional radiology in 2001 and 2007 [15, 18] but it is still a long way from their effective application. The National Council on Radiation Protection and Measurements (NCRP) in USA has recently published a document on this issue [33]. The ICRP formed a working party in 2012 to provide more specific advice on the use of DRLs in interventional procedures and new imaging techniques.

Radiation protection and optimization are very important in paediatric practice especially in those procedures using high doses such as CT and interventional procedures. The Commission has prepared recommendations for 'Radiological Protection in Paediatric Diagnostic and Interventional Radiology' [23]. The IAEA is promoting programs on RP in paediatric interventional radiology in Latin America [54] and several relevant papers with results on patient and staff doses have recently been published [45–47]. Image Gently, conducted by The Alliance for Radiation

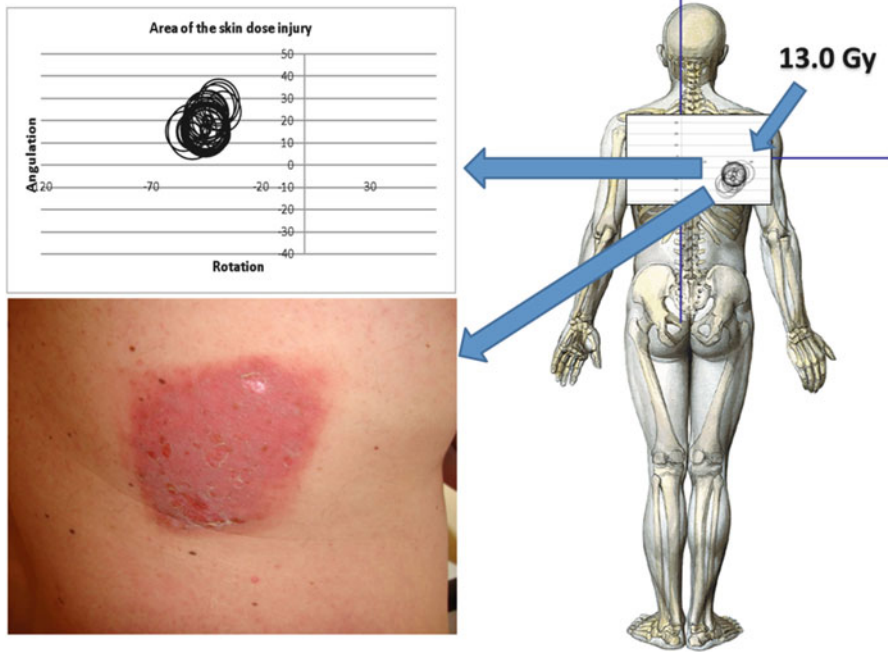


Fig. 2.3 A case of radiodermatitis. This occurred following a complex interventional cardiology procedure resulted in a peak skin dose of 13 Gy [50]. The DOLIR system enables immediate clinical intervention and the skin lesion resolved within a few months [42]. Patient dose audit and clinical follow-up of potential skin injury should be part of a quality improvement program for all interventional radiology and cardiology procedures (Reproduced after modification from Vano et al. (2012) Importance of a patient dosimetry and clinical follow-up program in the detection of radiodermatitis after long percutaneous coronary interventions. *Cardiovasc Intervent Radiol*. With kind permission from Springer Science + Business Media)

Safety in Pediatric Imaging, has formed a paediatric interventional radiology group and recently launched the ‘Step Lightly’ Campaign [43]. The European Commission is expected to launch a program to review the use of DRLs in Europe for pediatrics including their application in interventional procedures in 2013.

The follow-up of patients suspected of potential radiation injuries arising from complex interventional or CT procedures is a performance indicator that should be incorporated into a quality program. Two recent papers reported the incidence of and criteria for patient inclusion in the follow-up protocol. Applying the SIR-CIRSE recommendations [38], the first paper on cardiac procedures reported a follow-up rate of 0.31 % and a skin injury rate of 0.03 % [50]. An example of radiodermatitis after a complex interventional cardiology procedure is shown in Fig. 2.3. The second paper was on neuroradiology procedures performed in the same hospital. Following optimization and applying the peak skin dose criteria of >3 Gy as stated in the CIRSE and SIR guidelines, a patient follow-up rate of 1 % was reported [53].

3.5 Built-in Optimization

Hybrid rooms catering for conventional surgery and fluoroscopy-guided procedures are expected to increase in the future and RP is an important consideration. Some of the critical RP issues to be considered include: appropriate shielding, structure required for ceiling-suspended screens, protective garments for staff, patient dose monitoring and recording, appropriate personal dose monitoring, RP training for staff, designation of an individual responsible for RP, and support from qualified medical physicist.

The Multispecialty Occupational Health Group (MSOHG) has prepared recommendations on innovative designs for these rooms [26]. The involvement of medical, paramedical, engineering, construction, equipment, management, and other stakeholders is required to comprehensively consider various economic and stakeholder needs. A team approach, involving the specialists working together rather than in competition, will most likely lead to better patient outcome. Collectively, solutions will be developed to underpin the quality and safety requirements for: structure, space, ventilation, cooling, infection control, supporting infrastructure, and medical imaging (including hardware, operating table, software, imaging protocols, data archive and supporting equipment) etc. The safety needs of patients and staff, including radiation safety, should be one of the priorities.

4 Impact of Radiation Protection Recommendations

4.1 ICRP Recommendations

The ICRP revised the risk factors for stochastic effects in 2007 [17] and there are no substantial changes to the overall cancer risk coefficient since the 1990 report [14]. However, relevant changes were proposed for some organs such as breast and lung. The Commission emphasized the higher radiation risk for children and the need for caution when applying effective dose in medical exposure. Some refinements were made to the medical use of radiation by recommending the use of DRLs for interventional radiology and the use of staff doses as part of justification and optimization [18].

For tissue reactions, i.e. deterministic effects, the most relevant changes proposed in 2011 are new threshold doses for radiation opacities (cataracts) in the lens of the eyes and for circulatory disease to the heart and brain. These changes, especially that on lens opacities, should have significant impact on the radiation safety of professionals involved in fluoroscopy-guided interventional procedures and on the requirements in quality programs. The ICRP released its statement in April 2011 and included an update on the dose limit for the lens of the eye for occupationally exposed persons [21]. The immediate consequence was the adoption and incorporation of this change in the International Basic Safety Standards [12] and European Basic Safety Standards [9].

The Commission has recently produced three documents detailing the recommendations for diagnostic and interventional radiology: Publication 117 on 'Radiological protection in fluoroscopically guided procedures performed outside the imaging department' [20]; Publication 120 on 'Radiological protection in cardiology' [22]; and Publication 121 on 'Radiological protection in paediatric diagnostic and interventional radiology' [23].

4.2 European Commission Actions

The European regulations are quite strict on quality programs for medical imaging procedures. In fact, many requirements are included as part on the current Medical Exposure Directive [3], which will be further improved in the upcoming Directive on Basic Safety Standards [9]. Quality assurance programs, clinical audits and inspections by competent authorities are required. These quality programs include the quality control of the imaging equipment, patient dosimetry and involvement of Medical Physics Experts. Training of professionals involved in medical exposures, including RP training, is another aspect of the European Directive.

Quality assurance is defined in the European Directive [3] as all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component, or procedure will perform satisfactorily and comply with the agreed standards. Quality control is part of quality assurance. The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled.

In the new European Basic Safety Standards [9] optimization includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical exposure procedures, quality assurance, and the assessment and evaluation of patient and staff doses. Accidental and unintended exposures shall be part of the quality assurance program. Member States of the European Union 'shall implement a system for the registration and analysis of events involving or potentially involving accidental or unintended exposures'.

5 Impact of Radiation Protection on Quality Programs

5.1 Improve Quality by Radiation Protection

Radiation protection and radiation safety are key elements for quality program for medical imaging and interventional radiology. Radiation protection must be considered in: (a) the design of a facility, i.e. x-ray room, waiting area, patients and staff flow, shielding, equipment selection, informatics infrastructure, and personnel

training etc.; (b) equipment installation and commissioning, i.e. acceptance testing, connectivity between modalities with RIS and PACS, and staff training etc. and (c) equipment use, i.e. routine daily practice, quality assurance program, quality clinical audits including patient and staff doses and image quality, and on-going training in quality and safety etc.

Good management in a medical imaging and interventional radiology facility includes leadership in radiation safety and RP by advocating the importance of RP to the health professionals and ensuring RP is a substantial part of a quality management system in practice [48].

Scientific and professional societies and organizations, agencies, competent authorities, industry, and standard organizations etc. have contributed to improvements in radiation safety in imaging and intervention. The best outcome will be achieved when all the stakeholders, i.e. medical doctors, radiographers, medical physicists, other health professionals, regulators, health authorities and industry are working together.

5.2 Radiation Protection Actions in Quality Programs

The following is a list of RP actions, which could form part of a medical imaging quality program [41, 48]:

- To improve the RP competences of medical doctors, medical physicists, engineers, radiographers, technicians, nurses, etc. by education and training;
- To promote a closer working relationship between medical physicists and other health professionals, e.g. collaboration between medical physicists and cardiologists is still uncommon;
- To promote a closer working relationship between radiologists, radiographers and medical physicists to improve justification and optimization and to reduce errors;
- To provide adequate infrastructure in a medical imaging facility, including radiation dose management and radiation safety for patients and staff [34];
- To improve interdisciplinary cooperation in research projects in radiation health effect and radiation health risk, especially with epidemiologists and radiobiologists;
- To define staffing requirements for RP and radiation safety, e.g. RP may be compromised by inadequate or unqualified staff;
- To integrate patient and staff RP into medical practice, e.g. interventional radiology;
- To improve the integration of RP into clinical quality programs;
- To address safety issues and to prevent incidents and radiation injuries when introducing new technologies and techniques, especially in interventional radiology;
- To improve RP in paediatric imaging, CT and interventional radiology;

- To improve the measurement, recording, analysis and archival of individual patient dose, which will impact on procedure justification and optimization [1];
- To refine criteria for the justification of radiological procedures in asymptomatic individuals after taking into account of the radiation dose;
- To optimize the use of new imaging technology, e.g. flat detectors, PET/CT etc.;
- To collaborate with equipment designers and manufacturers in RP, image quality improvement and dose reduction;
- To improve the automated collection of patient and staff doses and data transfer to individual and population exposure databases;
- To promote the proper use of DRLs in diagnostic and interventional procedures;
- To improve the communication to patients on radiological risks and to minimize self-referral for certain procedures; and
- To increase the support to medical physics in medical imaging facilities.

6 Conclusion

Quality in medical imaging and interventional radiology needs radiation safety on board. Radiological protection and good radiation management are integral elements for quality imaging and intervention. Successful implementation of justification and optimization requires a close cooperation between radiologists, radiographers, medical physicists and other stakeholders. Patient dose estimation, recording and audit are challenges and solutions are needed. Radiation safety for staff is a priority for some procedures. Radiation safety should be covered in education and training programs and in research projects dealing with radiological imaging and intervention. While an individual action addresses a certain aspect of RP, collectively they will improve quality in medical imaging, interventional radiology and patient care. Many stakeholders contribute to these improvements worldwide through RP actions. The ICRP leads by developing and publishing RP recommendations and collaborates with other stakeholders by facilitating the implementation of innovative RP actions. These combined efforts will ensure the common RP and quality objectives are reached in the not too distant future.

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