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Individual Exposure and Monitoring in Interventional Radiology and Cardiology

Eleftheria Carinou, Isabelle Clairand, Jérémie Dabin, Paolo Ferrari, Mercè Ginjaume, Oliver Hupe, María Gracia Ochoa, Una O'Connor, Filip Vanhavere.

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Executive Summary

The aim of this report is to summarise the technical and legal aspects of individual monitoring requirements in interventional radiology and cardiology (IR/IC) workplaces, incorporating some of the most recent research in this area. The report is aimed at all those working in dose monitoring in the interventional field such as radiation protection experts, radiation protection officers, medical physicists, dosimetry services and other relevant stakeholders.

This report provides information on dose limits, operational quantities used in radiation protection, and classification of workers in IR/IC. The establishment of dose constraints as an optimization tool is discussed. Typical occupational dose levels from various international projects are detailed for information and guidance.

Radiation protection equipment available to staff during IR/IC procedures is presented. Figures of the general level of effectiveness and practical attention points are given. Details of the effectiveness of equipment, along with advice on storage and maintenance are presented.

The importance of individual dose monitoring for staff working in IR/IC to demonstrate compliance with regulatory dose limits is detailed in the report. A variety of personal monitoring devices are available from different manufacturers and a summary of the most commonly used devices for monitoring occupational radiation doses is shown. Passive dosemeters remain as the dosemeter of choice in most countries for demonstrating compliance with the dose limits. However, the use of active personal dosemeters (APDs) for real-time monitoring is increasing. Hybrid solutions allowing for frequent local readouts of staff doses are also becoming widely used.

One of the major challenges in setting up an individual monitoring programme in interventional workplaces is the wearing position of the dosemeters (either for the whole body, eye lens or extremities). Due to the inhomogeneity of the field, the assessment of the respective dose is strongly dependent on the dosemeter position and other important parameters such as the energy and angular distribution of the X-ray beam, the beam projections or the distance between the operator and the patient.

In terms of assessment of the effective dose, there are generally two methods in use: (i) the "doubledosimetry" approach, which consists of using two dosemeters at the level of the trunk, one worn under the apron, and the other worn over the apron (the effective dose is estimated by the use of various algorithms based mainly on the radiation protection garments); and (ii) the single dosimetry, i.e. to wear the dosemeter over the apron or under the apron, preferably at the central position to minimise the dependence on the beam projection. When the dosemeter is worn under the apron, the effective dose is assumed to be the dosemeter reading itself. When the dosemeter is worn above, the effective dose is estimated by dividing the dosemeter reading by a factor (typical range from 10 to 20) which depends on the type of practice, the thickness of protection, the position of dosemeters, etc. The use of two dosemeters is particularly relevant in fluoroscopically guided interventional procedures, when it is possible to reach or exceed the effective dose limit of 20 mSv per year.

For the assessment of the dose to the lens of the eye, the use of a specific eye-lens dosemeter located close to the most exposed eye and measuring $H_p(3)$ is generally the preferred option. Another common option is the use of an unprotected whole body dosemeter situated at the chest or collar level and the use of a multiplication factor (the most common value being 0.75) to convert the reading of the whole body dosemeter to dose to the lens of the eye.

To estimate extremity doses, a dosemeter capable of measuring $H_p(0.07)$ is used, ideally placed as close as possible to the most exposed area of the skin and oriented towards the radiation beam. For the majority of interventional procedures, the most exposed area appears to be from the little finger to the middle finger. Ring dosemeters worn on the little finger are proposed as the most appropriate monitoring method. Lower extremities might also need to be considered when table shielding is not used or is not long enough. Wrist dosemeters can be used at the ankles to provide assessment of the lower leg exposure if required.

1. General Introduction

The continuous increase in the use of radioactive sources and X-ray generators in medical practice, especially for interventional procedures, has raised concerns and specific interest amongst the scientific community regarding occupational exposure. In this context, the latest international and European basic safety standards (BSS) (EU, 2014; IAEA, 2014) have incorporated the recommendations by the International Commission on Radiological Protection (ICRP) for the decrease of the annual dose limit for the lens of the eye from 150 to 20 mSv (ICRP, 2012). The dose limits for the effective dose and the extremities remain the same.

More specifically, medical staff performing interventional cardiology and radiology (IC/IR) procedures stand close to the patient and thus close to the primary and scattered radiation beam. Although they wear a radiation protection apron and, most of the time, a thyroid collar, their hands, legs and eyes are not always protected. Therefore, these parts of the body could receive significant doses. Moreover, the dose ranges for the same kind of procedures vary considerably, as many factors affect extremity and eye lens exposure. Additionally, there is evidence that doses to the lens of the eye can be high in IR/IC (Ciraj-Bjelac et al., 2016), and cases of cataracts or opacities have been reported in the literature (Vaño et al., 2013; Jacob et al., 2013).

These significant exposures raise many questions, such as, which protective equipment is best suited to the exposure situation, which dosemeters should be used, and how to position them.

Another important issue is the use of 'double dosimetry' (ICRP, 2000; Jarvinen et al., 2008). Despite the fact that this methodology has been implemented for many years, it is not common practice in Europe and there is no consensus on the use of the algorithms and position of the dosemeters. There is renewed interest in double dosimetry due to the use of the unprotected dosemeter for the estimation of the doses to the lens of the eye. Harmonisation is needed to ensure that the recorded dose values in different countries are comparable, which is actually not the case. In some countries, the dose value in the national dose register is the one measured below the protective clothing, in other countries it is the value above the protective clothing.

Finally, all the above issues should be reviewed in the light of new active and hybrid dosemeters that are being developed and new types of material used for radiation protection garments.

The main aim of this document, prepared by EURADOS Working Group 12 (WG12) members, is to provide guidance on individual monitoring requirements in IR/IC workplaces. This is addressed to all those working in dose monitoring in the interventional field such as radiation protection experts, radiation protection officers, medical physicists, dosimetry services and other relevant stakeholders whose concern is the radiation protection of workers in interventional workplaces in medical facilities.

The document is structured as follows:

- > Chapter 1 is the general introduction,
- Chapter 2 presents general information on individual monitoring in IR/IC, in particular the safety standards and regulation requirements and dose levels,
- > Chapter 3 is dedicated to protective equipment: types, efficiency and effectiveness,
- Chapter 4 provides information on the types of dosemeters (whole body, eye lens and extremity dosemeters), differences between active and passive dosimetry, calibration issues and future solutions in this field,

- > Chapter 5 addresses the topics of dosemeter positioning and dose assessment: effective dose, doses to the eye lens and extremities,
- > Chapter 6 includes a summary and the conclusions of the main aspects discussed in the report.

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2. Radiation Exposure to Staff in Interventional Radiology and Cardiology: Regulations and Dose Levels

2.1 Standards and regulations

2.1.1 International standards, European Council directives

The development of safety standards and their implementation are the first steps in setting a framework for the control of occupational exposure. In addition, it is a national responsibility to regulate safety and, therefore, many countries have transposed international and/or European BSS to national legislation. The regulatory authorities are responsible for checking compliance with the implementation of the safety standards. In the last step of responsibility hierarchy are the employers who have the prime responsibility for the safety of their workers. The ultimate goal of this structure is to assure and enhance safety of workers in all exposure situations and for all facilities and activities from the highest risk practices to applications in industry, research or medicine.

The basis for control of occupational exposure was set by ICRP who developed the recommendations for a system of radiological protection (ICRP, 2007). Complementary to this, the system of quantities and units was set by the International Commission on Radiation Units and Measurements (ICRU) (ICRU, 1998; ICRU, 2011). The calculation of doses from measurable quantities is based on scientifically established coefficients and relationships. For external exposure, these values have been published following the methodology established by ICRP in Publication 116 (ICRP, 2010).

Following the ICRP recommendations on the occupational exposure (ICRP, 2007, 2010) the international BSS were published by the International Atomic Energy Agency (IAEA) (IAEA, 2014a). In addition, the European BSS were developed and included in the Council Directive 2013/59 EURATOM (EU, 2014) with the latest ICRP recommendations (ICRP, 2007, 2010). The provisions of the European BSS are legally binding for the EU Member States. Furthermore, a technical document was developed by the IAEA to provide guidance on the implementation of the requirements for the occupational exposure to planned exposure situations (IAEA, 2018). The document is addressed to regulatory bodies, licensees and employers in hospitals, general industry and nuclear installations.

Next to the above international and European BSS, other standards in the field of individual monitoring have been developed by international standardization bodies that specify procedures for individual monitoring (ISO, 2015) or describe characteristics applicable to dosimetry systems that measure external radiation (see paragraph 4.3).

2.1.2 Dose limits, operational quantities, classification of staff and dose constraints

2.1.2.1 Dose limits

For external radiation the term "dose limit" is used for the effective dose or the equivalent dose in a specified period which shall not be exceeded for exposed workers. The occupational exposure and the related risks are subject to control to ensure that the specified dose limits are not exceeded. In this framework, the governmental mechanism that sets the levels of dose limit is the respective legislation. Following this, the regulatory authorities are empowered to enforce compliance with the dose limitation requirement.

The IAEA, at the international level, and the European Council, lay down uniform dose limits to provide for the basic standards and are set in the framework of "maximum permissible doses compatible with adequate safety" (IAEA, 2014a; EU, 2014).

Based on the above for occupational exposure of workers (over the age of 18 years), the dose limits are as follows:

- > for the effective dose: 20 mSv in any single year; in special circumstances: up to 50 mSv in a single year (the average annual dose over any five consecutive years must not exceed 20 mSv);
- > for the equivalent dose for the lens of the eye: 20 mSv in a year or 100 mSv in any five consecutive years (subject to a maximum dose of 50 mSv in any single year);
- > for the equivalent dose for the skin and extremities: 500 mSv per year. The equivalent dose limits for the skin apply to the average dose over 1 cm2 of the most highly irradiated area of the skin.

The current dose limit for the eye lens of 20 mSv per year is quite recent and comes from a statement made by the ICRP (ICRP, 2012). This statement was adopted by the IAEA and the EC, while both organisations agreed on maintaining the current dose limits for the effective dose and equivalent dose for extremities. This lowering of the dose limit to the eye lens has a particular impact in the context of dosimetric monitoring of IR/IC workers who are likely to receive "significant" doses, compared to the limits, if they have a high workload or if they do not use personal protection means appropriately.

The limit on the effective dose for apprentices and students aged between 16 and 18 years shall be 6 mSv in a year.

Additional restrictions apply to occupational exposure for a female worker who has notified her employer of pregnancy or is breast-feeding. In these cases, the foetus or the child is considered as member of the public. The employment conditions shall be such that the equivalent dose to the unborn child or the breastfed child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy or 1 mSv per year, respectively.

It is noted that dose limits do not include radiation doses received by the occupationally exposed individual while that individual is undergoing a medical examination, nor do they include any radiation dose from natural radiation sources, such as cosmic rays and naturally occurring radioactivity in the environment.

2.1.2.2 Operational quantities

The protection quantities "equivalent dose" and "effective dose" cannot be measured and, due to this, they cannot be used directly in individual monitoring. Therefore, operational quantities used for the assessment of effective dose or equivalent dose in tissues or organs have been developed to demonstrate compliance with regulations on occupational exposures.

Individual monitoring is performed using operational quantities set by the ICRU and, more specifically, the personal dose equivalent, $H_p(d)$, defined as the dose equivalent in soft tissue below a specified point on the human body at an appropriate depth, d. The soft tissue is the ICRU 4-element tissue (ICRU, 1985). For the assessment of effective dose, a depth of 10 mm is recommended, and for the assessment of equivalent dose to the skin and the lens of the eye, depths of 0.07 mm and 3 mm, respectively, are recommended.

In most practical situations for photons, $H_p(10)$ provides a reasonable estimate of the effective dose, E, and avoids both underestimation and excessive overestimation. The correspondence between E and $H_p(10)$ is based on the assumption of uniform whole body exposure. Coefficients have been calculated for conversion from the operational quantities to effective dose in anthropomorphic phantoms using ICRU phantoms (ICRU, 2010). When the radiation field is heterogeneous and when the expected levels of effective dose are high, as it is the case in IR/IC, the use of more than one dosemeter (over and under the protective clothing) is recommended by the ICRP (ICRP, 2000, 2013) to obtain an accurate estimate of E. In these cases, the correct positioning of the dosemeters and the application of the appropriate algorithm are essential for the final estimate of the radiation protection quantity.

In terms of personal monitoring, it is worth emphasising that recently the ICRU has issued a report (ICRU, 2020) that introduces new definitions of operational quantities. The aim of these new definitions is to replace the ICRP protection quantities, so Ambient Dose would replace Ambient Dose Equivalent, and the Personal Dose would replace the Personal Dose Equivalent. The new definitions are based on conversion coefficients (both evaluated in kerma approximation and with full secondary charged particles transport) calculated employing adult reference voxel models. For monitoring the exposure at the lens of the eye, the Personal Absorbed Dose in the Lens of the Eye is recommended, and the Personal Absorbed Dose in Local Skin is recommended for the skin exposure. The report suggests a gradual and prudent period of adoption to balance the costs of implementation with the benefit of a more coherent system of operational quantities, nonetheless, these new definitions would produce some effect on the design and calibration of dosemeters and monitoring instruments. A recent EURADOS report has considered all these aspects (Gilvin et al., 2022). Assuming that the new operational quantities are perfectly implemented in practice, a limited decrease in the monitored doses is expected in IR/IC (Abdelrahman et al., 2023). According to the ICRU's view, the process of adopting the new operational quantities should be carried out over a timescale of decades.

2.1.2.3 Categories of workers

Without prejudice to the dose limitation principle and for the purposes of monitoring and surveillance, a distinction is made between two categories of exposed workers:

- category A: those exposed workers who are liable to receive an effective dose greater than
 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or
 greater than 150 mSv per year for skin and extremities,
- category B (non category A): those exposed workers who are not classified as category A workers.

The individual monitoring of exposed workers is based on the category in question. Category A workers should be systematically monitored based on individual measurements performed by an approved dosimetry service. In cases where category A workers are liable to receive significant exposure of the lens of the eye or extremities, an adequate system for monitoring shall be set up (EU, 2014). Monitoring for category B workers should be at least sufficient to demonstrate that such workers are correctly classified as category B.

2.1.2.4 Dose constraints for occupational exposure

The term "dose constraint" has been used in radiological protection since 1991. Based on the ICRP's recommendations (ICRP, 2007), the benefits and risks from radiation exposure are not likely to be distributed equally through workers and an inequity of radiation exposure between workers does occur. This inequity can be limited by using the tool of "dose constraints" during the process of optimisation, in order to reduce occupational exposure of some individuals who are subjected to relatively higher radiation dose levels than the "average worker". Therefore, in practice, for occupational exposure, the dose constraint is a value of individual dose used to limit the range of options in such a way that only the options expected to cause doses below the constraint are considered in the process of optimisation.

European BSS (EU, 2014) defines the notion of dose constraint as "a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation". For occupational exposure, the dose constraint is established as an operational tool for optimisation by the undertaking under the general supervision of the competent authority and it is lower than the dose limit (Figure 1).

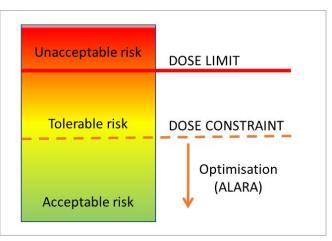


Figure 1: Relationship between dose limit and dose constraint

Most European countries have introduced the term "dose constraint" into their national regulations but the practical application of this concept varies from country to country. In some countries, the numerical values of dose constraints are determined by the employer, whereas other dose constraints are given by the regulatory authority. For example, in Poland, in the facility design phase, the proposed dose constraint for the effective dose for workers in IR/IC is set to 1 mSv per year (Piwowarska-Bilska et al., 2014). The same value is adopted in Ireland, where this value is used for exposed workers when designing and planning new medical facilities (RPII, 2009). Moreover, based on the previous concept of Council Directive 96/29/Euratom, in Greece the dose constraints are set at 70% and 75% of the dose distribution taken from the national registry of occupational doses (Kamenopoulou et al., 2000). In Poland, it is proposed to set local dose constraints by considering the upper third quartile, below which 75% of annual institutional dose values were respectively included (Piwowarska-Bilska et al., 2014).

In the specific case of IR/IC, the diversity of radiation fields, in terms of intensity and gradient, makes it complex to establish dose constraints for members of staff who are submitted to widely varying exposure levels. The dose constraints in these types of practices should be adjusted to the local conditions of radiation protection of workplaces and tasks performed by various professional groups

(nurses, medical doctors, technologists). According to a commentary from Mairs et al. (2016) consideration should be given to developing dose constraints using maximum expected doses in high-workload facilities with good radiation protection practices, and with the application of a factor allowing for attenuation by lead protective equipment such as the lead glasses. Using data from well-managed practices and accounting for attenuation by lead glasses a level of 7 mSv per year is suggested for the eye lens.

At the time of writing, there is no published literature compiling dose constraints for occupational exposure after the current BSS (IAEA, 2014a and EC, 2014).

In conclusion, it is stressed that the dose constraint for occupational exposure is an important tool of the optimisation principle. Dose constraints do not represent a border between safe and dangerous levels of dose. They are to be considered as a boundary between acceptable and unacceptable level of protection. In this concept, the methodology to set dose constraints should be used to address variations in the level of protection based on experience and recommendations from professional bodies.

2.2 Occupational exposure in interventional radiology and cardiology

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) regularly reviews, through surveys and literature, the levels of occupational exposure in various industry and medical sectors such as diagnostic radiology (separately for conventional and interventional diagnostic radiology), nuclear medicine, radiation therapy, dental practice, and veterinary medicine for different work categories (physicians, nurses, technicians, and others). The data of the latest review are included in the Scientific Annex D (UNSCEAR, 2022).

Moreover, in early 2009, the IAEA initiated the Information System on Occupational Exposure in Medicine, Industry and Research, referred to as the ISEMIR project (IAEA, 2014c), with a key aim to gain an overview of the current worldwide status of radiation protection practice in the specific field of interventional cardiology. Data was collected from questionnaires sent to individual interventional cardiologists, chief interventional cardiologists and radiation protection regulatory bodies.

At European level, ESOREX (European Platform for Occupational Radiation Exposure) platform (<u>https://esorex-platform.org/</u>) was established with a main aim to provide an overview of exposure levels of radiation workers employed in various fields in different European countries. The ESOREX platform is updated on a voluntary basis, and it contains data of the exposure levels for whole body doses, extremity doses as well as doses to the lens of the eye for various workplace categories.

In addition to the studies undertaken by some international and European organizations, there are many references in literature with measurements and calculations performed in various IR/IC workplaces. Most of these studies report the level of exposure for various types of interventional procedures as well as the relevant radiation protection measures used for optimisation. The level of doses received by staff in IR/IC depends on the type and the complexity of procedures, fluoroscopy time, protection measures, occupational category, as well as on the method used for the assessment of the effective dose (single or double dosimetry).

According to all these studies, some orders of magnitude on the exposure levels can be given.

The annual effective dose levels can reach approximately 4 mSv for physicians (Basic et al., 2011; Ingwersen et al., 2013; Chida et al., 2013; IAEA, 2014b; UNSCEAR, 2022; Askounis et al.,

2022) and 1 mSv for the other professionals, such as nurses or radiographers (IAEA, 2014b; Mori et al., 2015).

The extremities and eye lens doses can reach approximately 0.4 mSv/procedure or even more for complex interventional procedures (e.g. embolisations) (Martin, 2009; Efstathopoulos et al., 2011; Vanhavere et al., 2011; Vanhavere et al., 2012; Principi et al., 2015; O'Connor et al., 2015; Vano et al., 2016; Ciraj-Bjelac et al., 2016; Sánchez et al., 2016; Liu et al., 2017; Haga et al., 2017; Struelens et al., 2018; Merrachi et al., 2021; Borrego et al., 2020; UNSCEAR, 2022). The ORAMED study (Vanhavere et al., 2012) concluded that 4% of the monitored workers in IR/IC could receive an annual skin dose above 500 mSv and 25% an eye lens dose above 15 mSv.

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3. Protective Equipment

3.1 Generalities on protective equipment

3.1.1 Types of protective equipment for use with ionising radiation

There is a large variety of equipment to reduce the radiation exposure of staff performing IR/IC procedures. This equipment can be divided into personal protective equipment (PPE) and "remaining" protective equipment or engineered controls (IAEA, 2014). PPE is defined as all equipment "designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety" (EU, 2016). Engineered controls can be defined as all equipment not intended to be worn or held by the staff, whether built into the room or designed as part of the X-ray system.

PPE can take the form of (in alphabetical order) aprons, caps, face masks, glasses, gloves and thyroid collars; whereas engineered controls can be cabins, ceiling-suspended screens, drapes, table-suspended curtains and suspended systems such as the Zero-Gravity[®] (ICRP, 2018; NCRP, 2010).

3.1.2 Effectiveness of protective equipment

3.1.2.1 Introduction

There are no practical criteria supporting radiation protection officers or radiation protection experts in the selection of protection measures in the current European regulatory framework. The European BSS simply states the need for providing, testing and checking "appropriate personal protective equipment" (EU, 2014). The regulation on PPE 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" (EU, 2016). Furthermore, the international standards on, among others, the properties of the materials (IEC, 2014a) and the equipment themselves (IEC, 2014b), are not sufficient to ensure effectiveness in clinical practice.

Based on results of the European MEDIRAD project (McCutcheon et al., 2020; Zanca et al., 2021; Huet et al., 2023) an overview of the effectiveness of protective equipment is presented below. Furthermore, the effectiveness of the PPE is completed with selected literature including, among other sources, the European ORAMED project (Koukorava et al., 2011; 2014) for lead glasses and ceiling-suspended screen and the ICRP (ICRP, 2018) for equipment such as lead aprons and thyroid collars. A summary of the dose reduction levels attainable with common protective equipment is reported in Table 1. Advice on the control of the equipment efficiency is also presented. The reader should also keep in mind that, in addition to the effectiveness, other factors, such as ergonomics and costs should be considered when selecting protective equipment.

General guidance for selection, use and maintenance of PPE for staff exposed to diagnostic X-rays can be found in Hiles et al. (2016). In particular, practical considerations over aprons, thyroid collars, glasses and face mask, gloves, leg shields, surgical caps and drapes are presented in detail; while engineered controls are, by definition, outside the scope of that guidance.

Table 1: Dose reduction potential, features affecting the reduction potential and cost of common radioprotective equipment. Dose reduction values from MC simulations are presented as average and range over several configurations and, possibly, equipment models; correct equipment positioning is considered. The reported figures are only illustrative of the reduction and cost magnitude. Cost symbols are: $\in = \in 0$ to $\in 1000$, $\in \in = \in 1000$ to $\in 10000$, $\in \in \in = \in 10000$ to $\in 10000$.

Equipment type	Dose reduction level	Comments	Cost	References
Personal protective	equipment			·
Lead aprons	Effective dose ^b : ~80% (70% to 95%)		€€	Huet et al., 2023
Lead-free aprons ^a	Effective dose ^b : ~80% (70% to 95%)	Effectiveness depends on apron composition and irradiation conditions	€€	Huet et al., 2023
		Lead-equivalence usually insufficient for estimating effectiveness		
Thyroid collar	Thyroid: 85% (80% to 92%)	Effectiveness strongly affected by proper fitting	€	ICRP, 2018; Marshall et al., 1992
Glasses	Eye lens: ~50% (25% to 90%)	Strongly affected by design and exposure conditions	€€	Koukorava et al., 2011 and
Gloves	Hands: 0% to 60%	Risk of increase in patient and staff exposure if gloves in the primary X-ray field	€	ICRP, 2018; Wagner and Mulhern, 1996
		Risk of longer exposure duration due to loss of tactile sensitivity and dexterity		
Сар	Brain: ~35% (10% to 60%)	Strongly affected by exposure conditions	€	Huet et al., 2023
Face mask	Duraine (50/ (00/ to	Not all brain region protected	€€	
Face mask	Brain: ~65% (0% to 70%)	Strongly affected by design and exposure conditions	tt	Huet et al., 2023
	Eye lens: ~25% (0% to 80%)	Not all brain regions protected		
Room protective equ	uipment			
Ceiling-suspended screen	Hands: ~30% (10% to 70%)	Strongly affected by screen positioning	€€€	Koukorava et al., 2011 and 2014 ; Silva et al., 2017
	Effective dose ^c : ~40% (5% to 90%)	Lead drapes at the screen bottom aid proper positioning		
	Eye lens: ~55% (20% to 90%)			
	Brain ^d : ~85% (75% to 95%)			
Table-suspended curtain	Leg dose: ~70% (50%% to 95%)		€€	ICRP, 2018; Martin, 2009; Vanhavere et al., 2012

Drape	Hands: ~40% (10% to 70%)	Dose increase if drape in primary beam	€ (disposable) / €€ (reusable)	Huet et al., 2023
Zero-Gravity suspended system -	Effective dose ^f : ~80% Eye lens: >=95%	Bulkiness of the Zero Gravity might limit its use for complex and emergency procedures	€€€€	Huet et al., 2023 ; Dragusin et al., 2007
Cabin ^e	Brain: >=95%			un, 2007

^atwo lead-free compositions were modelled.

^beffective dose includes contribution from hands and arms placed along the staff body.

^ceffective dose simulated as WB dosemeter dose.

^dbrain as a whole not simulated, only white matter and hippocampus.

^ecabin not simulated but considered to be equivalent to ZG in terms of radiation protection.

^feffective dose includes contribution from hands and arms.

3.1.2.2 Effectiveness of personal protective equipment

• Aprons

The results of MC simulations showed a comparable reduction of the effective dose for - two specific - lead-free alloy aprons from 70% to 90%, which is comparable to conventional lead apron performance (Huet et al., 2023). However, the clinical conditions of use (i.e., energy spectrum of the scattered X-rays) and the composition of the apron should always be considered since they determine the attenuation properties of the apron (ICRP, 2018). In particular, equivalent lead thickness as stated on the label by the manufacturers is usually insufficient to determine the apron effectiveness for specific conditions of use.

• Thyroid collars

Monte Carlo (MC) simulations have shown that a thyroid collar could reduce the dose to the thyroid by more than 85% (Marshall et al., 1992; ICRP, 2018). However, the ideal conditions modelled in the MC simulations are rarely met in clinical practice and thyroid collars are often worn more loosely, reducing the effectiveness to approximately 80% (ICRP, 2018).

Lead glasses

There is extensive literature on the effectiveness of radiation protection glasses to protect the eyes and various levels of effectiveness levels were reported. A 50% reduction is often considered as a representative effectiveness (Petrucci, 2020). For instance, from extensive MC simulations of the influence of the exposure conditions (Koukorava et al., 2011; 2014), it was found that factors having a major influence on the glass effectiveness were the projections, the glass design, notably the eye coverage and the air gap between the eyes and the glasses, and the head orientation. Studying three glass models, the authors observed a wide range of reduction, with an average reduction to the left and right eye lens from 44% to 87% and from 24% to 46%, respectively. More recent studies (Kirkwood et al., 2020; Silva et al., 2022) reported that conventional glass models were likely less effective than expected, and highlighted further the importance of the glass design, especially the size of the gap between the eyes and the glass.

Gloves

Various levels of effectiveness were reported for protective gloves, with reduction factors ranging from 15% to 60% (ICRP, 2018). In addition, two main drawbacks should be considered. If the protective gloves enter into the primary X-ray field, they might interfere with the automatic exposure

system and lead to an increase in dose rate and thus higher patient and staff doses (Wagner et al., 1996; ICRP, 2018). The possible loss of tactile sensitivity and dexterity due to the gloves may lead to an increase in procedure duration and then to an increase of the exposure (NCRP, 2010).

• Caps

Clinical studies investigated the effectiveness of commercially lead and lead-free caps (Figure 2) by placing dosemeters under and over the caps to extrapolate the dose savings to the brain (Uthoff et al., 2013; Alazzoni et al., 2015) and reported more than 50% dose reduction. However, more recent MC simulation studies (Honorio da Silva et al., 2017; Huet et al., 2023) showed that this methodology could lead to large overestimation of the cap effectiveness. Huet et al. (2023) observed a link between effectiveness and staff position and head orientation. The closer the staff were to the centre of the incident X-ray field, the smaller was the dose reduction: indeed, when the staff are close to the beam, the backscattered X-rays mostly come obliquely upwards from the patient through lower head regions not covered by the cap; when the staff is further away from the beam, a higher proportion of X-rays is intercepted by the cap. For example, simulations of the staff close to the field (40 cm) with the head perpendicular to the patient resulted in only about 13% reduction on average whereas it was 37% when staff is further away from the beam (70 cm).

In addition, the protection offered by a cap is only limited to upper regions of the brain. Phantom measurements showed a considerably lower average reduction (7%) when taking into account all brain regions, emphasising again the great dependency on the irradiation conditions and the difficulty to predict the cap efficiency in clinical conditions (Huet et al., 2023).



Figure 2: Picture of two commercially available RP cap models: x-Ray Protective Cap (left, MAVIG, source: <u>https://mavig.com</u>) and RADPAD No Brainer X-ray Protective Surgical Cap (right, Worldwide Innovations & Technologies; source: <u>www.varaylaborix.com</u>).

• Masks

Radioprotective face masks or face shields (Figure 3) have been available for decades. Nevertheless, very little information on their effectiveness in clinical conditions is available in the literature. MC simulations of three different mask models indicated that the best mask model offered an average dose reduction of 73% and 61% to the eyes and the brain, respectively, while the reduction was only 2% and 12% on average for the worst models (Huet et al., 2023). Differences were explained by model design (length, lateral coverage of the face and gap). The exposure conditions (projections, position with respect to the X-ray field) also had an important effect on the mask effectiveness. For instance, the dose reduction to the brain and the left eye was very limited close to the beam (on average, 12% and 0.5%, respectively) but was more significant further away from the beam (on average, 43% and 4%, respectively).

In addition, the protection offered by the mask is limited to some regions of the brain. As for the cap, MC simulations and phantom measurements demonstrated that the dose reduction at the level of the eye lens dosemeter or at dosemeters positioned under and above the mask was not representative of the reduction to the eye lens and could lead to a severe underestimation of the dose to the lens of the eye (Huet et al., 2023).



Figure 3: Pictures of two commercially available RP face mask models: VIS400 face mask (left; Longkou Sanyi Medical Device Co., China, source: <u>www.varaylaborix.com</u>) and full-face style mask (right; Phillips Safety products, source: <u>www.phillips-safety.com</u>).

3.1.2.3 Effectiveness of room protective equipment

Ceiling-suspended screen

The ceiling-suspended shield is one of the most effective equipment to reduce the overall staff exposure at the level of the head and chest region, although a considerable variation in the ceiling shield effectiveness is observed in clinical practice. Vanhavere et al. (2011) observed a median reduction ranging from 38% to 86% for the left eye and from 55% to 64% for the right eye from measurements during about 1300 procedures performed in the framework of the European ORAMED project. The reason for this variation was suspected to be different positioning of the shield. This was investigated by Koukorava et al. (2011; 2014) by means of MC simulations. The irradiation conditions had a considerable effect on the dose reduction, with the ceiling screen being more effective when positioned close to patient and the primary X-ray field. A comparable effectiveness magnitude was observed with, on average, a reduction by 55% for the left eye and 58% for the right eye. A maximal dose reduction of up to 90% to the left eye lens and up to 93% for both eyes was reported. At the level of the chest (Whole body dosemeter), the authors reported a reduction up to 90% and 40% on average. According to a more recent simulation study (Silva et al., 2017) the dose to the brain tissues could also be reduced by 74% up to 94%.

Table curtains

Lead curtains attached to the side of the table are very effective in reducing the exposure to the legs of staff. A reduction of more than 90% can be achieved if they are positioned correctly throughout a complete procedure (Martin, 2009; ICRP, 2018). In clinical practice, however, a lower reduction range is usually observed (50% to 85%) (Vanhavere et al., 2012; ICRP, 2018).

Drapes

Numerous clinical studies evaluated the effectiveness of radioprotective drapes placed over the patients (Figure 4), whether disposable or re-useable. Most studies reported a significant but variable dose reduction to the whole-body, hand and eye lens dosemeters. For instance, Anadol et al. (2019)

observed a 20% decrease in the whole body dosemeter, while McCutcheon et al. (2020) reported about 50% decrease in the whole body dosemeter as to the left hand and eye lens dosemeters. Nevertheless, MC simulation results only supported a decreased dose to the hands, and the effect of the drape on the whole-body and the eye lens dosemeter was negligible (Huet et al., 2023). MC simulations also showed the importance of proper drape positioning. The drape effectiveness increases when it is placed closer to the primary beam and completely covers the patient side. Finally, it is worth remembering that, if the drape is partially positioned in the primary beam, it may interfere with the automatic exposure control system and increase the delivered dose.



Figure 4: Pictures of two commercially available lead-free drape models: RADPAD subclavian shield (left, Worldwide Innovations & Technologies; source: <u>www.radpad.com</u>) and radial X-ray protection drape (right; MAVIG; source: McCutcheon et al., 2020).

Zero Gravity

In the only MC simulation study dedicated to the Zero Gravity (ZG) (Figure 5), Huet et al. (2023) reported an average dose reduction of at least 90% for all the organs in the head and neck region. For the organs normally protected by the apron, the protection offered was at least equivalent. A significantly higher dose reduction could even be observed, likely due to the higher lead thickness of the ZG compared to a conventional apron. However, considering the low absolute dose value attained when a lead apron is worn, this is of little significance for radiation protection purposes.



Figure 5: Pictures of the Zero Gravity suspended radiation protection system (Worldwide Innovations & Technologies): Floor Unit suspended system (left; source: <u>www.biotronik.com</u>) and clinical use (right; source: (Savage et al., 2013), CC BY 4.0).

Clinical measurements confirmed the dose reduction magnitude, even compared to conventional shielding, including ceiling suspended screen, with at least 75% reduction to the head region (to eye lens dosemeters) (Savage et al., 2013, Zanca et al., 2021) and 90% to the whole body dosemeter (Zanca et al., 2021). Similar trends were observed in phantom measurements with a reduction to the brain and eye lens from 65% up to 96% (Zanca et al., 2021). Although the ZG eliminates the need for the physician to wear a lead apron, the steep learning curve associated with the use of the ZG could limit its use for very complex or urgent cases at first (Zanca et al., 2021). In addition, owing to the ZG design and the presence of a front lead glass, the operator cannot easily see the foot pedals of the X-ray system.

• Cabin

The effectiveness of radioprotective cabins was not specifically investigated in the frame of the MEDIRAD project. However, it seems reasonable to assume a similar or higher level of protection than the ZG, considering the design and the composition of the cabins. This is also supported by the results reported in the literature such as Dragusin et al. (2007), who reported non-measurable dose levels in the cabin. As with the ZG, the use of a cabin also eliminates the need for wearing a lead apron but no specific discomfort or limitation resulting from the cabin use were reported in the literature (Dragusin et al., 2007, Ploux et al., 2010).

3.2 Practical aspects on protective equipment

3.2.1 Inspecting protective aprons and thyroid collars and criteria for rejection

A programme for routine inspection of protective aprons (lead and non-lead) and thyroid collars should be established by the hospital in order to ensure the items remain fit for purpose and that doses to those wearing them are "As Low as Reasonably Achievable". New items should undergo an acceptance test by the hospital before first use, and thereafter annual assessment is recommended (Hiles et al., 2016). This should be coordinated by the radiation protection officer and the radiation protection expert to formally assess the integrity of each device. Each item should be given an individual identification number and the findings should be recorded. A small amount of wear and tear, such as sagging of heavy lead towards the bottom of the apron, and cosmetic tears to the outer fabric is commonly observed. Non-lead or composite aprons tend to be lighter with less sagging, however anecdotally, the resilience of aprons made of new lead-free materials may not be as good as traditional lead rubber; it is essential that all types of PPE are monitored regularly (Hiles et al., 2016). Following inspection, it is possible that items with small amounts of wear and tear may continue to be used. However, routine screening (combining a visual inspection and fluoroscopic/radiographic assessment) is vital in order to (i) identify significant defects requiring the item to be withdrawn from use and (ii) provide assurance that items with only minor defects are satisfactory for continued use and do not require any replacement.

An efficient way to test is by using a fluoroscopy system to screen for any defects. If fluoroscopy is not available in the hospital, it may be possible to arrange with a nearby facility. If radiographic imaging is used, care must be taken to ensure the entire surface area is imaged, and that manual handling is minimized (Hiles et al., 2016).

Rejection criteria for lead aprons have been recently recommended by the British Institute of Radiology (BIR) (Hiles et al., 2016) based on work done by Lambert et al. (2001) and Stam et al. (2008) and reproduced in Table 2. The important criteria are the size and the location of the defects, for example, more strict criteria should apply if the defect is over a critical organ. Defects not in close

proximity of critical organs, which are along the seam, or in overlapped areas, or on the back of the lead protective apron, may continue in use as long as the size and location of the defect are clearly marked on the apron itself and the results logged in the records of inspection. Examples of damage to lead aprons and thyroid collars are shown in Figure 6.

Location of defect		Maximum tolerable defect area	Maximum tolerable defect tear length
	Over a critical organ	15 mm² (4.3 mm diameter circle)	20 mm
Lead apron	Clearly not over a critical organ	670 mm² (29 mm diameter circle)	50 mm
Thyroid shield	Anywhere	11 mm² (3.8 mm diameter circle)	20 mm

Table 2: Outline rejection criteria for damage to protective equipment (reproduced with permission from BIR, Hiles et al., 2016)

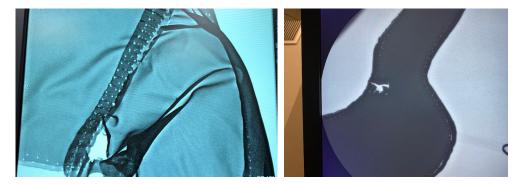


Figure 6: Damage to protective equipment (photos courtesy of St. James's Hospital, Dublin). The damage to the apron on the left is significant and observable on visual inspection alone. The tear in the thyroid collar on the right is less obvious and detected by screening.

3.2.2. Storage and Maintenance of Lead Aprons and other PPE

The careful storage (Figure 7) and proper maintenance of protective aprons and thyroid collars is an important part of the radiation safety programme within a hospital. Investing in high-quality PPE is costly, and well-cared for lead aprons should last for many years. In a busy hospital environment, too often the correct storage of lead aprons is not given due care and attention. Aprons should never be casually discarded or stored folded-over as this can lead to damage such as cracks in the lead (Hiles et al., 2016). Lead aprons should be hung carefully after use on dedicated reinforced hangers in a spacious area just outside the interventional room where they can be accessed promptly by staff when needed.

For full aprons, one hanger is sufficient. For vest and skirt style, two hangers should be available with a coat hanger style on the top for a vest, and a lower hanger suitable for a skirt. Ensuring that there are enough hangers helps to facilitate good storage and easy access for users in a short time frame. Thyroid collars can usually be stored at the end of the same hanger, using the collar Velcro or clip to attach. A dedicated area or cabinet for storage of smaller items such as lead glasses, caps and gloves should also be provided (Hiles et al., 2016).

The manufacturer should provide detailed instructions on the care and maintenance of PPE including which cleaning products should be used. Lead aprons are heavy and cumbersome, but the internal composition is fragile, hence folding and sagging can be a problem. They should be generally stored away from extreme sources of temperature such as radiators, air-conditioning units and sunlight.



Figure 7: Correct storage of lead aprons and thyroid collars on reinforced hangers (photo courtesy of St. James's Hospital, Dublin)

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4. Types of Dosemeters

4.1 Whole body, eye lens and extremity dosemeters

4.1.1 Dosemeter technology

The importance of individual dose monitoring for staff working in IR/IC has been introduced in chapter 2. To achieve this, a variety of personal monitoring devices (dosemeters or sometimes known as 'badges') are available from different manufacturers and can be chosen to best suit the needs of the organisation. Technology in this area has developed over the years, with older film-style badges now tending to be replaced with newer detector technology. Advanced 'hybrid' solutions providing immediate read-out options are becoming more available. The number of "hybrid" personal dosimetry systems participating in EURADOS regular intercomparisons, although relatively small compared to conventional dosemeters (about 5% of the systems), is steadily increasing year after year (Stadtmann et al., 2020; 2018).

The number and position of dosemeters that are recommended will vary from country to country and will depend on legislation and the radiation safety programme of the organisation, however in an inhomogeneous radiation field, such as that found in IR/IC, it is advisable to use one dosemeter under the protective clothing and one on an unshielded part of the body (IAEA, 2018) (see chapter 5). For monitoring compliance with the reduced eye dose limit of 20 mSv per year, dedicated eye lens dosemeters are now more widely available and come in a range of designs that can be positioned on the arm of glasses or worn on a headband, to increase comfort and wearing compliance (see chapter 5).

In general, the choice of personal dosemeter by an employer should be made in consultation with a radiation protection expert and medical physics staff. In routine IR/IC practice, where only photon radiation is important, most dosemeters are adequate. For a wide range of photon energies, TLDs, OSL, radiophotoluminescent (RPL) glass or film dosemeters can be used, provided that they exhibit acceptable energy dependence and angular dependence (EC, 2009; IAEA, 2018). In addition, the IAEA note that many active dosemeters (or hybrid semi-active dosemeters, such as the 'direct ion storage' dosemeter) are available that can reliably measure $H_p(10)$ (IAEA, 2018). For individual monitoring purposes the characteristics of a suitable personal dosemeter should be, among others: the ability to measure the appropriate operational quantity, a suitable response with acceptable accuracy to a variety of angles and energies encountered in the scattered field of workplaces and, in particular for the extremities and the eyes, being comfortable for the operator (IEC, 2020). Another factor that should be kept in mind is the use of the dosemeter in sterile environment, so the possibility of its sterilization would be an advantage for its use in IR/IC procedures.

The relevant personal dose equivalent operational quantities that are measurable with these devices are:

- > whole body ($H_p(10) + H_p(0.07)$);
- > ring, finger stalls , wrist, leg ($H_{p}(0.07)$);
- > eye lens ($H_p(3)$).

4.1.2 Current trends in usage of personal dosemeters in interventional radiology and cardiology

Accurate and traceable measurements of radiation exposure are a vital component of a radiation protection and safety programme for staff. The use of IR/IC is increasing, which raises new issues in terms of occupational protection in medicine. For interventional procedures, passive dosemeters remain the most widely used option (ICRP, 2018) for all quantities i.e., whole body, eye lens and extremities. For whole body monitoring, active personal dosemeters (APDs) are however increasingly used in IR/IC settings and it has been shown that there is now regular use of APDs in European hospitals (Ciraj-Bjelac et al., 2018). Staff are typically more interested and aware of their radiation dose records if it is instantly available. Rapid feedback of doses to staff can encourage changes in behaviour that are beneficial in terms of radiation protection. Due to the number of dosemeters, the complexity of positioning them, the need of authorities' approval as personal dosimetry service and other challenges described in the next section, it is unlikely that passive dosimetry will be fully replaced with APDs. Individual APD units are quite expensive compared to passive dosemeters, and the costs would generally be prohibitive for all the staff monitoring requirements in most diagnostic imaging departments. In addition, for extremity monitoring, APDs have not been widely developed for routine use on the fingers or near the eyes (ICRP, 2018).

Another option that is becoming more widely used is the direct ion storage (DIS) technology which is considered a hybrid solution, harnessing the benefits of smaller devices and lower costs of passive dosimetry, with the advantages of an almost instant readout. The DIS technology is now approved in some countries as a legal dosemeter. There is typically no display on a DIS device but rather the dose can be read out at any time by connecting wirelessly to a local readout station. The technology is based on the combination of an ion chamber and a non-volatile electronic charge storage element. The readout takes only a few seconds and can be performed by the worker at their convenience. The dosemeter does not need to be returned to the dosimetry service, except for resetting or calibration (e.g., every two years). A DIS dosemeter is designed to measure the personal dose equivalent $H_p(10)$ and $H_p(0.07)$ to the required accuracy.

4.2 Active Personal Dosemeters (APDs) in interventional radiology and cardiology

APDs were initially developed for measurement conditions at nuclear power plants. However, the use of APDs is becoming more widespread in hospitals and generally found to be beneficial due to the instant reading.

International guidance on the use of APDs is available in the IAEA General Safety Guide GSG-7 (IAEA, 2018). APDs are mainly used as a tool when new techniques in IR/IC are introduced and for optimising protection and training staff (ICRP, 2018; Ginjaume, 2011). The relatively high unit cost, combined with a lack of Approved Dosimetry Services (ADS) offering APDs (due to implementation difficulties linked to problems of APD technical approval, data transmission, data security, responsibilities...) means that APDs are rarely used as the sole dosemeter. Passive dosemeters are small, lightweight, and do not require power and can be worn in small packages that do not interfere with the staff's actions and comfort. Nonetheless, the absence of an instant reading, and alarm functions, is a disadvantage, especially for the training of workers involved in interventions to help prevent any overexposure (ICRP, 2018). Therefore, the use of real-time dosimetry with APDs continues to increase.

Due to the specificity of the X-ray fields used in IR/IC (low energies – 20 keV to 150 keV – and pulsed fields), some APDs can be inadequate as it has been shown in the ORAMED (Optimization of

Radiation protection of MEDical staff) project which concluded in 2011 (Clairand et al., 2011a, Clairand et al., 2011b; Struelens et al., 2011; Vanhavere et al., 2012). However, in recent years, in parallel to the publication of new standards on tests in pulsed radiation fields (IEC, 2019; ISO, 2015), new designs of APDs have become available and they are more and more adapted to these types of fields.

In addition, advances in battery power management and wireless transmission have overcome some of the disadvantages of using electronic dosemeters. Some manufacturers of IR/IC systems have integrated wireless data transmission allowing the doses to the staff to be followed in real-time during interventional practice (ICRP, 2018).

Considering the expected increase of APDs used for medical staff monitoring, EURADOS WG12 completed several comprehensive studies on these device including a survey on their acceptance and usage in hospitals (Ciraj-Bjelac et al., 2018), tests on the influence of lead aprons on their calibration (Ginjaume et al., 2019); tests on their response in reference continuous and pulsed X-ray fields (Hupe at al., 2019); and tests to assess the performance of APDs during interventional practice (Vanhavere et al., 2020). It was concluded that comparing active and passive dosemeters is not straightforward in hospital settings. Also, the relative position on the body of the operator is a significant factor. Further details on the type of APDs that were tested can be found in the above referenced series of papers published by EURADOS WG12. The aim of this coordinated set of actions was to formulate updated recommendations (summarised below) on the selection and use of APDs in hospitals, where guidance on their use (particularly in pulsed fields) is needed (O'Connor et al., 2021).

- Standards. The APD should meet all the requirements of the relevant IEC standards including those for pulsed fields
- Legal approval. APDs can be approved as a dosemeter for regulatory compliance once the criteria required for approval have been set by the national framework, and fulfilled by the APD and dosimetry service.
- > Use with Passive Dosemeters. If passive dosemeters and APDs are used in parallel, it is crucial that the interpretation of results is carried out by a suitably qualified radiation protection expert
- Instruction for Wearing and Use. Clear guidance and instruction should be provided. APDs should be worn above the lead apron at chest height.
- > **Calibration**. Guidance from regulatory authorities on the periodic calibration of APDs, including the calibration radiation quality.
- > **Range of Operation and Product Evaluation**. APDs should be acceptable in terms of their energy and angular response, sensitivity, linearity and accuracy.
- > **Pulsed Fields**. If the dosemeter is to be used in pulsed fields the users must be aware that it may indicate incorrect values such as: large underestimations if placed in the direct beam, and a greater influence (again usually an underestimation) when the instantaneous dose rate is higher.
- > Alarms. APDs should include an alarm to indicate that the dosemeter is out of its range. It should not be an audible alarm and only the visual alarm should be used.
- > **Software Options.** Software to manage a set of APDs is a useful tool and should be considered when acquiring dosemeters.
- > **Data Integrity**. The APD must be of a suitable design for use as the dosemeter of record, including the protection from data manipulation, software security, and protection against electromagnetic disturbances.

APDs designed specifically for fingers, wrists, or eye lenses, comprise a small radiation detector sensor. This sensor is attached to the extremities or positioned near the eyes, and it is connected via thin cables to a unit that contains the electronic components and display. There are limited options in this field. At the time of writing, there are very few manufacturers, perhaps only one, that continue to supply measurement systems suitable for extremity and lens dosimetry for interventional procedures. Between the years of 1990 and 2010, there was an electronic system that was primarily used in nuclear medicine and is no longer in production (Salesses et al., 2016). Major advancements in APDs for extremity use are not anticipated in the near future.

4.3 Calibration and testing of dosemeters

4.3.1. Standards for calibration and testing

The IEC 61526 (IEC, 2010) standard specifies general characteristics, requirements and test procedures, radiation characteristics as well as electrical, mechanical, safety and environmental characteristics for APD type testing. However, this standard does not include special requirements for dosemeters to be used in pulsed fields of ionizing radiation. The IEC Technical specifications IEC/TS 62743 (IEC, 2012) and 63050 (IEC, 2019) provide guidelines in this regard.

The IEC 62387 (IEC, 2020) standard specifies general characteristics for the dosemeter design and the software, performance requirements and test procedures related to radiation as well as to influence quantities such as environmental conditions, electromagnetic and mechanical disturbances for dosemeters with integrating passive detectors.

The variation of the relative response due to a change of the radiation energy and angle of incidence should be done with reference radiation qualities specified in ISO 4037-1 (ISO, 2019a) as testing with monoenergetic radiation is not feasible. Performing the type test with the narrow-series radiation quality will ensure a good estimate of the performance in realistic fields with a broader distribution of photon energies and a satisfactory response in realistic radiation fields. However, in addition to these quantities, some tests using IEC 61267 (IEC, 2005) diagnostic qualities which are closer to the radiation beams found at the workplace are a good complement.

The calibration of personal dosemeters shall be performed following ISO 4037-3 (ISO, 2019b) standard. This requires irradiating the dosemeters on a phantom made of PMMA or a combination of PMMA and water, which simulates the part of the body where the dosemeter is worn i.e., a slab phantom for the whole body dosemeter, a pillar phantom for the wrist dosemeter, a rod phantom for the ring dosemeter and a cylinder for the eye-lens dosemeter. The dimensions and materials of each phantom are given in ISO 4037-3 (ISO, 2019b). The standard also contains recommended conversion coefficients $h_{pA}(d)$ to convert air kerma free-in-air to the phantom related operational quantities $H_p(0.07)$, $H_p(3)$, and $H_p(10)$ defined in body and calculated in ICRU 4 elements tissue phantoms (ICRU, 1992).

4.3.2. Impact of the lead apron on the dosemeter's response

The calibration and testing procedures described in the standards noted above requires the irradiation of the dosemeters on a calibration phantom. However, in IR/IC, the personal dosemeter is sometimes worn above the lead apron (see chapter 5) that influences the contribution of the radiation backscattered by the body measured by the dosemeter.

EURADOS WG12 designed a study to analyse the changes in the response of 7 passive and 8 active personal dosemeters when they are placed above a lead or lead-equivalent garment for S-Cs and X-

ray diagnostics qualities (see irradiation setup in Figure 8). MC simulations were used to support the experimental results (Ginjaume et al., 2019). The passive dosemeters included the most common types of passive detectors such as: films, OSLs, RPLs and TLDs. The APDs were selected among those more frequently used in Europe and with a known satisfactory energy response for photon radiation in the energy range of 30 keV to 100 keV.

It was shown that for passive dosemeters, the influence on the passive dosemeter's response of the lead or lead equivalent garment was within the range 15%-38% (average 25%) for X-rays qualities. This effect was smaller, of the order of 10%, when lead-free garments were used and much smaller, within 1% to 10% for most of the APDs used in the study.

This issue was partially analysed for LiF personal dosemeters by Damet et al. (2011), Saldarriaga Vargas et al. (2018) and Quintero-Quintero et al. (2018) with similar conclusions.



Figure 8: Irradiation set-up using the passive and active detectors on ISO slab phantom (left), with lead apron (centre) and with lead-free apron (right).

4.4 Future directions in occupational dosimetry in interventional radiology and cardiology

As mentioned before, recently new individual dosemeters associated with connected technologies (i.e., those allowing "smart" connections with other internet-accessible devices) have become available opening up new opportunities in the field of online (real time) personal dosimetry. These systems will certainly become more widespread in the coming years (Bottollier-Depois et al., 2020; Harrison et al., 2021; Sánchez et al., 2021).

In addition, research of MC calculations (GPU based) applicable to individual monitoring is rapidly increasing. The development of real-time individual dosimetry applications based on computer simulations and tracking devices, in addition to conventional "physical" individual dosimetry, or even by replacing conventional methods in the long-term, is a topic of interest in the field of radiation protection.

As previously discussed, personal dosimetry is typically performed by issuing staff with physical dosemeters. An EC-funded project (PODIUM), completed in 2019, pursued an innovative approach: the development of an online dosimetry application based on computer simulations without the use of physical dosemeters. This PODIUM approach was performed using a combination of (i) monitoring of the position of workers in real time and (ii) calculating the spatial radiation field, including its energy and angular distribution. The position of workers in relation with the radiation source was monitored using 3D motion cameras and the associated software. The radiation field map of the workplace was based on analytical calculations or more advanced MC calculations. The validation experiments were performed using clinical X-ray equipment, where X-ray field size and tilting of the

X-ray tube was modified accordingly. The measurements gave useful information to improve the simulations, source specifications and geometry mapping. Secondly, a full-scale feasibility test in clinical settings during real patient treatment in hospitals was performed. (García Balcaza et al., 2021; Almen et al., 2021; O'Connor et al., 2022; Abdelrahman et al., 2020).

PODIUM is an example of how new techniques such as computational dosimetry or artificial intelligence can change established paradigms in occupational dosimetry for IR/IC, overcoming some of the disadvantages of conventional personal dosimetry based on the use of several physical dosemeters.

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5. Personal Dose Monitoring and Dose Assessment

5.1 Background and challenges

5.1.1. Introduction

Estimating the effective dose or equivalent dose to medical staff in interventional procedures is not an easy task because the scattering field produced by the patient is not homogeneous (Vano et al., 2011). Since the operator is very close to the patient, the exposure of the different parts of the operator's body is subject to large gradients. In addition, there can be relatively high doses to the head, neck and extremities which are not shielded by radiation protection garments such as lead aprons and thyroid shields (Padovani et al., 2001).

In the literature, it is recommended (NCRP, 1995; ICRP, 2000; ICRP, 2013; Jarvinen et al., 2008; von Boetticher et al., 2010) to use two personal dosemeters for the control of the occupational exposure in interventional workplaces: one worn under the radiation protection apron on the level of the trunk and the other one worn over the apron at the level of the collar or the left shoulder or chest, the socalled "double dosimetry". Besides the fact that the double dosimetry should provide more accurate estimates of the effective dose, in some workplaces only a single dosemeter is employed, for practical reasons. In those situations, if the dosemeter is worn *under* the lead apron, it can provide an estimate of effective dose. Whilst, when it is worn over the lead apron, an estimate of the effective dose can be obtained through a correction factor (typically in the range of 10 to 20). The same unshielded dosemeter is able to provide an estimation of the doses received by the parts of the body that are not protected by the apron, such as the lens of the eye and the head.

Nevertheless, because of the intrinsic inhomogeneity of the radiation field, the position of the unshielded dosemeter can affect the evaluated dose with a certain variability, as was underlined by Schultz and Zoetelief (2008) who suggested that the dosemeter may best be worn over the apron at a central position, high on the chest, in cardiac interventional procedures.

In summary, occupational dosimetry is still a challenge in interventional procedures and a series of recommendations and training activities have been suggested in order to increase the awareness of the radiological risk connected to these practices (ICRP, 2018; IAEA, 2018). The use of multiple dosemeters for individual monitoring is one of the methodologies implemented with the aim of ensuring more accurate dosimetry in a radiation field characterized by a large dose rate variability which could influence indeed the accuracy of the measurement associated to the dosemeter's position.

5.1.2. Status of individual monitoring in Europe when radiation protection garments are used in medicine.

In 2017-2018, EURADOS WG12 prepared an EU-wide survey addressed to European regulatory authorities to investigate how European countries are dealing with determination of effective dose and eye lens dose when protective garments, such as thyroid collars or lead aprons are worn, in particular for workers in medical imaging departments (Carinou et al., 2019). Authorities from 26 countries responded to the distributed questionnaire (responses were received from 25 European countries and Israel).

The number of dosemeters used for individual monitoring of the whole-body dose is either one or two. The responses are summarised in Table 3.

Prescribed wearing position	Number of countries
One dosemeter below protection	7
One dosemeter above protection	3
One dosemeter below protection and a second dosemeter above protection under specific conditions	13
Two dosemeters	3

Table 3: Number of countries in the EU per number of dosemeters used for individual monitoring (based on the 26 responses received in the EURADOS WG12 survey)

In some countries, the number of dosemeters is based on a decision protocol depending on the expected dose. The wearing position on the body, as prescribed by the regulatory authorities, varies a lot as shown in Figure 9.

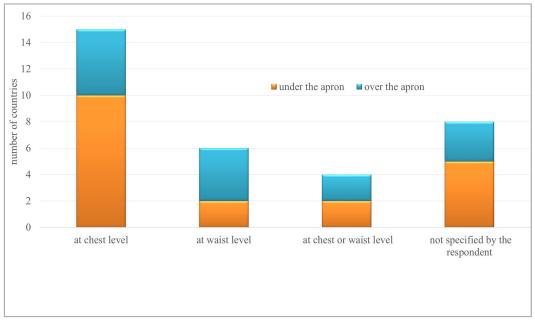


Figure 9: Number of countries in the EU per wearing position of the dosemeters

The survey also showed that in more than 50% of the countries there are legal requirements about the number and the position of dosemeters used for estimation of the effective dose when radiation protection garments are used. However, in only five out of 26 countries (19%) are there nationally approved algorithms for the estimation of the effective dose.

In only 14 (54%) of the 26 countries, there was a legal requirement in place to estimate the dose to the lens of the eye at the time the questionnaire was distributed. In almost half of the countries a dosemeter above the protection is used for estimation of the dose to the lens of the eye. In seven (27%) countries, dedicated eye lens dosimetry is being used. Only two countries reported an algorithm for the estimation of the dose to the lens of the eye when radiation safety glasses are used. The results of the survey should not be interpreted as a clear realistic view on the current regulatory Status of occupational exposure framework due to the time period in which the survey was conducted and because not all countries were included in the study. However, the results highlight that there is a need for harmonisation of the methods for assessment of effective dose and eye lens equivalent dose.

5.1.3 The influence of position of dosemeters on the operator's trunk

A recent study (Nowak et al., 2020) showed the different fluence, energy spectrum distribution and mean energy of the scattered radiation at different heights on the operator. Rigatelli et al. (2016) report the same situation: there is a clear difference in over-apron doses registered at two heights of personnel working in a cardiovascular unit, for dosemeters placed on the trunk, if an individual is lower or taller than 165 cm. These results were also confirmed through phantom measurements. That situation is indeed consistent with the results of Principi et al. (2016) where it was shown through simulations that operators taller than the standard man (ICRP, 2002) receive lower doses to the lens of the eye, because of geometrical factors. Vanhavere et al. (2020) also depicted this effect in a recent paper, where coupled electronic and passive dosemeters were employed in hospital measurements.

From all these studies, it appears that the particular scattering field generated in interventional procedures could have some impact on the different values that can be registered by a dosemeter placed in different positions over the operators' apron.

In order to investigate that variability a study was performed by EURADOS WG12 considering a dosemeter worn at the chest level, over the apron, in a typical interventional cardiology procedure. The parameters affecting the recorded dose and taken into account were:

- a) the quality/energy of the X-rays;
- b) the beam projection employed (and position of the image device);
- c) the position of the operator in the scattered field (and employment of the ceiling shielding);
- d) the dosemeter vertical position on the chest, from the xiphoid process to the clavicles;
- e) the dosemeter horizontal position on the chest, from the right anterior axillary line to the left anterior axillary line.

Considering that an interventional procedure is a sequence of various steps including different beam projections and clinical phases, it is not easy to determine and distinguish the effects of all the above parameters through direct measurements. For that reason, MC simulations have been employed, the results of which have been presented in the IM2022 conference (Ferrari et al., 2023). What has been shown is that, within the limit of the rigidity of the investigated scenario it is plausible to associate to a dose evaluated through a dosemeter put on operator's chest, over the apron, a variability of the order of 30% - 40%. That variability should be taken into account in the uncertainty associated with the effective dose, together with the other sources of uncertainty (Duran et al., 2013).

5.2. Dose assessment

5.2.1. Methods for the estimation of the effective dose

As already mentioned in paragraph 5.1, individual monitoring in IR/IC workplaces is especially challenging due to the non-uniform exposure. The estimation of the effective dose of exposed workers is carried out using either one or two dosemeters.

When a single dosemeter is used, it can be worn either over or under the apron. In the work of Schultz and Zoetelief (2008) it is proposed to wear the dosemeter over the apron at a central position high on the chest for least dependence on the beam direction. In this case the effective dose is estimated by dividing the dosemeter reading by a factor of 20 (when apron and thyroid collar are of 0.25 mm Pb). In the work presented by Negri et al. (2019) it was proposed to divide the reading of the dosemeter by a factor close to 10, as also proposed by Martin and Magee (2013). The user should pay particular attention to the exact dosemeter placement required by the chosen algorithm (e.g., not confusing a dosemeter worn on the "collar position" with a dosemeter worn "over the trunk").

Several authors recommend the use of an over apron dosemeter to further estimate the dose to the lens of the eye (Gracia et al., 2020; Martin et al., 2019), while others recommend the double dosimetry approach. An overview of algorithms for double dosimetry as well as for dosemeters used over the apron is included in Jarvinen et al. (2008). Negri et al. (2019) presented another recent interesting work where eight irradiation setups were used to experimentally verify the accuracy of the algorithms. The study highlighted the complexity of giving the correct evaluation of the effective dose during interventional procedures. However, among the analysed algorithms and for their experimental tests they concluded that the best results were obtained with the three following algorithms:

- > $E_{McEwan} = 0.71 H_p(10)_{under} + 0.05 H_p(10)_{over}$ (McEwan, 2000),
- > $E_{\text{Swiss}} = H_{\text{p}}(10)_{\text{under}} + 0.1 H_{\text{p}}(10)_{\text{over}}$ (Swiss Ordinance, 1999),
- > $E_{\text{Boetticher}} = 0.79 H_{p}(10)_{\text{under}} + 0.1 H_{p}(10)_{\text{over}}$ (von Boetticher, 2008).

They also showed that, although most of the published algorithms refer to the definition of the effective dose reported in ICRP 60 (ICRP, 1990) instead of ICRP 103 (ICRP, 2007), this has only a minor effect on the effective dose assessment.

In this respect, the double dosimetry issue was discussed by EURADOS WG12 (Carinou et al., 2015) with an emphasis on the estimation of the level of exposure of the lens of the eye from the dosemeters used for the estimation of the effective dose. The study revealed that there is a wide range of correlation coefficients for the estimation of the dose to the lens of the eye from the values of the thyroid and chest dosemeter, depending on the setup of the radiological procedure and the exact position of the dosemeter. This issue is further discussed in the next paragraphs.

For both double dosimetry and single dosimetry approaches, the use of radiation protection garments creates a complex geometry and energy and angular distribution which affects both dosemeters (over and under the apron) and leads to a complex dependence of the estimation of the effective dose (Vargas et al., 2018).

5.2.2. Methods of assessing levels of exposure for the eye lens

5.2.2.1 Eye lens monitoring

Lens radiosensitivity and the existence of a lens equivalent dose limit have been established in radiation protection for many years (ICRP, 1990). However, because the dose limits for occupational exposure of workers was an effective dose of 20 mSv per year averaged over 5 consecutive years and an equivalent dose to the eyes of 150 mSv per year, lens doses were not specifically monitored. The dose limit for the lens of the eye requirement was ensured by controlling that the effective dose did not exceed 20 mSv in a year.

Since the publication of the new ICRP recommendations and the new regulations reducing the equivalent dose limit to the lens of the eye for workers to 20 mSv per year, averaged over 5 years (ICRP, 2012 and EU, 2014), eye lens dose monitoring has become an important issue, mainly when radiation fields are not homogeneous. This is the case of staff working in IR/IC, who usually partially protect their body, but whose eyes may be exposed to the scattered field from the patient. As presented in paragraph 2.2, in this scattered field, it is possible to receive an annual equivalent dose

of the lens of the eye higher than 20 mSv, depending on the workload and the correct use of the protection means.

Several organizations have provided guidance on how and when eye lens monitoring should be undertaken (ISO, 2015; IAEA, 2013; Cantone et al., 2017; Martin et al., 2019; Damen et al., 2018; Kollaard et al., 2019).

There is general consensus that the best procedure for assessing dose to the lens of the eye is to use a specific eye-lens dosemeter located close to the most exposed eye and measuring $H_p(3)$. $H_p(3)$ dosemeters are now generally available on the market. There are international standards stating the performance of dosemeters with integrating passive detectors to measure $H_p(3)$ (IEC, 2020) and international standards establishing the corresponding calibration procedures (ISO, 2019). Moreover, several intercomparisons organized by EURADOS (Clairand et al., 2016 and 2018) highlight that, globally, the performance of the participants to assess $H_p(3)$ for photon qualities are satisfactory (over 90% of the results fulfilled the ISO 14146 requirements (ISO, 2018).

5.2.2.2 Alternative procedures to the use of an eye-lens dosemeter

Although, currently, $H_p(3)$ can be correctly measured, its practical use remains a challenge. Due to their lack of comfort, the inconvenience of wearing several dosemeters and the possibility of their loss, the above-mentioned organizations often propose alternative procedures for an easier and more practical way to assess $H_p(3)$ in some situations (Carinou et al., 2015; Broughton et al., 2013; Cantone et al., 2020). Clerinx et al. (2008) analysed Pearson correlations between the MC computed effective doses and the dosemeter readings for several X-ray configurations and suggested to obtain a conservative estimate of the dose to the lens of the eye by multiplying the $H_p(0.07)$ unprotected dosemeter at collar level by a factor of 0.75. This multiplication factor has been confirmed by some experimental measurements with dosemeters at the eye level and over the apron (Farah et al., 2013) and is recommended by several authors (Martin 2011; Carinou et al., 2015).

Other proposals for eye lens assessment are based on the use of correlation coefficients of patient dose parameters, such as the air kerma area product, and $H_p(3)$. But, in general, in these cases, the correlations are lower than those obtained with an unprotected dosemeter (Ciraj-Bjelac et al., 2016).

5.2.2.3 Eye-lens dosimetry and protective equipment

An additional difficulty when monitoring doses to the lens of the eye is to carry out a correct assessment when using eye protectors, like lead glasses. ISO 15382 (2015) suggests that the dosemeter should preferably be placed behind the protection but, at the same time, recognizes that this is not very practical. Another option is to cover the front of the dosemeter with a filter that mimics the attenuation of the lead glasses, but this is neither a practical solution unless lead glasses have been specifically designed for this purpose (HoedImoser et al., 2019).

The easiest way to correct the measurement of the eye lens dosemeter when protective eyewear is worn is to apply a correction factor that accounts for the attenuation provided by the eyewear. The correction factor depends on the shape and design of the glasses in particular on the existence of lateral shielding and on its fit on the worker's face. This factor can be determined by measurements, but if not, ISO 15382 (2015) as well as the Institute of Physics and Engineering in Medicine (IPEM) (Martin et al., 2019) suggests a conservative value of 0.5.

The previous paragraphs highlight the difficulties in providing an adequate measurement of the doses to the lens of the eye. The various simplifying options introduce uncertainties in the estimation

of the dose to the lens of the eye. Thus, it is recommended to use a stepwise approach in defining the eye lens monitoring programme based on each individual's work risk assessment.

5.2.3. Assessment of the effective dose and the dose to the lens of the eye based on routine dosimetry data - a EURADOS study

Regarding the number and position of dosemeters to be used for assessment of the effective dose and the dose to the lens of the eye, EURADOS WG12 proposed to further investigate the issue based on data from routine measurements and not from pilot or review studies. In this framework measurements of the personal dose equivalent at depth 10 mm over and under the protective apron, $H_p(10)_{over}$ and $H_p(10)_{under}$, and personal dose equivalent at depth 0.07 mm over the radiation protection apron, $H_p(0.07)$, were collected from various dosimetry services in Europe using a common template. The information included also the position of the dosemeters, the occupational category and the duration of the monitoring period.

Data were collected from 6 dosimetry services of Greece, Serbia, Spain, Switzerland and Czech Republic, countries where double dosimetry is implemented. Most data were provided by Greece, Serbia and Spain. The data included 12,756 coupled measurements (over and under the protective apron) with 8,091 and 4,665 measurements for interventional cardiology and radiology, respectively. Details about the criteria followed for the data selection are provided in Askounis et al. (2022).

As it is seen from the distribution pies in Figure 10, 85% of the under the apron dosemeter data are related with monthly dose values less than 0.2 mSv, whereas for the over the apron dosemeters the values with exposure less than 0.2 mSv is only 16%. In an attempt to investigate any correlation between the routine data sets of over and under the protective apron the box plots of the distribution of $H_p(10)_{over}$ values, for the 5 groups of $H_p(10)_{under}$ considered in Figure 10, is presented in Figure 11.

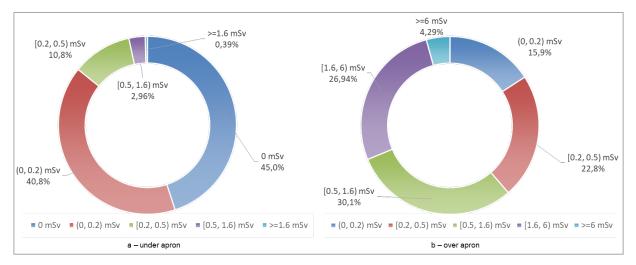


Figure 10: Pie charts with the percentage of dose levels in various ranges (in mSv). The left pie chart (a) refers to the dose levels under the apron and the right one (b) to the dose levels over the apron.

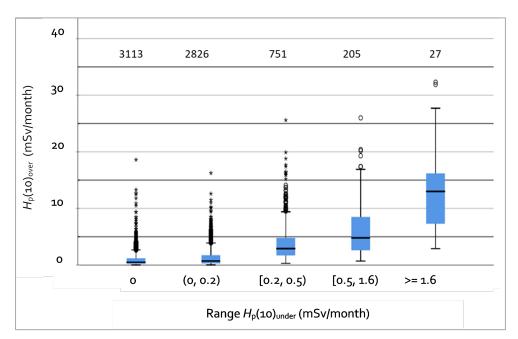


Figure 11: Box plots of the distribution of $H_p(10)_{over}$ values, for the 5 groups of $H_p(10)_{under}$ considered in Figure 10. At the top of each box plot the number of data is shown. The outliers are marked with circles and asterisks as defined in the SPSS[®] software criteria (SPSS[®], 2009).

Figure 11 shows that for a reading of '0.0 mSv' from the under apron dosemeter, $H_p(10)_{over}$ varies between 0.1 mSv and 18.6 mSv, with a mean value of 0.9 mSv and a median of 0.5 mSv. Similarly, a reading in the range [0.5, 1.6) from the dosemeter worn under the apron corresponds to values over the apron up to 26 mSv. Figure 11 highlights that it is not possible to predict the exposure of the non-protected parts of the body with the dosemeter under the apron.

5.2.3.1 Assessment of the effective dose

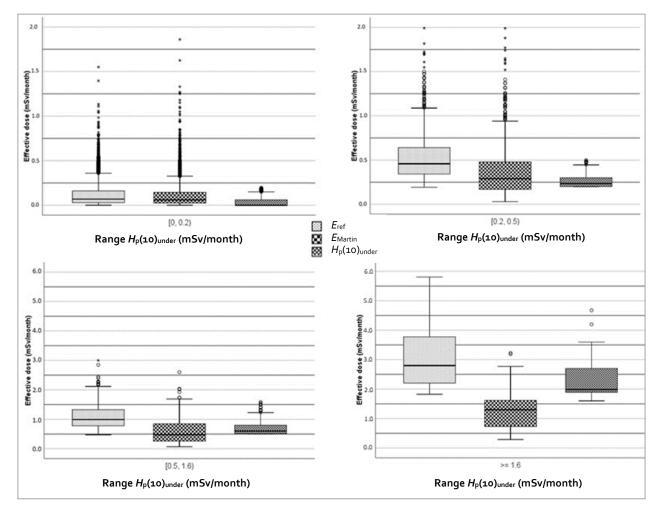
In the analysis that was performed, the best estimate for the effective dose (when two dosemeters were used), \overline{E}_{ref} , was considered as the mean value of the effective dose calculated with each of the algorithms presented in paragraph 5.2.1:

$$\bar{E}_{ref} = \frac{E_{\text{McEwan}} + E_{\text{Swiss}} + E_{\text{Boetticher}}}{3}$$

This value is then compared with $H_p(10)_{under}$ and with the effective dose estimated from the dosemeter *over* the protection using the equation proposed by Martin and Magee (2013):

$$E_{\text{Martin}} = 0.1 \times H_{\text{p}}(10)_{\text{over}}$$

Box plots of the three methods considered for the effective dose assessment i.e. E_{ref} , E_{Martin} and the data from $H_p(10)_{under}$ were produced (Figure 12). The box plots correspond to different $H_p(10)_{under}$ ranges: [0. 0.2); [0.2. 0.5); [0.5. 1.6) and >= 1.6. From Figure 12 it is shown that a single dosemeter under the protection ($H_p(10)_{under}$) as well as the formula provided by Martin and Magee (2013) provide an assessment of the effective dose close to what was considered as reference value (E_{ref}) for the dose ranges of $H_p(10)_{under}$ of [0,0.2), (0.2,0.5) and [0.5,1.6). However, for $H_p(10)_{under}$ values higher than 1.6 mSv, it is shown that the estimation of the effective dose by using one dosemeter under and the algorithm proposed by Martin and Magee (2013) provide lower values than the reference ones. From the Figure 12, we can assume that the use of one single dosemeter can provide values close to the reference ones, either worn under or over the protection, the latter corrected with an



appropriate coefficient, except when the measurement below the apron is higher than 1.6 mSv/month.



In summary, we can conclude that the use of two dosemeters does not significantly improve the assessment of the effective dose in fluoroscopically guided interventional procedures, in general, except in situations where it is possible to approach or exceed the effective dose limit (20 mSv per year).

5.2.3.2 Assessment of the dose to the lens of the eye

As shown in Figure 11, the dose to unprotected parts of the body, including the lens of the eye, cannot be assessed by the dosemeter worn under the apron. Figure 10 highlights that more than 60% of $H_p(10)_{over}$ measurements correspond to a monthly dose of more than 0.5 mSv. In addition, if we use the coefficient of 0.75 suggested by Clerinx et al., (2008), as mentioned in paragraph 5.2.2, for the assessment of the dose to the lens of the eye we end up with 40% of cases with monthly dose values for the lens of the eye higher than 0.5 mSv. Therefore, given this high percentage of cases, eye lens assessment should be performed in regular basis in IC/IR. However, considering the wide range of coefficients proposed in the literature, care should be taken if the dose calculated using this method reaches the investigation level or even the dose limit. At this point more accurate evaluations through direct measurements should be performed.

5.2.4. Methods of assessing levels of exposure for extremities

5.2.4.1 Generalities

In non-uniform radiation fields such as those found in the vicinity of patients in interventional procedures, the extremity doses can be significantly larger than the whole-body dose measured on the trunk (ISO, 2015). Moreover, the skin of the extremities is mostly the limiting organ rather than the extremities themselves, and as such, the extremity monitoring requirements follow the requirements for the skin to measure $H_p(0.07)$. The limits on the equivalent dose for the extremities and the skin are both the same, 500 mSv in a year. For the skin, the limit shall apply to the dose averaged over any area of 1 cm², regardless of the area exposed. For interventional procedures, the most exposed area is usually the operator's hand closest to the radiation field. Accurate assessment of extremity doses is important because, in some cases with high workload, the established dose limit may be exceeded (Damilakis et al., 1995). Depending on the type of procedure and the access route used, the position of the operators varies which affects the proximity of their hands to the X-ray tube making this parameter crucial for dose estimation (ICRP, 2018).

According to the European BSS (EC, 2014) when a worker is liable to receive an equivalent dose greater than 150 mSv per year for skin or extremities then an adequate monitoring system for the extremities shall be setup. Considering the dose distribution on the hands and the difficulty to place the dosemeter in the most exposed area, as well as the risk of a direct exposure to the primary beam, the IPEM proposes different extremity monitoring programmes based on the monthly monitoring readings (Martin et al., 2018). The IPEM and the World Health Organization (WHO) (WHO, 2000) also recommend dose action levels for monthly extremity dosemeter readings between 15 mSv and 20 mSv in order to identify when there may be a potential problem or when practices may need to be further optimized.

5.2.4.2 Upper extremities

To estimate the extremity dose, a dosemeter capable of measuring $H_p(0.07)$ is used, ideally placed as close as possible to the most exposed area of the skin (ISO, 2015), and oriented towards the radiation beam. ICRP 139 indicates that the ulnar aspect of the hand is the most exposed area for operator's skin, since it is the closest part to the irradiated volume of the patient and, therefore, the dosemeter should be worn either on the little finger or on the side of the wrist closest to the X-ray tube (ICRP, 2018; Whitby and Martin, 2005; Vanhavere et al., 2012; Martin, 2011). If the most exposed area is unknown a priori, the use of several dosemeters might be necessary to monitor different locations, for example in both hands (ISO, 2015).

For the monitoring of the upper extremities, wrist, ring or fingertip dosemeters (Figure 13) can be used. Some of the advantages of the wrist dosemeters are easy adjustment under surgical gloves and low interference with the tactile sensation of the worker. However, if wrist dosemeters are chosen, the recorded dose may be lower than the actual maximum extremity dose, due to the inhomogeneity and the gradients of the field. Moreover, the possibility of introducing the hands into the primary radiation beam cause another issue of concern in the extremity monitoring. Hand dose distribution has been studied for interventional radiologists and cardiologists, depending on the procedure, resulting as the best approximation of the most exposed area to be the area from the little finger to the middle finger, with the bases of the fingers as the most exposed parts. For those workers performing mainly percutaneous procedures the most exposed parts were the tips of the middle and ring fingers (Whitby and Martin, 2005). Therefore, the use of finger stalls might be a suitable option to estimate radiation exposure in this scenario. However, they are not very often used

because they can have an impact on the worker's tactile sensation and are not very comfortable (ICRP, 2018). Ring dosemeters often are the best option for interventional procedures because they provide a better estimate of the maximum skin dose than the wrist dosemeter, and they are more comfortable than the finger stall.



Figure 13: Extremity dosemeters available models. Wrist (left) and ring (centre) dosemeters (source: Spanish National Dosimetry Centre) and finger stall (source: <u>www.ukhsa-protectionservices.org.uk</u>)

Regarding the type of dosemeter to be used, for a worker with maximum skin doses estimated between 2 mSv and 4 mSv per month, a ring dosemeter would be adequate, whereas for a worker with more than 4 mSv per month working in a less uniform field fingertips or rings on the second phalanx, if the fingertips impede their work, would be more appropriate (Martin et al., 2019).

Regardless of the dosemeter and the chosen position for monitoring workers, when analysing dose measurements, it is helpful to consider correlations between the doses recorded in various parts of the hands. In the European ORAMED study (Vanhavere et al., 2012), the correlation found between the doses recorded on the finger and wrist of the left hand was excellent when no ceiling shield was used. In other studies, the doses recorded on the index finger were found to be 10% to 30% lower than on the little finger, while a significant difference in radiation dose measurements has been observed between the finger and wrist in percutaneous procedures (Martin, 2011). Therefore, in order to make comparisons between different dose readings obtained from dosemeters positioned in different parts of the hand, it is important to consider that the dose distribution across the hands may not be homogeneous and is procedure-dependent. This information is essential for accurate assessment of radiation exposure in workers and must be taken into account when selecting appropriate dosemeter positioning for monitoring purposes.

5.2.4.3 Lower extremities

The upper extremities are not always the most exposed area (ISO, 2015). If a table shield is not used, several studies show that in fact the dose to parts of the lower extremities that are not protected can be equal to or higher than the doses received by the hands (Vanhavere et al. 2012; Nikodemova et al. 2011; Whitby and Martin 2003; Vanhavere, 2008). In this case, wrist dosemeters can be worn at the ankle for leg monitoring. The monitored leg shall be the closest to the radiation source (the exposed part of the patient) and the dosemeter should be oriented towards it (ISO, 2015).

An alternative approach is to estimate the dose to the left leg from the kerma-area product (KAP) value, since these values are strongly correlated when no table shielding is used (Whitby and Martin, 2003; Krim et al., 2011) which, in fact, corresponds with the cases in which the dose to the lower extremities is relevant. Approximately 100 Gy cm⁻² correspond to 1 mSv to the legs when shielding is not used, or 0.02 mSv, when it is used (Whitby and Martin, 2003).

Consequently, leg monitoring would not be necessary as long as the table shielding is used correctly (Krim et al., 2011). The KAP value can be used as an estimate when shielding is not present. Finally, the doses to the lower extremities of the staff located on the opposite side or at the limit of the table protection should be considered (Koukorava et al., 2011).

5.2.5. Practical guidelines on monitoring programme and dose assessment

Based on the previous paragraphs, we propose several practical guidelines which balance the complexity of the monitoring programme with the potential exposure levels and the associated radiation risk. The approach is in line with the vision of the IRPA seeking 'reasonableness' while applying the System of protection (Cantone et al., 2017) and the recommendations of IPEM (Martin et al., 2018). The monitoring programme should always be based on an individual risk assessment and local regulations.

5.2.5.1 Effective dose assessment

When there is no need for monitoring the lens of the eye (i.e., because the lens are properly protected, or the workload is low) the radiation protection expert may propose one of the following:

- > The use of one dosemeter worn under the whole body protection garments and measuring $H_p(10)$, as it can provide an adequate estimation of the effective dose when the expected level is up to 1.6 mSv per month.
- > The use of one dosemeter over the protection; however its reading should be corrected using the algorithm proposed by Martin and Magee (2013).
- The use of two dosemeters, one over and one under the protection, which can provide a conservative estimation of the effective dose. The algorithms proposed in (Swiss Ordinance, 1999; von Boetticher et al., 2008) could be chosen especially in cases where it is likely to approach or exceed the effective dose limit (>1.6 mSv per month). In this situation attention should be paid using the proper labeling of the dosemeters so that the users do not mix them up.

When there is a need for monitoring the lens of the eye but no dedicated eye lens dosemeter is used the radiation protection expert may propose:

> The use of one dosemeter worn over the protection and measuring $H_p(10)$ as it can give an acceptable estimation of the effective dose using the algorithm proposed by Martin and Magee (2013). The measurement of $H_p(0.07)$ can also be used for the estimation of the dose to the lens of the eye (Clerinx et al., 2008).

5.2.5.2 Dose assessment to the lens of the eye

- > One dosemeter worn over the protection and measuring $H_p(10)$ or $H_p(10)$ and $H_p(0.07)$ is recommended, as long as the monthly measurement is below 0.5 mSv. It can give an acceptable estimation of the dose to the lens of the eye (Askounis et al., 2022; IRPA, 2017).
- > One specific eye lens dosemeter placed close to the eyes and measuring $H_p(3)$ provides the best estimate of the dose to the lens of the eye. Its use is highly recommended when the monthly over apron dosemeter measurement exceeds 0.5 mSv.

In cases where radiation protection glasses are used, a 50% reduction is often considered as a representative correction factor for effectiveness (see chapter 3)

5.2.5.3 Extremity dose assessment

Extremity dose monitoring shall be performed with dosemeters suitable for measuring $H_{\rm P}(0.07)$. The proposed dose levels follow the extremity dose monitoring recommendations of IPEM (Martin et al., 2018) for staff working in interventional procedures.

- An initial monitoring programme to establish dose levels and to assess the most exposed area is recommended for monthly dosemeter readings of 2 mSv to 4 mSv for the hands and 10 mSv for the legs.
- > Regular monitoring with preferably ring, or wrist, dosemeter should be considered when the dosemeter reading is in the range of 4 mSv to 10 mSv per month.
- Ring dosemeters placed at the base of middle to little finger is recommended if monthly dosemeter readings exceed 10 mSv. Wrist dosemeters may be used if a correction factor to assess for the most exposed area is known.
- > For the lower leg or feet in case the initial monitoring programme shows monthly dosemeter readings exceeding 10 mSv, improvements on the protection means are recommended in particular to ensure the presence of a table shield and/or to reduce the gap between the protective shield and the floor.

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6. Summary and Conclusions

This report summarises the technical and legal aspects of individual monitoring requirements in IR/IC workplaces and includes information which should be useful at each stage of the dose monitoring programme. Technical data and results from the latest scientific literature have been provided to improve understanding of how different factors influence occupational dose, to increase awareness of the importance of individual monitoring, and the correct use of protection tools.

The topics analysed are:

- > the identification of workers that need to be monitored, considering their expected dose levels (chapter 2),
- > the use of appropriate protective equipment and their regular maintenance (chapter 3),
- > the types of dosemeters that are available (chapter 4),
- > the methods for dose assessment (chapter 5).

6.1 The expected dose levels

In IR/IC, the annual effective dose levels can reach approximately 4 mSv for physicians and 1 mSv for other professionals. Workers are mainly exposed at the level of the extremities and the eye lens, as these parts of the body are often less protected. The annual limits can even be exceeded in some cases, especially the dose limits for the lens of the eye. Monitoring of the eye lens, and the hands, in addition to whole body monitoring, should then be considered for IR/IC procedures.

6.2 The protective equipment and their regular maintenance

Many types of PPE are available, with varying degrees of dose reduction, as summarised below.

- > The radiation protection effectiveness strongly depends on the equipment design, use and exposure conditions. For instance:
 - Lead glasses can reduce the eye lens dose by 25% to 90% depending on the eye coverage and the gap between their surface and the face.
 - The ceiling-suspended screen can protect the physician's upper body (10% to 70% dose reduction to the hands and 20% to 90% to the eye lens) depending on the screen position.
- > The radiation protection effectiveness, as reported in the scientific literature or by the manufacturers, should always be considered with caution and, if feasible, validated in the planned conditions of use.
 - Clinical conditions can differ from MC models, phantom measurements or from one hospital to another.
 - Dosemeters can be protected by the PPE more than or less than the organs they are intended to monitor, and, thus, under or over-estimate the effectiveness at the organ level.
- > The absolute dose level should be considered: PPE that provides a low dose reduction factor for an organ exposed to very low dose might be acceptable, while a low dose reduction factor for a highly exposed organ is not an optimised choice of PPE.
- > Factors such as ergonomics, frequency of use, and economic factors should be considered along with the radiation protection effectiveness.

A programme for routine inspection of PPE should be established by the hospital in order to ensure the items remain fit for purpose, and rejection criteria should be established. Staff should be trained

on how to wear PPE, where to place their dosemeter (i.e. above/below PPE), and the importance of correct storage when not in use.

6.3 Type of dosemeters

Whole body badges with passive detectors remain the most widely used dosimetry methods for the assessment of occupational exposure in IR/IC. Several technologies, such as TLDs, OSLs, RPLs, are available and they all can provide, in general, satisfactory performance. Passive dosemeters are cheap and easy to use. However, the use of APDs for real-time monitoring is increasing. Hybrid solutions allowing for frequent local readouts of staff doses are also becoming more widely used.

Passive dosimetry should be performed by Approved Dosimetry Services who are authorized by the national regulators; this is intended to give confidence that they provide an appropriate service. Passive dosemeters should meet the requirements included in the specific standards and provide good dose linearity, sensitivity and reduced fading after the exposure. The dosimetry service should perform quality tests on a regular basis and participate in national or international individual monitoring intercomparisons. In practice, as many dosimetry services show satisfactory performance, characteristics such as the comfort of wearing of the dosemeters, the possibilities of sterilization or even the geographical proximity of the supplier are determining factors in the selection of the dosemeters.

In general, the requirements for APDs, and indeed hybrid solutions, are the same as for passive dosimetry discussed above. All dosemeters should meet the requirements of the relevant standards. They should have acceptable energy and angular response, sensitivity, linearity and accuracy. APDs and hybrid dosemeters can be approved as the "dosemeter of record" for regulatory compliance once the criteria for approval have been set by the regulator and fulfilled by the provider. Care has to be taken for APDs when used in pulsed fields, they can underestimate the dose compared to passive dosemeters. Alarms on APDs are useful for training, however a visual alarm is preferable to an audible alarm. Management of associated software and data transfer is important for any IT aspects of a dosimetry system.

6.4 The adequate position of the individual dosemeters

6.4.1 For the effective dose

- > When only an over apron dosemeter is employed, a central position high on the chest is preferable to minimise the dependence on the beam projection. This is particularly true if the dosemeter is also used to provide an estimation of the eye-lens dose. When two dosemeters are worn (double dosimetry) the dosemeter over the apron should be placed in accordance with the position identified in the algorithm used to calculate the effective dose from the two dosemeters.
- > When only the under apron dosemeter is worn, the attenuation of the apron tends to mask the variability related to its positioning.

6.4.2 For the dose to the lens of the eye

- > Preferably a specific eye-lens dosemeter located close to the most exposed eye and measuring $H_p(3)$,
- > Alternatively, an unprotected whole body dosemeter situated at the chest or collar level.

6.4.3 For the extremity monitoring

- > Ring dosemeters at the base of the little or middle fingers (if the field is highly inhomogeneous)
- > Wrist dosemeters may be used (although they generally underestimate the skin dose compared to a ring dosemeter)

The sensitive part of the detector for either the ring or the wrist dosemeter should point in the direction of the radiation (patient).

6.5 Methods for dose assessment

6.5.1 For the effective dose

The effective dose may be estimated by the use of:

- > double dosimetry, using one dosemeter under and another over the lead apron. This approach is the most accurate method when protective aprons are used. In addition, the unprotected dosemeter can provide an estimate of the dose to the lens of the eye.
- single dosimetry, i.e. to wear the dosemeter over or under the apron, preferably at the central position high on the chest to minimise the dependence on the beam projection.
 - when the dosemeter is worn under the apron, the effective dose may be considered equal to the dosemeter reading itself,
 - when the dosemeter is worn above, the effective dose is estimated by dividing the dosemeter reading by a factor in the typical range from 10 to 20 (derived from a series of evaluations that varies depending on the type of practice, the thickness of the protective apron, and the position of dosemeters).

6.5.2 For the equivalent dose for the lens of the eye

- > A factor of 0.75 for the unprotected whole body dosemeter situated at the chest or collar level may be used to give an estimation of the dose to the lens of the eye.
- > In addition, when protective eye glasses are worn, a conservative correction factor of 50% is suggested to account for the attenuation
- > As always, the design of the specific monitoring programme depends on the national regulations and local guidelines.

6.6 Training of workers

Although outside the scope of this report, it is important to highlight that training (and continuous training) is one of the pillars of the radiation protection safety culture as reported in (EC, 2014). "Education and training are widely recognised as key components of justification and optimisation programmes. An appropriate balance between education and training should be ensured, and hands-on training courses with a problem-solving approach should be organised and promoted."

In the past years, different European initiatives showed how proper education and training can improve the "as low as reasonably achievable" (ALARA) culture (Shaw et al., 2015; Rainford et al. 2022).

Staff involved in interventional procedures need initial and periodic education and training (ICRP, 2018). This report addresses important issues that need to be considered to define a successful

radiological protection programme and can provide guidance to implement an appropriate and updated training programme.

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