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[1] SCK•CEN, Belgian Nuclear Research Centre – Mol, Belgium

[2] GAEC, Greek Atomic Energy Commission – Athens, Greece

[3]ENEA, Ente per le Nuove Tecnologie, l'Energia e l'Ambiente – Bologna, Italy

[4]IRSN, Institut de Radioprotection et de Sûreté Nucléaire – Fontenay-aux-Roses, France

[5]CHUV, University Hospital Center – Lausanne, Switzerland

[6]UPC, Universitat Politecnica de Catalunya – Barcelona, Spain

[7]SMU, Slovak Medical University – Bratislava, Slovak Republic

[8]NIOM, Nofer Institute of Occupational Medicine – Lodz, Poland

[9]CEA, LIST, Laboratoire National Henri Becquerel (LNE LNHB) – Gifsur Yvette, France

[10]BfS, Bundesamt für Strahlenschutz – Berlin, Germany

[11]Radcard– Krakow, Poland

[12]MGPi, Mirion Technologies – Lamanon, France

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Bundesallee 100
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office@eurados.org
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Content

Executive Summary

The medical staff performing interventional cardiology and radiology (IC/IR) procedures stand close to the patient and thus close to the primary radiation beam. Although they wear a lead apron and thyroid collar, their hands, legs and eyes are not protected. Therefore, these parts could receive significantly high doses. Moreover, the dose ranges for the same kind of procedures vary a lot, as many factors affect extremity and eye lens doses. Additionally, there is evidence that eye lens doses can be high in IR/IC, and cases of cataract have been reported in recent years. A lack of an appropriate eye lens dosemeter as well as an appropriate calibration procedure has been identified.

Medical staff in IR/IC could benefit from the use of active personal dosemeters (APDs) as optimisation tool. However, a lack of appropriate APDs is identified for typical fields in IR and IC. Very few devices can detect low energy fields, and none of them are really designed for working in pulsed radiation fields.

In the field of nuclear medicine (NM) the extremity doses to the technologists are also known to be very high. One can highlight the difficulties in estimating the dose distribution across the hands, and the need for greater knowledge of doses received during the main tasks of a nuclear medicine department, especially using unsealed sources.

The ORAMED project, (www.oramed-fp7.eu) was set up to optimize the working procedures in these medical fields with respect to radiation protection. ORAMED was structured in 5 work packages:

- Extremity and eye lens dosimetry in IR and IC
- Development of practical eye lens dosimetry
- Optimization of the use of APDs in IR and IC
- Extremity dosimetry in NM
- Training and dissemination

A coordinated measurement program in European hospitals was organised both in IR/IC and NM departments. Moreover, simulations of the most representative workplaces/procedures were performed to determine the main parameters that influence the extremity and eye lens doses. Some dedicated studies on improving the eye lens dosimetry and active personal dosimetry were conducted.

Based on the measurement and simulation results, a series of practical guidelines and training packages were developed. The influence of the different radiation protection measures (like shields) in IR/IC have been quantified, and clear monitoring requirements have been formulated for a series of medical procedures. A formalism for the use of the operational quantity for eye lens dose measurements have been worked out (calibration phantom, conversion coefficients, type test procedures,…). A dedicated eye lens dosemeter has been developed that can be used in routine monitoring. The different existing APDs have been tested in fields that are representative for hospital fields (like pulsed fields), and a series of guidelines for the use of these APDs in hospitals have been made. Also, an improved APD device specifically for IR/IC fields has been developed.The extensive measurement and simulation campaign for extremity doses in NM lead to a systematic

evaluation of the different radiation protection measures. These are condensed in a series of practical guidelines to be used. The dose distribution across the hands of the technologists was characterised, and recommendations for routine monitoring have been formulated.

The outcome of the ORAMED project will improve the radiation protection standards for medical staff. The systematic measurements and simulations are the new standards that will be used for many years to come. The practical guidelines that have been developed can be used in the hospitals by the medical staff. In particular, the developments on the eye-lens dosimetry and the active personal dosemeters will result in an improvement of the practical measurement capabilities in the field.

The ORAMED project: General Introduction

The state-of-the-art analysis performed in the FP6 CONRAD project highlighted high extremity doses and a lack of systematic data analysis on exposures to the staff in interventional radiology (IR) and nuclear medicine (NM). To optimize the working procedures in the medical field with respect to radiation protection, a project focussed on improving the knowledge on extremity and eye lens exposures, combined with an optimization in the use of active personal dosemeters, was submitted for funding within the FP7 programme. This project was accepted and was called ORAMED: Optimization of Radiation Protection of Medical Staff.

ORAMED was set-up as a collaboration between twelve partners:

- Belgian Nuclear Research Centre,SCK•CEN, Belgium (coordinator)
- Greek Atomic Energy Commission, GAEC, Greece
- ENEA Radiation Protection Institute, ENEA, Italy
- Institute for Radiological Protection and Nuclear Safety, IRSN, France
- University Hospital Center Vaudois,CHUV, Switzerland
- Institute of Energy Technology – Universitat Politècnica de Catalunya, UPC, Spain
- Laboratoire National Henri Becquerel (LNE-LNHB) at the Comissariat à l'Energie atomique, CEA, France
- Slowak Medical University, SMU, Slovak Republic
- Nofer Institute of Occupational Medicine, NIOM, Poland
- Federal Office for Radiation Protection, BfS, Germany
- RADCARD, Poland
- MGP Instruments, France

The ORAMED project started in January 2008 and was concluded with a workshop by February 2011. In the course of the project and afterwards a lot of effort has been devoted to the dissemination of the results. A major tool for this dissemination is the ORAMED website: www.oramed-fp7.eu, which will remain active for many years after the project has ended. A lot of information is freely available at this website:

- The official public deliverables of the project
- Reports with the detailed results of all measurements and simulations
- Scientific papers on ORAMED results that have been published
- The guidelines for optimization of the radiation protection of Medical Staff
- Training material (video, dose estimation tool, presentations)
- The presentations given at the ORAMED workshop

Even though all this material is available, there was still the need to have an extensive overview of all the important ORAMED results in one document. This EURADOS report will act as an extensive ORAMED overview report. For each work package the methodology, the detailed results, the analyses of the results, the conclusions and the guidelines are given.

Interventional radiology and cardiology

The medical staff performing IR/IC procedures stand close to the patient and thus close to the primary radiation beam. Although they wear a lead apron and a thyroid collar, their hands, legs and

eyes are not protected. Therefore, these parts could receive significantly high doses.The dose ranges for the same kind of procedures vary a lot, as many factors affect extremity and eye lens doses such as the use of protective devices, X-ray beam geometry and X-ray spectra, the irradiated part of the patient, etc. There are cases mentioned in the literature where the extremity doses can approach the dose limits. In these cases either the high workload or the lack of a proper radiation protection policy are responsible for the high doses observed. Routine monitoring of extremities is difficult, since "the most exposed area" defined by ICRP recommendations cannot easily be found. In most cases only finger or hand doses are reported; doses to the eye lens or legs have not been evaluated. In some studies (especially when no protective shielding on the couch is used) doses to the legs can be even higher than doses to the hands. Even when ring/hand dosimetry is used for extremity monitoring the position of the dosemeter is not clear. Moreover, there is evidence that eye lens doses are high in IR/IC, and cases of cataract have been reported in recent years. However, eye lens doses are never measured in routine applications, and also very few data can be found in the literature. There was no suitable dosemeter available and the standards for the operational quantity measurements are not complete. This situation is partly due to the lack of conversion coefficients and a suitable calibration procedure. A lack of appropriate equipment is also identified in the field of active personal dosemeters (APD) for typical fields in interventional radiology. Very few devices can detect low energy fields, and none of them are really designed for working in pulsed radiation fields. In summary, in interventional radiology, there is an insufficient knowledge about which is the most exposed part of the body in the different procedures and the influence and effectiveness of protection measures. Furthermore, there are no suitable eye-lens dosemeters or active personal dosemeters available.

Nuclear medicine

The literature concerning radiation exposure and protection of nuclear medicine staff is limited and mostly refers to conventional diagnostic nuclear medicine. As a consequence of the definition that the dose limit for the skin has to be applied to 'the dose averaged over any area of 1 cm^2 regardless of the area exposed' it is advisable to measure the local skin dose at the location with presumably the highest exposure. This requirement is the central dilemma of extremity dosimetry and causes severe practical difficulties. In daily practice when preparing and administering radio-pharmaceuticals in nuclear medicine it is not easy to comply with that requirement since it is often not known which part of the hand receives the highest dose. Moreover, the dose distribution over the hand may vary during a single process as well as when various persons perform the same procedure. Unsealed radiation sources are being increasingly used in nuclear medicine diagnostics and therapy, in particular, nuclides that emit beta or mixed beta/gamma radiation.Considering the preferential use of beta emitters, the dosemeters must be appropriate for detection of beta radiation, taking into account both the energy spectra of the nuclides and the spectral dose response of the dosemeter. In nuclear medicine therapy, staff may be exposed to high doses, even exceeding the annual limit of the dose to the skin of 500 mSv. Thus, adequate safety measures including extremity monitoring of personnel is a strict requirement.

The ORAMED project: Structure and Objectives

The ORAMED project proposed to develop methodologies for better assessing and reducing exposures to medical staff**.** This general objective has been achieved through the development of 5 main topics, structured in 5 work packages.

- WP1: Extremity dosimetry and eye lens dosimetry in interventional radiology and cardiology
- WP2: Development of practical eye lens dosimetry
- WP3: Optimization of the use of active personal dosemeters in interventional radiology and cardiology
- WP4: Extremity dosimetry in nuclear medicine
- WP5: Training and dissemination

The objective of WP1 was to obtain a set of standardized data on doses for staff in interventional radiology and cardiology and to optimize staff protection. A coordinated measurement program in different hospitals in Europe has been performed to help towards this direction. Moreover, simulations of the most representative workplaces/procedures in IR/IC were performed to determine the main parameters that influence the extremity and eye lens doses.

The objective of WP2 was to establish a sound theoretical and experimental basis to assess eye lens doses. This implied the need to revise the approach for the definition and calculation of conversion coefficients for $H_p(3)$, the operational quantity for the measurement of equivalent dose to the eye lens (H_T(lens)). This was done using the Monte Carlo codes MCNPX and PENELOPE during the first two years of the project. A second important objective was to develop a practical eye lens dosemeter. During the third and last year of the project a final design of an eye lens dosemeter was produced. In addition, a guide for type testing and calibration of eye lens dosemeters was implemented.Finally, after the characterization of the prototype, it was also used in a trial campaign in some European hospitals during IR/IC procedures.

The objective of WP3 was to optimize the use of active personal dosemeters (APDs) in interventional radiology. Interventional radiology procedures can be very complex and they can lead to relatively high doses to medical staff that stand close to the primary radiation field and are mostly exposed to radiation scattered by the patient. Very few devices can detect low energy radiation fields and none of them are specially designed for working in pulsed radiation fields. Therefore, an extensive test programme has been performed, leading to specific guidelines for the use of APDs. Finally, taking into account the aforementioned tests and the characteristics of the X-ray fields used in IR/IC, a new device with an improved response under such conditions has been developed.

The objective of WP4 was to detect the most exposed part of the skin by measuring the extremity doses and dose distributions across the hands of the medical staff working in nuclear medicine departments. Afterwards, the most suitable position of an extremity dosemeter had to be assessed. To achieve this, an extensive measurement and simulation program was performed in many European hospitals.

The last objective of the project (WP5) was to design and develop an accurate teaching and knowledge dissemination program and to make sure that the conclusions and recommendations

of the project are transmitted to the stake-holders, mainly medical staff, radiation protection officers, dosimetry services and authorities in the field. The main dissemination activities include the publication of reports and scientific articles together with the preparation of training material.

Acknowledgement

The ORAMED group would like to warmly thank all the persons from the many hospitals for their help in collecting these data.

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1 Extremity dosimetry and eye lens dosimetry in interventional radiology and cardiology

1.1 Introduction

Medical procedures using ionising radiation constitute by far the largest contribution to people's exposures by man-made sources (UNSCEAR, 2010). Moreover, the increasing use of ionising radiation in the medical sector has also a very important impact on occupational doses. As part of the medical procedures using ionising radiation, IR/IC procedures are performed in increasing large numbers worldwide. There are more and more different types of applications in a wide range of medical specialties using fluoroscopy guided interventional techniques, which represent huge advantages for patients over invasive surgical procedures such as lower risk of infection, shorter recovery time, etc. However, these procedures often imply high radiation doses to patients, but also to the medical personnel. Workers exposed in medicine constitute a significant percentage of the European workforce that is occupationally exposed to radiation (G.Frasch, 2007).

Major areas of concern are the ones that involve new technologies and methodologies resulting in high doses to hands and legs, as well as, to the eye lens of the physicians (Vanhavere et al., 2008, Kim et al., 2008, Martin 2009). Recent research data on the effects of eye lens exposure increase the concerns about possible late effects such as lens injuries or cataracts for the medical staff (Chodick et al., 2008; Junk et al., 2004; Vano et al., 2010; Ciraj-Bjelac et al., 2010; Mrena et al., 2011).

IR and IC procedures require the operator and assisting personnel to remain close to the patient, and thus close to the primary radiation beam. Despite the fact that the body area can be individually shielded by protective lead aprons, the hands, legs and the eye lenses often remain practically unshielded. The ICRP Publication 85 (ICRP, 2000) has given examples of the doses of the occupationally exposed workers for various X-ray procedures. The dose ranges for the same kind of procedures vary a lot, since there are many factors that affect the extremity doses like the use of protective devices, the X-ray beam geometry and X-ray spectra, the irradiated part of the patient's body, etc.

The state-of-the-art analysis has highlighted high extremity doses and a lack of systematic data analysis on exposures to the staff in IR/IC (Vanhavere et al., 2008, Donadille et al., 2008). The ORAMED project addressed these issues. More specifically, the overall objective of Work Package 1 (WP1) of ORAMED was to obtain a set of standardized data on doses for staff in the above sectors and to optimize staff protection.

A coordinated measurement program in different hospitals in Europe was performed together with a set of simulations of the most representative workplaces/procedures in IR/IC in order to determine the main parameters that influence the extremity and eye lens doses. More specifically, the objectives of WP1 were:

- To perform a systematic study of measurements and simulations of extremity and eye lens doses of medical staff in selected IR/IC procedures
- To study the parameters that influence the extremity and eye lens doses for the medical staff in IR/IC
- To propose a methodology for reducing the doses of medical staff (recommendations)

1.2 Measurement campaign

1.2.1 List of procedures

. The list of procedures includes 3 cardiac and 5 radiology (diagnostic and therapeutic) examinations. More specifically, the list is composed of:

- cardiac angiographies (CA) and angioplasties (PTCA)
- radiofrequency ablations (RFA)
- pacemaker and cardiac defibrillator implantations (PM/ICD)
- angiographies (DSA) and angioplasties (PTA) of the lower limbs (LL), the carotids and the brain (C/B) and the reins (R)
- all types of embolisations
- endoscopic retrograde cholangiopancreatographies (ERCP).

The choice of the procedures was based on their potential impact on the annual exposure of the staff, so two main selection criteria were defined: high annual frequency and possible high KAP values. However, some procedures of low frequency were included in the study, in order to take into account different parts of the patient body that areirradiated. Finally, ERCP procedures were selected not only for their high frequency but also for the fact that they are performed by gastroenterologists who, usually, don't have any training on radiation protection issues. For each procedure at least ten measurements were performed in each irradiation room.

The final distribution of the procedures for which measurements were performed in each country is shown in Table 1.1.

Table 1.1: Number of procedures followed per country

	Interventional Cardiology			Interventional radiology				
Country	CA/ PTCA	RFA	PM/ ICD	DSA/PTA LL	DSA/PTA C/B	DSA/PTA R	Embolisation	ERCP
Belgium	102	70	60	38	11	16	54	93
Greece	33	22	30	43	24	12	32	28
France	20	24	24	30	0	26	25	26
Switzerland	37	33	26	19	0	2	23	25
Poland	40	20	41	22	20	3	28	0
Slovakia	30	19	16	18	7	6	12	17
TOTAL	261	183	197	170	62	65	174	189
							Total number of procedures	1329

1.2.2 Measurement protocol

For the measurement campaign a unified protocol was used in all countries for the collection of data in terms of parameters related to the angiographic system, the type of procedure, the position of the operator, the use of protective equipment, the experience of the operator and some field parameters (kVp values, filtration, projections, KAP -Kerma Area Product- values etc.). For the dose measurements it was decided to use thermoluminescent dosemeters (TLD) of LiF:Mg,Cu,P type. They were sealed in small plastic bags and taped on the parts of the operator's body to be monitored. More specifically, 8 TLDs were used, one on each ring finger (L finger & R finger) and wrist (L wrist & R wrist), two on the legs about 5 cm below the lead apron (L leg & R leg), one between the eyes (M eye) and one near the left/right eye (L/R eye) depending if the tube is on the left/right side of the operator, respectively. The TLDs on the hands were placed on the palmar side when the tube was below the table and on the dorsal side for over-couch configurations. The position of the TLDs is shown in figure 1.1. The operational quantity $H_p(0,07)$ suitable to monitor the equivalent dose to the skin has been used. In the present study, the same quantity has been used for the measurement of the doses near the eyes. At the end of the measurement campaign, additional dose measurements were performed with an eye lens prototype dosemeter, calibrated in terms of $H_p(3)$. The $H_p(0.07)$ measurements, near the eyes, and the $H_p(3)$ measurements were comparable with mean differences of 15%. The measurement protocol is a two page form with 7 tables to be filled in and is presented in Annex 1.

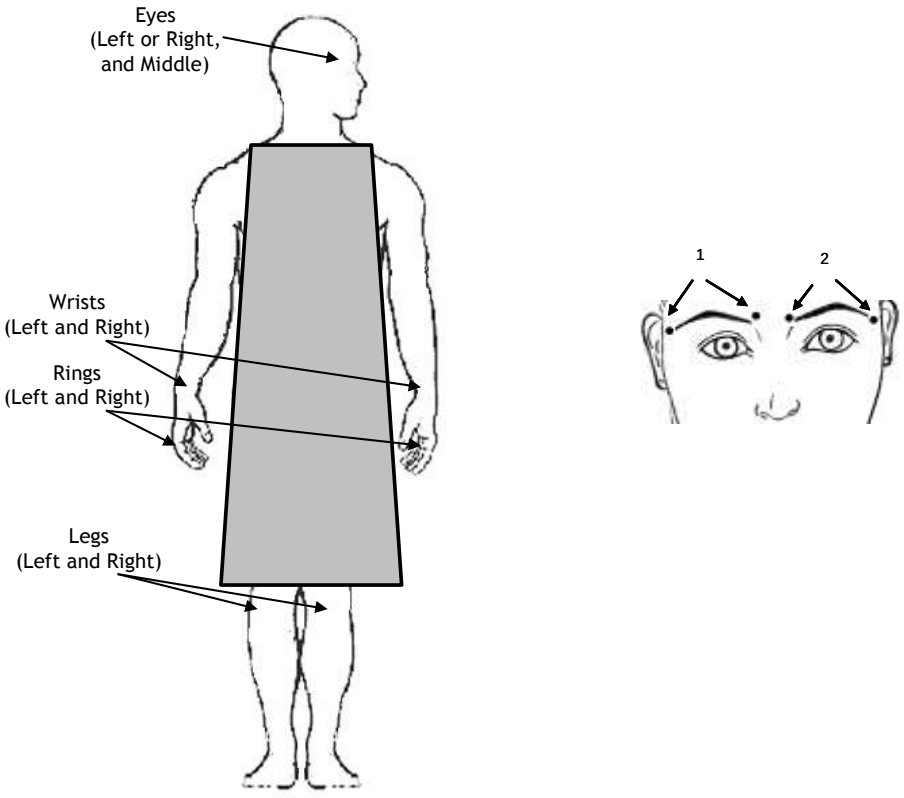


Figure 1.1: The position of the TLDs (eyes, wrists, fingers and legs) on the operator's body

1.2.3 Measurement's database - Methodology for the statistical analysis of the results

The whole series of measurements has been grouped in a database with all the data recorded for each measurement:

- the name of the partner who performed the respective measurements,
- the type of procedure,
- the name of the hospital and worker's ID,
- his/her experience,
- his/her task,
- the access of the catheter,
- the position of the operator according to Figure 1.2,
- the shielding equipment (personal and other shields installed in the room, see Figure 1.3),
- the tube configuration (tube above/below the table or a bi-plane system, see Figure 1.4),
- whether the operator goes out of the room during image acquisitions,
- the dose measurements on fingers, wrists, legs, and eyes (in mSv),
- the KAP values (in µGym2),
- the doses normalised by the respective KAP values and
- some comments.

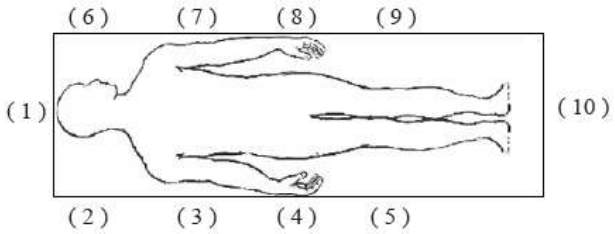


Figure 1.2: The possible operator's positions relatively to the patient's body

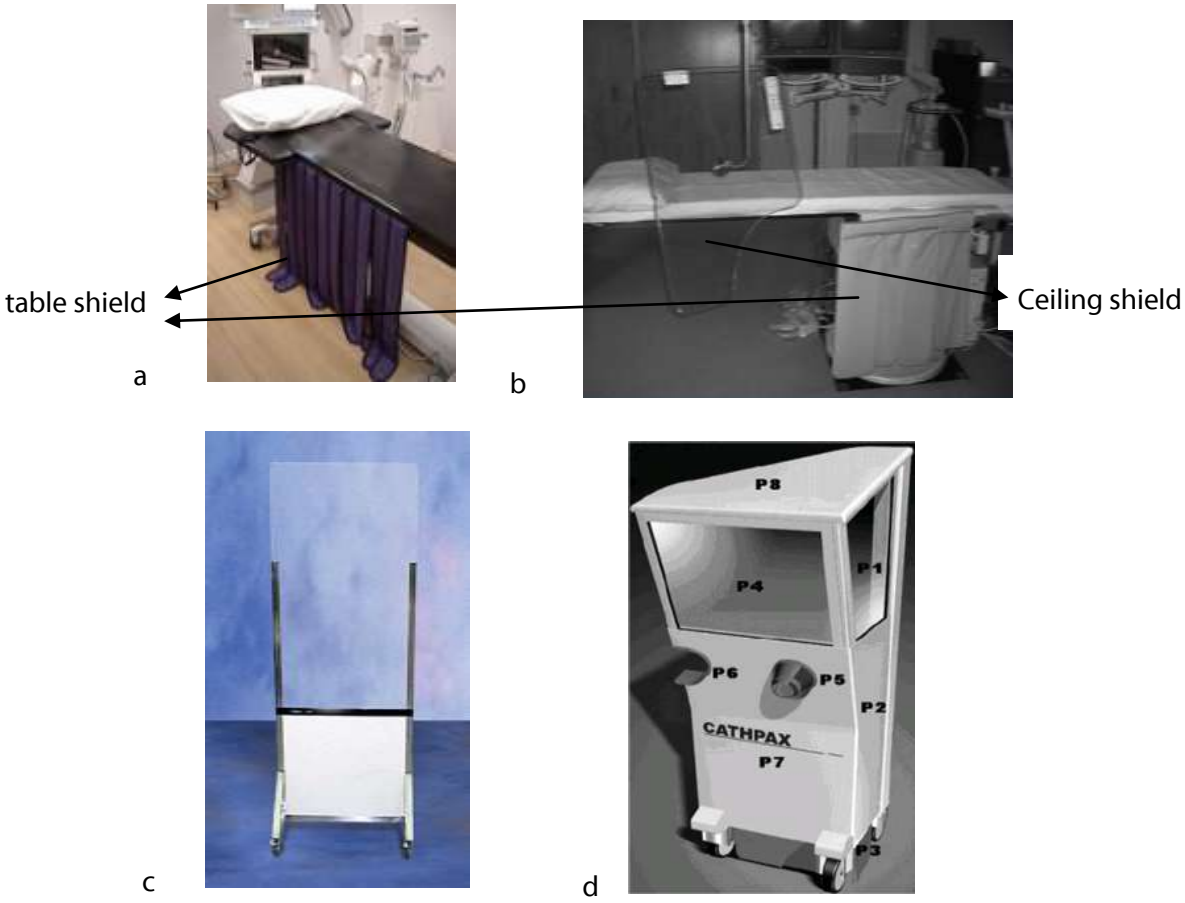


Figure 1.3: Protection equipment in interventional rooms: (a) table shield, (b) ceiling suspended shield, (c) mobile shield and (d) radiation protection cabin

Figure 1.4: (a) Tube below configuration, (b) Tube above configurations and (c) bi-plane configurations

Afirst analysis of the measurements was performed using simple statistics. The measurement results are presented in box plots (presenting minima and maxima, the 1st and 3rd quartile and median and average values). Two-way analysis of variance (ANOVA) tests that measure the effects of two factors simultaneously were used for the study of the parameters that affect the results. The significance levels that were used for testing the null hypotheses were 0.05. The statistical packages used for this purpose were the SPSS and STATISTICA.

For each type of procedure parameters influencing the doses were analyzed: the use of protective equipment (table shield or ceiling suspended shield), X-ray tube configuration (tube above and tube below configurations and bi-plane systems), catheter access route (radial or femoral) and the

use of automatic contrast injector which allows the operator to go outside the room during the image acquisitions.

The analysis was applied on the median values of the doses normalised to the respective KAP values, $H_p(0.07)$/KAP. When the influence of one parameter was investigated the measurement results were compared to cases with similar irradiation conditions. For example, when the effect of the ceiling suspended screen was studied, comparisons were made for the same type of procedure, the same tube configuration (tube below, biplane, tube above) and/or catheter access route (radial or femoral).Conversely, for studying the effect of the tube configuration the shielding conditions of all data includedin the analysiswere similar (with or without ceiling screen, table shield).

Finally, the position of maximum dose was investigated for each procedure. As the annual limit is not the same for the extremities (500 mSv) and for the eyes (150 mSv), a similar analysis has been performed for maximum doses normalised to the respective annual limit.

1.2.4 TLD measurements

Since every partner used its own set of TLDs (of LiF:Mg,Cu,P type) and calibration procedure, to assure that coherent results would be obtained an intercomparison exercise was organized before starting the measurements in the hospitals. Samples of TLDs of each partner contributing in the measurement campaign were irradiated to ^{137}Cs beams and a more realistic X-ray field (70 kV, with a 4.5 mm Al and 0.2 mm Cu filtration) on an ISO slab phantom (ISO, 1999). They were read blindly by each partner using their own calibration procedure, and the response of the TLDs was checked against the conventionally true $H_p(0.07)$ value of the corresponding irradiation. Reference $H_p(0.07)$ values were equal to 8.0 and 6.6 mSv for ^{137}Cs and the 70 kV X-ray field, respectively. For the X-ray field the reference was calculated using Monte Carlo simulations. The range of the relative deviations of dosemeters' responses of all partners was within ±15% and was considered acceptable.

For every measurement in hospital the dosemeters worn by the monitored operator were accompanied by unused ones for subsequent background subtraction. The lower detection limit (LDL) of each partner was evaluated as twice the standard deviation calculated from the set of background dosemeters. LDLs ranged from 4 to 32 μSv, depending on the partner. Any dosemeter reading below the LDL was set equal to the LDL. Finally, for single measurements relative uncertainties were estimated in the range 13% – 20%, depending on the partner, taking into account the following components: calibration, repeatability, homogeneity, and dose, energy and angle responses.

1.2.5 Limitations of the measurement's methodology

The main limitation of the measurement campaign lies in the fact that since real procedures were monitored the different parameters influencing the doses, i.e. time, distance, shielding and intensity and characteristics of the radiation field, varied simultaneously during any single procedure and also between procedures of the same type. This lead to strong interactions in the data analysis, attenuating the effect of some parameters.

Another limitation was the exact knowledge of the use and positioning of the collective protection equipment. In the data base these equipment were marked as either 'used' or 'not used'. However,

it was observed that they were frequently not appropriately positioned, efficiently used only for a fraction of the time or even almost not used at all though available. From the protocol this was not always clear, so the 'partial use' or 'inappropriate use' have been regarded as 'used' in the analysis.

1.3 Simulation campaign

Measurements performed within the ORAMED project helped to define the dose levels to the operators' hands, wrists, legs and eye lenses during several types of IR/IC procedures, and also to determine the parameters that affect the doses. Assessing the influence of each parameter separately is very important in order to provide specific guidelines concerning the radiation protection of the occupationally involved personnel during interventional procedures. However, studying the effect of each parameter separately is only possible using Monte Carlo simulations, as in clinical practice many of those parameters change simultaneously.

1.3.1 Description of the input file

The numerical simulations have been performed using the MCNP-X v.2.5 code (Pelowitz, 2005). MIRD type anthropomorphic models (Snyder, 1978) have been used for simulation of the patient and the operator. The "patient" phantom is in supine position, and the "operator" one is standing next to it (Figure 1.5), in a configuration that is typical for an IR/IC procedure. The original model of the "operator" phantom was modified in order to represent more realistically the irradiation scenario: eyes have been added, the arms have been redefined and the forearms and the hands are bent in a more realistic position. A thyroid collar and a lead apron of 0.5 mm Pb in front of the body have also been added. Finally, a cell filled with air representing the KAP chamber and an image intensifier (II) have been added to the input file.

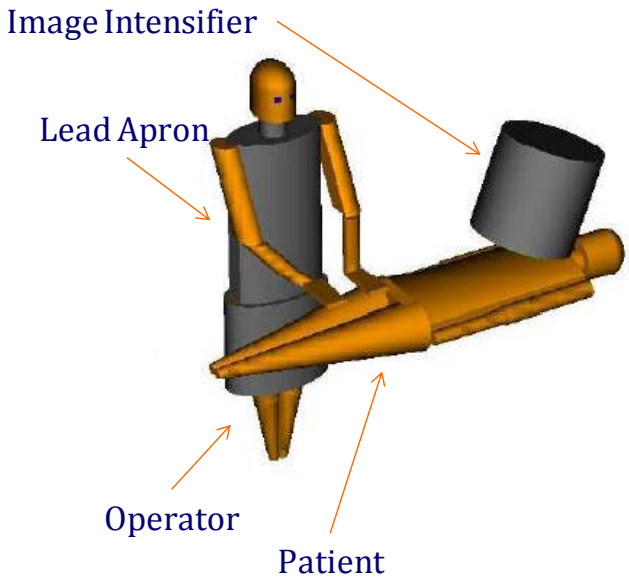


Figure 1.5: The anthropomorphic phantoms as patient and operator. The hands of the operator have been added and are bent above the patient. A lead apron and thyroid collar are added. The image intensifier is also shown above the patient phantom

MCNP-X related F6 tallies (absorbed dose in a volume) were used for the calculation of the doses to the eye lenses, hands, wrists and legs. The tally volumes were positioned at 0.07 mm and at 3 mm depth for the calculation of $H_p(0.07)$ and $H_p(3)$ respectively. It should be mentioned that, within MCNP-X v.2.5, the f6 tally is a dose estimator that can be employed in the photon energy range and situations in which kerma approximation is valid i.e. when the equilibrium of secondary charged particles (electrons in this case) is guaranteed, which is the case of the present calculations. For the determination of the KAP values the f2 tally (particle fluence through a surface) was chosen. This tally calculates the photon fluence through the front surface of the KAP cell volume. To determine the air kerma in the KAP chamber, the f2 tally is folded with the air kerma per unit fluence coefficients taken from ICRU 57 report (ICRU 1998).

1.3.2 Geometry characteristics

The X-ray tube was simplified to a point source. The energy spectra for the selected kV_p and filtrations were determined using the X-ray data of the Institute of Physics and Engineering in Medicine (IPEM), Report 78 (Cranley et al., 1997). Moreover, the lead collimator was not simulated explicitly, but defined as a volume killing all the photons (not further simulated) entering inside it.

The first parameters examined within the simulation campaign are the tube voltage and the filtration. More specifically, the tube voltage was changed from 60 to 110 kV_p, and the filtrations from 3 to 6 mm Al and from 0 to 0.9 mm Cu.

Also a range of beam projections were considered in the simulation campaign:

- Anterior Posterior (AP) and Postero-Anterior (PA),
- Left Anterior Oblique (LAO) and Right Anterior Oblique (RAO) at angles of 30°, 60° and, 90°
- Caudal (CAU) and Cranial (CRA) projections at 20° and 40°

Several combinations of these beam projections are considered as observed in clinical practice (see figure 1.6).

The irradiation of the patient was simulated for 4 parts of the body: head/neck, thorax, abdomen/pelvis and lower limbs.

The X-ray field size at the II is changed from a diameter of 14 to 40 cm, depending on the part of the body that is considered to be irradiated.

Different positions of the operator were considered, representing for example femoral or radial access for which the operator is positioned at the groin level or the arm level of the patient, respectively.

The influence of protective lead glasses for the operator was investigated by performing simulations in the following situations:

- no glasses,
- lead glasses of 0.5 mm and 1 mm Pb equivalent thickness
- different sizes/diameters for the glasses.

The influence of the collective protective equipment in the room was evaluated by simulating the table shield and ceiling suspended shield in different positions and shapes.

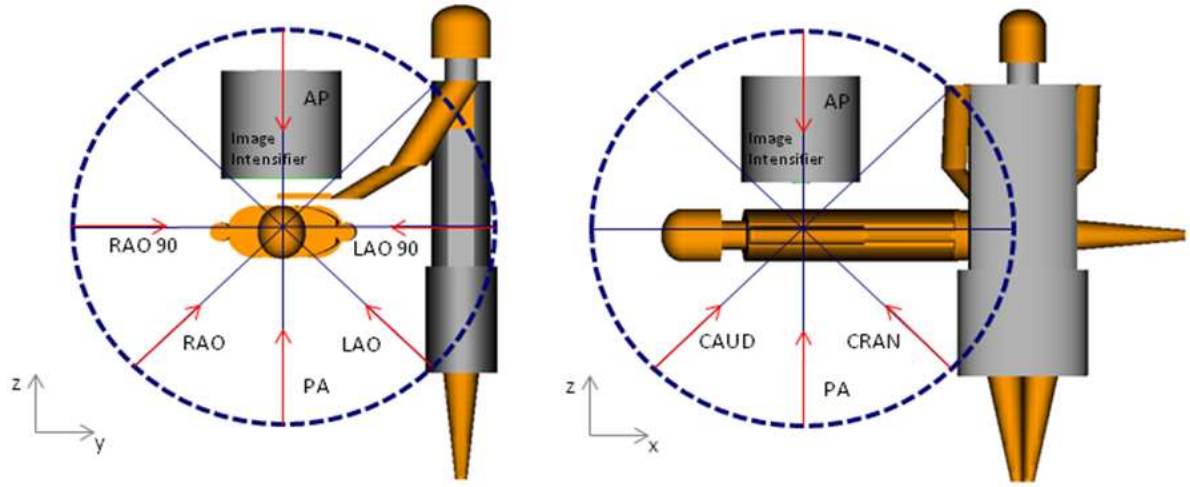


Figure 1.6: The various beam projections used at the simulation campaign

1.3.3 Sensitivity study

The number of simulations and computing time increased to an unrealistic level when trying to include all these parameters one by one. Therefore, it was decided to investigate the influence of the beam energy with a simplified geometry, where the patient is simulated by a slab or a cylindrical phantom depending on the irradiated part of the body, and no phantom for the operator is included. More specifically, for the head and neck irradiations, a head phantom is used (a PMMA cylinder of 20 cm diameter and 20 cm height, filled with water); for the lower limbs and abdomen irradiations the ISO 4037(ISO, 1999) slab phantom is used and for the thorax irradiations a lung phantom is used (a PMMA slab with outside dimensions of 20x20x14 cm^3 and 15x15x12 cm^3 tissue insert). The difference in extremity and eye lens doses for different energy beams is assessed on realistic positions around the patient phantom. The tube voltage is changed from 60 to 110 kV_p, filtration from 3 to 6 mm Al and from 0 to 0.9 mm Cu. Using this setup, the tally values (at eyes, wrists, hands and legs) were calculated, using the f5 tally instead of the f6 that was used in the detailed geometry. Unlike the f2 and f6 tallies, the f5 does not require a particle to reach the detection location for scoring, but it scores at every collision the probability that the next event will reach the detector site. Thepositions for scoring (tally detectors) in this simplified set-up are shown relative to the geometry of the detailed input file in Figure 1.7.

It is obvious that when the operator is standing at the femur of the patient, the distance between the X-ray beam and the operator is larger for head and neck irradiations, than it is for the abdomen irradiations. This was taken into account when the tally positions were defined for the simplified geometries.

Finally, it is noted that for normalisation purposes, every result is divided by the dose in the air cell at the entrance of the II and not at the KAP chamber. Since the MCNP results are normalised to the number of photons emitted by the source, the tally values normalised to the KAP ones would not have taken into account the differences in the scattered field. Real angiographic systems use the

Automatic Exposure Control (AEC), which means that tube voltage (kVp), tube load (mAs), filters, etc. all change automatically depending on the patient thickness, the projection, the chosen protocol, in a such way that a constant dose at the detector is maintained.

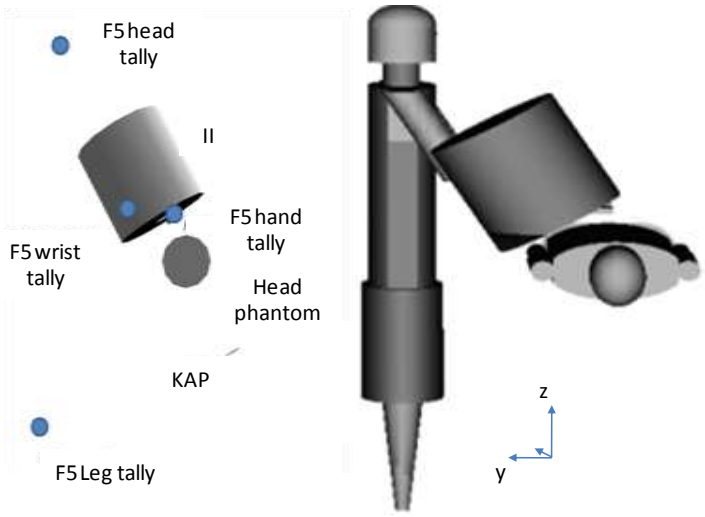


Figure 1.7: The MCNP-X geometry of the simplified (left) and detailed(right) simulations

1.3.4 Validation methodology

In order to validate the numerical methodology described in the previous paragraph, a series of measurements in the primary and scattered beam were performed and compared with the results of similar simulations.

The measurements were performed by two partners, GAEC and SCK.

1.3.4.1 GAEC measurements

The irradiations in laboratory conditions were performed at the Secondary Standard Dosimetry Laboratory at GAEC. The irradiations were performed using a PANTAK X-ray tube with an RQR5 (70 kV) beam. For the measurements a spherical A3 Exradin chamber was positioned once in the primary beam at 1 m from the source (without slab phantom), and then in the scattered beam on the side of the slab phantom, representing the operator's position. The irradiations in hospital conditions were performed on a C-arm angiographic system. 5 TLDs taped on Styrofoam were positioned at a distance of 10 cm from a 30x30x20 cm^3 PMMA phantom.

Both of the above setups were simulated using the MCNP-X v.2.5 code. The results of the measurements and the simulations, all normalized per KAP, were in quite good agreement. The discrepancies between simulation results and measurements were less than 5%.

1.3.4.2 SCK measurements

The laboratory measurements were performed at the nuclear calibration laboratory at SCK•CEN. A source beam spectrum of 60 kVp ; 4 mm Al and 0.6 mm Cu (ISO N-60) was used. A PMMA slab phantom to represent the patient was positioned at 1 m from the focal spot. Measurements were performed with an ionization chamber (Farmer, 600 cc) and with TLDs. The measurements in the scattered field were performed at 15 cm from the slab phantom. Monte-Carlo calculations were performed with the MCNP-X code, for which the same geometry of the measurements is applied.

The comparison showed that the measurements and the simulations were in agreement better than 4%.

Moreover measurements were performed in hospital conditions. A source beam spectrum of 70 kVp, 4.5 mm Al and 0.1 mm Cu was used. A PMMA slab phantom to represent the patient was positioned on the patient support table at 45.7 cm from the focal spot. The tube was positioned under the patient support table. The measurements were performed using TLDs. The measurements in the scattered field were performed at 15 cm from the slab phantom. For the simulation the MCNP-X code was used. The comparison showed again good agreement between the measurements and simulations (differences less than 9%).

1.4 Results

1.4.1 Measurements

1.4.1.1 Generalities

In the following Figures (1.8,1.9 and 1.10) the frequency of the observed use of personal and room protective equipment, the access of the catheter, the tube configuration and the use of the automatic contrast injector (leaving the room during cine acquisition) are shown for IR, IC and ERCP procedures, respectively. As it can be seen from the pie charts the majority of the operators wear a protective apron and thyroid collar. Only 2% of the operators in IR do not use any personal protective equipment. Protective eye glasses are used in around 30-35% in the IR and IC procedures, but only 6% use them in ERCP procedures. Only a very small fraction (2%) of the operators in IR uses protective gloves. The small percentage is mainly due to the fact that the gloves are not so comfortable.

For the room protective equipment, it is noted that there is a percentage of 24% to 46% who does not use any room protective equipment, with the highest fraction for the ERCP procedures. As it can be seen from the pie charts the table shield is used more often than the ceiling suspended shield. The table shield is used in the majority of the cases that were monitored. Special protective equipment like a radiation protection cabin and a floor movable shield were observed in a few cases.

As far as the tube configuration is concerned, the cases with the X-ray tube below the operating table are used most frequent, in almost 90% of the IR/IC procedures. There were cases where biplane systems are used (from 4% in IR to 8 % in IC). For the ERCP procedures, it is noted that there is a large percentage of cases (46%) where the X-ray tube is positioned above the operating table.

From the pie charts it is seen that the femoral access is preferred over the radial one, especially in the IR sector. For the ERCP procedures, the access of the endoscope and the catheter for contrast injection is always done through the mouth of the patient.

Finally, we observed that the automatic contrast injector system is mainly used at IR procedures. Almost 50% leaves occasionally or always the room during image acquisition.

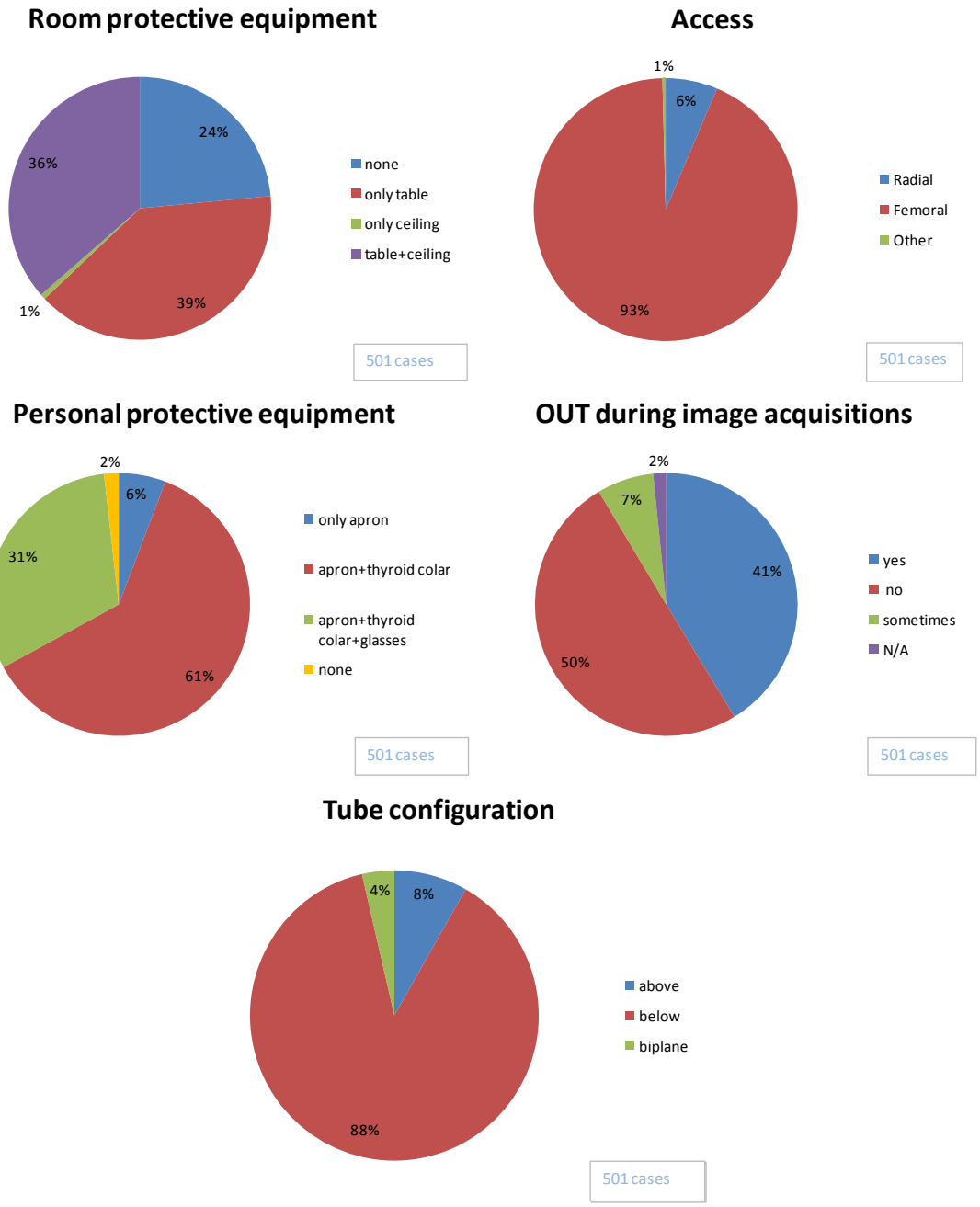


Figure 1.8: Statistics in interventional radiology about the use of the room and personal protective equipment, tube configuration, access, and use of automatic contrast injector (operator goes outside the room during the image acquisitions)

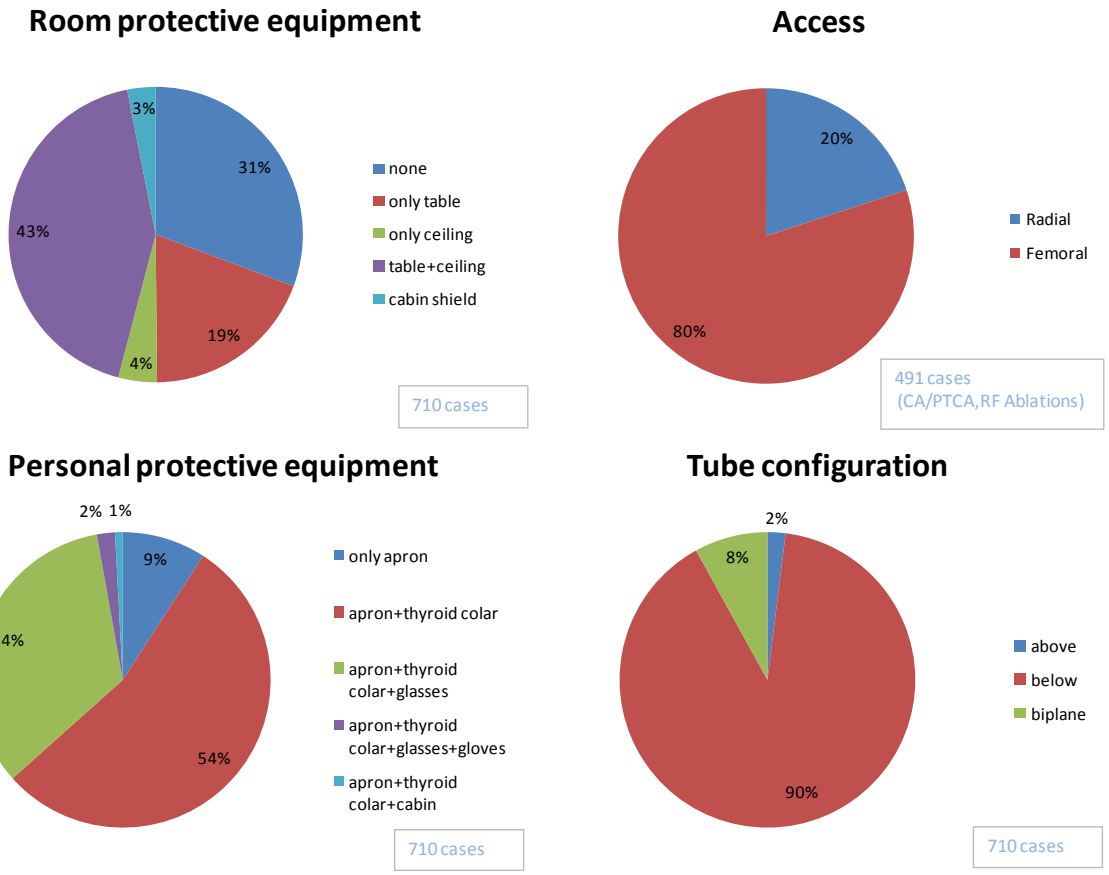


Figure 1.9: Statistics in interventional cardiology about the use of the room and personal protective equipment, tube configuration and access

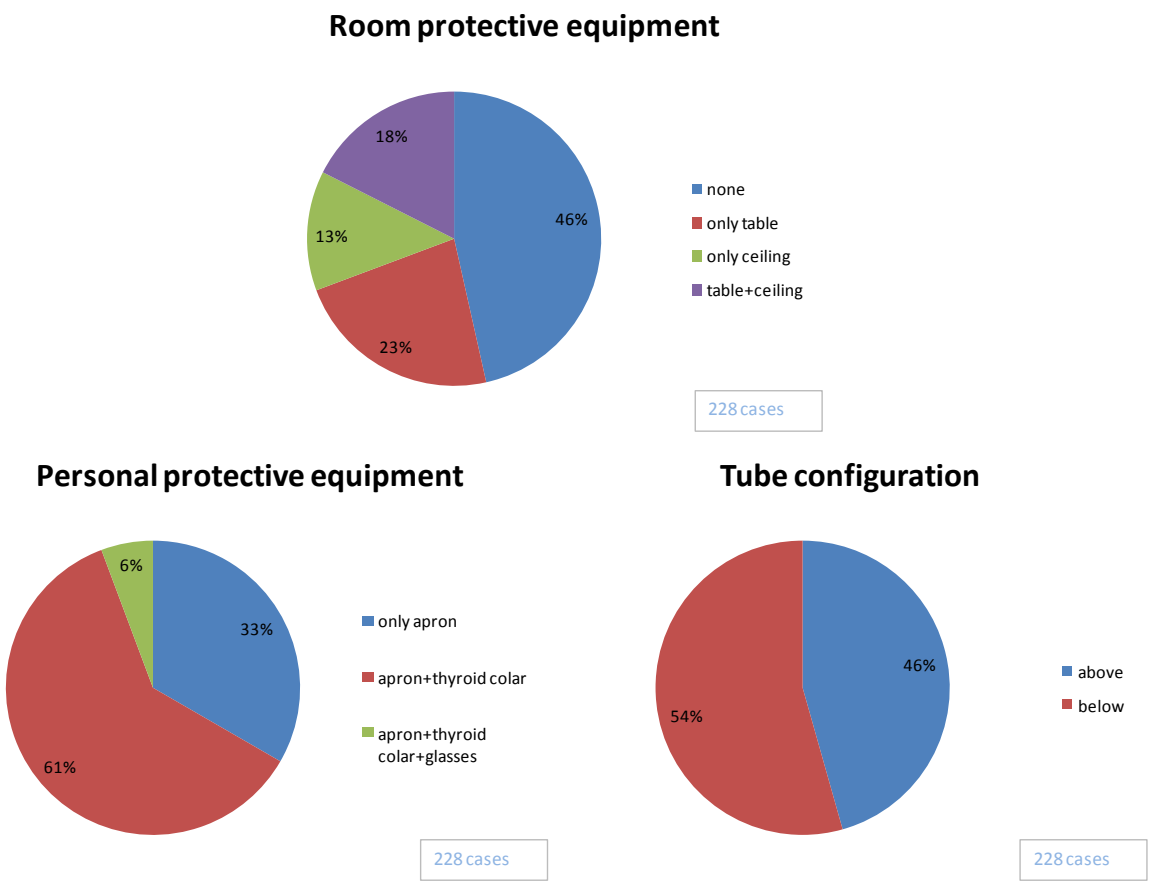


Figure 1.10: Statistics in ERCP procedures about the use of the room and personal protective equipment and tube configuration

In Figure 1.11 a box plot of the recorded KAP values for the studied procedures is presented. It is clearly seen that for embolisation and PTA procedures the highest KAP values were recorded, while the lowest were observed for ERCP. In general, the cardiology procedures have lower KAP values compared to the radiology procedures. For PM/ICD and RF ablations mainly fluoroscopy is used and much less images are acquired compared to the radiology procedures. The same accounts for the ERCP procedures.

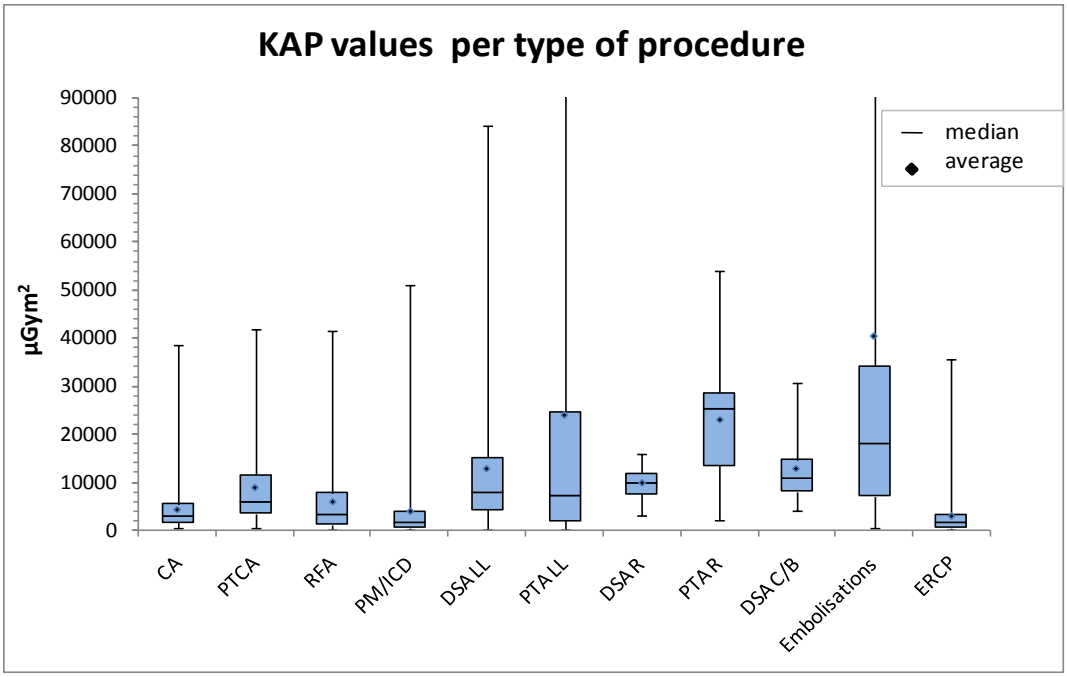


Figure 1.11: KAP values for all IR procedures

µGym²	CA	PTCA	RFA	PM/ICD	DSA LL	PTA LL	DSA R	PTA R	DSA C/B	Embolisations	ERCP
minimum	432	470	92	13	169	176	2928	2071	3920	370	35
1st quartile	1665	3350	1165	445	4192	1866	7471	13394	7950	7119	504
median	2777	5669	3026	1364	7818	7236	9896	25340	10750	18113	1516
3rd quartile	5385	11507	7698	3922	15138	24653	11860	28662	14524	34120	3179
maximum	38409	41966	41500	50980	84205	256025	15840	53952	30690	358110	35673
average	4283	8878	5861	3801	12712	23805	9718	22968	12598	40378	2832

1.4.1.2 Measured Dose values

In Tables 1.2, 1.3 and 1.4 the minimum, 1st quartile, median, 3rd quartile, maximum and average values of $H_p(0.07)$ at the various monitored positions are presented for the three types of categories (IR, IC and ERCP). Among the IR procedures special attention should be paid to embolisations, particularly to the doses to the eye lenses. Operators are also significantly exposed during therapeutic procedures such as angioplasties of the lower limbs and the renal arteries. During cerebral and carotid procedures the doses are relatively low since femoral access is usually used and the operator stands at a larger distance from the irradiated part of the patient's body compared to other procedures performed in the thoracic or abdominal region.

In general, an average dose to the left hand for the DSA/PTA of the lower limbs is obtained around 240 µSv, for the embolisations around 320 µSv and for the cerebral DSA/PTA procedures around 60 µSv. Average eye doses for the DSA/PTA procedures are around 40 µSv, but for the embolisations around 120 µSv. Average doses to the left leg are of the order of 60 µSv. Among the cardiac

procedures that were included in the measurement campaign, the doses to the operators are higher during the pacemakers and implantation of cardiac defibrillators, even though the respective KAP values are relatively low since only fluoroscopy is used. During these procedures the operators work very close to the irradiation field and most of the time without any protective shielding. Average doses of 410 μSv have been recorded for the left finger for the PM/ICD, while for the CA/PTCA and RFA the respective values are 180 μSv and 60 μSv. For the eyes, the average doses lie within the range 40 and 60 μSv. Finally, the leg doses are a little bit higher, 160 to 250 μSv.

Finally, for ERCP procedures the doses are generally low. Average doses for the monitored positions lie within the range [50-110] μSv.

Table 1.2: The minimum, 1st quartile, median, 3rd quartile, maximum and average values of $H_p(0.07)$) and the mean $H_p(0.07)$/KAPat the various monitored positions are presented for the monitored IR procedures

DSA PTA LL								
µSv	L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	Middle Eye
minimum	8	8	8	8	4	4	8	8
1st quartile	27	17	19	16	13	13	11	12
median	73	32	58	35	25	24	20	18
3rd quartile	275	127	167	90	57	58	55	39
maximum	4017	857	2178	865	828	902	664	354
average	242	105	166	91	70	64	52	37
meanµSv $Gy^{-1}cm^{-2}$	36.4	15.2	2.5	10.1	3.0	5.2	4.6	1.0
DSA/PTA C/B								
µSv	L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	Middle Eye
minimum	8	8	8	8	8	8	8	5
1st quartile	18	13	25	17	18	13	18	13
median	19	18	46	30	23	20	24	18
3rd quartile	92	21	79	56	33	24	50	22
maximum	377	98	353	115	226	370	276	167
average	60	27	68	38	35	31	48	28
meanµSv $Gy^{-1}cm^{-2}$	1.6	0.9	1.1	0.7	1.0	0.8	0.6	0.4
DSA/PTA Renal								
µSv	L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	Middle Eye
minimum	8	8	8	8	0	4	8	8
1st quartile	20	13	25	13	19	13	13	12
median	84	45	81	50	49	35	24	18
3rd quartile	170	111	203	143	167	72	51	36
maximum	1470	514	1036	715	2342	470	595	533
average	190	80	150	108	218	78	57	42
meanµSv $Gy^{-1}cm^{-2}$	2.5	1.1	1.8	1.3	2.5	1.6	0.5	0.4
Embolisations								
µSv	L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	Middle Eye
minimum	8	6	6	4	4	4	8	8
1st quartile	28	18	39	20	9	8	32	18
median	82	41	88	49	31	26	80	43
3rd quartile	266	86	281	109	91	63	180	116
maximum	7325	912	9506	780	7822	1741	2441	1224
average	318	90	359	100	202	87	193	116
meanµSv $Gy^{-1}cm^{-2}$	5.1	1.2	3.6	1.1	1.1	1.0	2.3	1.3

Table 1.3: The minimum, 1st quartile, median, 3rd quartile, maximum and average values of $H_p(0.07)$ and the mean $H_p(0.07)$/KAP at the various monitored positions are presented for the monitored IC procedures

CA/PTCA								
µSv	L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	Middle Eye
minimum	8	8	8	8	6	4	4	4
1st quartile	29	18	32	22	16	13	17	13
median	66	32	83	47	37	29	32	23
3rd quartile	154	63	192	82	191	59	54	42
maximum	5000	503	1775	579	1567	1232	820	644
average	176	57	163	70	163	62	52	42
mean µSv $Gy^{-1}cm^{-2}$	3.3	1.3	3.4	1.6	3.0	1.2	1.0	0.8
RFA								
µSv	L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	Middle Eye
minimum	5	4	4	4	5	4	4	4
1st quartile	10	8	24	12	13	8	8	8
median	28	17	53	29	33	31	18	16
3rd quartile	57	32	137	58	156	57	39	32
maximum	896	446	1838	880	1819	780	880	633
average	59	34	124	56	159	55	44	30
mean µSv $Gy^{-1}cm^{-2}$	2.3	1.6	3.8	2.4	3.8	2.0	1.6	1.8
PM/ICD								
µSv	L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	Middle Eye
minimum	5	8	4	4	4	4	4	4
1st quartile	60	34	32	32	20	18	8	8
median	167	106	99	83	67	64	29	22
3rd quartile	405	278	234	219	233	258	62	61
maximum	6564	4328	4852	3825	4996	4046	1083	810
average	418	281	309	237	250	241	60	51
mean µSv $Gy^{-1}cm^{-2}$	22.9	17.4	15.3	14.8	12.9	13.0	5.5	5.5

Table 1.4: The minimum, 1st quartile, median, 3rd quartile, maximum and average values of $H_p(0.07)$) and the mean $H_p(0.07)$/KAP at the various monitored positions are presented for the ERCP procedures

	ERCP							
µSv	L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	Middle Eye
minimum	8	8	8	8	8	8	8	8
1st quartile	8	8	8	8	8	8	8	8
median	20	23	24	23	18	18	18	18
3rd quartile	32	40	45	32	32	32	40	32
maximum	1983	916	828	1317	3717	2784	4072	3166
average	89	58	66	56	89	59	146	102
meanµSv $Gy^{-1}cm^{-2}$								

1.4.1.3 Effect of the collective protective equipment

In this section the effect of the protective equipment to the doses of the eyes, hands and legs is studied.

1.4.1.3.1 Effect of ceiling suspended shield

The overall database of measured eye doses demonstrates a reduction of the eye dose from a factor 2 to 7 with a ceiling suspended shield. The reduction is higher in cases where the X-ray tube is placed above the operating table. In Table 1.5 the reduction ratios as they are calculated from the median normalised doses are shown for their effect on the eye doses. Moreover, the ceiling suspended shield can also have an effect for the doses to the hands (fingers and wrists). The reduction ratios for the different procedures vary from 1.3 to 19 and from 1.3 to 13, for the fingers and wrists respectively. The highest effect of the ceiling suspended shield to the hands is observed for the embolisation procedures. In Tables 1.6 and Table 1.7 the reduction ratios, as they are calculated from the median normalised doses, are shown for their effect on the finger and wrist doses respectively.

Table 1.5: Reduction ratios (without/with ceiling suspended shield) of the median values of personal dose equivalent $H_p(0.07)$ measured at the eyes per the respective KAP values

	Reduction ratio: median $H_p(0.07)/KAP_{without\ shield}$/ $H_p(0.07)/KAP_{with\ shield}$	
Procedure:	Left/Right Eye	Middle Eye
CA/PTCA[a]	1.6	2.3
DSA PTA Re	3.0	2.8
Embolisations	7.4	2.5
ERCP	1.7	2.2

[a] For cases where the tube was positioned below the operating table and radial artery access was used

Table 1.6: Reduction ratios (without/with ceiling suspended shield) of the median values of personal dose equivalent $H_p(0.07)$ measured at the fingers per the respective KAP values

	Reduction ratio: median $H_p(0.07)/KAP_{without\ shield}$/ $H_p(0.07)/KAP_{with\ shield}$	
Procedure:	Left Finger	Right Finger
CA/PTCA[a]	1.3	1.6
DSA PTA Re	2.2	1.0
Embolisations	19.3	3.8
ERCP	1.9	1.8

[a] For cases where the tube was positioned below the operating table and radial artery access was used

Table 1.7: Reduction ratios (without/with ceiling suspended shield) of the median values of personal dose equivalent $H_p(0.07)$ measured at the wrist per the respective KAP values

	Reduction ratio: median $H_p(0.07)/KAP_{without\ shield}$/ $H_p(0.07)/KAP_{with\ shield}$	
Procedure:	Left Wrist	Right Wrist
CA/PTCA[a]	1.7	1.3
DSA PTA Re	2.5	1.0
Embolisations	13.0	2.5
ERCP	2.5	1.0

[a] For cases where the tube was positioned below the operating table and radial artery access was used

For CA/PTCA procedures there is a statistically significant effect of the ceiling suspended shield on median normalised doses to fingers, wrists and eyes only for the radial access and tube below the table setup: finger and wrist normalised doses are reduced by a factor of 1.3 to 1.6 and 1.3 to 1.7, respectively. The median normalised eye doses are reduced by a factor of 1.6 and 2.3 at the left and middle positions, respectively when a ceiling suspended shield is used for the aforementioned setups (Figure 1.12).

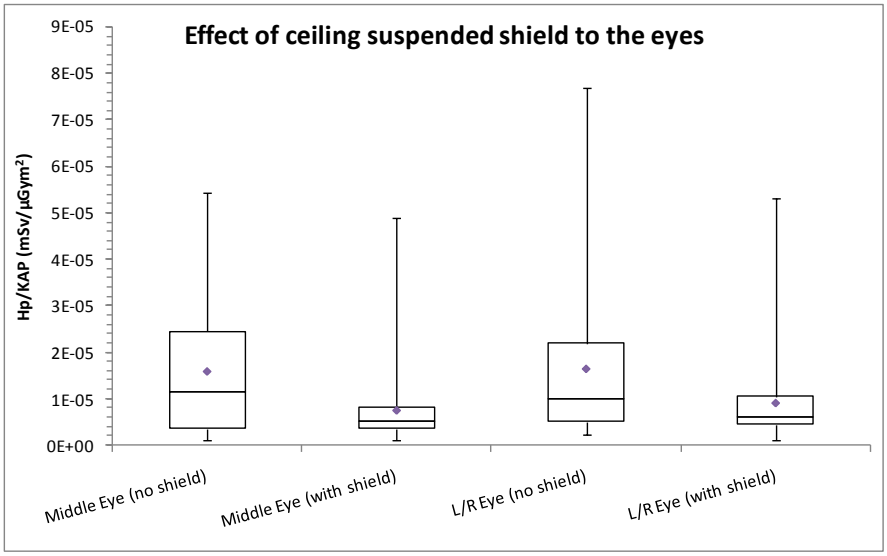


Figure 1.12: Box plot of the eye doses measured for CA/PTCA procedures when radial access was used showing the effect of the ceiling suspended shield

For RFA procedures and tube below configuration no statistically significant effect of the ceiling suspended screen on the normalised doses to fingers, wrists and eyes is observed.

For PM/ICD, no significant effects of the ceiling suspended shields are observed for the doses to fingers, wrists and eyes. This can be explained by the fact that the hands are very close to the primary beam during PM/ICD implantations and even when the ceiling shield is used the hands are not protected (see Figure 1.13). Concerning the eyesit could be due to the image intensifier which provides significant protection when positioned correctly, that is as close to the patient as possible.

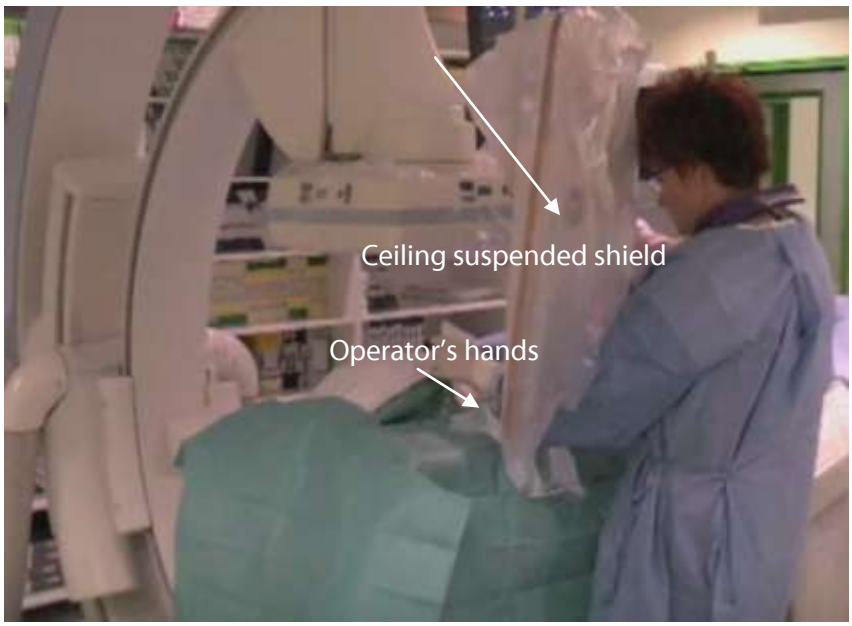


Figure 1.13: Operator's hands close to the irradiation field, not protected by the ceiling suspended shield

For all the IR procedures the effect of room protective equipment on the hand and eye normalised doses is clear. The calculated reduction ratios are 2.3 for the right finger and 1.9 for the left finger (Figure 1.14). For the eyes the reduction ratios range from 1.3-to 1.6 (Figure 1.15).

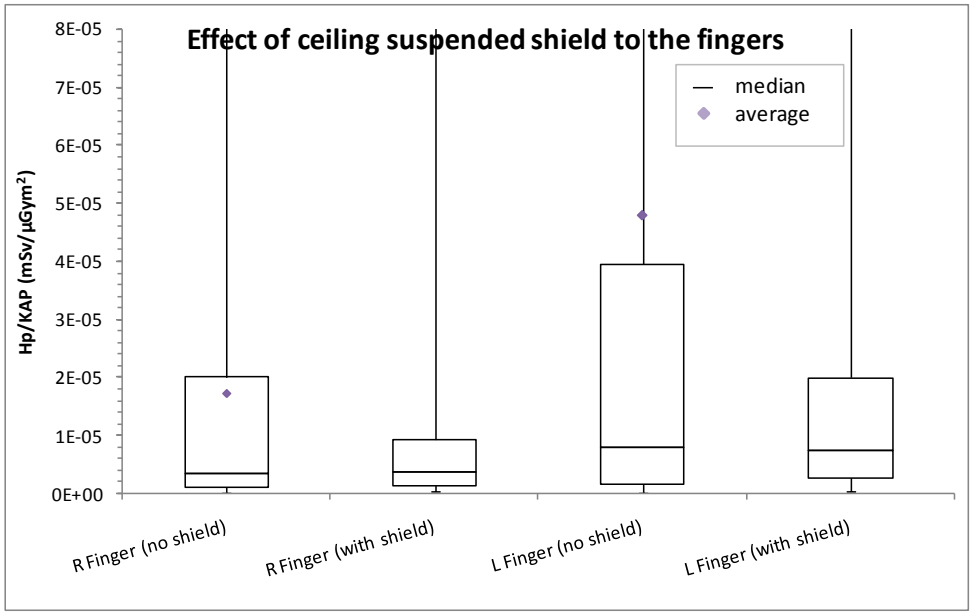


Figure 1.14: Box plot of the finger doses measured for IR procedures showing the effect of the ceiling suspended shield

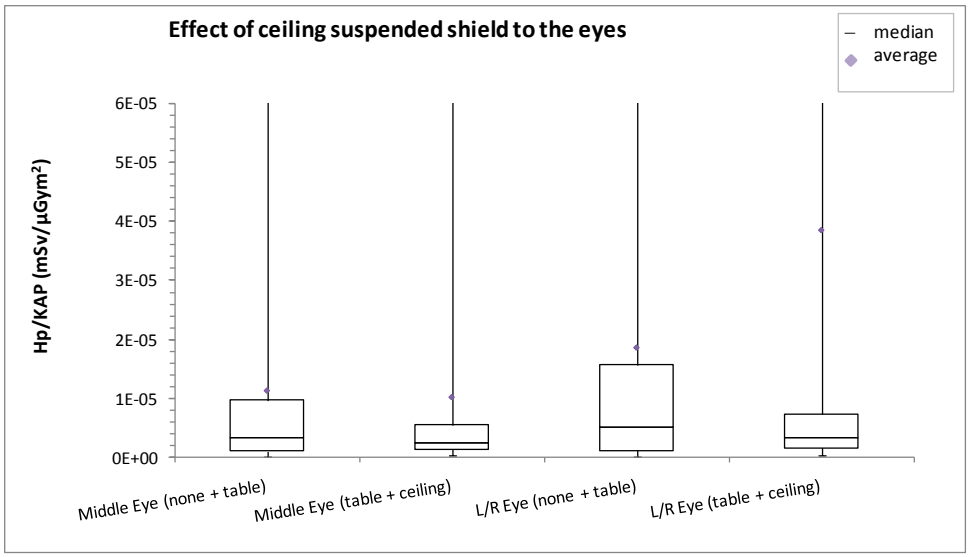


Figure 1.15: Box plot of the eye lens doses measured for IR procedures showing the effect of the ceiling suspended shield

1.4.1.3.2 Effect of table shield

The proper use of the table shield can reduce the doses to the legs from 2 to 7 times. A typical table shield is of 0.5 mm Pb equivalency. In Table 1.8 the reduction ratios are shown for the various

procedures that were monitored. The range of the reduction ratios that is observed is due to fact that the table shield is usually fixed in one position on the table, however the operators' position as well as the beam orientation usually change during the procedures.Also there is a big influence whether the tube is above or below the table.

More specifically, for CA/PTCA procedures a significant effect on the normalised leg doses is observed when the table shield is used for femoral access and tube below setup only, with a reduction factor of 3.5 and 1.3 for left and right leg, respectively. Also, for RFA a significant effect of the table shield on leg doses is shown, with a reduction factor of 4 and 1.9 for left and right sides, respectively. Finally, for PM/ICD with tube below configurations the table shield reduces doses to legs by a factor of 1.4 and 1.6 for left and right sides, respectively (Figure 1.16).

For the legs in the IR field a significant effect of the table shield is also observed. The leg doses are reduced 4.5 and 6.8 times for the right and left leg respectively when table shield is used (Figure 1.17).

Table 1.8: Reduction ratios (without/with table shield) of the median values of personal dose equivalent $H_p(0.07)$ measured at the legs per the respective KAP values

	Reduction ratio median $H_p(0.07)/KAP_{without\ shield}$/ $H_p(0.07)/KAP_{with\ shield}$	
Procedure:	Left Leg	Right Leg
CA/PTCA[a]	3.5	1.3
RF Ablations	4.0	1.9
PM/ICDs	1.4	1.6
DSA PTA Re	5	2.1
DSA PTA LL	1.1	1.4
Embolisations	2.1	1.5
ERCP	1.8	1.8

[a]For cases where the tube was positioned below the operating table and radial artery access was used

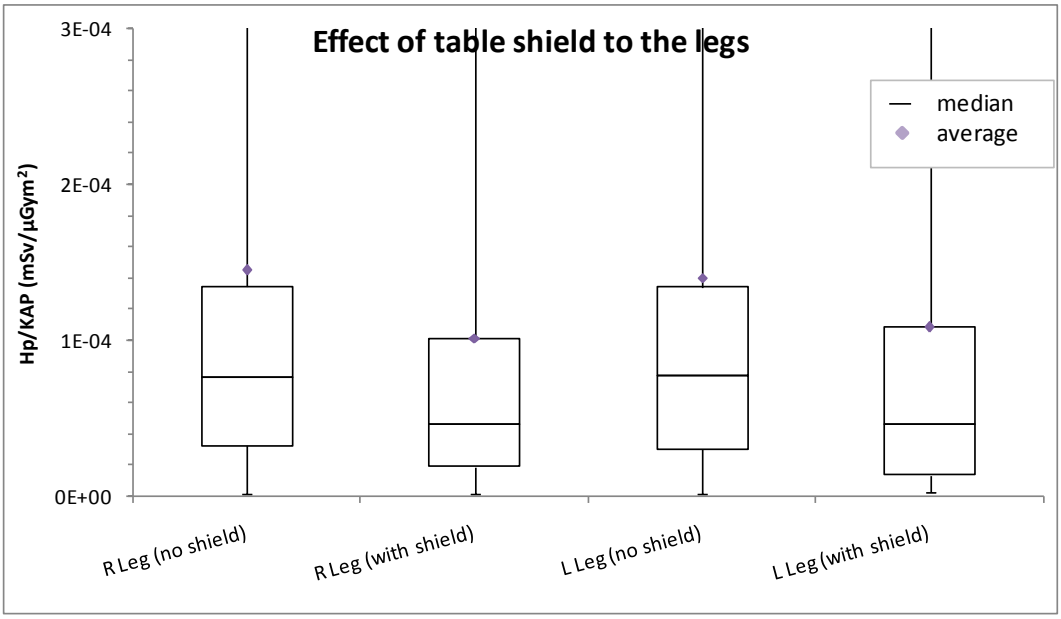


Figure 1.16: Box plot of the leg doses measured for PM/ICD procedures showing the effect of the table shield (ZOOM graph)

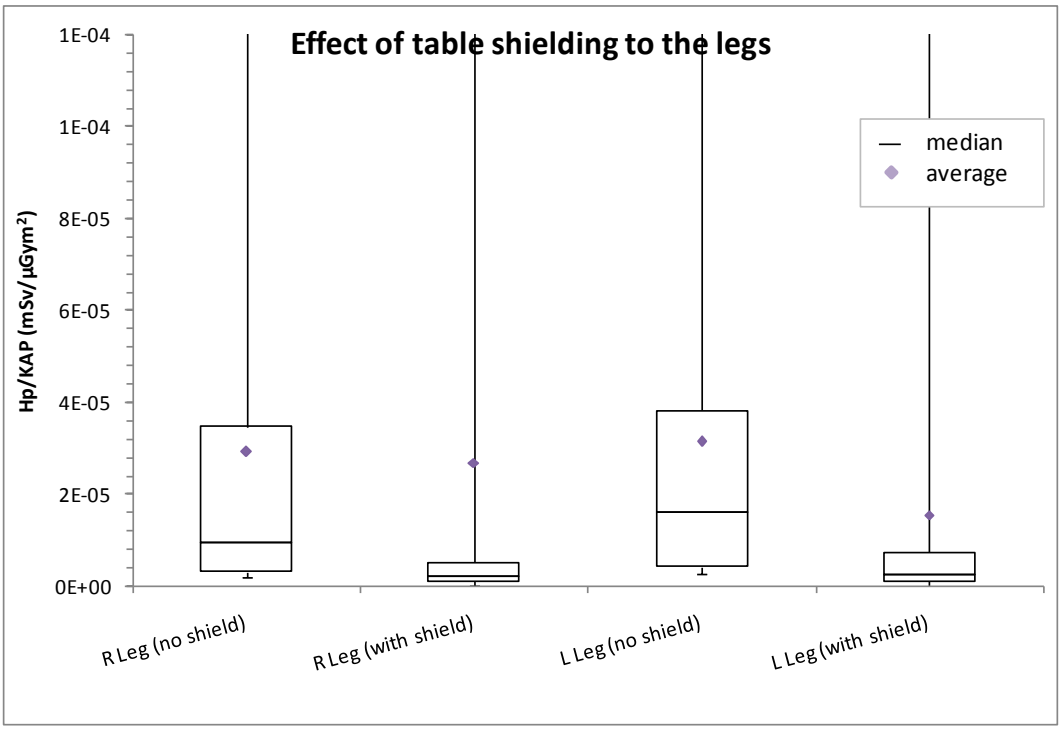


Figure 1.17: Box plot of the leg doses measured for the various IR procedures showing the effect of the table shield (ZOOM graph)

1.4.1.4 Effect of the X-ray tube configuration

From the measurement campaign it was observed that when the X-ray tube is placed below the operating table the doses to the eyes and to the hands are 2-27 times and 2-50 times lower, respectively, compared to above the table configurations. However, the doses to the legs are higher in these cases. The ratios that show the increase in the leg doses when the tube is positioned below the operating table vary from 1.5 to 10. This effect can be compensated by the use of a properly positioned table shield as it was discussed in paragraph 1.4.1.3.2. In many cases biplane systems were used for CA/PTCA, RFA and embolisation procedures. Hand doses are higher for bi-plane systems compared to the tube below configurations.

More specifically, for CA/PTCA procedures the effect of tube configuration was studied only for two cases: tube below the table and biplane systems.The other parameters that could affect the doses were similar: femoral access and ceiling and table shields were used in all cases. The finger and wrist normalised doses are statistically similar between biplane systems and tube below configurations. In the biplane cases the normalized eye doses are lower than in tube below cases, by a factor 0.3 to 0.5 (see Figure1.18). In these cases the eyes were either very well protected by the ceiling or lateral suspended shield or they were protected by the image intensifier of the lateral X-ray tube of the biplane system.

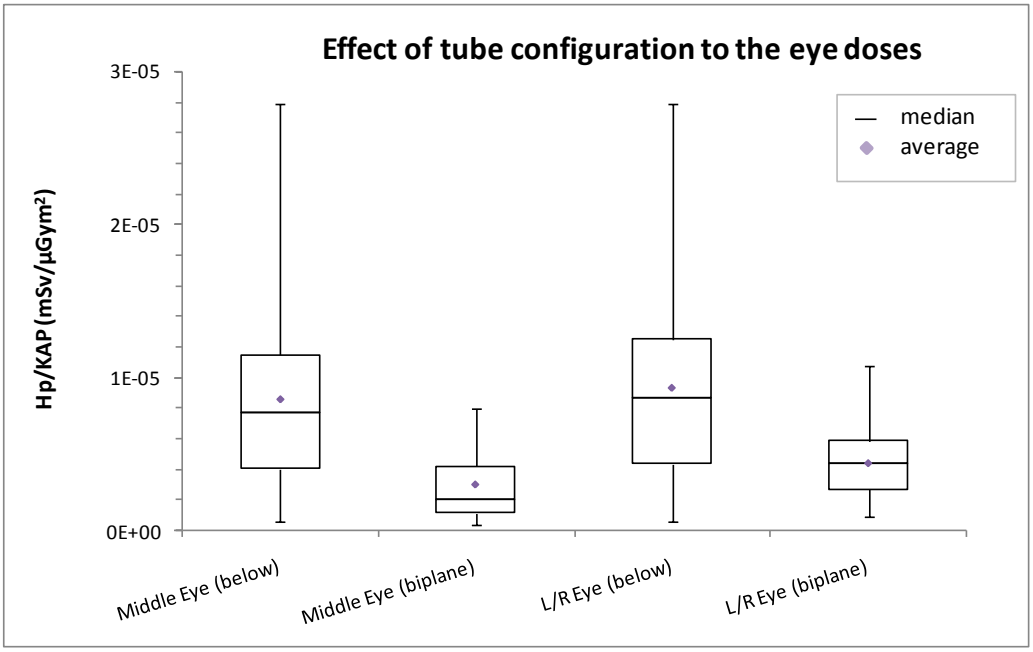


Figure 1.18: Box plot of the eye doses measured for CA/PTCA procedures showing the effect of the tube configuration

For RFA with only considering the shielded cases finger and wrist normalised doses were 1.9 and 1.7 times higher in biplane than in tube below configurations, respectively. The situation is reverted for the eyes, and the observations are explained by the improper use of the ceiling shields.

It has to be noticed that although biplane systems resulted in lower normalized doses to the eyes, this wasn't the case for the absolute doses because total KAP values associated with biplane configurations were higher than those with below configurations and are distributed over 2

different X-ray tubes: mean KAP was 11800 for bi-plane against 5700 µGym² for tube-below for CA/PTCA and 5500 against 5200 µGycm² for RFA, respectively.

For PM/ICD comparisons were made between tube below and tube above configurations, with no room protective equipment present. As expected the doses to the eye positions are increased by a factor 2.3-2.4 for the tube above configuration compared to the tube below configuration (see Figures 1.19).

An overview of the ratios for different procedures and tube configurations are shown in table 1.9.

Table 1.9: Ratios (biplane/below) of the median values of personal dose equivalent $H_p(0.07)$ per the respective KAP values

	Ratiomedian $H_p(0.07)/KAP_{biplane}$/ $H_p(0.07)/KAP_{below}$		
Procedure:	Eyes	Hands	Legs
CA/PTCA[a]	0.4	**	**
RF Ablations[b]	0.3	1.8	0.38
	Ratiomedian $H_p(0.07)/KAP_{above}$/ $H_p(0.07)/KAP_{below}$		
PM/ICD[c]	2.4	**	0.11
Embolisations	8-18	6.8-28	0.2-0.7
ERCP	1.7-1.8	1.4-2.4	0.5-0.7

[a]For femoral access and table and ceiling shields present

[b]Shields are present

[c] No shields are present

** Not statistically observed difference

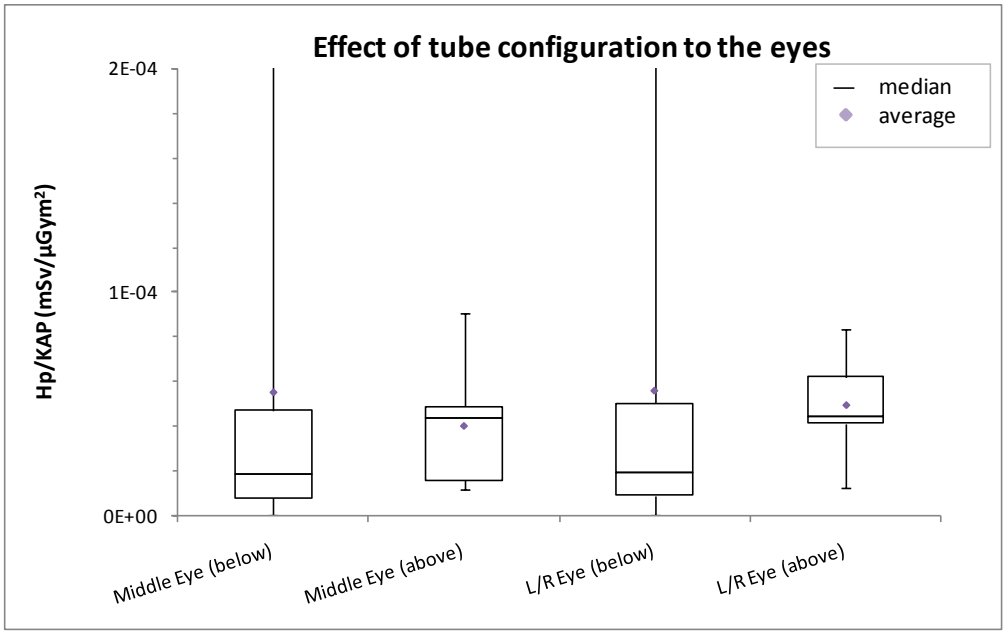


Figure 1.19: Box plot of the eye doses measured for the PM/ICD procedures showing the effect of the tube configuration (ZOOM graph)

For the ERCP procedures, when the tube is positioned below the operating table the doses to the eyes, wrists and fingers are lower than in the case where the tube is above. The reduction ratio that is observed goes up to 2.4. It should also be noted that the effect of the tube configuration is not so strong for the eye and hand doses when a ceiling suspended shield is present (Figure 1.20).

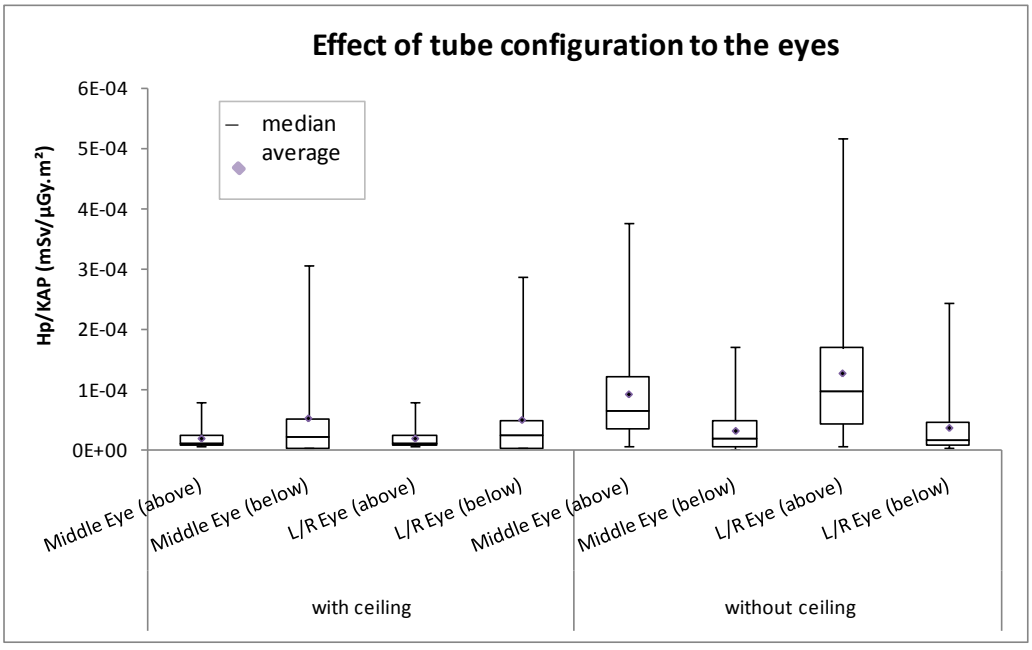


Figure 1.20: Box plot of the eye doses measured for the ERCP procedures showing the effect of the tube configuration with and without the use of ceiling suspended shield

Finally, for the embolisations, when the tube is located below the operating table or biplane systems are used, the normalized doses to the eyes are 8 to 18 times lower compared to the case where the tube is above the table. As far as the wrists and fingers are concerned, the respective reduction ratio is 6.8 (for the right wrist) and 28 times(for the left finger).

As far as the doses to the legs are concerned, for CA/PTCA procedures there is no significant difference between the leg normalised doses between biplane systems and tube below configurations.

For RFA and shielded cases leg normalised doses are observed to be 2.6 times lower in biplane than in tube below configurations.

For PM/ICDs, the normalised doses to the legs are reduced by a factor 5.5-5.9 when the tube is above the operating table (see Figure 1.21).

For the embolisation procedures, the doses to the legs were found higher 1.5 to 4.3 times when the X-ray tube was below the table compared to tube-above.

For the ERCP procedures, similar effect is observed for the legs where the reduction ratios range from 1.45 to 2 for the tube above configuration, compared to the tube below configuration.

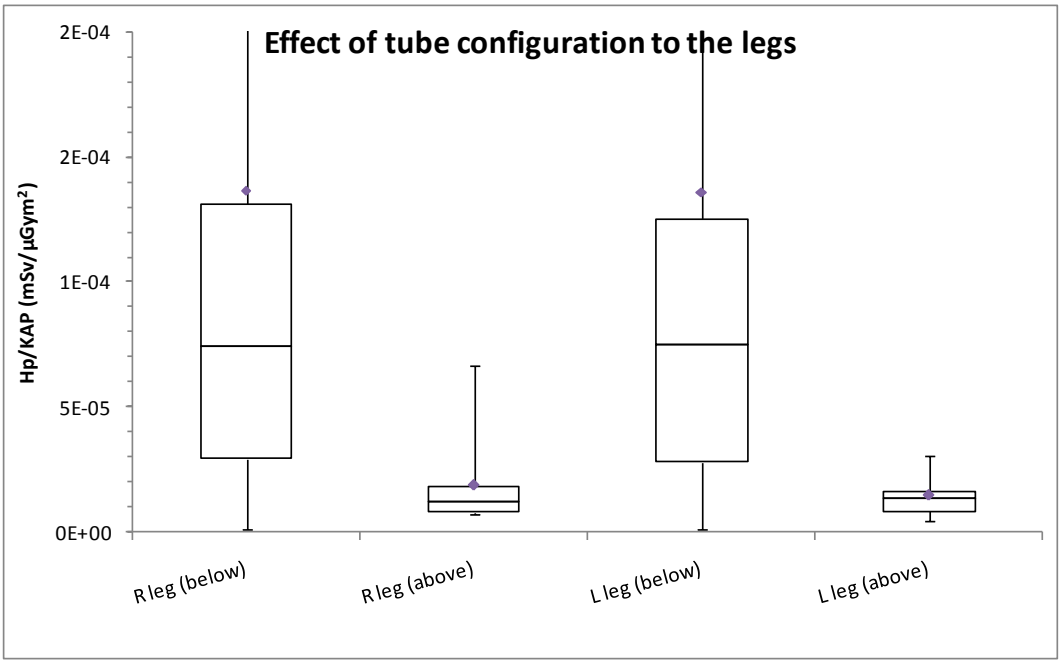


Figure 1.21: Box plot of the leg doses measured for the PM/ICD procedures showing the effect of the tube configuration (ZOOM graph)

1.4.1.5 Effect of the access of the catheter

The effect of the access of the catheter was studied for CA/PTCA, comparing radial and femoral accesses. This was the only procedure, where both cases appeared on a regular basis and enough

data was available to compare. When no ceiling shield is used and the X-ray tube is below the table, higher doses to fingers, wrists and eyes are observed for the radial access, by factors ranging from 1.1 to 4.8 as, in this case, the operator is closer to the X-ray beam compared to the femoral access (Figure 1.22).

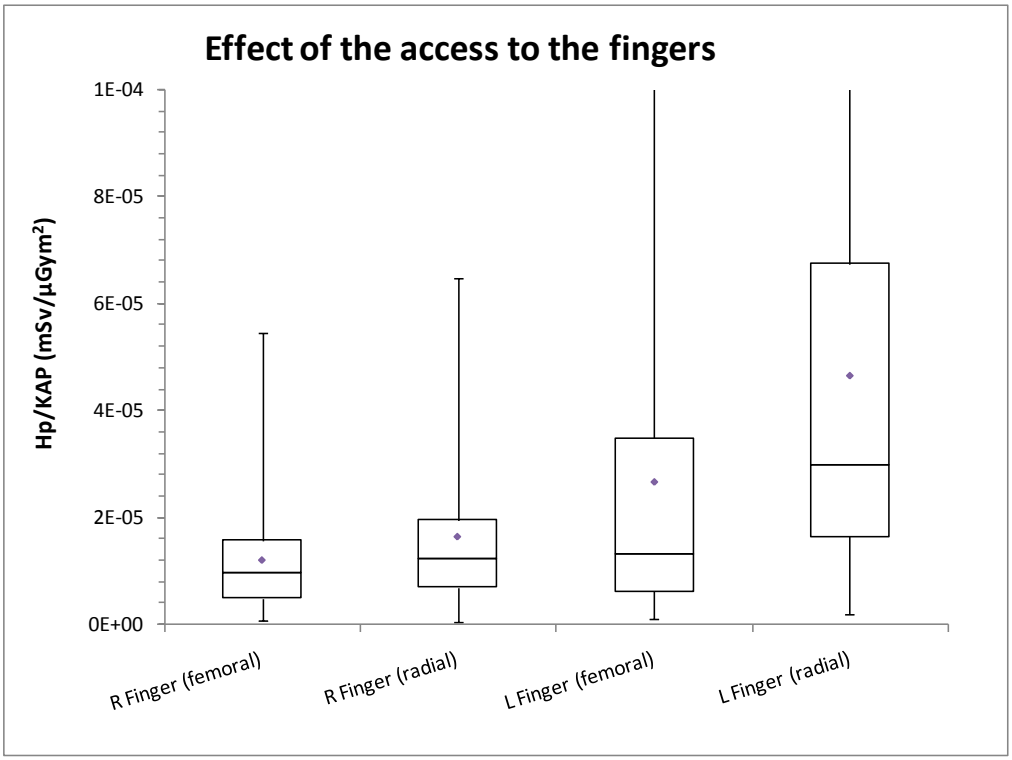


Figure 1.22: Box plot of the finger and wrist doses measured for the CA/PTCA procedures showing the effect of the catheter access (ZOOM) when the ceiling suspended shield is absent and the X-ray tube is below the table

However, if a ceiling shield is used, the differences are smaller and even adverse effects could be observed. A possible explanation is that the ceiling shield can be more easily positioned for procedures with radial access as the operator is closer to the X-ray beam and can be more efficiently be protected from the scattered radiation.

The influence of the catheter access on the leg doses were studied for cases with table shield present and it was observed that higher doses are received for femoral access than for radial access, by a factor 1.7 (Figure 1.23). This can again be explained by the fact that when the operator is closer to the X-ray beam (radial access), it is easier to position the shielding for efficient protection.

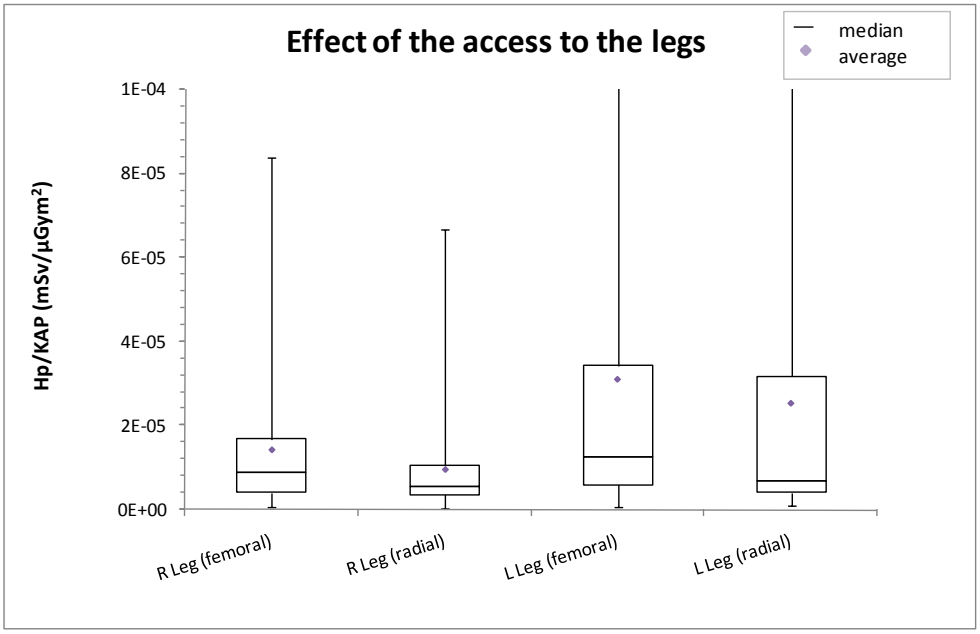


Figure 1.23: Box plot of the leg doses measured for the CA/PTCA procedures showing the effect of the catheter access (ZOOM) when the ceiling suspended shield is present and the X-ray tube is below the table

1.4.1.6 Effect of the use of automatic contrast injector

When the operator uses the automatic contrast injector he can leave the room during the image acquisition. The effect of the use of the automatic contrast injector is shown in Figure 1.24. From all procedures monitored in the IR workplaces, 38% use this technique and the operator will thus leave the room when image acquisitions are performed. The operator is only in the room when fluoroscopy is performed. The use of this technique reduces the doses for all monitored positions by a factor of 2.3 to 4.1.

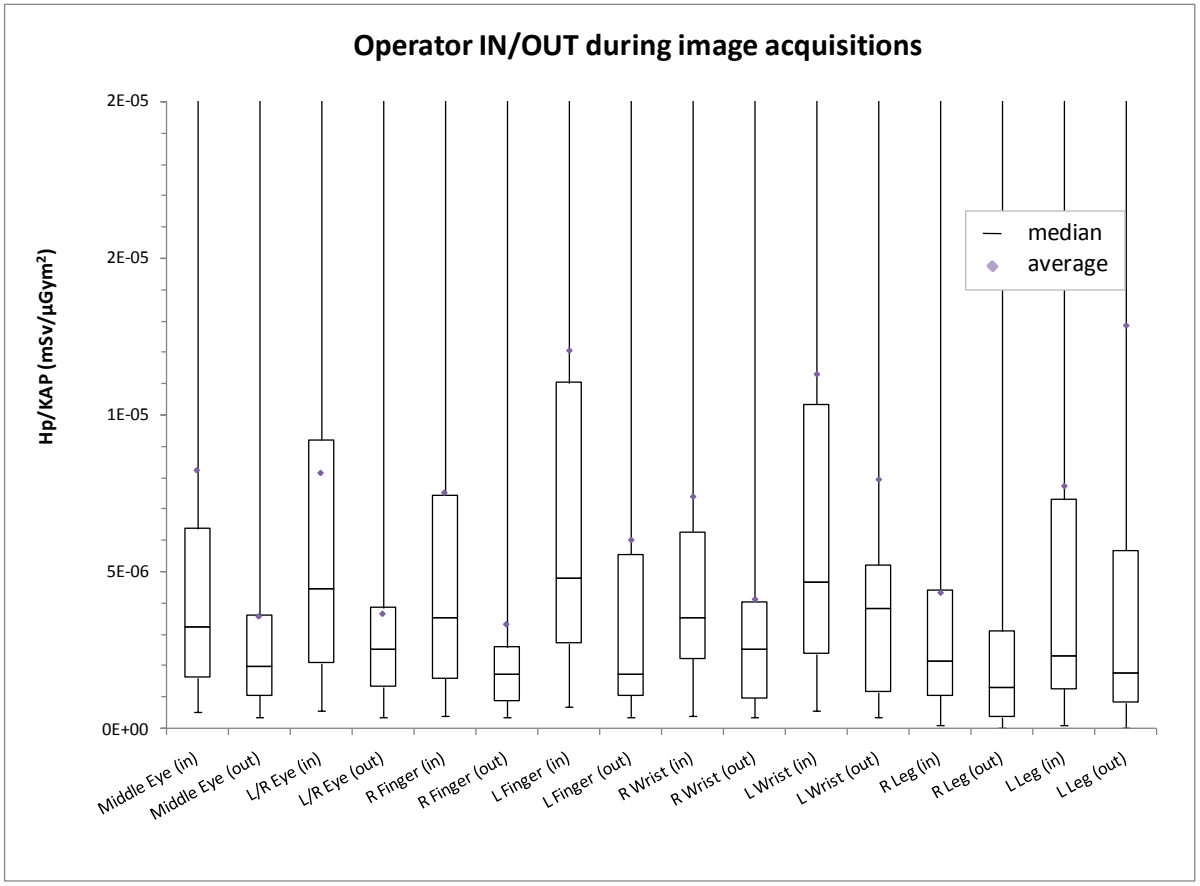


Figure 1.24: Box plot of the normalised doses at the various positions for the embolisation procedures when the operator stays inside the room or goes outside during image acquisitions

1.4.1.7 Position of the maximum dose

From the database of measurements, it was investigated on which of the monitored positions the maximum dose was measured most frequently. This could give an idea of what the most important place for possible dose monitoring would be. On almost all occasions, the maximum dose was recorded at the left part of the operator's body. On figure 1.25 the frequency of the position where the maximum dose was recorded is shown. It can be seen that most frequently the maximum dose was recorded at L-Finger, L-Wrist and L-Leg positions. Clear pre-eminence of L-Finger is seen for PM/ICD because with a direct access the left hand is very close to, and even sometimes inside, the direct X-ray beam. For the IR procedures (Figure 1.26a) the highest frequency of the location of the maximum dose is on the left hand, 23% on the finger and 22% on the left wrist.

However, since the annual limit for hands and legs (500 mSv) is different to that for eyes (150 mSv)(ICRP, 2007), thiscan be taken into account by dividing the maximum dose by the respective annual limit. This is done on figure 1.26b which shows the frequency of the position where the maximum ratio of the dose to the annual limit for the corresponding position is given. In this case

we can conclude that also the eyes come into the picture (65% for the IR procedures) on where the highest doses (with respect to the limit) are observed.

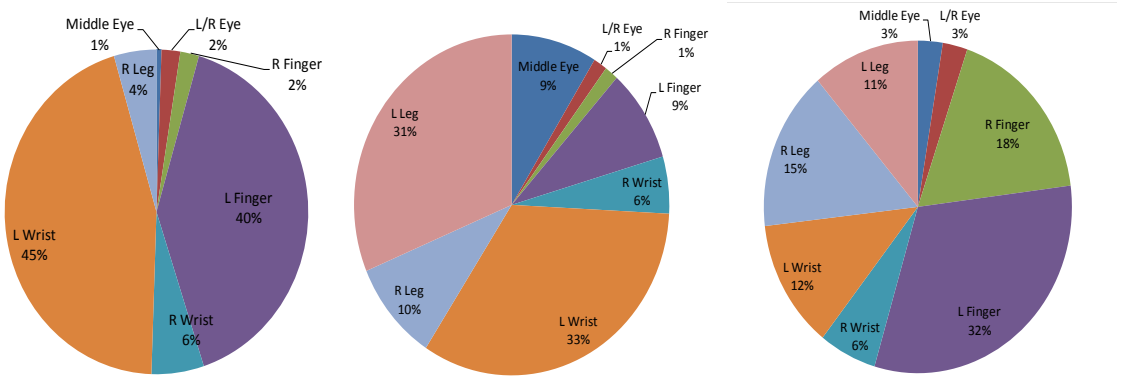


Figure 1.25: Pie Chart showing the frequency of the location of the maximum dose for the IC procedures (a) CA/PTCA (b) RF Ablations and (c) PM/ICDs

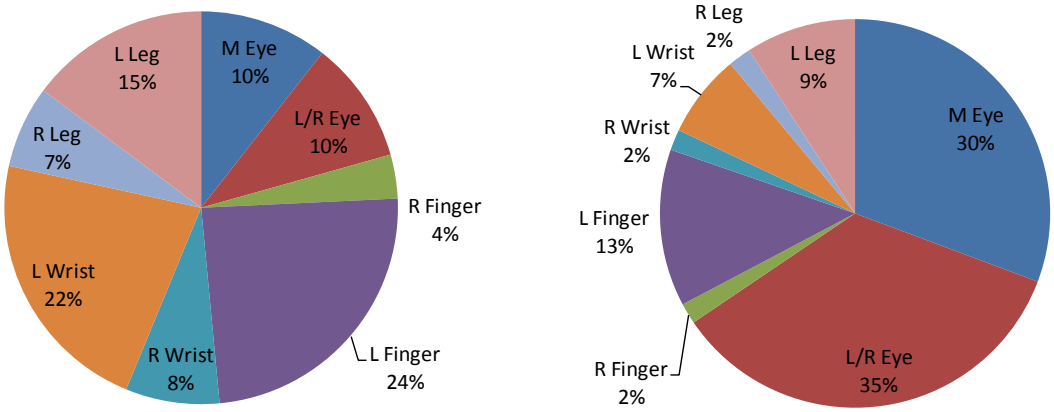


Figure 1.26: (a) Pie Chart showing the frequency of the location of the maximum dose for the IR procedures (b) Pie Chart showing the position of the maximum dose when the respective annual limits are taken into account

1.4.1.8 Extrapolation to annual doses

Apart from the doses measured per procedure, as discussed above, extrapolation to the annual doses was performed for the eyes, hands and legs. According to the ICRP recommendations (ICRP, 2007) the annual dose limit for deterministic effects to the skin is set to 500 mSv averaged over 1cm^2 area of skin regardless of the area exposed. For the eyes the annual limit is set at 150 mSv.

Annual doses are estimated by multiplying the average measured dose to the hands, legs or eyes for a specific operator with his given annual workload per procedure. If different procedures were monitored for a specific operator the annual doses for each procedure are added. Information on the annual workload was gathered from 84 physicians.

When it is possible that 3/10th of the annual limit can be reached, it is legally required that doses are routinely monitored. Therefore, frequency distributions are determined for:

- Annual doses larger than the annual limit (500 mSv for skin and 150 mSv for eyes)
- Annual doses larger than 3/10th of the annual limit (150 mSv for skin and 45 mSv for eyes)
- Annual doses larger than 1/10th of the annual limit (50 mSv for skin and 15 mSv for eyes)
- Annual doses smaller than 1/10th of the limit

In Figure 1.27 (a,b and c) the frequency distributions are shown for the eyes, hands and legs, respectively for all procedures together.

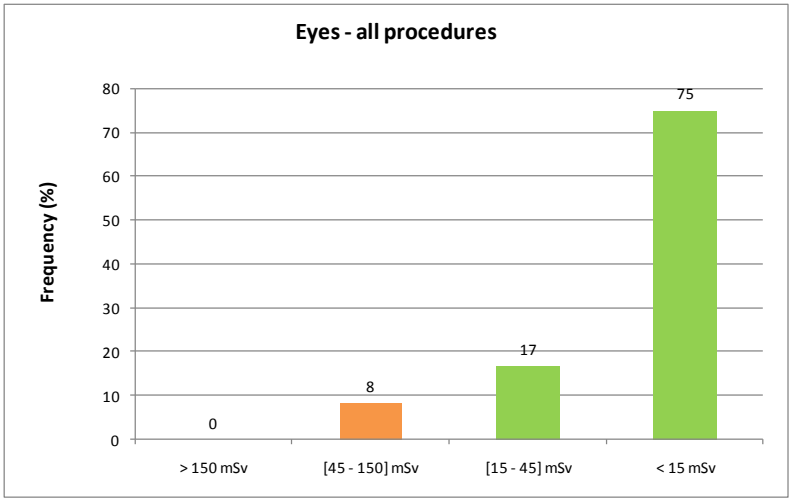
We can observe that the annual doses to the eyes have never exceeded the annual limit. For 8% of the operators for which annual doses could be estimated, the annual dose to the eyes exceeds the 3/10th of the limit. There is not even one specific procedure that can be attributed to this 8% resulting in the higher annual eye doses. All interventional procedures, except ERCP, can give relatively high doses to the eyes. However, it should be noted that the eye doses do not take into account the reduction due to the use of eye protective glasses.

Concerning the eye lens dose limit, a recent ICRP statement recommends reducing the limit to 20 mSv/year, averaged over a period of 5 years, with no single year exceeding 50 mSv (ICRP 2011). With this new proposed limit, 45% of the operators have annual eye doses above 3/10th of the annual limit of which 24% exceed the new proposed annual limit.

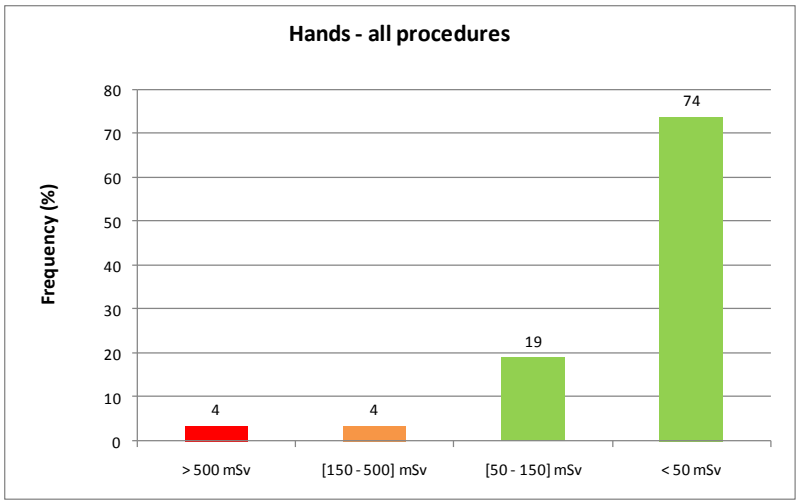
For the annual doses to the skin of the hands, 4% of the operators receive annual doses above the limit. The procedures for which these highest doses are observed are mainly pacemaker procedures and orthopedic procedures, like vertebroplasty (Struelens et al., 2011). For both procedures ceiling suspended shields are seldom used and the hands are regularly in the primary beam. However, also for the CA/PTCA procedures it is important to monitor hand doses as 12% of the operators received annual doses to the hands larger than 3/10th of the limit. In general, the annual doses to the hands calculated for RFA are low, as the operators for which the annual workload was received were well protected. It is important to notice that operators who perform RFA, often also perform pacemaker procedures. The operators performing ERCP procedures have in general low annual doses to the skin of the hands; 90% of the estimated annual doses were lower than 50 mSv, the remaining 10% was around 70 mSv.

For the annual doses to the skin of the legs, 1% of the operators received annual doses larger than the annual limit. These are observed within the field of interventional radiology. However, also for cardiology procedures, like CA/PTCA and PM/ICD procedures, annual doses to the legs were estimated above 3/10th of the annual limit. For the ERCP procedures, all estimated annual doses to the legs were below 50 mSv.

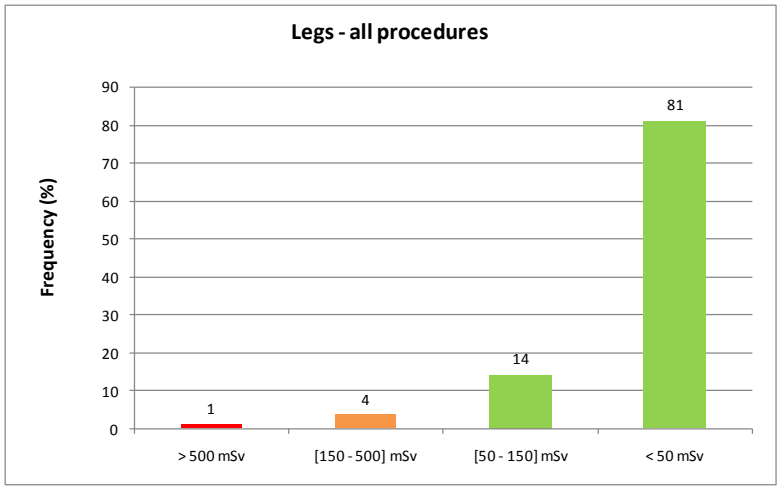
The annual doses estimated in the ORAMED project were based on the procedures which are monitored within the project. This means that the annual doses could be underestimated, as the monitored operators could also perform other procedures which were not monitored withinORAMED. This is especially true for the interventional radiology procedures, for which there exist a very broad range of procedures.



(a)



(b)



(c)

Figure 1.27: Frequency distribution of the annual doses estimated for the eyes (a), hands (b) and legs (c) for the various monitored procedures

As a general conclusion it can be said, that monitoring of eye lens doses can be recommended for all procedures, except ERCPs. If the dose limit will be reduced to 20 mSv, many physicians will surpass this limit, and monitoring and the proper use of radiation protection equipment will even be more important. Also for the annual hand doses it is possible that 3/10th of the annual limit can be exceeded. Therefore, routine monitoring of hand doses is necessary, except for ERCP procedures. If the table shield is properly used, leg doses can be reduced significantly and no routine monitoring is necessary.

1.4.1.9 Correlations

Another objective of the analysis of the measurement result was to determine if the measured doses could be correlated to the KAP values. Moreover, it was investigated if doses to the eyes could be linked to the doses to the hands and if the doses to the fingers could be estimated by the doses to the wrists. If this was the case, it would provide a simple mean to estimate the extremity doses of the operator.

In order to examine the correlation between the various quantities mentioned above Pearson's productmomentcorrelation coefficient, r, was used which gives an indication of the strength ofa linear relationship between X and Y and can range from -1 to +1inclusively. If the correlation is strong, it can be approximated by a straight line called 'regression line' or least squares line that is determined such as the sum of the squared distances of all data points from the line is the lowest possible when the Pearson correlation coefficient, r, is squared then theresulting value, r^2, called coefficient of determination ranges between 0 and 1. The coefficient of determination represents the proportion of common variation in the two variables showing thus the strength of the correlation. If there is no correlation between X andY in the overall population, there might still be a chance that randomsampling could result in a correlation coefficient different from zero. The P value helps in quantifying how often this could actuallyhappen. If the P value is large, then there is no reason to conclude that the two variables have a real meaning. For P values below 0.05 the correlation can be considered reliable i.e. with a chance of mistake of 5% (Campbell et al., 2007; Bland et al., 2000).

In the measurement database general correlations were very difficult to find and their strength was mostlyinfluenced by three main parameters: the X-ray tube configuration, the room collective radioprotectiveequipment and the access of the catheter.

1.4.1.9.1 Correlations between the doses to the eyes and the KAP for operator

The quality of the correlations between the doses to the eyes and the KAP values depends strongly on two main parameters, the X-ray tube configuration and the use of collective radiation protection equipment liable to shield the eyes i.e. ceiling screen, radiation protection cabin or mobile protective wall. The use of lead glasses could not be investigated as the measurements were performed with the TLDs outside the glasses when the operator does wore any.

When the procedures are performed without any room collective radiation protection equipment, the doses to the eyes are strongly linked to the KAP values with a value for r^2 of0.78 and 0.72 for

respectively below and above X-ray tube configurations as it is often the case correspondingly for cardiac procedures, and for ERCP and embolisations procedures (figure 1.28).

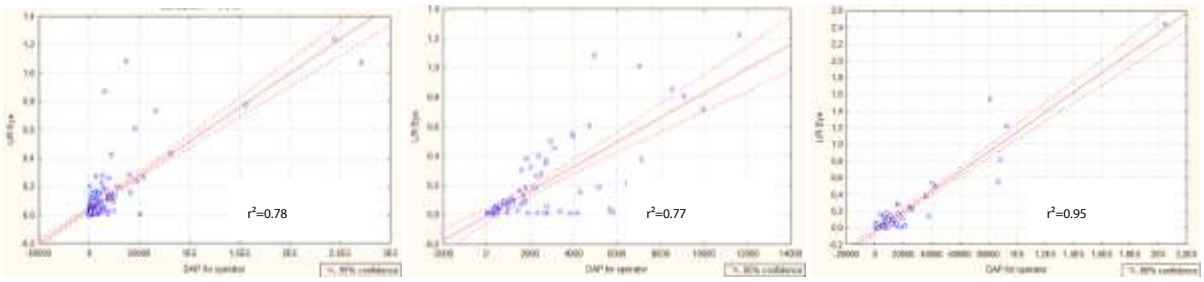


Figure 1.28 Correlations between the KAP values and the doses to the L/R eye for respectively tube below and no shielding, for tube above and no shielding and for biplane tubes

For biplane tubes employed mostly during CA/PTCA and RF ablations procedures, excellent correlation was found between the doses to the eyes and the KAP values for operator even though measurements performed with or without collective radiation protection equipment liable to shield the eyes are considered together (figure 1.28).

1.4.1.9.2 Correlations between the doses to the legs and the KAP for the operator

The doses to the left leg are strongly correlated to the KAP for operator with a r^2 value of 0.8when no table shield was used and for femoral access such as for embolisations or RF ablations procedures.

When the legs were shielded, the correlation was statistically significant only for the doses to the right leg.

1.4.1.9.3 Correlations between the doses at the ring and wrist positions and the KAP for the operator

Three parameters needed to be considered in order to find statistically significant correlations: the absence of ceiling shield, the access of the catheter and the X-ray tube configuration.

Table 1.10: Correlations between the doses at the ring and wrist positions and the KAP for the operator

			Left finger	*Right finger*	*Left wrist*	*Right wrist*
no ceiling shield, femoral access and tube above	KAP for operator	r^2	0.68	0.59	0.81	0.58
tube below and no ceiling shield and shoulder access	KAP for operator	r^2	0.57	0.59	0.54	0.62

Given the quality of the correlations, the doses to the fingers or the wrists can be estimatedbased on the KAP values when no ceiling shield is used and when either the procedures are performed with tube above and through a femoral access of the catheter(e.g. DSA PTA LL and embolisations procedures) or with tube below and shoulder access for PM and ICDs implantations (table1.10).

1.4.1.9.4 Correlations between the doses at the ring and wrist positions

The main parameter in this case is the use of ceiling shield that can protect the hands. Excellent correlation was found between the doses to the left finger and to the left wrist when no ceiling shield was used (r^2=0.69). The coefficient of determination is even closer to one when the procedures are either performed through the shoulder access for PM and ICDs implantations (r^2=0.85) or with an above X-ray tube configuration used mainly for ERCP or embolisations procedures(r^2=0.82).

The doses at the right ring and at the right wrist positions were only statistically significantly correlated when the procedures were performed with an above X-ray tube configuration used mainly for ERCP or embolisations procedures (r^2=0.61) or when the procedures were carried out with a ceiling shield and with both a below X-ray tube configuration and a femoral access of the catheter such as in CA&PTCA, RF ablations, embolisations and general angiographies or angioplasties procedures (r^2=0.69).

As the left ring and wrist positions are likely to be more exposed than the right ones, the most important correlation remains between the dose to the left and the dose to the left wrist.

1.4.1.9.5 Correlations between the doses to the hands and to the eyes

The main parameters in this case are the X-ray tube configuration and the use of ceiling shield.

Table 1.11 Correlations between the doses to the eyes and the doses to the ring and wrist positions

			Left/Right Eye	*Middle Eye*
Tube below and ceiling shield present	Left finger	r^2	0.62	0.63
Tube above and ceiling shield present	Left finger	r^2	0.53	0.67
	Left wrist	r^2	0.76	0.86
Shoulder access and no ceiling shield	Left finger	r^2	0.91	0.91
	Left wrist	r^2	0.66	0.69

Quite good correlationswerefound between the doses to the left ring and wrist positions and the doses to the eyes when a ceiling shield is used for both below and above X-ray tube configurations (table 1.11).

When no ceiling shield is present, correlations were difficult to be found. The doses to the eyes were strongly correlated with the doses at the ring and wrist positions only forPM and ICD implantations (table 1.11).

In practice, the dose to the eyes can be estimated given the dose to the fingers or to the wrists but the X-ray tube configuration and the use of ceiling have to be considered.

1.4.2 Simulation results

1.4.2.1 Effect of the beam projections

Interventional procedures are dynamic procedures, where the X-ray beam moves around the patient. The effect of these different beam projections on the doses to the left hand, wrist, leg and eye lens, were tested. Monte Carlo calculations are performed for different beam projections, without any protective shielding present and each time using the same X-ray beam energy (80 kVp; 3 mm Al and 0 mm Cu).The X-ray field size was always kept at a diameter of 20cm at the entrance of the II. The influence of the beam projection is investigated for all irradiated parts of the patient (head, thorax, abdomen, lower limbs). The results for head irradiation, when the operator stands at 40 cm from the irradiation field, are presented in Figure 1.28.

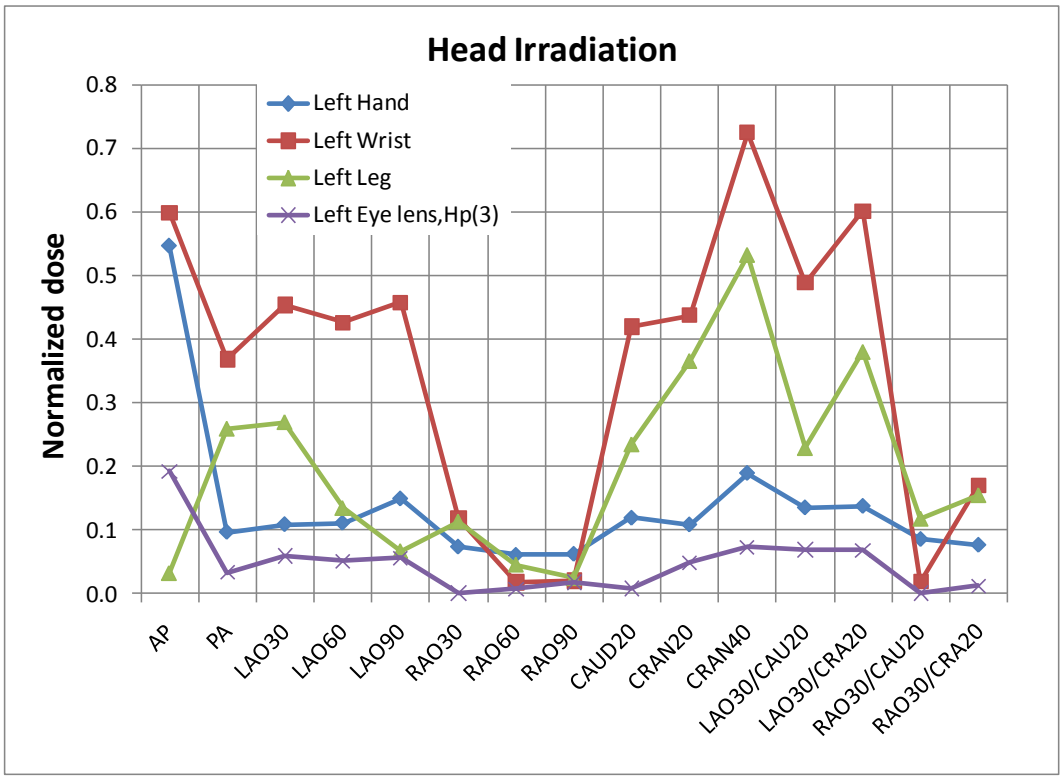


Figure 1.29: The doses normalised to the dose at the II for different beam projections for head irradiation are presented. The X-ray spectrum is 80 kVp, 3 mm Al, 0 mm Cu and the field diameter at the II is 20 cm

The following conclusions can be drawn from Figure 1.29:

- the LAO projections (X-ray tube nextto the operator) present higher doses than the RAO projections,
- the cranial projections present the highest doses for undercouch irradiations,
- the left wrist of the operator seems to be the most exposed part and the eye seems to be the least exposed for most projections for this specific geometry.

One should also notice the difference between overcouch (AP) and undercouch (PA) irradiation, as well as the difference between the two lateral projections LAO 90° and RAO 90°. The ratios AP/PA and LAO 90°/RAO 90° for head, abdomen and thorax irradiation are presented in Table 1.12.

Table 1.12: The dose ratios for overcouch (AP)/undercouch (PA) irradiation, and for the two lateral projections LAO 90°/RAO 90°, for head, abdomen and thorax irradiations, are presented.

Head Irradiation				
	Left hand	Left wrist	Left leg	Left eye lens
AP/PA	5.6	1.6	0.1	5.8
LAO 90°/RAO 90°	2.4	22.1	2.7	3.1
Abdomen Irradiation				
AP/PA	6.0	3.7	0.1	12.3
LAO90°/RAO90°	3.0	13.7	1.0	1.3
Thorax Irradiation[a]				
AP/PA (radial)	4.6	2.9	0.1	8.1
AP/PA (femoral)	8.3	4.4	0.1	7.0

[a]RAO 90° is not usually used for thorax irradiation and was not included in the study.

The results in Table 1.12 indicate that all doses, except for the legs, are higher when the tube is above the operating table (AP projection). More specifically, the doses to the left hand, left wrist and left eyes lens are found to be up to 8, 4 and 12 times higher respectively for overcouch irradiations. The eye lens is the most affected part in this case, which makes very important the proper use of shielding equipment (lead glasses and/or ceiling suspended shield) when such systems are used.

For the lateral projections, all doses are found higher for the LAO 90° projection (the X-ray tube is at the side of the operator). For this tube configuration, which is very common in clinical practice, the doses to the left hand, left wrist and left eyes lens are found up to 3, 22 and 3 times higher respectively. The left wrist seems to be most affected in this case. When lateral projections are needed, the RAO projection should be preferred where the X-ray tube is on the opposite side of the operator's position and the image intensifier is next to the operator. First of all, the largest part of

the scattered radiation is backscattered, in case of RAO projections, means away from the operator. Secondly the large image intensifier partly will shield the operator from the scattered radiation.

1.4.2.2 Effect of the collective protective equipment

One of the most important radiation protection measures during interventional procedures is the use of protective shielding. Monte Carlo simulations have been used to study the effect of the ceiling suspended shield, the lead glasses and the shield attached to the operating table, on the protection of the eyes, hands, wrists and legs for four beam projections: PA, LAO 90°, RAO 30° and CRA 40°. An X-ray spectrum corresponding to 80 kVp, 3 mm Al, 0 mm Cu (HVL=3.1 mm Al) was used for the simulations.

Three scenarios were selected to study the effect of the ceiling suspended shield on the doses to the eyes, hands and wrists of the operator, for a specific patient-operator setup: thorax irradiation, 20 cm field diameter at the II, operator's distance from the centre of the field 70 cm representing femoral access. In the first scenario (A1) an arc type ceiling suspended shield of 0.5 mm Pb is positioned very close to the patient and is slightly rotated around the z axis towards the operator (Figure 1.30a). In the second case (A2) the same arc-type shield is (incorrectly) positioned leaving a gap of 15 cm between the patient and the shield (Figure 1.29b). The third scenario (B1) describes a rectangular ceiling shield positioned in touch with the patient, without tilt (Figure 1.30c). The effect of the table shield (0.5 mm Pb) to the leg doses was studied at the same time (Figure 1.30e). Finally, the effect of the lead glasses (0.5 mm Pb) to the eye lens doses was studied when there was no ceiling shield present (Figure 1.30d).

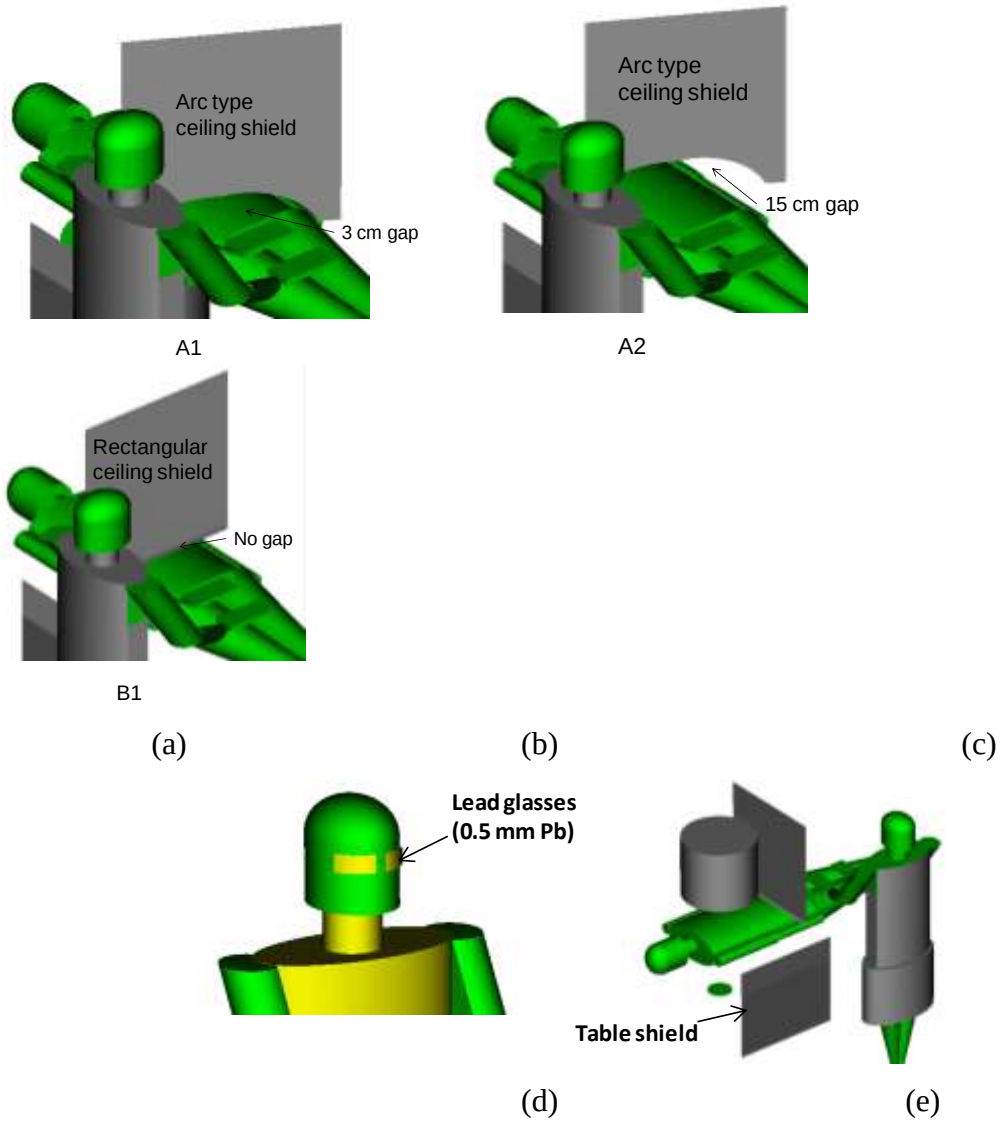


Figure 1.30: (a) Arc type ceiling suspended shield of 0.5 mm Pb, tilted and positioned close to the patient (A1). (b) Arc type ceiling suspended shield of 0.5 mm Pb, tilted and positioned 15 cm above the patient (A2). (c) Rectangular ceiling shield positioned in touch with the patient, without tilt (B1). (d) The lead glasses of 0.5 mm Pb and the (e) table shield of 0.5 mm Pb are also presented.

The dose reduction from the different protective barriers and the different setups for PA projection are shown in Figure 1.31. All results are normalised to the situation without the respective shielding condition.

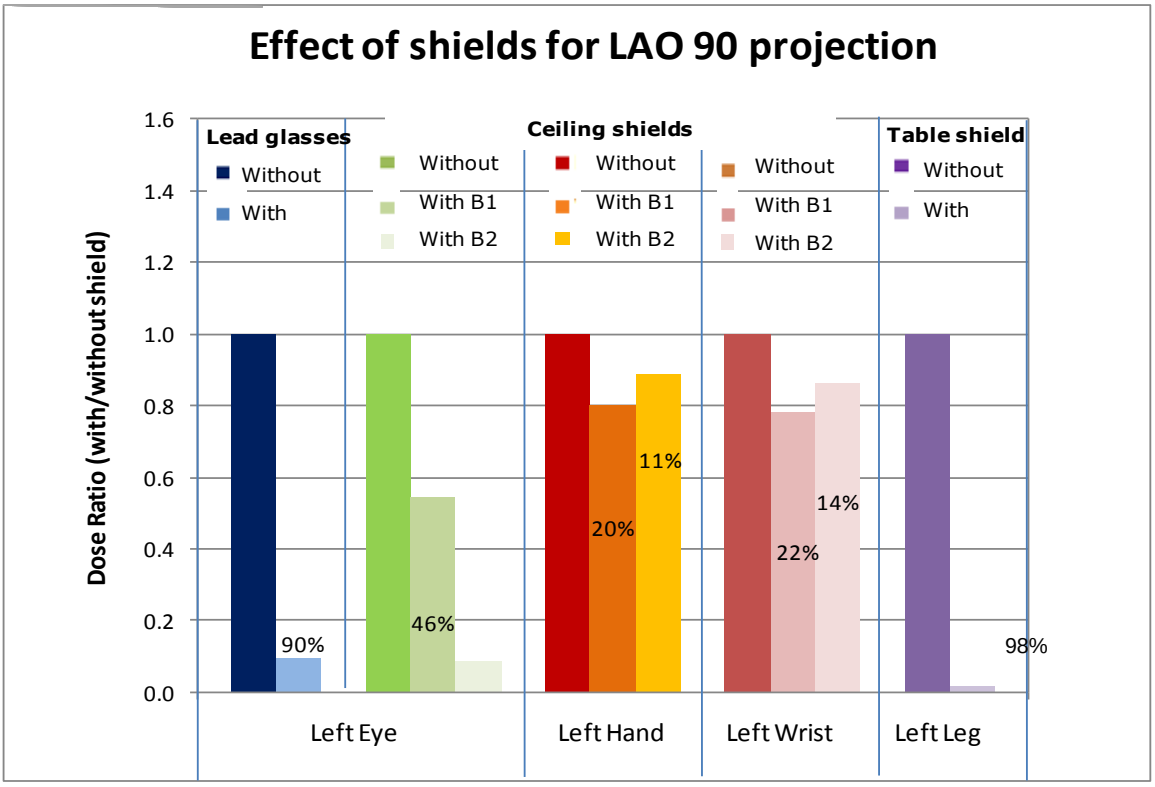


Figure 1.31: The effect of the different protective shields for thorax irradiation, 20 cm field diameter at the image intensifier and PA projection, as well as the respective dose reduction is presented

For the LAO 90° projection, an additional setup (B2) is considered, where the rectangular ceiling shield is positioned on the left side of the operator and not above the patient (Figure 1.32). The effectiveness of B1 and B2 case is examined and the results are shown in Figure 1.33.

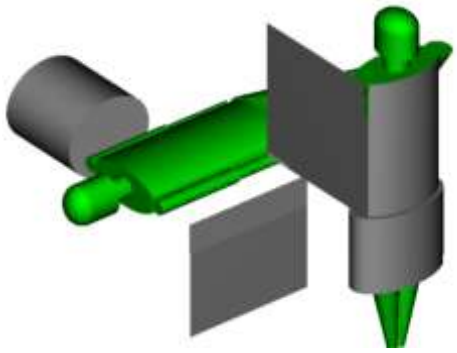


Figure 1.32: B2 case, the ceiling suspended shield is placed on the left side of the operator for the LAO 90° projection

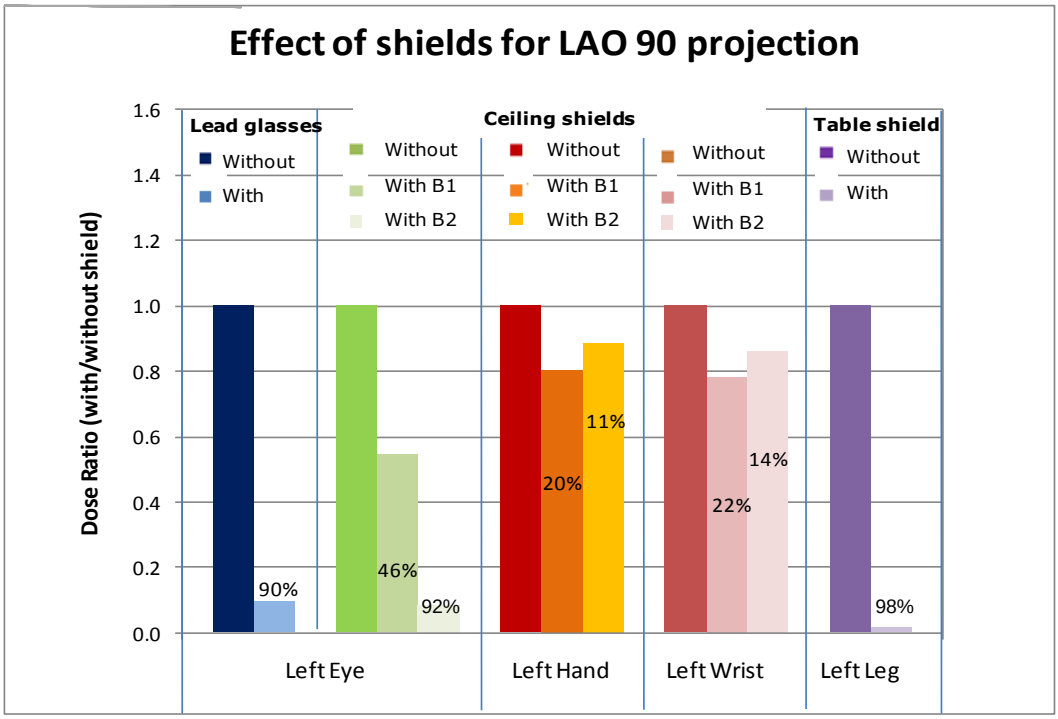


Figure 1.33: The effect of the position of the B1 ceiling shield, for thorax irradiation and LAO 90° projection and the respective dose reductions are presented

Including all four tested projections (PA, LAO 90°, RAO 30° and CRA 40°) the results can be summarized in the following;

- The lead glasses are very effective for the protection of the left eye lens reducing the dose 83-90%.
- The table shield is very effective for the protection of the legs when it is properly positioned (dose reduction 83-99%).
- About the ceiling suspended shield, it is very effective for the protection of both eye lenses (dose reduction up to 93%), except for the LAO 90o projection. The dose reduction to the left eye lens for this projection is only 22% for the A1 and A2 cases and 46% for the B1 case. However, when the ceiling shield is positioned at the side of the operator (B2 case) there is an important effect on the dose to the left eye lens and the dose reduction is 92%.
- The effect of the ceiling shield to the doses of the hands and wrists is very interesting. The dose reduction to the hands for the A1 scenario is only 21% compared to the 68% for the B1 case for the PA projection. This is due to the fact that in the A1 case there is a small gap between the patient and the shield, while for B1 the shield is touching the patient. The dose reduction to the left wrist was up to 73% for the A1 case. Finally, in the A2 case, where there is a large gap between the patient and the shield, the dose reduction to the left hand and wrist is 2-29% depending on the projection. This emphasizes the importance of placing the ceiling shield correctly. In practice, in order to avoid gaps between the patient and the shield, a ceiling shield with lead flexible stripes at the bottom is advised.

1.4.2.3 Effect of lead glasses

Additionally to the protective equipment, a "sensitivity study" on the effect of the lead glasses was performed. Four cases were selected; a small area lens with lead equivalent thickness of 0.5 mm and 1 mm Pb, and a large area lens that covered better the eyes, with the same lead thicknesses. The results for an X-ray beam of HVL=3.5 mm Al and for two beam projections are presented in Table 1.13.

Table 1.13: The effect of 4 different types of lead glasses on the eye lens dose, for PA and CRA 20 projection is presented.

Left eye	**Ratio with/without glasses**	
	PA	**CRA20**
Small lens (0.5 mm Pb)	0.30	0.28
Large lens (0.5 mm Pb)	0.15	0.14
Small and thick lens (1.0 mm Pb)	0.26	0.25
Large and thick lens	0.14	0.13

Lenses of thickness higher than 0.5 mm Pb did not improve the protection of the eye lens significantly. However, larger lenses that provide better coverage of the eye lens had a higher influence on the eye lens dose.

1.4.2.4 Effect of the field size

The effect of the field size was studied for the case of thorax irradiation for two positions of the operator representing radial and femoral access. Two field sizes 30 cm and 20 cm, for a beam quality of HVL=3.5 mm Al (90 kV_p, 3 mm Al, 0 mm Cu), were tested and the respective ratios are presented in Figure 1.34.

For all monitored positions the doses are higher when a larger field size is used as more scattered radiation is produced when a larger part of the patient is irradiated. When the operator stands close to the irradiation field (radial access) the dose reduction due to the more collimated beam is more significant, especially to the hands and wrists. The highest dose decrease is observed for radial access to the left hand (~10 times) which is the closest to the irradiation field, while for femoral access the dose is reduced only 1.3-1.7 times for all positions monitored. The doses to the legs and the eye lenses seem to be the less affected by the beam collimation.

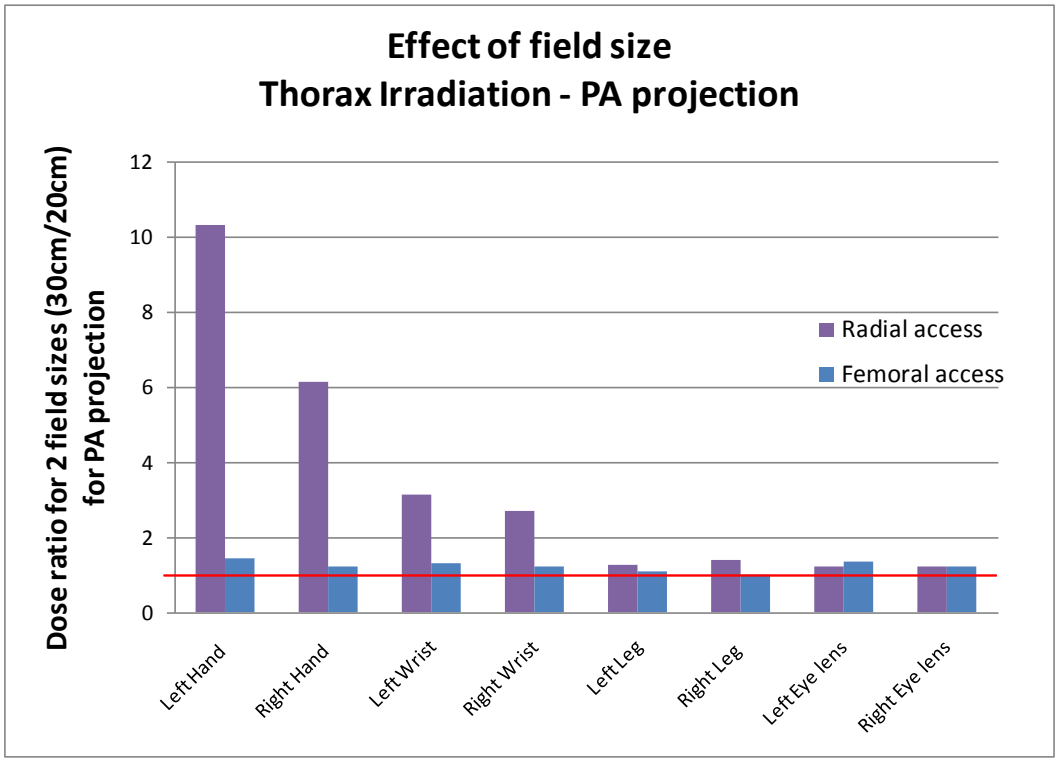


Figure 1.34: The ratios of the doses calculated for two field sizes 30 cm and 20 cm, for two positions of the operator representing radial and femoral artery access, are presented

1.4.2.5 Effect of the beam quality

The effect of different beam qualities was investigated by using the simplified geometry explained in paragraph 1.3.3. The dose ratios of the different HVL values relative to the lowest HVL of3.1 mm Al are presented in Figure 1.35 for the head irradiation and the dose to the leg.

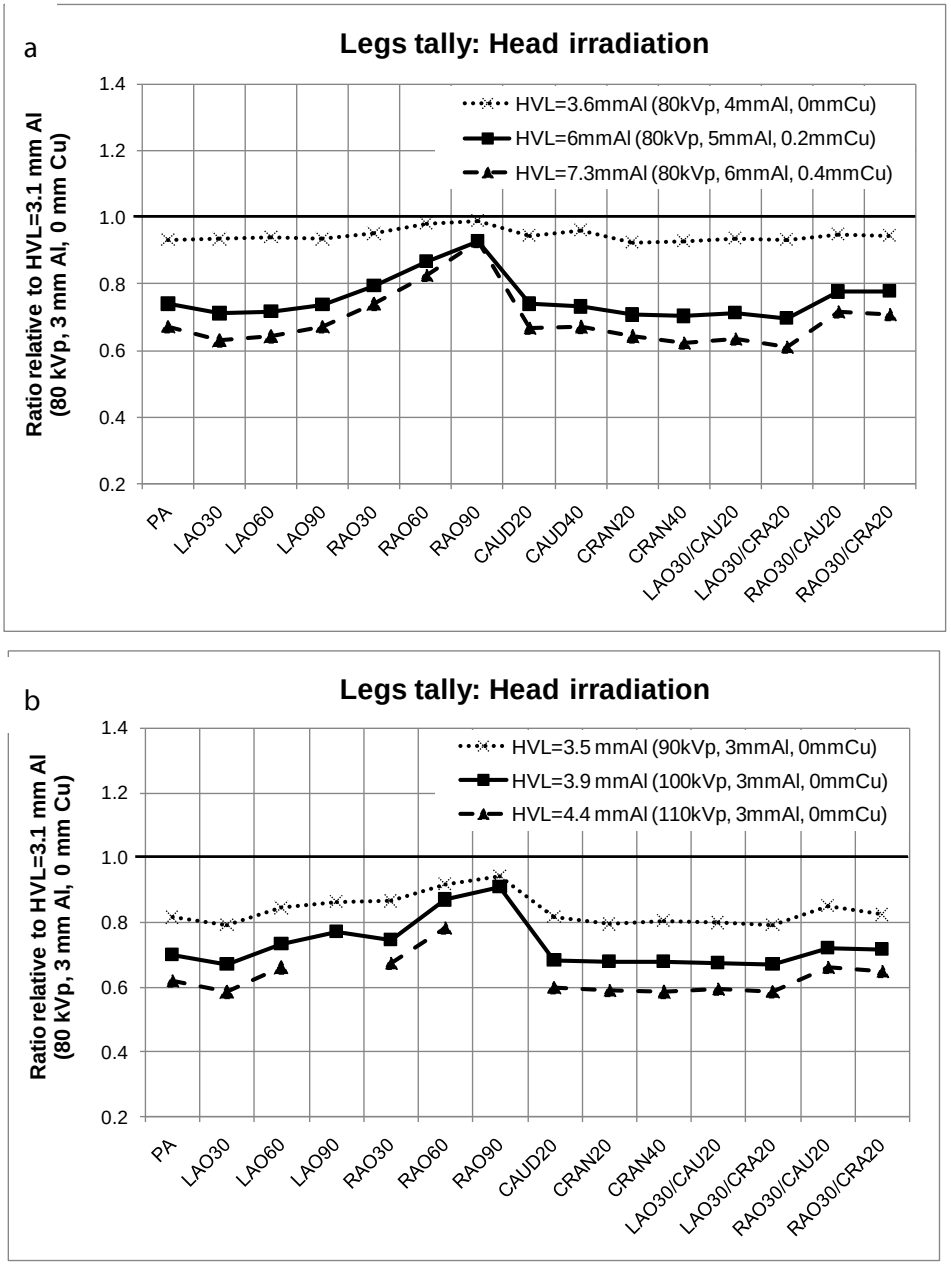


Figure 1.35: The effect of different beam qualities to the leg doses is presented a) same kVp different filters, b) same filter different kVps (the missing points are cases that were not simulated)

The use of higher filtration has an influence not only to the patient dose but also to the dose of the operator. For the specific conditions that were studied, the doses to all the anatomic regions of the operator are found lower when the filtration is higher. It is stressed again that the evaluated doses are normalised to the doses at the entrance of the II. The reduction is more significant to the legs among all other anatomic positions, for undercouch irradiations. This can be explained as with higher filtration, the beam is more energetic and therefore less backscatter is created. For the highest kV_p value and filtration that was tested (110 kV_p, 4 mm Al, 0.9 mm Cu, corresponding to HVL=10.7 mm Al) the dose reduction compared to HVL=3.1 mm Al was 22-60% to the eye lenses, 15-50% to the hands and wrists and 30-60% to the legs, depending on the beam projection. It

should be noted however, that the use of higher filtration could result in deterioration of the image quality.

1.4.2.6 Effect of the operator's position

The position of the operator is usually related to the artery access of the catheter. 36% of the 265 CA/PTCA procedures that were monitored within the ORAMED project were performed using radial artery access. Both cases were simulated and the doses normalised to the dose at the II for both femoral and radial access, for thorax irradiations, are presented in Figure 1.36.

In the case of femoral access the legs were the most exposed, while for the radial access the left hand and left wrist were the most exposed parts of the operator's body, when no shielding was present.

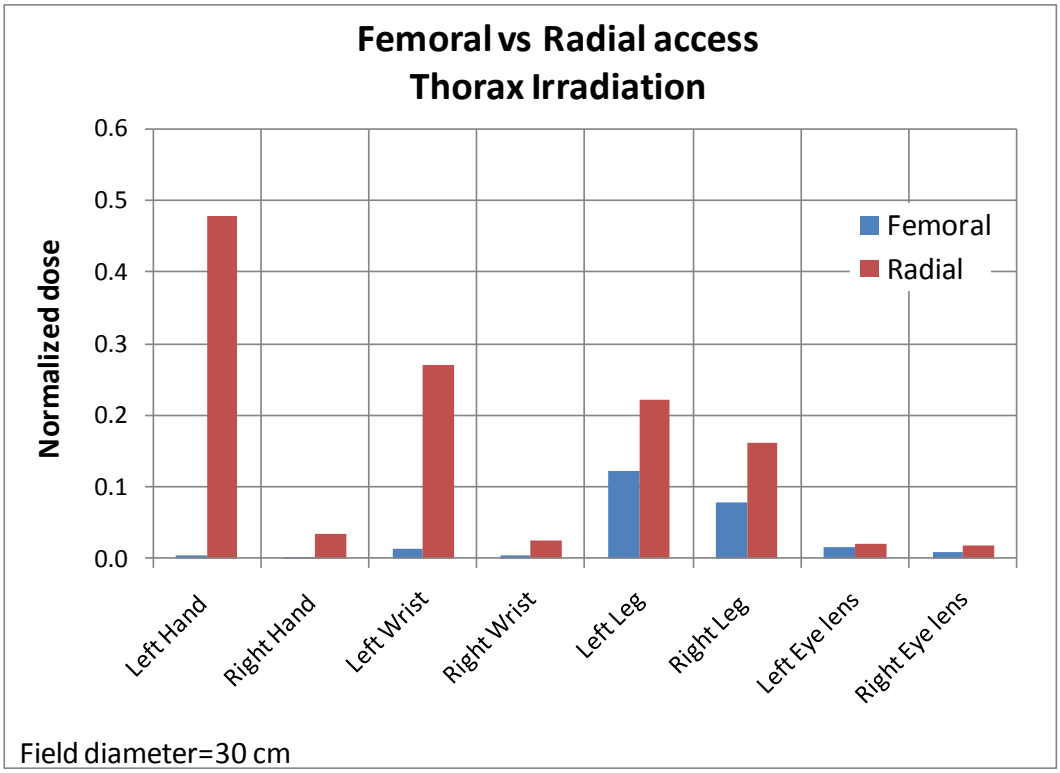


Figure 1.36: The doses to the different anatomic positions using femoral and radial artery access are presented for thorax irradiation, for PA projection

1.5 Recommendations

The measurement and simulation campaign performed within the ORAMED project revealed a large variability of practices in clinical work followed in different hospitals. As a consequence, the measured doses, even for specific procedures, vary significantly from one case to another. On the other hand, the simulation data showed the way that the various parameters can influence the extremity and eye lens doses separately and not in combinations as it is the case from the measurement results. The combined data led to the following recommendations. It is important to note that some of the proposed guidelines cannot easily be adopted since there are restrictions from the medical point of view. However, some of them are easily adjustable and can improve the protection of the medical staff significantly.

- The equipment used for interventional cardiology and radiology should fulfil specific requirements and standardisation in their design, manufacture, acceptance and maintenance (AAPM 2001, IEC 2010). A wide range of equipment of various degrees in imaging technology has been encountered during the campaign. Advances in the field have lead to very complex equipment. Therefore, there is a need to follow specific equipment requirements and standards in order to fill in the gap between the technology and the end users.
- Personal protective equipment should be used for all the personnel in the room (at least lead collar and aprons). From all the procedures that were monitored it was observed that the majority of the operators wear protective apron and thyroid collar.
- The ceiling suspended shield should be placed just above the patient, especially in the cases that the tube is above the operating table; the operator should stand well behind it. The combination of transparent ceiling shield and lead drapes that touch the patient is very efficient for the protection of the hands. When the ceiling shield is properly used there is a significant reduction of the eye dose (2-7 times), especially in cases where the tube is placed above the operating table. During the measurement campaign it was observed that the use and position of this ceiling shield can be very different between operators. Moreover, the effectiveness of the ceiling shield also depends on the position of the operator with respect to the X-ray beam and the X-ray beam geometry, which explains the wide range in reduction ratios for the eyes.
- When ceiling suspended shield is not available protective lead glasses should be used; most effective are the ones designed with large area lenses, well covering the eyes, and with the lateral shadow.
- The table shield should be always properly adjusted to protect both legs. The proper positioning of the table shield is very important for the assistant operator, who, in many cases, stands close to the main operator but his legs are not protected. There are also cases where the operator needs to change his position during the procedure, and stands close to the table without having his legs protected anymore. The proper use of table shield can reduce the leg doses from 2 to 5 times. A typical table shield is of 0.5 mm Pb equivalency. The range of the reduction ratio that is observed is due to the various distances of the legs from the table shield, and from the X-ray beam. The degree of reduction also depends on thebeam projection.

- The tube should be placed below the operating table. As compared with an overcouch configuration, there is a significant reduction at the eye (2-27 times) and hand doses (2-50 times). However, the increase at the leg doses in this setup has to be compensated by the use of a properly positioned table shield. The large variation of the reduction factors that is observed is related to the different conditions that are studied. For example, it should be noted that when no ceiling suspended shield is used the influence of the tube configuration is much stronger than when the shield is used.
- If biplane systems are used, the proper use and positioning of a ceiling shield is very important for the protection of the eyes. The operator is exposed in these cases to scatter radiation produced from two different beams. In this setup, lateral projections are very common and the simulation campaign showed that an extra lateral ceiling shield, positioned at the side of the operator (or next to the operator) is very effective for the protection of the eyes.
- Mobile floor shield should be used for the assisting personnel that need to be in the irradiation room. During the measurements campaign it was observed that many people need to be in the irradiation room. From radiation protection point of view, it is better for them to stand behind a mobile shield and move around the room when needed.
- The femoral access of the catheter should be preferred compared to the radial one, if it is possible from the medical point of view, and as long as it is associated with a larger distance from the X-ray field than when radial access is applied. The hand and eye lens doses, if the shields are properly used, are lower for femoral access, by 2 to 5 times.
- The use of an automatic contrast injector can reduce the doses to the various monitored positions significantly (4 to 16 times), especially to the hands. It is stressed that when this system is used the operator can leave the irradiation room during the image acquisitions. The above observed range is due to the different distances of the monitored positions from the scattering source and the differences in use of protection shields.
- The operators should avoid direct exposure of hands to primary radiation. Figure 1.37 shows the hand of the operator during a procedure which is in the irradiation beam. Many bad practices were observed during the measurement campaign where the hands of the operators were displayed on the monitors of the systems.

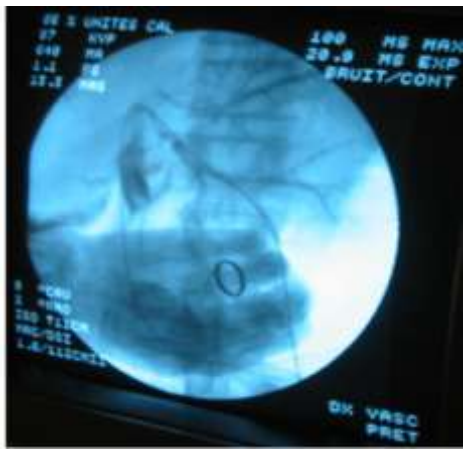


Figure 1.37: Operator's hand, as well as his ring, are shown in the irradiation field

- Monitoring of the eyes and fingers (or wrists) should be performed on routine basis. The dosemeters should be worn on the side of the operator which is closest to the X-ray tube. This is because the maximum dose was always observed on the part of the operator closer to the X-ray tube for all the procedures that were examined. The finger (or wrist) dosemeter should be placed on the dorsal or palmar side of the hand when the X-ray tube is placed above or below the operating table, respectively.

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1.7 Guidelines to reduce extremity and eye lens doses in interventional cardiology and radiology procedures

Version: 27 January 2011

GUIDELINES FOR REDUCING EXTREMITY AND EYE LENS DOSE IN INTERVENTIONAL PROCEDURES

These guidelines were established in the framework the ORAMED project (2008-2011), a Collaborative Project supported by the European Commission within its 7th Framework Program.

General problematic

During interventional radiology and cardiology procedures the medical staff can receive relatively high doses. The operator and assisting personnel is required to remain close to the patient and thus they are in the scattered field. Despite the fact that the body area can be individually shielded by protective lead aprons, the hands, legs and the eye lenses often remain practically unshielded.

Description of the work

A coordinated measurement program was performed in different hospitals in Europe. Moreover, simulations of the most representative workplaces/procedures in interventional cardiology and radiology (IC/IR) were performed to determine the main parameters that influence the extremity and eye lens doses.
A measurement protocol was established, according to which several parameters related to the angiographic system, the type and complexity of the procedure, the position of the physician and the protective equipment, some field parameters (kV values, filtration, projections, etc.) and finally the KAP values were recorded. For the measurements in the various positions TLDs were used, sealed in small plastic bags and taped on the parts of the body to be monitored.

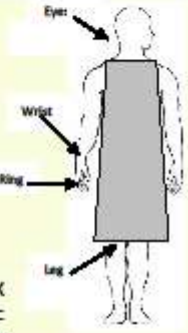

Figure 1. Location of the measuring points

Figure 2. The anthropomorphic phantoms used for the simulations

Numerical simulations were performed using the MCNP-X software. The input file contains 2 anthropomorphic phantoms, representing the patient and the operator. Some modifications were performed on the operator's phantom: eyes and hands were added, as well as a lead apron and a thyroid collar. Moreover, the arms of the phantom are bent in a representative position. An X-ray source and an image intensifier are also included.

MEASUREMENT CAMPAIGN

The list of procedures includes 3 cardiac and 5 general interventional diagnostic and therapeutic examinations. The list is composed of cardiac angiographies (CA) and angioplasties (PTCA), radiofrequency ablations (RFA), pacemaker implantations (PM), angiographies (DSA) and angioplasties (PTA) of the lower limbs (LL), the carotids (C) and the reins (R), embolisations and endoscopic retrograde cholangiopancreatographies (ERCP).

The aim was to evaluate extremity and eye lens doses of medical staff.
Data comes from:
- 42 hospitals/rooms across Europe
- 6 different European countries
- 1329 procedures

SIMULATION CAMPAIGN

The parameters examined are:
tube voltage, filtration, beam projection, field size, irradiated part of the patient, position of the operator and protective equipment (table and ceiling shield and lead glasses).

The aim was to evaluate the influence of different parameters on eye, hand, wrist and leg doses.

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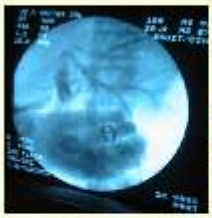
Conclusions

The various parameters which can influence the doses were studied and analysed through the measurements and simulations and the following conclusions were drawn:

- The ceiling suspended shield can reduce the eye dose (2-7 times)
- When ceiling suspended shield is not available protective glasses with side shield can be used (90% dose reduction)
- The proper use of table shield can reduce the doses to the legs from 2 to 5 times.
- The tube should be placed below the operating table. There is a significant reduction at the eye (2-27 times) and hand doses (2-50 times). However, there is an increase at the leg doses which can be compensated by the use of properly positioned table shield.
- If the biplane configuration is used the proper use of lateral shield is very important because otherwise the eyes and hands are practically unshielded.
- The femoral access should be preferred, if it is possible, from the medical point of view, than the radial one. The doses, if the shields are properly used, are lower in the femoral access, 2 to 7 times.
- Going outside the operating room during the image acquisition is a practice which can reduce the doses significantly (4 to 7 times), especially the hand ones.

Recommendations

- **Only dedicated interventional equipment and room (properly shielded) should be used.**
- **Personal protective equipment should be used (at least collar and lead aprons). Lead glasses with side shield should be preferred.**
- **The room protective equipment should be used and positioned properly.**
- **Care should be taken for the table shield when assisting personnel stands close to the primary beam or when the operators need to move around the table for medical reasons.**
- **The ceiling suspended shield should be placed as close to the patient as possible. The combination of transparent ceiling shield and lead drapes that touch the patient is very efficient.**
- **If biplane systems are used the proper use of lateral shield is very important for the protection of eyes .**
- **The tube should be placed below the operating table. The higher doses at the legs in this setup can be reduced by a properly positioned table shield.**
- **The femoral access should be preferred whenever it is possible from medical point of view.**
- **Going outside the operating room during the image acquisition is a practice which can reduce the doses significantly.**
- **Avoiding the direct exposure of hands to primary radiation.**
- **Monitoring of doses to fingers or wrists and eyes should be performed on routine basis .**



This study has received funding from the European Atomic Energy Community's 7th Framework Program (FP7/2007-2011 - grant agreement n°211361).

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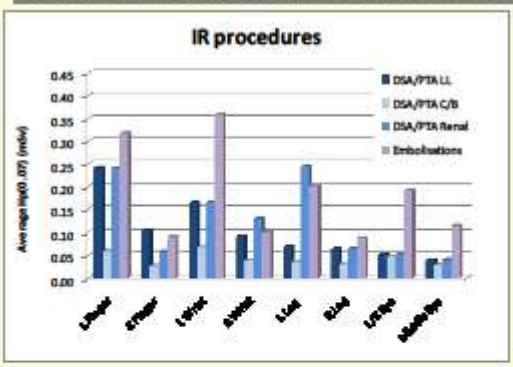
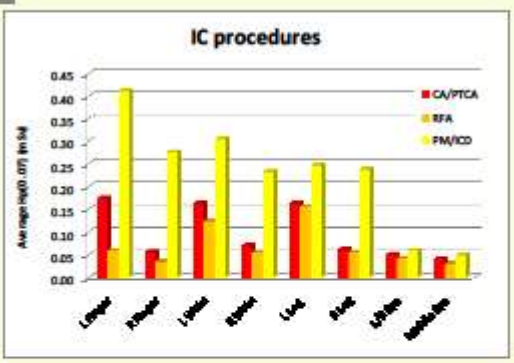
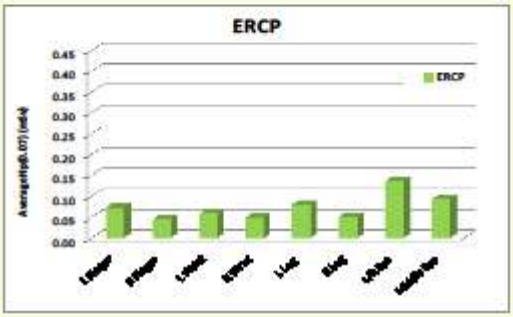
APENDIX - Main results of WP1

AVERAGE DOSES FOR THE DIFFERENT PROCEDURES



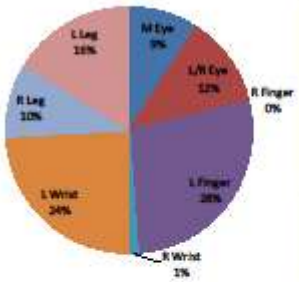




- Among the cardiac procedures studied, the doses to the operators are higher during PM and ICD implantations, even though the KAP values are relatively low. During these procedures the operators work very close to the irradiating field and most of the time without any protective shield.
- For the IR procedures special attention should be given to the embolisations, especially to the doses to the eye lenses. Operators are also significantly exposed during therapeutic procedures such as angioplasties of the lower limbs and the renal arteries.
- For ERCP procedures the doses are generally low. Special care should be taken regarding the use of a ceiling suspended shield, especially for the protection of the eyes, when over couch systems are used .

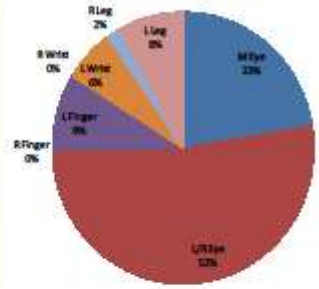
MAXIMUM DOSES

Position of the maximum dose in Embolisation procedures

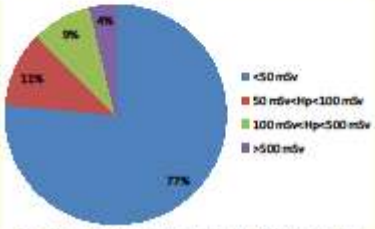


- The maximum doses were recorded most frequently on the left finger and on the left wrist most of the times.
- However, taking into account the respective annual limits for all positions (150 mSv for the eyes and 500 mSv for the extremities) the eye lens exposure seems to become more important.

Position of the maximum dose/annual dose limit in Embolisation procedures



EXTRAPOLATION TO ANNUAL DOSES

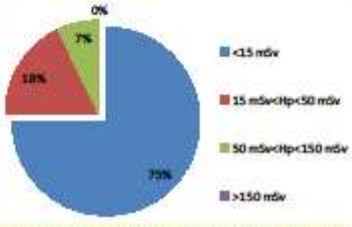


Frequency distribution of how many times the annual dose for hands exceed a certain dose level

In many cases the 3/10th of the extremity and eye lens limits were exceeded.

For the hands there were cases exceeding the limit.

Monitoring of the hands and eye should be performed in routine basis in all procedures except ERCPs.



Frequency distribution of how many times the annual dose for eyes exceed a certain dose level

1.8 APPENDIX 1:Measurement protocol

No.....

MEASUREMENT PROTOCOL Date .....

Hospital : _____

System / Detector : _____ **Tube Above/Below:** _____

Procedure : _____

Physician (initials) : _____

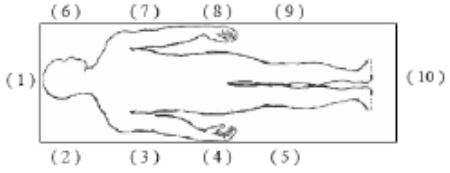
1. PROTECTIVE EQUIPMENT

		mm Pb
Lead Apron		
Thyroid Collar		
Eyewear		
Lead Gloves		
Table Curtain		
Patient Shield		
Ceiling		
Floor		

2. STAFF POSITION

Number of persons in the room / position[1]	
MDs :	A
	B
	C
Techn:	A
	B
	C
Nurses:	A
	B
	C
Others:	A
	B

Access [2] (R / F / P / IJV) _____



3. GENERAL PARAMETERS

FSD[3] _____

FDD[3] _____

FOV _____

ZOOM _____

Biplane (Y/N) _____ (Tube 1 / Tube 2)

DAP present (Y/N)? _____

4A. FLUOROSCOPY

Projection[4]					
kV					
mA					
Pulses/s					
Pulse duration ms					
Filtration mm Cu					
Mode					

B. CINE

Projection[4]					
kV					
mA					
Frames/s					
No of Frames					
Pulse duration ms					
Filtration mm Cu					
Mode					

[1] Define position as shown on picture e.g. MDs: A 4, B 5…
[2] Radial (R) / Femoral (F) / Percutaneous (P) / Internal Jugular Vein (IJV) access
[3] FSD = Focus-Skin Distance, FDD = Focus-Detector Distance
[4] Projections (PA, AP, LAO, RAO…) and degrees (°): e.g. LAO 30°/ CAUD 20°

No.....

5. *DAP VALUES* (units: .....)

FLUORO : _____ Fluoroscopy Time (.....) : _____

CINE : _____ Total Frames Acquired : _____

TOTAL : _____

6. *OTHER REMARKS*

Body part irradiated : _____ **Physician's Height** : _____

Patient size (child / S / M / L) : _____ **Complexity of procedure (Low / Medium / High)** : _____

Physician's experience (Low / Medium / High) : _____ **Physician's Dominant Hand (R / L/ Both):** _____

COMMENTS: _____

_____

_____

_____

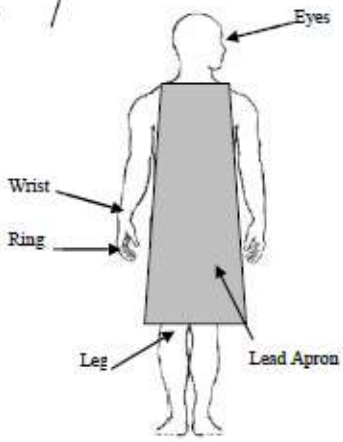
_____

_____

7. *TLDs – MEASURING POINTS - RESULTS*

TLD type : _____

Number of TLDs : _____



TLD positions	Pellet No R	Pellet No L	Measured Dose (mSv) R	Measured Dose (mSv) L
1. Ring finger [5]	☐	☐		
2. Wrist [6]	☐	☐		
3. Leg [7]	☐	☐		
	Middle	R/L side	Middle	R/L side
4. Eyes [8]	☐	☐		

[5] Outside surface of finger when the tube is above the table;
Inside surface of finger when the tube is below the table. (TLDs are stuck on MD's fingers)
[6] Outside surface of wrist when the tube is above the table;
Inside surface of wrist when the tube is below the table.
[7] Part of the leg not covered by lead apron
[8] Two measuring points as shown on picture, under the lead glasses: ① if the tube is on the right side of the MD
② if the tube is on the left side of the MD.

2 Development of practical eye lens dosimetry based on a new reference phantom

2.1 Introduction

Cataract is the loss of transparency of the lens of the eye. The cataracts progress slowly to cause vision loss and may eventually lead to blindness; they are typically associated with old age and metabolic conditions like diabetes. It is known that cataract can also be radiation induced. In the present ICRP approach, cataract induction is a deterministic effect with a definite threshold (ICRP, 2010). This threshold is between 0.5 and 2 Gy for acute exposures, and 5-6 Gy for prolonged exposures. There is a latency period that can last for many years. Until the beginning of 2011 the annual dose limit for occupationally exposed workers is set to 150 mSv per year.

Recently eye lens doses have received a lot of attention because of some epidemiological studies on Chernobyl clean-up workers, interventional radiology and cardiology physician and bomb survivors (Worgul et al., 2007, Junk et al., 2008, Vano et al., 2010, Cirac-Belaj et al., 2010) showed that the threshold dose for cataract induction could be lower than that assumed, even lower than 0.8 Gy. It is not even sure that there is a threshold at all. The previously explained arguments put in evidence the need of a detailed re-evaluation of the eye lens radio-sensitivity and to an associated reliable dose assessment. For this reason ICRP issued a "Statement on Tissue Reaction" containing a series of recommendations including a revision of the eye lens limit (Paragraph 3) that lowers the annual limit from 150 mSv to 20 mSv (ICRP 2011).

The operational quantity for eye lens is $H_p(3)$ but it was not usually monitored. Such scarce interest on the $H_p(3)$ quantity is also demonstrated by the lack of official data on the ICRP-74 and ICRU-57 (ICRP 1997, ICRU 1998). Some years ago a set of $H_p(3,\alpha)$/Ka conversion coefficients for photons were calculated for the 30x30x15cm^3 4-elements ICRU tissue slab at the former GSF in Munchen (actually Helmholtz Zentrum) by Till and Zankl (Till and Zankl 1995). In a more recent study by Ferrari et al. at ENEA it was also tried to propose a reduced dimension cuboid to better mimic the head shape (Ferrari, P. et al. 2005).

Following the previous considerations, it was felt within the ORAMED project that an overall procedure for a correct eye lens dose assessment should be proposed, starting from a better suited study on the operational quantity $H_p(3)$, the construction of a dosemeter prototype optimized to respond in terms of $H_p(3)$, the better suited reference and calibration phantoms and finally the definition of an adequate procedure for type test and calibration of eye lens dosemeters.

The studies herewith presented carried out within the ORAMED project had the main scope to guarantee an optimized approach to the eye lens dosimetric evaluations, in all the aspects, from the theoretical operational quantities to the operative practice.

It is worth to remark that individual dosemeters have to be calibrated on phantoms providing reasonable approximation of the backscatter properties of the part of the body on which they are worn. Therefore, a set of phantoms of different shapes (i.e. slab or cylindrical shapes) are suggested by the International Organization for Standardization (ISO) to be used for the calibration of individual dosemeters: a rod PMMA calibration phantom is required for the finger and a pillar phantom made of a PMMAwater filled cylinder is suggested for the wrist and ankle, whilst a 30 x 30

x 15 cm^3 water filled PMMA phantom is indicated for whole body dosemeter calibration in terms of $H_p(10)$ and $H_p(0.07)$. No special phantom is recommended for $H_p(3)$ but "if another phantom has not been agreed with the dosemeter manufacturer" the same slab, representing a human torso, is suggested by ISO 12794 (ISO, 2000) for calibrating personal dosemeters in terms of $H_p(3)$ independently on the place the dosemeter is worn (very likely the head).

This work, based on both Monte Carlo and experimental studies, was also aimed at analyzing the angle and energy dependence of response of photon personal dosemeters in terms of $H_p(3)$ on a new proposed square cylindrical phantom of ICRU tissue with 20 cm diameter and 20 cm height that can be more representative of the head than the previous phantoms.

2.2 Theoretical discussion on $H_p(3)$ operational quantity

A dosemeter designed in terms of the $H_p(3)$ quantity and consequently calibrated on the best suited phantom should be able to estimate as better as possible the eye lens equivalent dose.

The choice of a well suited theoretical phantom should be based on physical considerations on the scattering properties of this phantom compared with the head. It seems therefore intuitive that the phantom until now proposed, i.e. the trunk phantom made of 4 element ICRU theoretical material of 30x30x15 cm^3, is not a good solution to achieve an optimized procedure for eye lens dosimetry. In fact the mass of such a phantom (13500 cm^3) is far larger than a real head volume (about 6300 cm^3) with an associated larger quantity of tissue available asscatter of the incident radiation.

Secondly a thickness of 15 cm is too small to represent the head and this leads to unphysical lack of shield in a PA irradiation. Thirdly the presence of the edges leads again to unphysical effect at large incident angles, already criticized also for Hp(10) that exhibits a sharp drop at 90° impinging radiation incidence. Of course, according to the choice made by the MIRD Committee, the best simple structure could be an elliptical cylinder, but this choice seems to be rather unpractical especially from the point of view of the possible corresponding calibration phantom.

A reasonable compromise, in compliance with the mass under study and the shape, was a right cylinder of 20 cm diameter and 20 cm height. It could have been proposed a smaller diameter, but the decision was taken on the basis of two considerations:

- establishing a head simple model, taking into account the presence of the bone structures besides the only soft tissue. As the theoretical model is composed by only soft tissue, a slightly larger diameter might compensate the higher interaction properties of the bone, contributing both to absorption and scattering.

- Easy and cheap fabrication - a concern was based on the fact that a suitable PMMA pipe could be easily commercially found with no need to look for unusual dimensions that could increase very significantly the cost. A simple cylindrical container of 20 cm diameter with two disks and a water filling tip could cost about 200-300 euro.

2.3 $H_p(3)$ operational quantity study

The problem was investigated through Monte Carlomodelling. The codes MCNP5 (X-5 Monte Carlo Team, 2003), PENELOPE (Salvat, F, 2006) and MCNPX (Pelowitz, D.B. (ed.), 2005) were used to obtain the conversion coefficients. The phantom was simulated (in vacuum) as a 20 cm x 20 cmsquare

cylinder of 4 elements ICRU tissue (10.1% H, 11.1% C, 2.6% N and 76.2% O) with a mass density of 1.0 g·cm^{-3}.

2.3.1 Air kerma to Hp(3) conversion coefficients

$H_p(3)$ was calculated at the depth of 3 mm below the phantom surface in a set of forty scoring circular sector volumes (Figure 2.1). The values were evaluated with MCNP5 and PENELOPE (both used by CEA). A study on the influence of the usage of different photon interaction libraries was performed at ENEA with MCNPX comparing mcplib04 (White, M. C, 2003) and the older mcplib02 (Hughes, H. G, 1996).

Mono-energetic photons were transported with source energies from 10 keV to 10 MeV, in an aligned and expanded field. In figure 2.1 the irradiation model is shown.

A series of 23 monochromatic photon beams and 22 different incident angles were analyzed (Table 2.1).

Particular attention was devoted to the evaluation of photon-electron non equilibrium at 3 mm depth occurring for energies above 1 MeV source photons with MCNP5 and PENELOPE. Even if this energy domain is rather unusual for direct irradiation of the eye, it is anyway necessary to point out this effect shown in Figure 2.2.

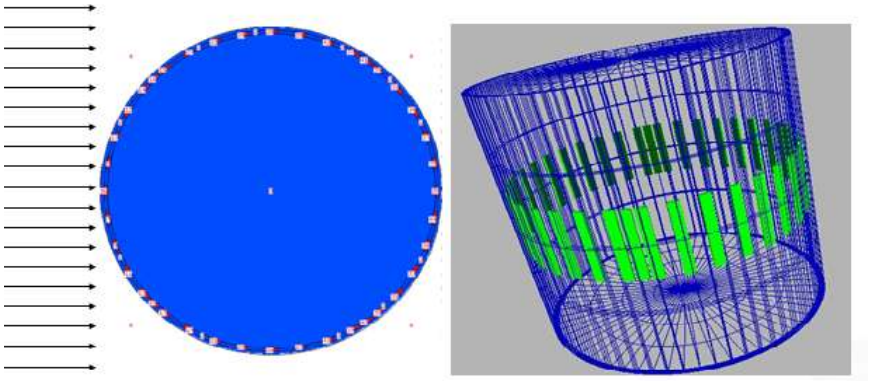


Figure 2.1: Schematic view of the set of forty scoring circular sector volumes used to provide $H_p(3)$

Table 2.1: Photon beams energy and directions with respect to the normalto the incident surface of the phantom.

Energy	Angles
10, 15, 20, 30, 40, 50, 60 keV,	0°, 10°, 20°, 30°,
70, 80, 90, 100, 200 keV,	40°, 45°, 50°, 60°, 70°, 75°,
300, 400, 500, 600, 800 keV,	80°, 90°, 100°, 110°, 120°,
1, 2, 3, 6, 8, 10 MeV.	130°,140°,145°,150°,160°,170°,180°.

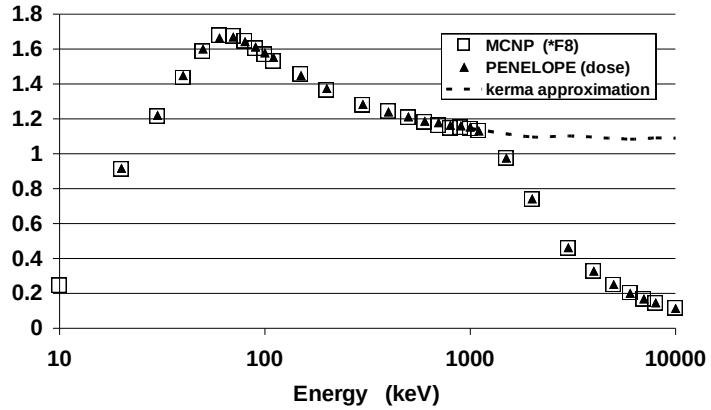


Figure 2.2: Photon-electron non equilibrium condition above 1 MeV at a depth of 3 mm in tissue

The complete tabulation of the conversion coefficients $H_p(3)/K_a$ is provided in Tables 2.2 and 2.3. The values reported are the averages between PENELOPE and MCNP5 (mcplib04) values.

In parallel with the ORAMED activities on the operational quantity, detailed computational studies on the radiation protection H_T(eye lens) both for electrons and photons were carried out by Behrens and Dietze (Behrens et al. 2009, Behrens and Dietze 2011, Behrens and Dietze 2011), with an improved detailed model of the eye. In Figure 2.3 the Behrens model is compared with a section of the MIRD head in which the eye is represented by a homogeneous cylindrical sector.

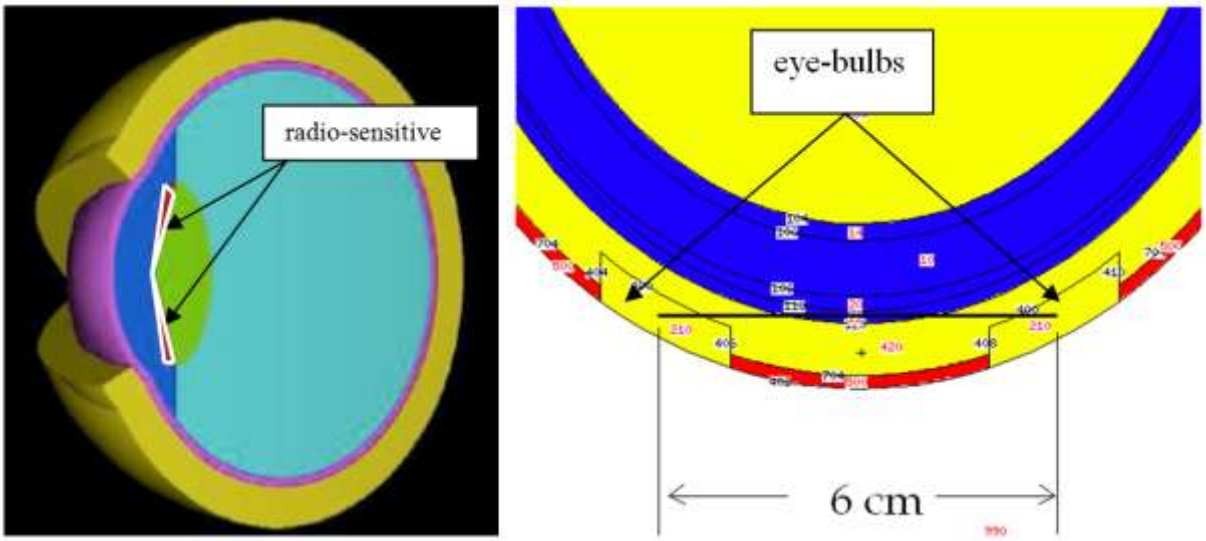


Fig. 2.3: The Behrens eye model (Courtesy R. Behrens) and an axial section of the MIRD head at the level of the eyes. In the first model, the dose is computed only in the radiosensitive volume.

Taking into account the recently calculated values of H_T(eye lens) by *Behrens et al.* for the sensitive volume of the eye, a comparison of the herewith presented data was performed to demonstrate at what extent the cylindrical shape was correctly simulating the head with embedded eyes. The comparison was also performed against conversion coefficients calculated on the trunk phantom 30x30x15 cm^3.

For this purpose the AP irradiation and the LAT irradiation were studied (see Figures 2.4 – 2.5 – 2.6). It can be seen that for AP irradiation the trunk phantom, as expected, produces a larger backscatter component (about 20% higher than the real head and the simplified cylinder (Figure2.5)). The difference is much more pronounced at 90° incidence (LAT irradiation). This is due to the presence of the edge in the slab, implying a non-physical effect compared with the head (cylinder), much more noticeable for high angles of incidence (Figure 2.6)

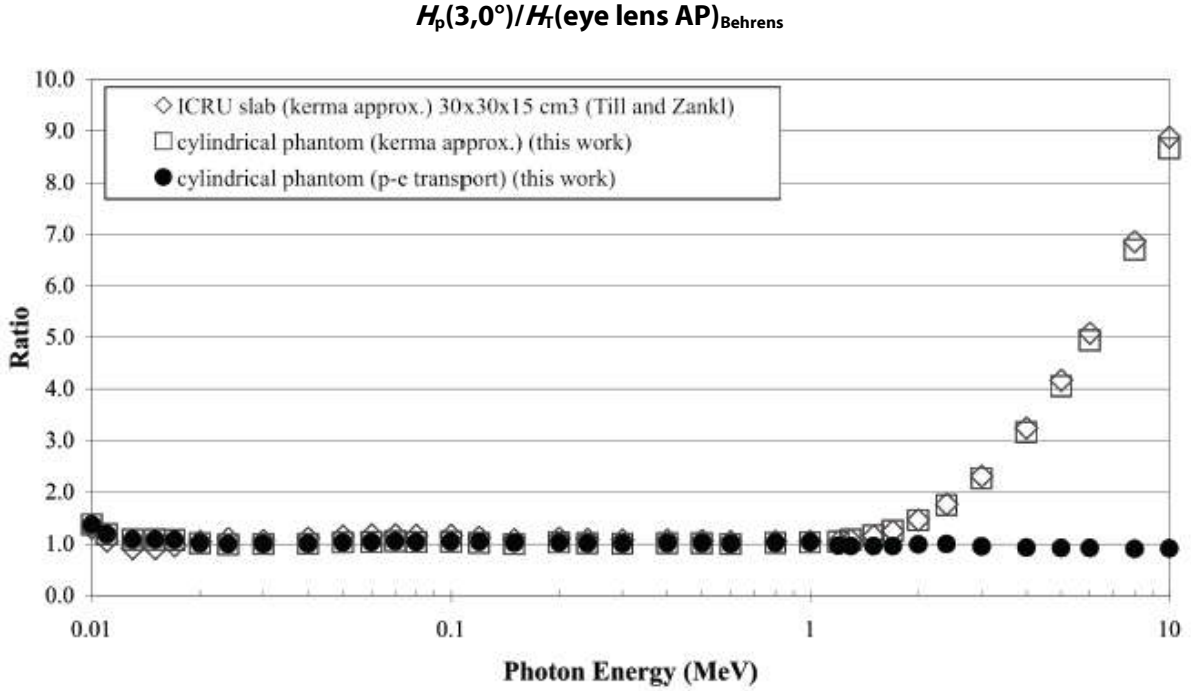


Figure 2.4: AP irradiation: $H_p(3.0°)/H_T$(eye lens) from 10 keV to 10 MeV

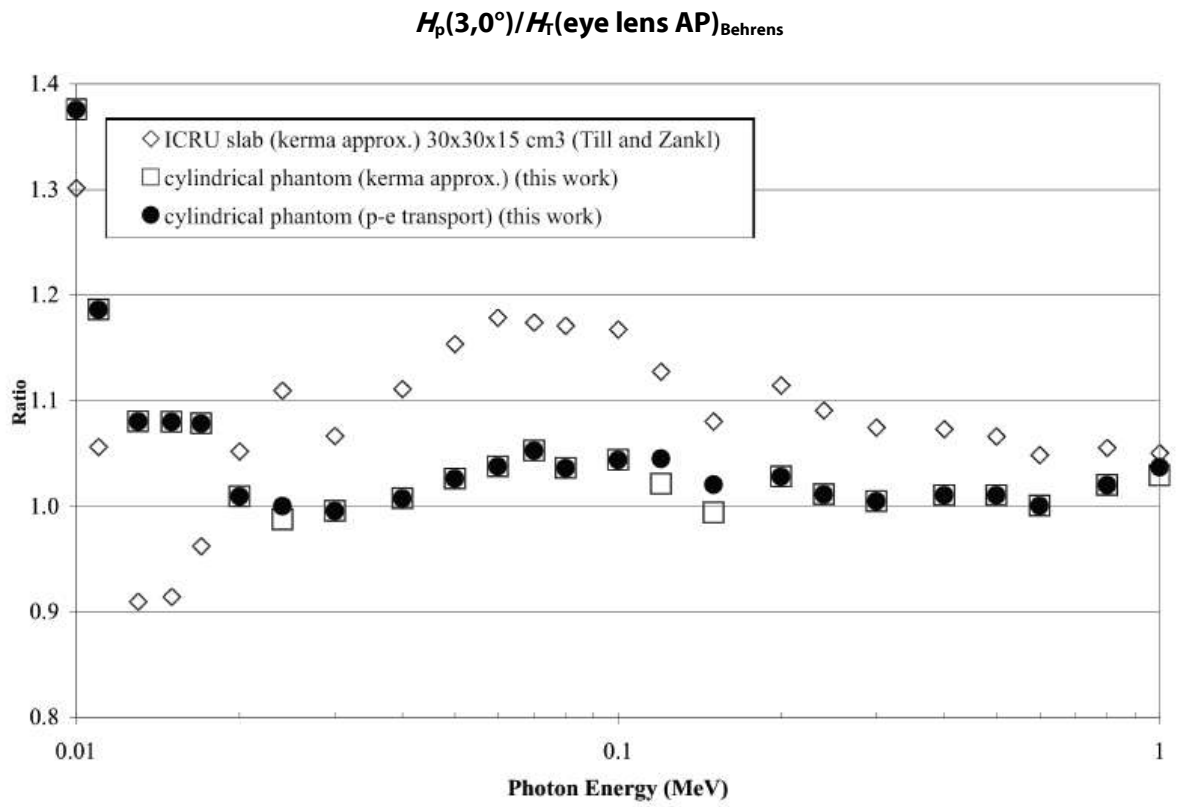


Figure 2.5: AP irradiation: $H_p(3,0°)/H_T$(eye lens) from 10 keV to 1 MeV

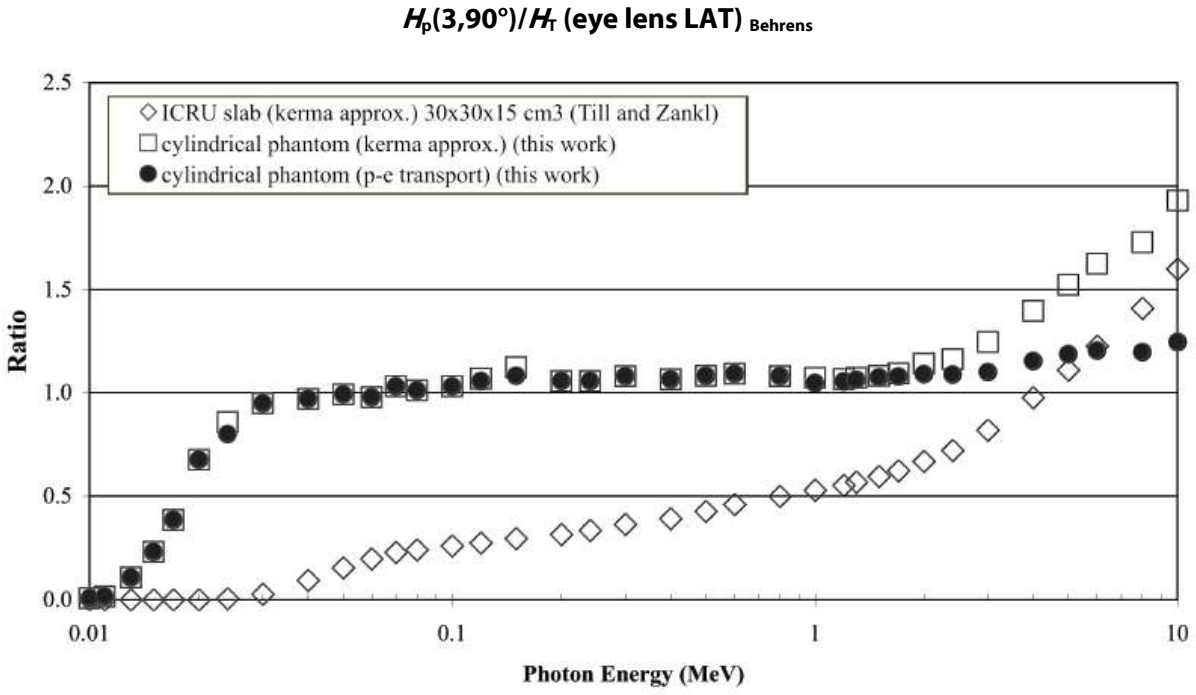


Fig. 2.6: LAT irradiation: $H_p(3,0°)/H_T$(eye lens) from 10 keV to 10 MeV

Table 2.2 $H_p(3,0°)/K_a$ and Ratio $H_p(3,\alpha) / H_p(3,0°)$ values averaged from PENELOPE and MCNP5 – kerma approximation

Photon energy	$H_p(3,0°)/Ka$	Ratio $H_p(3,\alpha) / H_p(3,0°)$ Kerma approximation														
(MeV)	(Sv/Gy)	0°	10°	15°	20°	30°	45°	60°	75°	90°	105°	120°	135°	150°	165°	180°
0.010	0.244	1.000	0.978	0.951	0.917	0.809	0.571	0.274	0.044	0.001	0.000	0.000	0.000	0.000	0.000	0.000
0.020	0.919	1.000	0.996	0.992	0.986	0.969	0.919	0.821	0.612	0.220	0.018	0.001	0.000	0.000	0.000	0.000
0.030	1.219	1.000	0.998	0.995	0.991	0.982	0.956	0.899	0.775	0.482	0.161	0.047	0.017	0.008	0.005	0.004
0.040	1.448	1.000	0.998	0.996	0.992	0.984	0.959	0.912	0.815	0.584	0.279	0.126	0.065	0.040	0.030	0.028
0.050	1.597	1.000	0.997	0.995	0.993	0.984	0.963	0.919	0.834	0.632	0.348	0.185	0.110	0.077	0.062	0.057
0.060	1.667	1.000	0.997	0.995	0.993	0.986	0.964	0.926	0.848	0.663	0.391	0.224	0.143	0.103	0.086	0.080
0.070	1.674	1.000	0.998	0.996	0.994	0.987	0.970	0.935	0.863	0.689	0.421	0.250	0.164	0.123	0.103	0.097
0.080	1.649	1.000	0.999	0.999	0.995	0.990	0.974	0.944	0.878	0.710	0.444	0.270	0.180	0.136	0.115	0.109
0.090	1.614	1.000	1.000	0.999	0.997	0.992	0.979	0.952	0.891	0.728	0.462	0.285	0.192	0.146	0.124	0.117
0.100	1.581	1.000	1.000	0.999	0.997	0.994	0.983	0.958	0.901	0.742	0.477	0.298	0.203	0.154	0.131	0.124
0.110	1.550	1.000	1.000	0.999	0.997	0.995	0.985	0.963	0.910	0.755	0.492	0.310	0.212	0.161	0.138	0.131
0.150	1.449	1.000	0.999	0.999	0.998	0.997	0.994	0.979	0.938	0.794	0.535	0.348	0.244	0.188	0.161	0.153
0.200	1.372	1.000	1.000	1.000	0.999	1.000	1.000	0.993	0.959	0.830	0.578	0.388	0.278	0.218	0.188	0.179
0.300	1.286	1.000	1.000	1.002	1.001	1.002	1.005	1.006	0.986	0.875	0.642	0.453	0.338	0.270	0.236	0.227
0.400	1.240	1.000	1.001	1.001	1.000	1.002	1.008	1.011	0.997	0.902	0.684	0.502	0.384	0.316	0.279	0.268
0.500	1.210	1.000	1.001	1.002	1.002	1.002	1.010	1.014	1.003	0.919	0.716	0.539	0.422	0.351	0.315	0.303

0.600	1.191	1.000	1.000	1.001	1.001	1.005	1.010	1.014	1.007	0.929	0.740	0.569	0.454	0.383	0.345	0.334
0.700	1.176	1.000	1.000	1.001	1.000	1.002	1.008	1.014	1.010	0.940	0.760	0.595	0.483	0.411	0.373	0.360
0.800	1.167	1.000	0.998	0.999	1.000	1.002	1.007	1.012	1.009	0.945	0.773	0.614	0.504	0.435	0.396	0.384
0.900	1.156	1.000	1.001	1.002	1.001	1.004	1.009	1.015	1.012	0.951	0.789	0.636	0.526	0.458	0.420	0.407
1.000	1.152	1.000	0.997	0.999	1.001	0.999	1.005	1.010	1.009	0.955	0.795	0.651	0.545	0.476	0.437	0.424
1.100	1.144	1.000	1.000	0.999	1.002	1.002	1.009	1.013	1.013	0.960	0.810	0.667	0.560	0.494	0.456	0.444
1.500	1.129	1.000	1.003	1.001	1.002	1.003	1.009	1.014	1.011	0.968	0.837	0.712	0.616	0.552	0.516	0.504
2.000	1.120	1.000	0.999	1.002	1.001	1.002	1.007	1.009	1.007	0.973	0.860	0.747	0.659	0.600	0.565	0.554
3.000	1.110	1.000	1.000	0.999	0.999	1.000	1.003	1.006	1.002	0.973	0.876	0.781	0.704	0.651	0.619	0.610
4.000	1.103	1.000	0.999	0.997	0.998	0.999	1.001	1.000	1.000	0.976	0.895	0.810	0.742	0.695	0.665	0.656
5.000	1.098	1.000	0.997	0.997	0.997	0.998	0.999	0.997	0.995	0.974	0.901	0.824	0.762	0.716	0.691	0.682
6.000	1.090	1.000	0.998	0.998	0.996	0.999	0.997	1.000	0.994	0.973	0.905	0.836	0.776	0.733	0.707	0.699
7.000	1.085	1.000	0.998	0.998	0.998	0.998	1.000	0.999	0.995	0.976	0.906	0.836	0.778	0.737	0.711	0.703
8.000	1.079	1.000	1.000	1.000	0.997	0.999	0.998	0.995	0.993	0.972	0.911	0.846	0.793	0.752	0.729	0.725
10.000	1.070	1.000	0.995	0.999	0.999	0.997	0.998	0.997	0.992	0.975	0.912	0.852	0.800	0.765	0.741	0.734

Table 2.3 $H_p(3,0°)/K_a$ and Ratio $H_p(3,\alpha) / H_p(3,0°)$ values averaged from PENELOPE and MCNP5 – electron transport

Photon energy	$H_p(3,0°)/K_a$	Ratio $H_p(3,\alpha) / H_p(3,0°)$ Dose														
(MeV)	(Sv/Gy)	0°	10°	15°	20°	30°	45°	60°	75°	90°	105°	120°	135°	150°	165°	180°
0.010	0.244	1.000	0.977	0.954	0.918	0.808	0.572	0.276	0.044	0.001	0.000	0.000	0.000	0.000	0.000	0.000
0.020	0.914	1.000	1.000	0.997	0.992	0.976	0.923	0.821	0.611	0.221	0.019	0.001	0.000	0.000	0.000	0.000
0.030	1.217	1.000	0.999	0.992	0.997	0.988	0.959	0.896	0.775	0.487	0.161	0.047	0.017	0.008	0.005	0.004
0.040	1.442	1.000	1.005	0.989	0.995	0.991	0.966	0.915	0.819	0.592	0.284	0.126	0.064	0.042	0.031	0.027
0.050	1.593	1.000	0.997	0.993	0.991	0.989	0.965	0.922	0.836	0.638	0.350	0.187	0.112	0.075	0.062	0.054
0.060	1.670	1.000	0.997	0.989	0.992	0.984	0.962	0.918	0.843	0.665	0.391	0.223	0.142	0.103	0.085	0.082
0.070	1.671	1.000	0.999	0.997	0.996	0.990	0.966	0.934	0.863	0.688	0.423	0.251	0.163	0.121	0.101	0.097
0.080	1.644	1.000	1.002	1.000	0.998	0.994	0.976	0.947	0.876	0.715	0.448	0.269	0.184	0.134	0.113	0.111
0.090	1.607	1.000	1.004	1.002	1.004	0.996	0.976	0.955	0.889	0.732	0.465	0.288	0.194	0.146	0.125	0.118
0.100	1.573	1.000	1.006	1.006	1.008	0.998	0.980	0.960	0.904	0.751	0.482	0.300	0.205	0.155	0.132	0.121
0.110	1.541	1.000	1.003	1.003	1.007	1.001	0.985	0.964	0.916	0.766	0.495	0.313	0.215	0.164	0.139	0.129
0.150	1.452	1.000	0.997	0.996	0.998	0.998	0.985	0.975	0.930	0.801	0.537	0.348	0.243	0.187	0.159	0.153
0.200	1.369	1.000	1.003	0.997	1.003	1.003	1.002	0.993	0.958	0.835	0.579	0.392	0.279	0.217	0.188	0.181
0.300	1.281	1.000	1.009	1.005	1.006	1.010	1.012	1.009	0.984	0.888	0.644	0.456	0.338	0.272	0.236	0.228
0.400	1.242	1.000	1.003	0.999	1.007	1.003	1.006	1.006	0.991	0.909	0.689	0.503	0.382	0.315	0.280	0.270
0.500	1.209	1.000	1.006	1.002	1.006	1.006	1.007	1.005	1.002	0.927	0.719	0.542	0.423	0.351	0.314	0.304
0.600	1.184	1.000	1.008	1.000	1.014	1.010	1.010	1.014	1.006	0.943	0.748	0.573	0.464	0.385	0.350	0.337

0.700	1.169	1.000	1.003	1.009	1.012	1.006	1.013	1.013	1.008	0.948	0.770	0.598	0.486	0.417	0.380	0.365
0.800	1.155	1.000	1.010	1.010	1.015	1.009	1.016	1.019	1.015	0.960	0.786	0.618	0.512	0.438	0.403	0.397
0.900	1.154	1.000	1.006	0.999	1.008	1.008	1.014	1.013	1.007	0.956	0.790	0.635	0.530	0.457	0.420	0.414
1.000	1.147	1.000	1.007	1.006	1.004	1.008	1.014	1.012	1.014	0.967	0.800	0.656	0.546	0.475	0.444	0.431
1.100	1.131	1.000	1.004	1.008	1.008	1.013	1.019	1.025	1.024	0.974	0.821	0.674	0.569	0.502	0.464	0.448
1.500	0.975	1.000	1.008	1.007	1.023	1.045	1.083	1.132	1.153	1.124	0.977	0.822	0.712	0.640	0.596	0.584
2.000	0.740	1.000	1.021	1.020	1.052	1.093	1.209	1.336	1.428	1.431	1.292	1.118	0.995	0.909	0.853	0.841
3.000	0.461	1.000	1.028	1.038	1.080	1.164	1.399	1.688	1.987	2.139	2.041	1.873	1.703	1.596	1.514	1.504
4.000	0.328	1.000	1.017	1.031	1.074	1.174	1.476	1.933	2.491	2.835	2.828	2.656	2.482	2.330	2.244	2.213
5.000	0.250	1.000	1.018	1.046	1.089	1.204	1.523	2.108	2.908	3.527	3.654	3.477	3.328	3.146	3.026	2.995
6.000	0.201	1.000	1.026	1.041	1.089	1.196	1.555	2.202	3.262	4.189	4.446	4.335	4.156	3.939	3.841	3.770
7.000	0.168	1.000	1.034	1.051	1.091	1.194	1.560	2.252	3.510	4.746	5.264	5.193	4.959	4.750	4.635	4.590
8.000	0.145	1.000	1.036	1.054	1.083	1.191	1.550	2.279	3.723	5.286	6.004	5.997	5.791	5.530	5.404	5.360
10.000	0.115	1.000	1.022	1.045	1.069	1.175	1.513	2.259	3.901	6.162	7.358	7.457	7.287	7.051	6.886	6.803

2.3.2 Uncertainties of the calculated values due to x-section libraries

The MCNPX values obtained, using mcplib02, are in good agreement with the other two sets of data (based on mcplib04) for energies above 80 keV, whilst for lower energies both $H_p(3)/\Phi$ and K_a/Φ show a remarkable difference due to the coarser interaction parameter representation. InFigures2.7 and 2.8 the total photon cross section for air and ICRU soft tissue for mcplib02 and mcplib04 are shown.

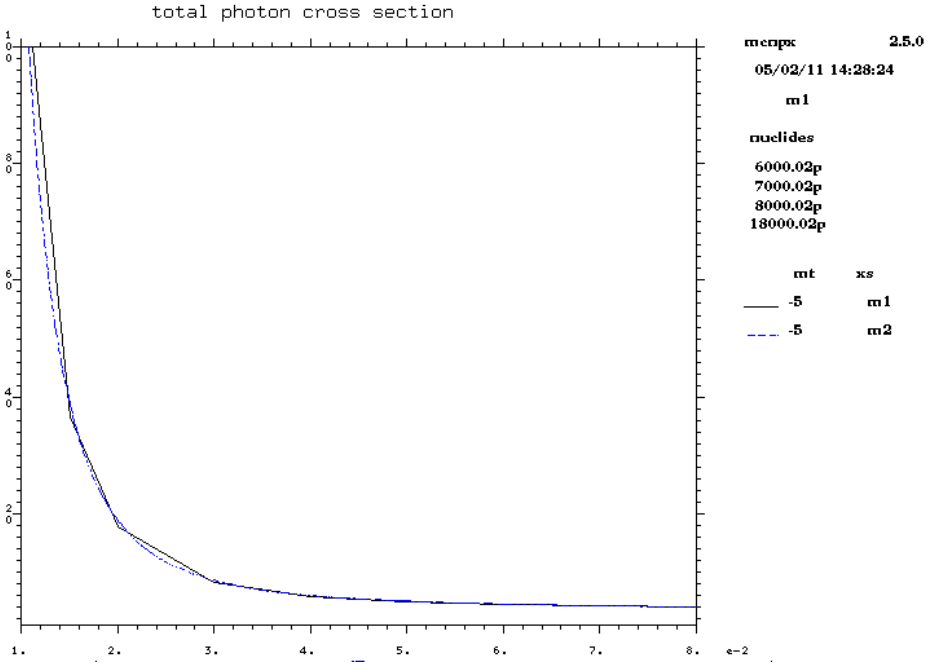


Figure 2.7: Air photon x-sections (m1-mcplib02, m2-mcplib04)

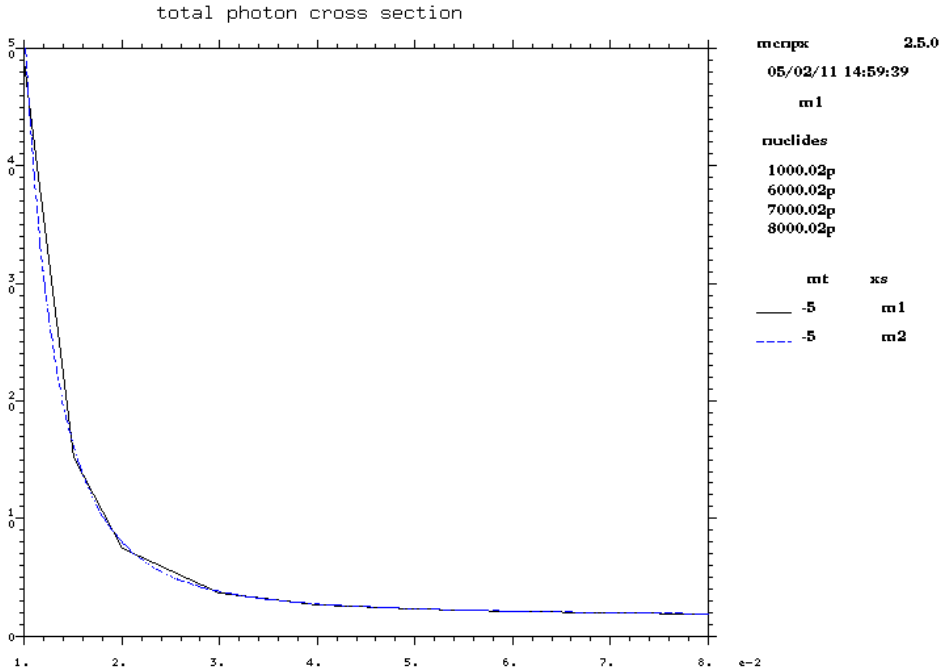


Figure 2.8: Soft tissue photon x-sections (m1-mcplib02, m2-mcplib04)

It has to be taken into account that the air kerma per unit fluence K_a/Φ value is evaluated only on the basis of the mass energy transfer coefficient for the source energy with no transport involved, whilst the $H_p(3)/\Phi$ is calculated following the transport of photons (kerma approximation) or photons and secondary electrons (coupled full transport) within the phantom. The ratio of the two quantities is of interest and it can be expected a compensation effect (at least partial) that could reduce the discrepancy due to the libraries.

In Figures 2.9 – 2.11 the ratios of the values obtained with mcplib02 (and MCNPX) and those based on mcplib04 (and MCNP5) are plotted.

Despite the deviations encountered in $H_p(3)/\Phi$and K_a/Φ evaluations below 80 keV, their ratios, $H_p(3)/K_a$, are in good agreement down to 10-20 keV, because of compensating effects between the two quantities as can be seen in figure 2.11 showing $H_p(3)/K_a$ at 0° and 60°.

However it has to be advised to use mcplib04 instead of mcplib02.

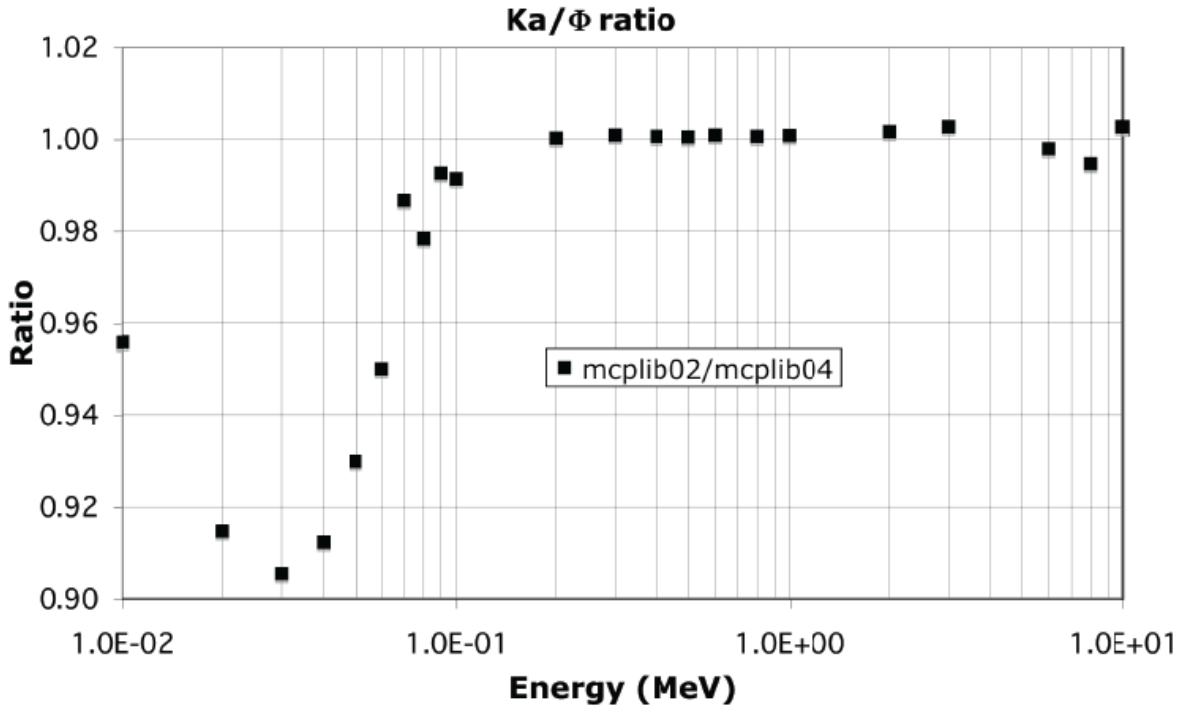


Figure 2.9:K_a/Φ ratio between values based on mcplib02 and mcplib04

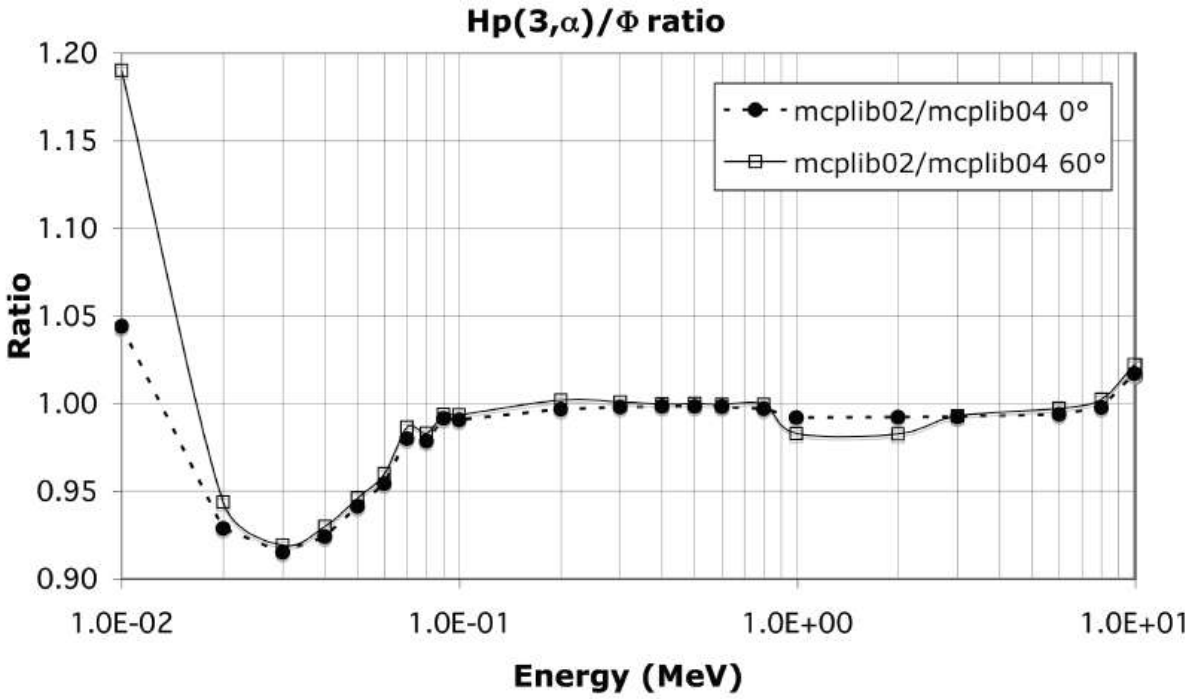


Figure 2.10:$H_p(3)/\Phi$ ratio between values based on mcplib02 and mcplib04

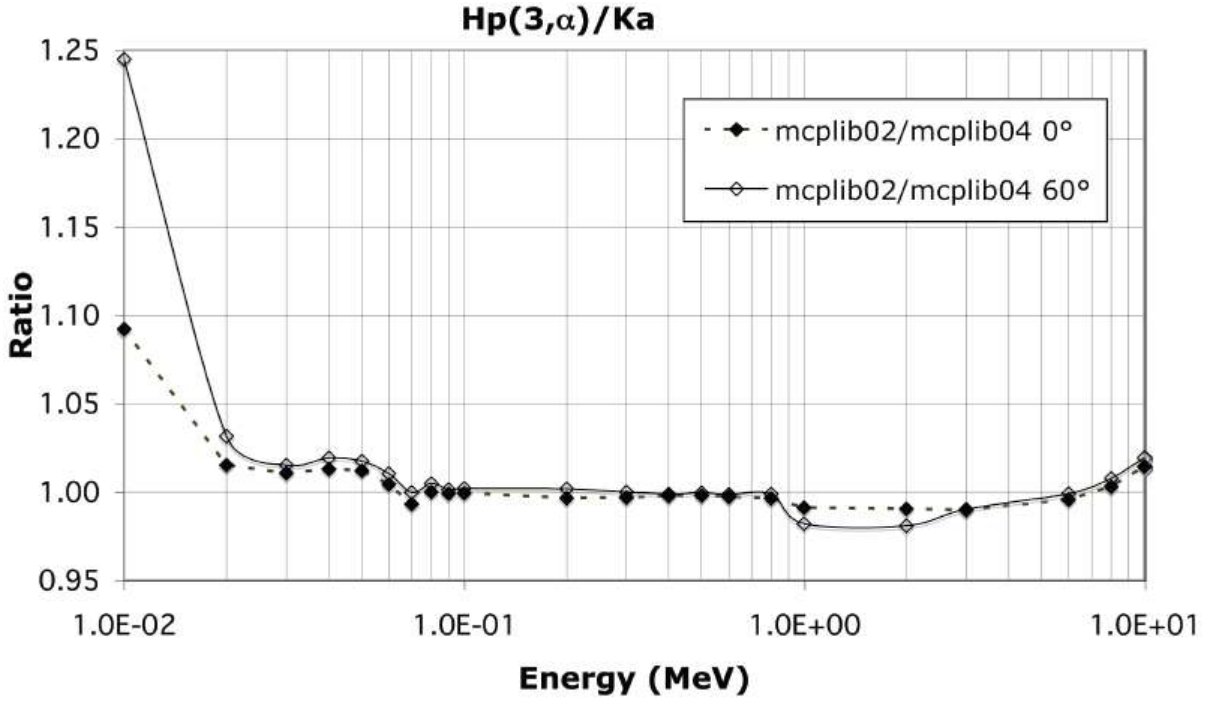


Figure 2.11 $H_p(3)/K_a$ ratio between values based on mcplib02 and mcplib04

2.4 Development of the eye-lens dosemeter prototype

One of the tasks of the ORAMED project was to develop a thermoluminescent (TL) dosemeter especially dedicated to measurements of $H_p(3)$. The dosemeter had to satisfy the following

conditions: 1-measuring correctly $H_p(3)$, 2- being comfortable for users and for dosimetric services, 3-waterproof, and 4- inexpensive.

From the beginning of the development process it was decided that the dosemeter would be designed in a modular form, consisting of two separate parts: the measuring element, i.e. a capsule with a thermoluminescent detector (TLD), and a holder, which would fix position of a capsule close to an eye. This approach ensured flexibility, both at the development stage and in future; because following feedbacks from the users changes to the holder could be needed.

The process of designing consisted of optimization of two main dosimetric characteristics: photon energy response and angular response. The photon energy range of interest is mainly 20-100 keV. The optimization could be achieved by variation of four factors: TLD type, TLD dimensions, capsule material and capsule dimensions.

2.4.1 Choice of TLD type

A variety of TL detectors is available, however the most commonly used are those based on lithium fluoride (LiF). It was therefore decided to limit the investigated TLD types to LiF detectors, which show very good dosimetric properties: sensitivity (detection threshold below 1 μSv), dose equivalent response (linear up to 1 Sv), quite flat energy dependence stability at various conditions. Two types of TLDs based on lithium fluoride, are available: the standard LiF:Mg,Ti (marketed by Radcard as MTS-N) and the high-sensitive LiF:Mg,Cu,P (marketed as MCP-N), which photon energy response is significantly different (Figure 2.12). It can be seen that the measured response of LiF:Mg,Ti is up to about 10% higher compared to what can be predicted from the mass energy absorption coefficients. The measured photon energy response of LiF:Mg,Cu,P is lower than predicted on the basis of mass energy absorption coefficients, with a characteristic minimum at 100 keV. The observed differences are due to the dependence of intrinsic thermoluminescence efficiency on ionization density and can be explained with microdosimetric models (Olko, 2002). Both LiF:Mg,Ti (MTS-N) and LiF:Mg,Cu,P (MCP-N) types of TLDs were considered for application in the eye-lens dosemeter.

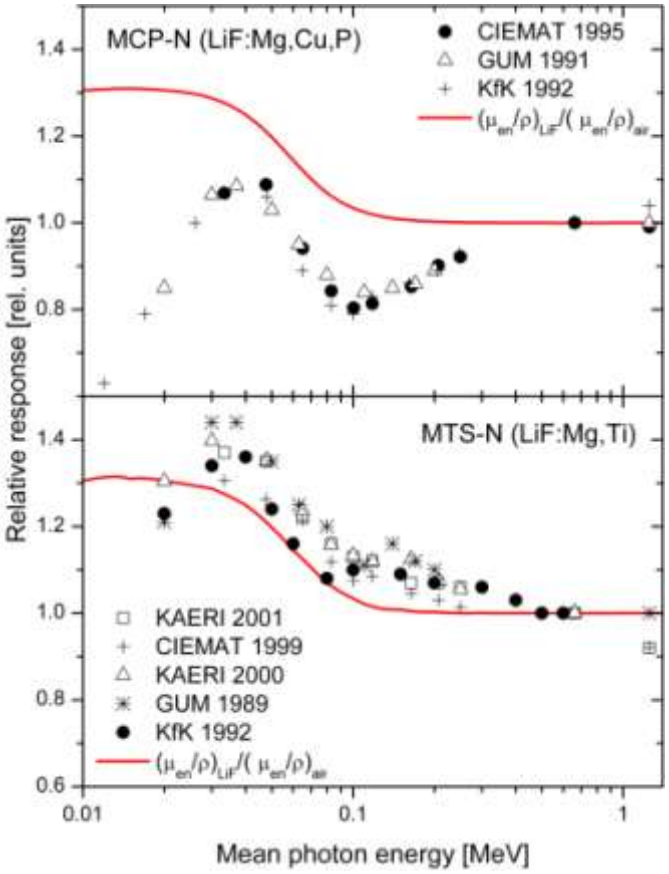


Figure 2.12: Photon energy response of LiF:Mg,Cu, P (MCP-N) and LiF:Mg,Ti (MTS-N) as measured in several experiments. Solid lines indicate dependence of the mass energy absorption coefficient (after Olko, 2002).

2.4.2 Designing of the dosemeter

The main tool in the dosemeter design process was computer modelling.

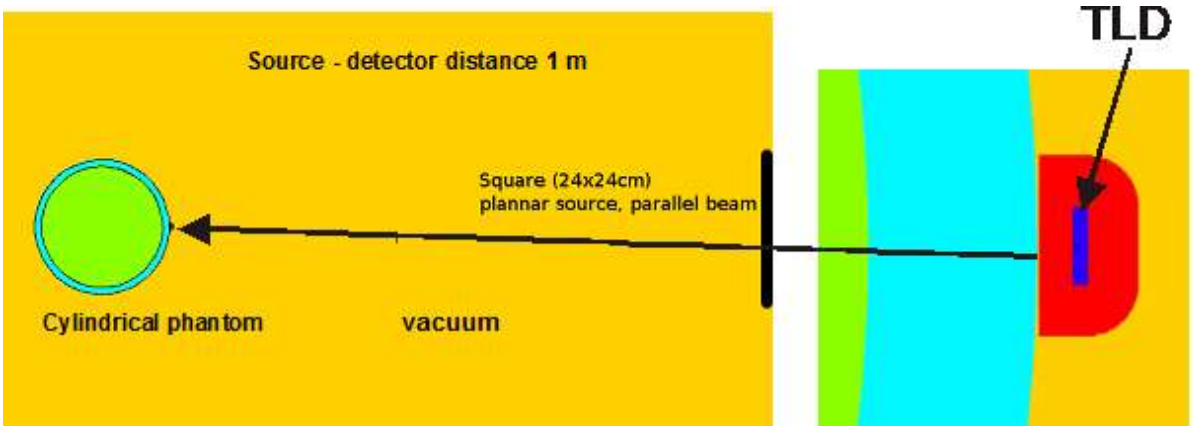


Figure 2.13: Model of the geometry used in the MCNP-X calculations. On the right, a zoom of the capsule with the TL sensor is shown.

The theoretical response of dosemeter models mounted on a 20 cm diameter 20 cm height cylinder with 0.5 cm PMMA walls, filled with water (Figure 2.13), was studied through Monte Carlo

simulations relying on MCNP-X. The applied irradiation geometry is illustrated in the Figure 2.13 $H_p(3)$ values were calculated according to the formalism described by Gualdrini et al (Gualdrini, G. et al. 2011). The response of TL detectorsfor the given photon radiation was calculated by folding the dose $D(E_e)$delivered in the detector by secondary electrons of energy $E_e$with the calculated relative efficiency of LiF:Mg,Cu,P for monoenergetic electrons $\eta(E_e)$.

$$R(E_{ph}) = \int D(E_e)\,\eta(E_e)\,dE_e \tag{1}$$

This was obtained employing the microdosimetric model of TL efficiency (Olko, 2002). Finally, the relative response (in terms of $H_p(3)$) $R(E_{ph})_{Hp(3)}$ of the dosemeter normalized to Cs-137, was calculated according to

$$R(E_{ph})_{Hp(3)} = \frac{R(E_{ph})/H_p(3)}{R(E_{Cs137})/H_p(3)_{Cs137}} \tag{2}$$

The first series of calculations were aimed at initially selecting a material for manufacturing of measuring capsules and TLD type, and was realized under several simplifications (smaller source dimensions, smaller statistics, etc). Many polymer materials were studied, as well as both types of TLDs with different thickness. Some examples of the results are presented in Figures 2.14 and 2.15. The results indicated that the optimum configuration of the dosemeter is a polyamide capsule with a LiF:Mg,Cu,P detector. It is also apparent that within the energy range of interest (above 20 keV) there is no need to decrease TLD thickness below the standard 0.9 mm. The choice of polyamide was also good from the technological point of view, as polyamide is a good material for the injection moulding, which was the preferred production technology.

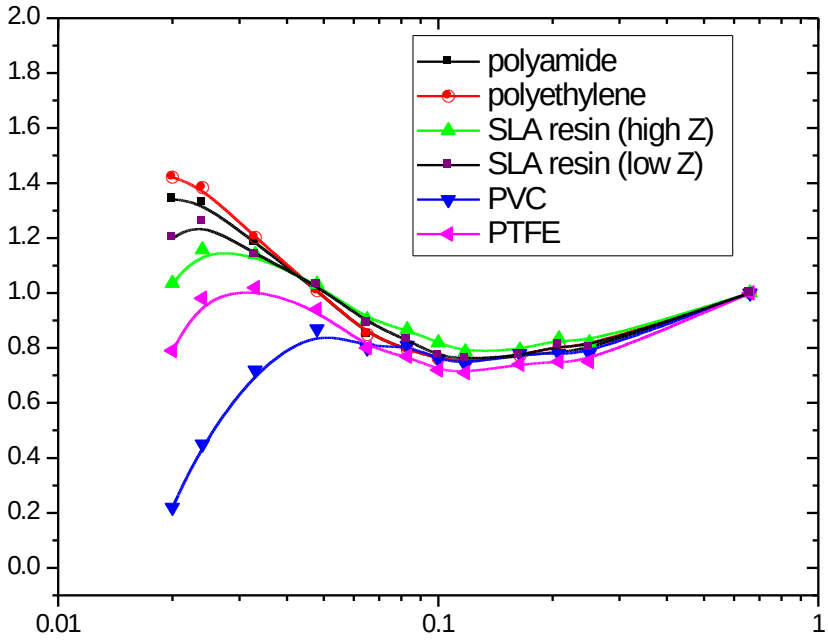


Figure 2.14. Calculated relative photon response of 0.9 mm thick MCP-N TLDs located inside a 3mm thick capsule of hemispherical shape, constituted by various materials.

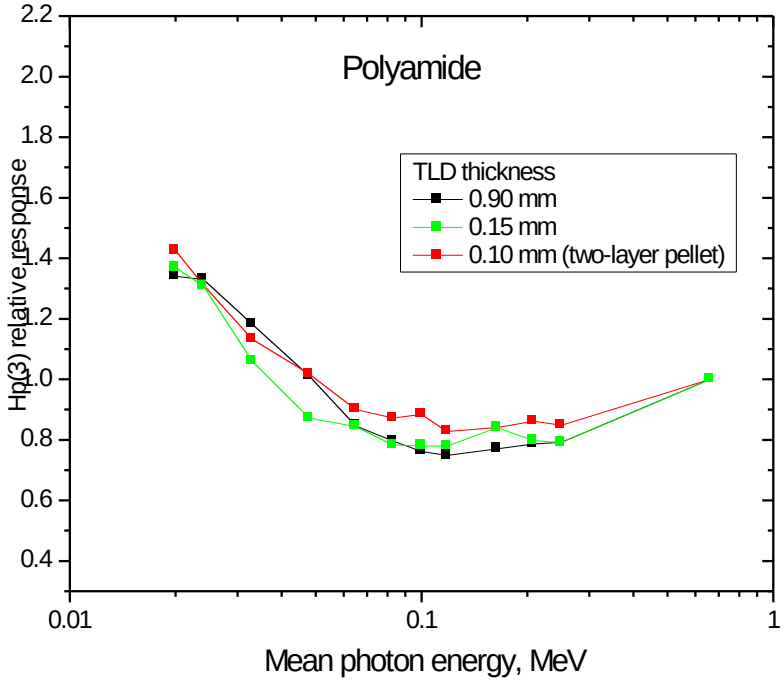


Figure 2.15. Calculated relative photon response of MCP-N TLDs of different thicknesses, located inside a 3 mm thick capsule of hemispherical shape constituted by polyamide.

The correctness of this choice was verified through measurements with different X-ray spectra. The irradiation tests were done at CEA LIST LNHB French primary laboratory using Cs-137 gamma rays and RQR spectra (IEC-61267 2005). RQR spectra are much wider than N spectra ISO series, but better resemble the spectra at workplaces. For testing, the capsule models were manufactured with the machine cutting technology from polyamide and also, for comparison, from PMMA and PVC. Similarly, for comparison, LiF:Mg,Ti detectors were also used.

The results of measurements, presented in Figure 2.16, confirm conclusions drawn from the calculations. The LiF:Mg,Ti detectors exhibited a significant over response, as expected. The photon energy response of LiF:Mg,Cu,P detectors in a polyamide capsule was the flattest. Therefore, it was decided to use the 3 mm thick polyamide capsule with the shape of a hollow hemisphere assuring the best energy and angular response. The polyamidedensity is 1.13 g/cm^3, higher than tissue, but the increased photon absorption of the polyamide for low energy photons was compensated by the slight over response of LiF:Mg,Cu,P in these energy regions.

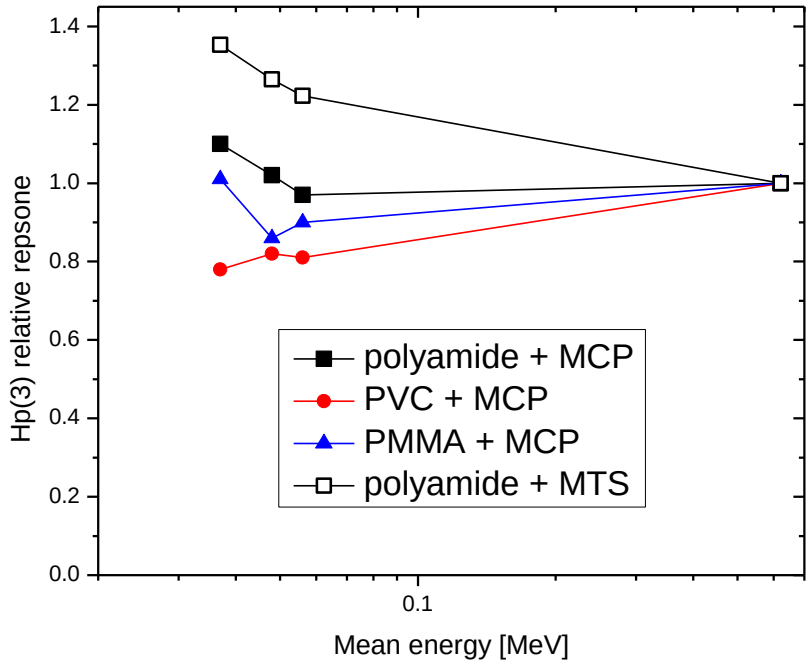


Figure 2.16. The measured photon energy response of the tested dosemeter configurations.

The capsule will be prepared to accommodate MCP-N LiF:Mg,Cu,P TL detectors in form of pellets (Ø4.5 mm x 0.9 mm). The capsules were theninserted into a holder, attached to a headband (Figure 2.17a). The new dosemeter was named *EYE-D™*. The capsule ensures is watertight, enabling cold sterilisation or disinfection. Opening of the dosimeter is easy with a special tool (Figure 2.17b). The holder and the capsule are designed for unlimited usage.

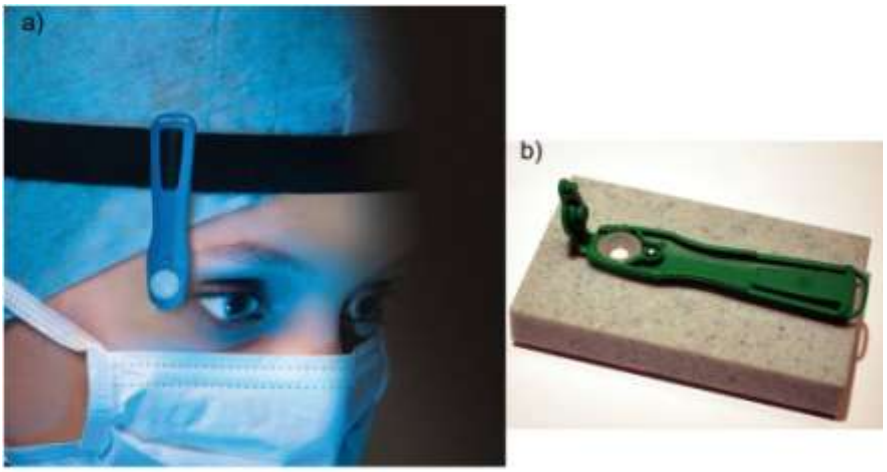


Figure 2.17. Illustration of the EYE-D™ as worn on head (a) and placed on the opening tool (b).

2.4.3 Characterization of the final prototype

After manufacturing of the prototype batch of dosemeters, a new series of calculations and measurements aimed atdetermining the photon energy and angular dependence was performed. Irradiations were again carried out at the LNHB. This time not only RQR but also ISO narrow series spectra were used (ISO-4037-1 1997).

The results are presented in Figures 2.18 and 2.19. Calculations were done using the complete N series of ISO, while measurements with a few well-chosen qualities allow validating these calculations over the all energy range of interest. Both calculations and measurements results indicate that the response of the dosemeter is within about 20% for narrow spectra and within 10% for RQR spectra (within an energy range from 8 keV to 662 keV), what should be considered as a very encouraging result. The minimum of the response for LiF:Mg,Cu,P occurs at 100 keV. The angular response is presented, normalized to normally incident Cs-137, representing the standard calibration condition. The obtained values are between 1.05 (RQR-4, 0°) and 0.81 (RQR-9, 75°). Whilst these results are quite satisfactory, they might be still improved by correcting a small (5-20%) under response observed at larger angles. This can be achieved by applying a 5-10% correction factor to the Cs-137 calibration and consequently shifting all results up. In this way the relative response of the *EYE-D™* for RQR wide spectra should be within about +/-12% around unity for all angles.

Simulation of the dosemeter response for beta-rays fields was not performed and is planned for the near future.

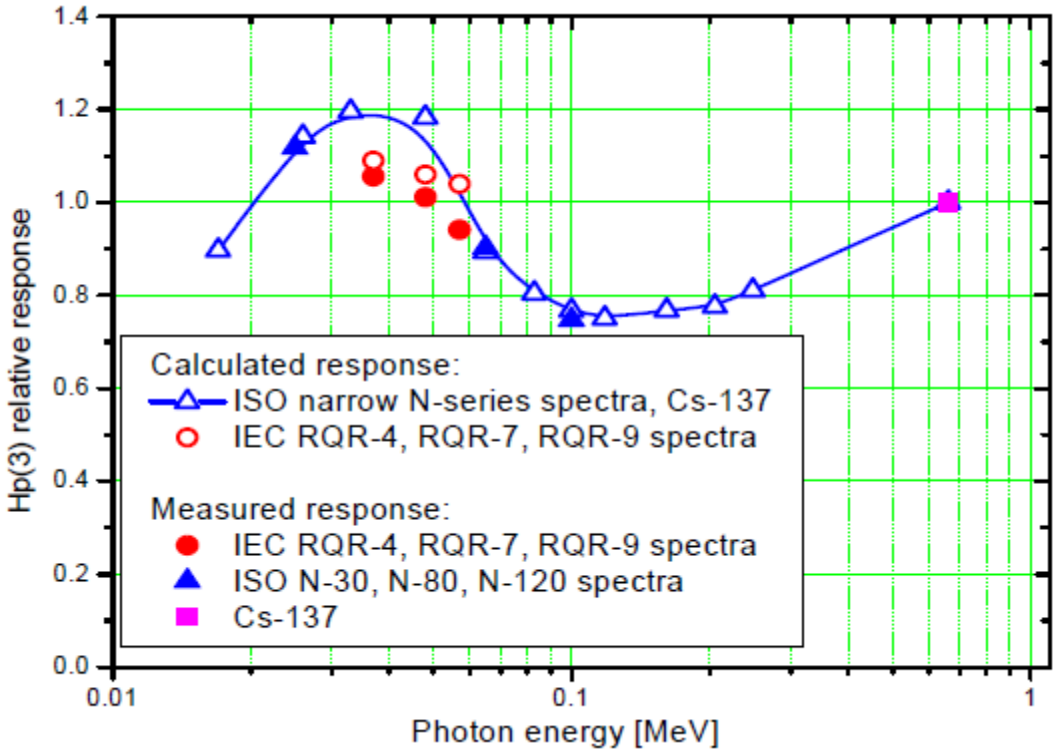


Figure 2.18. Calculated (open symbols) and measured (full symbols) $H_P(3)$ response of the new EYE-D™ dosemeters for RQR and ISO N X-ray spectra.

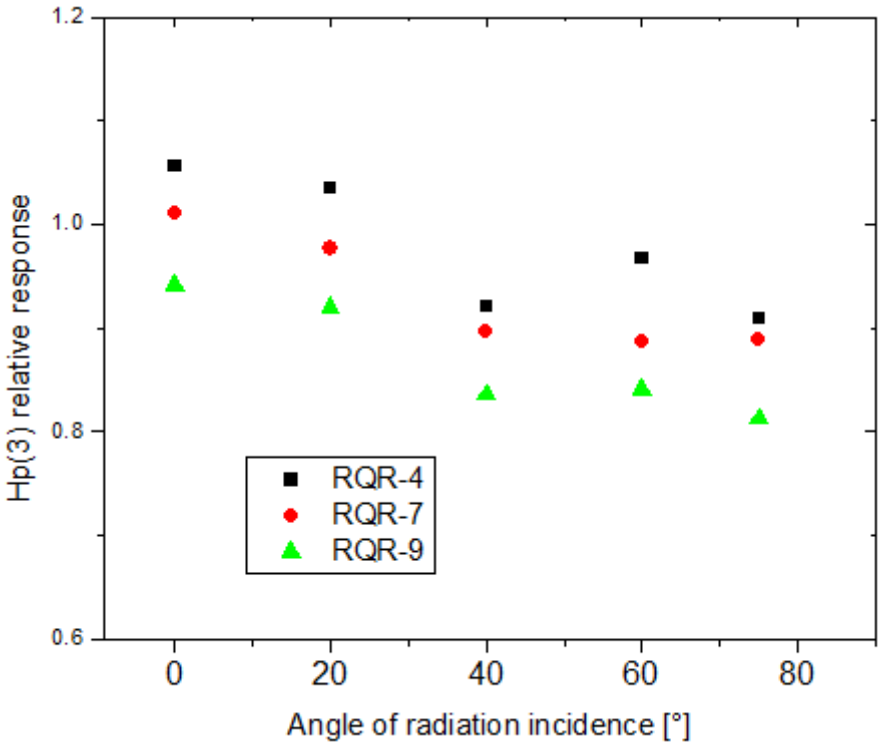


Figure 2.19. Angular $H_P(3)$ response of the new EYE-D™ dosemeter for RQR spectra (normalized to response to Cs-137 gamma rays, normal incidence).

2.4.4 Conclusions

The new eye-lens dosemeter responding in terms of $H_P(3)$ was designed, optimized and tested. It consists of a MCP-N (LiF:Mg,Cu,P) TL detector inside a polyamide capsule. The dosemeter holder enables comfortable wearing it on a head, at position fixed close to an eye. The dosemeter is designed for an unlimited usage and enables cold sterilization. The test measurements and Monte Carlo calculations of the photon energy response and angular response produced very satisfactory results: all obtained values are within about 20% around unity (with respect to Cs-137). The dosemeter fulfils all requirements (see next chapter) for its application in dosimetry for interventional radiology.

The dosemeterwas named *EYE-D*™ and is commercially available from the RADCARDcompany.

2.5 Establishing the calibration and type test procedures for $H_p(3)$

2.5.1 Scope

This chapter has not been conceived as a standard including all basic definitions but it is set to become the basis of the future standard or new version of existing standards which will include the eye lens dosimetry. Prior to going into the details of the type test criteria and the calibration procedure we should bear in mind a couple of basic information on dosimetry system, type testing and calibration, and on the specificity of exposures in IC/IR.

For passive dosemeters, the assessment of doses does not depend only onthe dosemeter itself. The doses are evaluated using electronic devices (readers). Therefore a "dosimetry system" includes any devices needed for assessing the doses e.g. dosemeter plus reader plus auxiliary equipment. The word "detector" refers only to the sensitive part of the dosemeter.

Before being available on the market, dosimetry systems are type tested according to the relevant EN/IEC or ISO standards to determine their rated ranges of use for all influence quantities. Comparing these rated ranges with those required for a given workplace, one can judge the suitability of the dosemeter for measurements in workplace conditions . It has to be noticed that this test is not mandatory in all countries. Failure of any part of the test should be clearly detailed and reasons for the failure considered (European Commission, 2009). To carry out type tests is the responsibility of the manufacturer. All the radiation fields used must be well characterized and traceable to a national standard. As long as the dosimetry system is unchanged, the results of the type test remain valid.

Afterwards, when used by dosimetry services, the dosimetry system must be calibrated against a national reference in order to ensure the traceability to the international system of units. This reference calibration of the dosimetry system should be repeated at regular intervals (every 2 or 3 years) depending on the stability of the dosimetry system and the uncertainty budget associated to dose measurements. There should be more frequent periodic checks on the performance of the dosimetry system which may be carried out using non-reference fields and a fixed procedure. (European Commission, 2009). The present chapter deals only with the suggested modifications to the type testing procedure required for Hp(3) passive dosimetry.

2.5.2 State of the art.

2.5.2.1 Available standards

Type tests are intended to demonstrate the basic performance of the type of the dosemeter. For dosimetry systems based on passive personal dosemeters, to monitor individuals occupationally exposed to external radiation, two International and European standards exist for type testing. They cover photon and beta radiations.

- IEC 62387-1 "Radiation protection instrumentation – Passive integrating dosimetry systems for environmental and personal monitoring – Part 1: General characteristics and performance requirements" (IEC, 2007).
- ISO 12794 "Nuclear energy – Radiation protection – Individual thermoluminescence dosemeters for extremities and eyes" (ISO, 2000).

A few remarks can be done about these standards:

- Even if the goal of these standards is the same, two slightly different approaches are used. ISO standard is based on the characteristic of the dosemeter itself while IEC standard studies a dosimetric system including other requirements about the reader and ancillary equipment and procedures for converting the reading into dose.
- Only the ISO standard takes into account the eye lens dosimetry,
- ISO standard is especially written for TLD based dosemeters while IEC standard includes any type of dosemeters.

- None of these standards takes into account the pulsed radiation fields.

Table 2.4: Comparison of the main requirements of ISO and IEC standards for passive photon dosimetry. (Adapted from [European commission, 2009]). The proposal of this work has been added in the first column.

<table>
<tr><th rowspan="2">(Influence) quantity</th><th>This work (proposal)</th><th>ISO 12794</th><th colspan="2">IEC 62387-1</th></tr>
<tr><td>All passive
Eyes lens</td><td>TLD,
Extremity and eyes lens
$H_p(0.07)$ and $H_p(10)$</td><td>All passive
$H_p(0.07)$</td><td>All passive;
$H_p(10)$</td></tr>
<tr><td>Radiation energy</td><td>(15 keV to 3 MeV)
0.6 ≤ response ≤ 1.4
(20 keV to 100 keV)
0.7 ≤ response ≤ 1.3</td><td>(15 keV to 3 MeV)
0.5 ≤ response ≤ 1.5</td><td rowspan="2">Energy
30 keV to 250 keV
and angle:
0.71 ≤ response ≤ 1.67</td><td rowspan="2">Energy
80 keV to 1.25 MeV
and angle:
0.71 ≤ response ≤ 1.67</td></tr>
<tr><td>Angle of incidence
(0 to 60°)</td><td>0.85 ≤ response ≤ 1.15
(0° to 60°)
0.7 ≤ response ≤ 1.3
(0° to 75°)</td><td>at 60 ± 5 keV:
0.85 ≤response≤ 1.15</td></tr>
<tr><td>Threshold</td><td>0.2 mSv</td><td>1 mSv</td><td colspan="2">0.01 mSv (from the “scope and object” chapter)</td></tr>
<tr><td>Linearity</td><td>0.2 mSv to 1 Sv
0.9 ≤ response ≤ 1.1</td><td>1 mSv to 1 Sv:
0.9 ≤ response ≤ 1.1</td><td>1 mSv to 3 Sv
0.91 ≤ response ≤ 1.11</td><td>0.1 mSv to 1 Sv
0.91 ≤ response ≤ 1.11</td></tr>
<tr><td>Coefficient of Variation</td><td rowspan="3">Criteria from both IEC and ISO standard are relevant</td><td>reproducibility: 10%
batch homogeneity: 15%</td><td>from 15% (< 1 mSv)
to 5% (≥ 11 mSv)</td><td>from 15% (< 0.1 mSv)
to 5% (≥ 1.1 mSv)</td></tr>
<tr><td>Environmental conditions and others</td><td>temperature up to +40°C
and humidity up to 90%:
0.9 ≤ response ≤ 1.1
light exposure:
0.9 ≤ response ≤ 1.1</td><td colspan="2">temp.:-10°C to +40°C,
humidity 40% to 90%,
fading, light, reader stability
and power supply combined:
0.83 ≤ response≤ 1.25</td></tr>
<tr><td>Additivity (1)</td><td rowspan="4">Not treated
in this paper</td><td rowspan="4">no requirement</td><td colspan="2">0.91 ≤ response ≤ 1.11</td></tr>
<tr><td>Electromagnetic Compatibility (EMC)</td><td colspan="2">IEC 61000-6-2
deviation (2) limited</td></tr>
<tr><td>Mechanics</td><td colspan="2">IEC 60068-2-32 ; deviation (2) limited</td></tr>
<tr><td>Software</td><td colspan="2">WELMEC Guide 7.2 (3)</td></tr>
</table>

(1) Additivity of measured values for different irradiation conditions.

(2) Deviation is an additional indication which is due to the influence quantity, e.g. to additional or lost pulses as a result of EMC.

(3) A guide to software requirements from the European Corporation in Legal Metrology, recommended for application all over Europe.

As it is mentioned in the introduction of ISO 12794, this international standard should be used in conjunction with IEC 61066 (which has been replaced by 62387-1) (IEC, 2006).Additional requirements relative to additivity and to the reader (electromagnetic compatibility, mechanics and software) could be added later on the basis of IEC standards.

2.5.2.2 Wearing conditions at the workplace and consequences on type test criteria and calibration procedure.

The most used high voltage in IR/IC lies between 60 and 110 kVp, therefore, the photon spectrum lies from 20 keV to the maximum high voltage values; usually the X-ray tube can reach 150 kVp. Taking into account this energy range, where a quite large variation of the energy response of the dosemeter can be encountered a stricter criterion for the energy response in the field of IC/IR could be set. It should be noted that this difficulty is not specific to the eye lens dosimetry, it is also the case for whole body and extremity dosimetry in IC/IR.

Collective and individual protective equipment (glasses, ceiling shielding) can be used to reduce radiation exposure to eye. Thus, the scattered X-ray spectrum incident on the eye and the associated dose equivalent rates depend on the use of protection [Carinou *& al.* 2009]. So, to measure the real exposure, it is advisable to wear the dosemeter (close to the eye at the level of the temple) in contact with the skin to account for the real shape of the head and on the side of the fore-head facing the X-ray tube. The sensitivity of the dosemeter system must be sufficient to measure low X-ray equivalent dose behind the shielding materials. Apart from accidental circumstances, the main part of the radiation, to which the medical staff is exposed, is scattered by the patient. The table curtain and ceiling suspended shield are used to screen part of this scattered radiation. So the angle of incidence of the radiations toward the medical staff could be restricted to a particular solid angle. Therefore, the angular response of the dosemeter is a critical parameter and a more drastic requirement than the one proposed in the IEC standard may be introduced. However, it has to be taken into account that such more drastic requirements for the angle and/or energy responses can be difficult to fulfil.

2.5.3 Type test procedure

Concerning the passive dosemeters for the eye lens dosimetry, the following table, taken from ISO 12794 (Individual thermoluminescence dosemeters for extremity and eyes) described the influence quantities and their associated criteria.

Table 2.5: Performance requirements for extremity and eye dosemeter (ISO, 2000)

No	Performance Characteristics	Class of dosemeter	Performance requirements	Test required
1	Batch Homogeneity	R/D	The coefficient of variation of the evaluated value for n dosemeters shall not exceed 15% for a dose of 10 mSv or less	Q
2	Reproducibility	R D	The coefficient of variation of the evaluated value for n dosimeters shall not exceed 10% for each dosemeter separately for a dose of 10 mSv or less No requirement	Q
3	Linearity	R/D	The response shall not vary by more than 10 % over the dose equivalent range 1 mSv to 1 Sv	T
4	Stability of dosemeters under various climatic conditions	R/D	The evaluated values of the dosemeters irradiated either at the beginning or at the end of a storage period shall not differ from the conventional true value by more than 5% for 30 d storage under standard test conditions, or 10% for 48 h storage at 40%C and 90% relative humidity	T
5	Detection Threshold	R/D	The detection threshold shall not exceed 1 mSv	T
6	Self irradiation	R/D	After a storage period of 60 days, the zero point shall not exceed 2 mSv	T
7	Residue	R	After irradiation with a conventional true value of 100 mSv, the detection threshold limit shall not exceeded and the response shall remain within the requirement for linearity at a dose level of 2 mSv (not clear-some language errors)	T
8	Effect of light exposure on the dosemeter	R/D	As a result of exposure to 1000 $W.m^2$ equivalent to bright sunlight (295 nm to 769nm) for 1 day. the zero point shall not change by more than 1 mSv and, for exposure during one week, the evaluated value shall not differ from the evaluated value of a dosemeter kept in the dark by more than 10%	T
9	Isotropy (photons)	R/D	When irradiated with photons of (60 +/- 5) keV, the mean value for the response at angles of incidence of 0°, 20°, 40° and 60° from normal shall not differ from the corresponding response for normal incidence by more than 15%	T
10	Energy response (photons)	R/D	When irradiated with photons in the energy range 15 keV to 3 MeV, response shall not vary by more than +/-50%	T
11	Energy response (Beta)	R/D	When irradiated with beta radiation in the energy range (E_{max}) 0.5 MeV to 3 MeV, response shall not vary by more than +/-50%	T

Two kinds of performance requirements are identified: type tests (T) and quality control tests (Q). Type tests are intended to demonstrate the basic performance of the type of the dosemeter and quality control tests are intended to verify the performance of a specific production or delivery

batch of dosemeters. Because IEC standards do not introduce such a distinction, we will deal with both aspects in the following.

Among the characteristics listed in the table 2.5, some are not entirely transposable to in IC/IRdosimetry:

- point 11 is out of the field of this study,
- points 5, 6, 8, 9 and 10 have to be changed following the information discussed above.

2.5.3.1 Detection threshold and linearity

The definition of the detectionthreshold used is in this study is taken from the ISO 12794: "minimum evaluated value for which the readout of a dosemeter or detector is significantly different (at the 95% confidence level) from the readout value of an unirradiated dosemeter or detector". A few methods, partly based on the evaluation of the uncertainty of the background level, are used to determine it (Hirning *& al.* 1992, ISO 2010). ISO 12794 and IEC 62387 propose the rather high value 1 mSv for $H_p(0.07)$ measurements, compared to values currently reported by the dosimetry services, 0.05 mSv (Carinou *& al.*2001, Vanhavere *& al.*2001). Taking into account that when protection is used, $H_p(3)$ can be very low, a good compromise solution, could be a threshold of 0.2 mSv. Such a threshold has consequences on the requirement for sensitivity to self irradiation which should be reduced down to 0.2 mSv, as well as on to the lower limit for linearity which should be set to this value with the same criterion in both ISO and IEC standards (that is ±10%). Thus, if it is foreseen that the average dose equivalent to be measured will be about one tenth of the monthly exposure limit (1.25 mSv), this criterion allows assessing accurately the dose equivalent.

On the other hand the recent ICRP decision to lower the eye-lens dose limit to 20 mSv/y induces to restrict the detection threshold putting it at 50 µSv per month, following the same criterion adopted for $H_p(10)$, which annual limit is 20 mSv.

2.5.3.2 Performance requirements for energy response.

The standard ISO12794was published to meet the needs in a range of energies between15 keV and 3 MeV, therefore broader than that met in IC/IR. For the dosemeters based on the TLD of the LiF type, the criterion of +-50% makes it possible to take into account the over response in terms of dose equivalent for energies lower than 100 keV. In the case of exposure to radiation in industry, it is generally retained as probable assumption that the worker can be exposed to a broad spectrum covering most of the energy range between 15 keV and 3 MeV and angles such that, on average, even an over-estimate of 50% on part of the energy domain does not generate a too important over-estimate of the dose. However, the range of over-response of LiF:Mg,Ti is precisely the field of energy of IC/IR, therefore this over-response could generate an important over-estimate of the doses. Taking into account that the exposures of the medical staff in IC/IR can be high, a more drastic criterion than +-50% could be used. Taking example from the data of EC 160 report [European commission 2009] for the values of assessed annual dose values at or near the dose limit, the maximum variation could be **+/-20%** or in a more general probabilistic approach the 95 % confidence interval should not exceed 0.67 to 1.5 ,i.e. about +/- 40% (with a coverage factor of 2).

Radiation qualities recommended for the photons are those of the ISO standard 4037. The "narrow" radiation qualities shall be used for studying the energy response, namely N-15 to N-150 for IC/IR.They must be traceable to the SI of units through a national reference. In most of the cases, routine calibrations are performed using ^{137}Cs or ^{60}Co. These radiation qualities are far from those met at workplace for IC/IR, so it could be useful to carry out a specific calibration choosing a radiation quality close to the one met at workplace especially if it is impossible for a dosemeter to respect the criterion in terms of response according to energy. Thesection "calibration" of this report deals with this issue. In such a case, and exclusively in the case of IC/IR, the energy range can be restricted to 20-150 keV with a maximum variation of ±30%.

2.5.3.3 Performance requirements for angle response

The requirement for isotropy proposed in the IEC standard is not enough drastic for the particular issue of IC/IR exposure. Therefore, for isotropy conditions, we would remain on the criteria of the ISO standard, that is to say: "the mean value of the response at angle of incidence 0°, 20°, 40° and 60° from the normal shall not differ from the corresponding response for the normal incidence by more than **15%** when irradiated with photons of 60 keV". If the angle range is extended to 75°, taking into account the difficulty of the measurements at such angles, the criterion could be enlarged up to 30%.

2.5.3.4 Other requirements.

IEC standard gives requirements on the reader, namely stability, ambient temperature, light exposure, primary power supply, electromagnetic disturbances… Additional requirements are also given in IEC standard about the mechanical performance of the dosemeter,

These requirements are not reported in the present document but have to be fulfilled.

2.5.4 Calibration

In case of IR/IC procedures the radiation fields are significantly different from the N series and specific calibration with beam qualities better approximating the field conditions are to be advised. Such a radiation qualities met at workplaces in IR/IC has been characterised at CEA LIST LNHB during the CONRAD project (Bordy et al. 2007 see table 2.6.it can be seen that the resolution of this spectrum is very large.

Radiation qualities close to the workplace field met in IC/IR in terms of resolution and energy range can be found:

(i) RQR qualities taken from IEC 61267, and (ii) W qualities taken from ISO 4037. The choice of the calibration beam has to be done by the calibration laboratory in accordance with the end user. Table 2.6 gives the conversion coefficients, from air kerma to dose equivalent at 3 mm depth for these radiation qualities calculated in the square the herewith presented right cylindrical phantom (20 cm of diameter and height made of 4 element ICRU tissue).

Table 2.6: Characteristics of radiation fields employed during the CONRAD project.

Quality	Tube potential (kV)	Mean energy (keV)	Resolution, % (keV)	Total filtration
ISO 4037- W 60	60	45	48 (29)	4 mm Al
ISO 4037- W 80	80	57	55 (44)	4 mm Al
ISO 4037- W 110	110	79	51 (56)	4 mm Al
ISO 4037- W 150	150	104	56 (84)	4 mm Al
CONRAD Primary beam	70	48	60 (29)	4.5 mm Al + 0.2 mm Cu
CONRAD scattered beam	-	42	52 (22)	-
IEC 61267 RQR 4 (1)	60	37	73 (27)	(2.2 + 0.52) mm Al
IEC 61267 RQR 7 (1)	80	48	67 (32)	(2.2 + 0.8) mmAl
IEC 61267 RQR 9 (1)	120	57	77 (44)	(2.2 + 1.19) mm Al

(1) Filtration defined at CEA LIST / LNE LNHB to reach the HVL of the standard

Table 2.7: Conversion coefficient $H_p(3) / K_a$ (Sv/Gy) from air kerma to dose equivalent at 3 mm depth in the square right cylindrical phantom. Monte Carlo calculations with PENELOPE (Salvat & al. 2006), standard uncertainties less than 0.3%

Angle (degree)	RQR4	RQR7	RQR9	W 60	W 80	W 110	W 150	N30	N80	N120	Conrad Primary beam 70 kV
0	1.239	1.376	1.461	1.47	1.58	1.65	1.57	1.019	1.665	1.588	1.495
20	1.229	1.373	1.452	1.46	1.58	1.63	1.54	1.009	1.659	1.584	1.484
45	1.179	1.326	1.406	1.42	1.53	1.60	1.54	0.955	1.599	1.554	1.429
60	1.108	1.253	1.347	1.34	1.47	1.54	1.50	0.875	1.546	1.516	1.367
75	0.953	1.107	1.210	1.20	1.34	1.45	1.40	0.698	1.420	1.424	1.231
90	0.599	0.768	0.884	0.87	1.02	1.15	1.17	0.336	1.118	1.167	0.900

To conclude this section 2 key points should be pointed out. The present proposals are based on the existing standard for eye lens dosimetry (ISO 12794) for which the requirement has been adapted to the particular case of IC/IR. The conversion coefficients have been calculated using the phantom described in section 2.2. For calibration purposes a phantom having the same shape and external dimensions but made of a PMMA tank (0.5 cm thick walls) filled with water isrecommended. The longitudinal axis of this phantom is perpendicular to the axis of the radiation beam. The axis of the beam crosses the phantom along its diameter at its middle height (Z level). The centre of the detector must be at this point in Z, being fixed at the surface of the phantom.

2.6 General conclusions on Hp(3) studies

The scope of the present ORAMED task was to discuss the operational quantity Hp(3), to evaluate a set of suitable conversion coefficients for photons and then to propose an optimized Hp(3) dosemeter prototype and a feasible calibration procedure. The present chapter provided all this

material, including the tables of the air kerma to personal dose equivalent conversion coefficients Hp(3)/Ka. It is worth to emphasize that the efforts of the present study someway anticipated the radiation protection implications subtended in the recent ICRP recommendations on the new eye lens dose limits.

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3 Optimization of the use of active personal dosemeters in interventional radiology and cardiology

3.1 Introduction

Active personal dosemeters (APDs) are used in the context of operational radiation protection (Ginjaume et al., 2007) taking advantage of an immediate dose reading and an alarm at a pre-set dose and/or dose rate level. In interventional radiology and cardiology (IR/IC), the possibility to assess the personal dose equivalent and the personal dose equivalent rate in real time is particularly interesting since operators can receive relatively high doses while standing close to the primary radiation field. However, the current technology of APDs does not suit all the specificities of the X-ray fields used in IR/IC. These X-ray fields are characterized by low energy photons [20-100 keV] and pulsed fields with instantaneous high dose rates.

In this context, the main objectives of this part of the ORAMED project were the following:

- to make a study of the behavior of several commercial APDs under laboratory conditions both in continuous and pulsed fields (Clairand et al., 2011; Clairand et al., 2011, Denoziere et al., 2009) and in hospitals (Struelens et al., 2011);
- to establish guidelines for the use of APDs in interventional radiology, using the input of above mentioned laboratory tests and tests in hospitals;
- to develop a new APD prototype with an improved response for IR/IC procedures.

3.2 Tests of several commercial APDs

3.2.1 Typical fields in IR/IC

In order to test some APDs in conditions as close as possible to those used in IR/IC, it was necessary first to determine the typical fields and parameters encountered for these specific applications. These data were gathered through a literature review and system quality control outputs. In addition, the dose equivalent rate at specific points of interest and typical scattered radiation spectra were calculated using the Monte Carlo codes MCNPX (Pelowitz, 2005) and Penelope (Salvat, 2006).

Table 3.1 gives an overview of typical radiation fields encountered in IR/IC whatever the considered procedure. The dose equivalent rate in the direct field at the level of the table ranges from 2 to 300 $Sv.h^{-1}$. The personal dose equivalent rate in the scattered beam at the level of the operator ranges from 5.10^{-3} to 10 $Sv.h^{-1}$.

Figure 3.1 shows the shape of the calculated scattered radiation spectra for both codes. In addition the corresponding incident primary beam spectra, determined with the XCOMP5 software, are presented. The average energy of the scattered radiation spectra determined with Monte Carlo calculations ranges from 20 to 100 keV.

Table 3.1: Typical radiation field characteristics in interventional radiology and cardiology

Parameter	Range
Peak high voltage	60 - 120 kV
X-ray tube current	5 - 1000 mA
Inherent Al equivalent filtration	4.5 mm
Additional Cu filtration	0.2 - 0.9 mm
Pulse duration	1 - 20 ms
Pulse frequency	1 - 30 s^{-1}
Personal dose equivalent rate integrated over the pulse in the direct beam (on patient table)	2 - 300 $Sv.h^{-1}$
Personal dose equivalent rate in the scattered beam (operator – above the lead apron)*	5.10^{-3} - 10 $Sv.h^{-1}$
Average energy range of scattered spectra	20 - 100 keV

*distance patient-operator = 30 cm

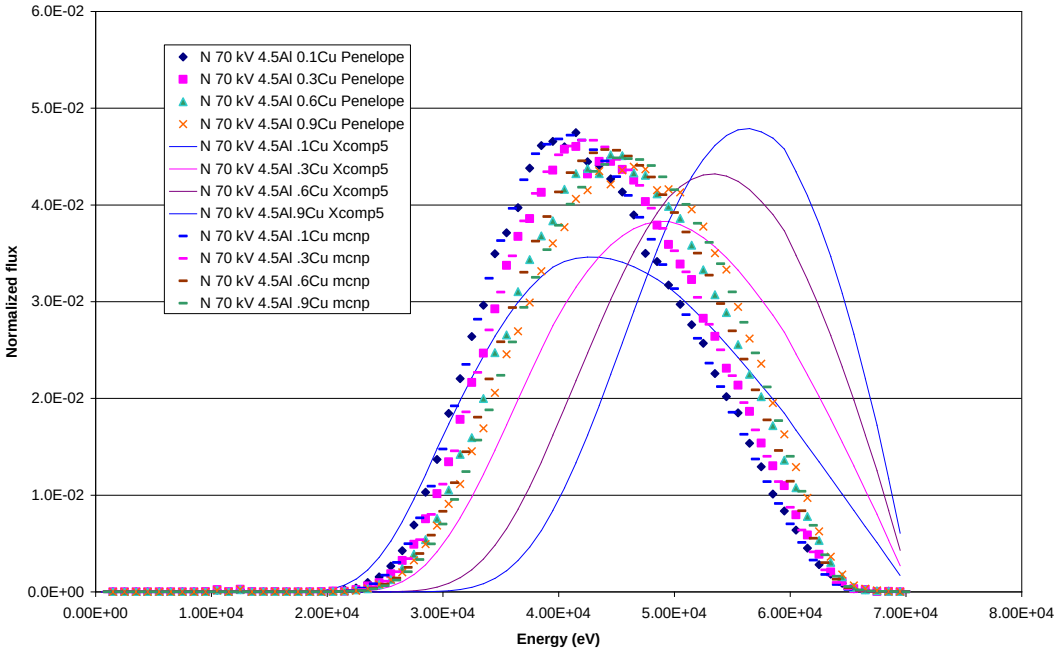


Figure 3.1: Scattered radiation spectra calculated with MCNPX and Penelope and incident primary beam spectra calculated with XCOMP5 for a tube high voltage equal to 70 kV

3.2.2 Selection of APDs

The selection of APD models was based on the results from two previous international intercomparisons: one performed in the framework of the CONRAD project, a coordination action supported by the European Commission within its 6th Framework Program (Bordy et al., 2008; Clairand et al., 2008) and another one organized by EURADOS and IAEA (International Atomic Energy Agency, 2007).

The following APDs were selected for the current study (Figure 3.2), according to their capability to detect low energy photons: DMC2000XB (MGPi), EPDMk2.3 (Thermo), EDMIII (Dosilab), PM1621A (Polimaster), DIS-100 (Rados), EDD30 (Unfors), AT3509C (Atomtex) and DoseAware (Philips). Their main characteristics as provided by the manufacturers in the technical notes are presented in Table 3.2.

Figure 3.2:Active personal dosemeters tested in this study

Table 3.2: Main characteristics of tested APDs as provided by the manufacturers in the technical notes

APD	Energy range		Personal dose equivalent rate range		Personal dose equivalent range		Detector type
	Min	Max	Min	Max	Min	Max	
DMC2000XB MGPi	20 keV	6 MeV	0.1 µSv.h^{-1}	10 Sv.h^{-1}	1 µSv	10 Sv	Silicon diode
EPDMk2.3 Thermo	17 keV	6 MeV	1 µSv.h^{-1}	4 Sv.h^{-1}	1 µSv	16 Sv	Silicon diode
EDMIII Dosilab	20 keV	6 MeV	0.5 µSv.h^{-1}	1 Sv.h^{-1}	1 µSv	1 Sv	Silicon diode
PM1621A Polimaster	10 keV	20 MeV	0.01 µSv.h^{-1}	2 Sv.h^{-1}	0.01 µSv	9.99 Sv	Geiger Muller tube
DIS-100 Rados	15 keV	9 MeV	1 µSv.h^{-1}	40 Sv.h^{-1}	1 µSv	50 mSv	Specific detector
EDD30 Unfors	*	*	0.03 mSv.h^{-1}	2 Sv.h^{-1}	1 nSv	9999 Sv	Silicon diode
AT3509C Atomtex	15 keV	10 MeV	0.1 µSv.h^{-1}	5 Sv.h^{-1}	1 µSv	10 Sv	Silicon diode
DoseAware Philips	33 keV	118 keV	10 µSv.h^{-1}	50 mSv.h^{-1}	1 µSv	10 Sv	Silicon diode

*not indicated in the technical note, but dedicated to interventional radiology

3.2.3 Tests of APDs with continuous X-ray beams in laboratory conditions

3.2.3.1 Material and methods

The tests with continuous X-ray fields were made in two calibration laboratories (IRSN in France and SCK•CEN in Belgium). These tests were performed to determine the response of selected APDs in terms of personal dose equivalent, energy, personal dose equivalent rate and angle. The following reference fields were used (N-15, N-20, N-25, N-30, N-40, N-60, N-80, N-100, N-120, S-Cs and S-Co) as defined in the ISO 4037-1 standard (International Organization for Standardization, 1996).

Three measurements per APD were performed. Two dosemeters of each type were tested. Dosemeters were placed on an ISO slab phantom (International Organization for Standardization, 1999). The results were analysed considering the requirements of the IEC 61526 standard (International Electrotechnical Commission, 2010). Each type of irradiation was repeated three times for the same APD unit and the repeatability of each APD system resulted in a dosemeter reading standard deviation smaller than 5% (k=2). The reference dosimetry was realized with cavity ionization chambers linked to a primary reference laboratory. The reference dose equivalents

$H_p(10)$ considered for the tests in continuous mode are given with an uncertainty smaller than 5% (k=2).

3.2.3.2 Results

A. Personal dose equivalent response

The personal dose equivalent response of the tested APDs is linear over the dose range of interest in radiation protection, i.e. up to 500 mSv (Figure 3.3).

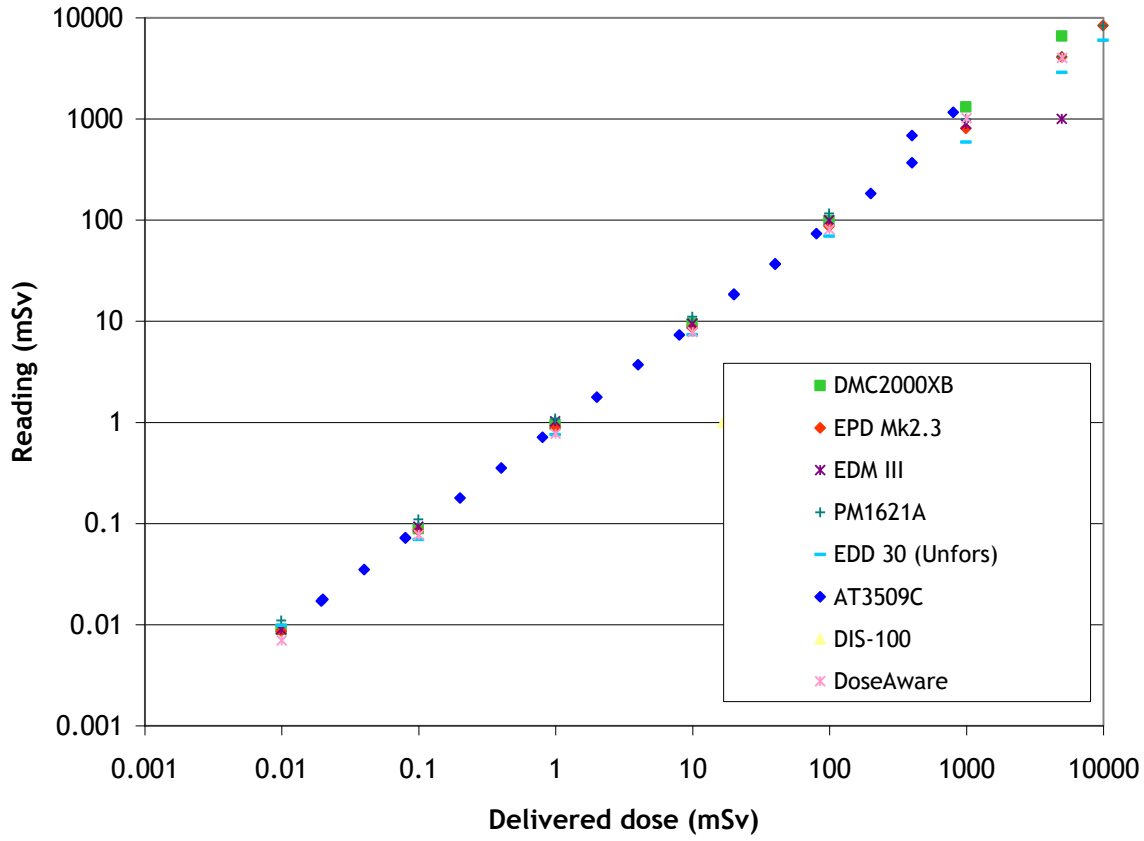


Figure 3.3: Dose response of APDs in continuous mode (for a personal dose equivalent rate $\dot{H}_p(10)$ around 10 mSv.h^{-1})

B. Energy response

The energy response of tested APDs (Figure 3.4) is within the interval [0.71 – 1.67] as required in the IEC 61526 standard (International Electro technical Commission, 2010) from S-Co energy down to N-30 for all APDs except EDD30 and DoseAware. The response is within the required interval between N-80 and N-20 for EDD30 and between N-120 and N-40 for Dose Aware. These two APDs, however, are intended to be used only in the low energy range.

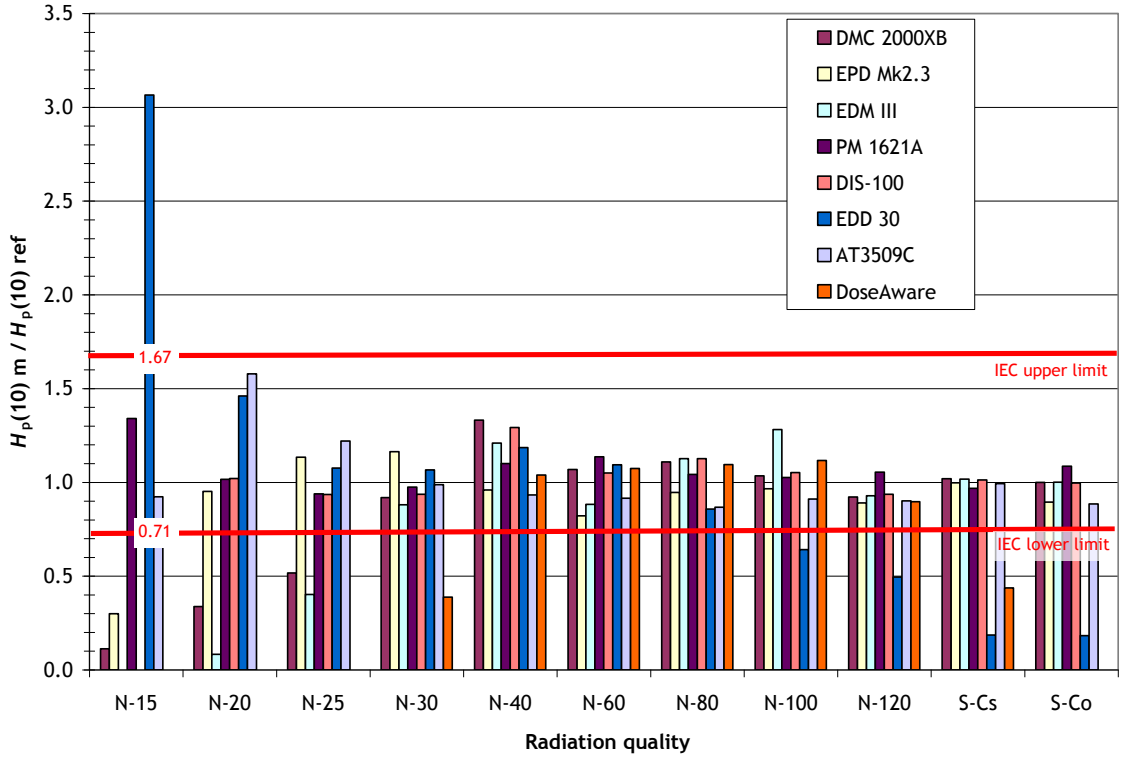


Figure 3.4: Energy response of APDs in continuous mode (for a personal dose equivalent rate $\dot{H}_p(10)$ around 10 mSv.h^{-1}, and an integrated personal dose equivalent $H_p(10)$ around 0.5 mSv)

C. Personal dose equivalent rate response

The personal dose equivalent rate response of APDs is presented in figure 3.5. $H_p(10)_m$ is the APD reading and $H_p(10)_{ref}$ is the reference value of the personal dose equivalent defined by the calibration laboratory. For all APD types, the mean response of the two devices is plotted, since the respective values were very close, except for the PM1621A. For the Polimaster device the response was completely opposite for both types.

The requirement of IEC 61526 standard (International Electrotechnical Commission, 2010) concerning the personal dose equivalent rate response is [0.83-1.25]. Most APDs satisfy this requirement up to 1 Sv.h^{-1} and their response is more than 0.5up to 10 Sv.h^{-1}, except for PM1621A, for which the response diverges rapidly from 0.5 Sv.h^{-1}. In addition, EDD30 and DoseAware saturate for personal dose equivalent rates above 2 and 4 Sv.h^{-1} respectively, according to their specifications. It is interesting to notice that most APDs can stand personal dose equivalent rates higher than those indicated in their technical note (Table 3.1).

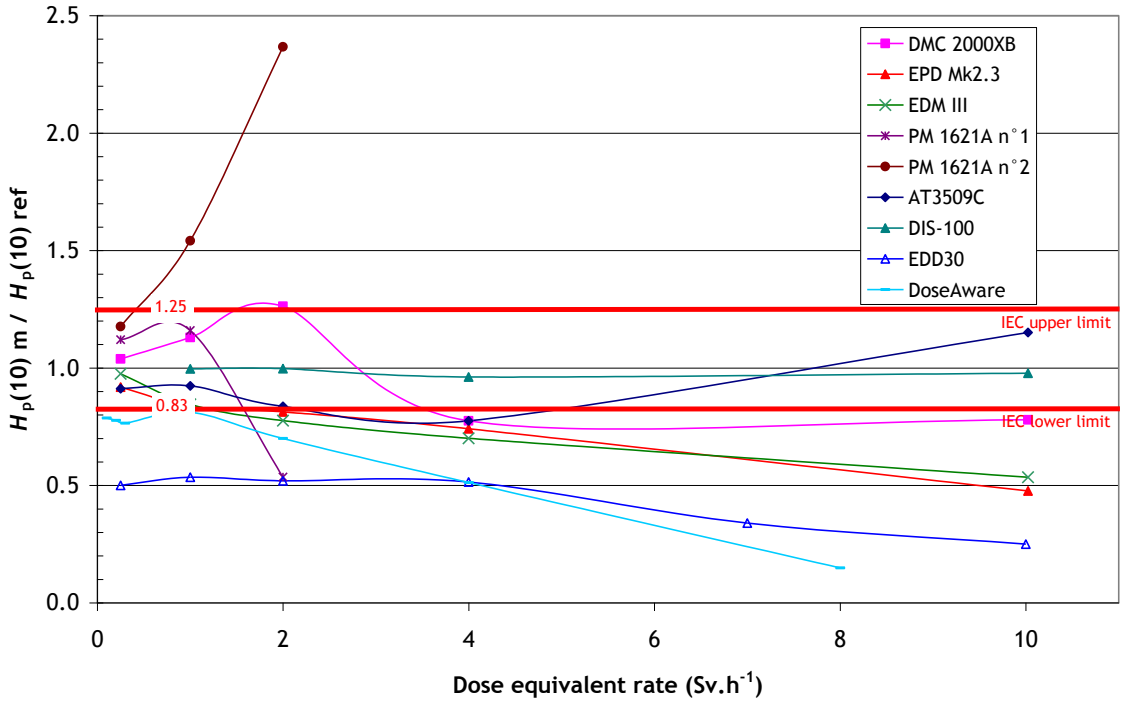


Figure 3.5: Personal dose equivalent rate response of APDs in continuous mode, tests made with S-Co for all APDs and N-150 for Dose Aware (except for PM1621A, whose response diverged, the mean value of the 2 units of each APD type is represented).

D. Angular response

The angular response is shown for all APDs tested in figures 3.6 to 3.13. ($H_p(10, \alpha)_m$ is the APD reading for an angle alpha and $H_p(10, \alpha)_{ref}$ is the reference value of the personal dose equivalent for that specific angle. To perform the tests, the APDs were shifted between 0° to +/-60° according to their vertical and horizontal axis.

The angular response is within the interval [0.71 – 1.67] as required in the IEC 61526 standard (International Electro Technical Commission, 2010) for energies down to N-30 and angles up to 60° for all APDs, apart from AT3509C(Figure 3.12), for which the angular response is within the before mentioned interval at 60° and 45° only for N-80.

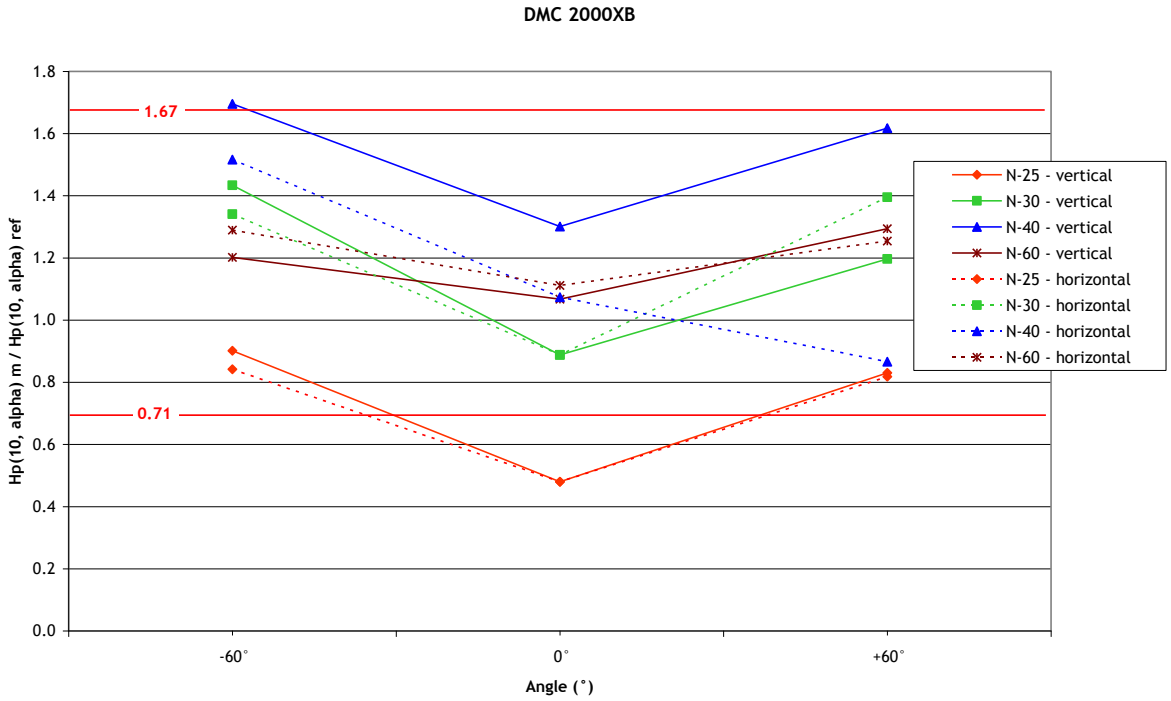


*Figure 3.6: Response of **DMC2000XB** at different photon radiation energies and angles of incidence*

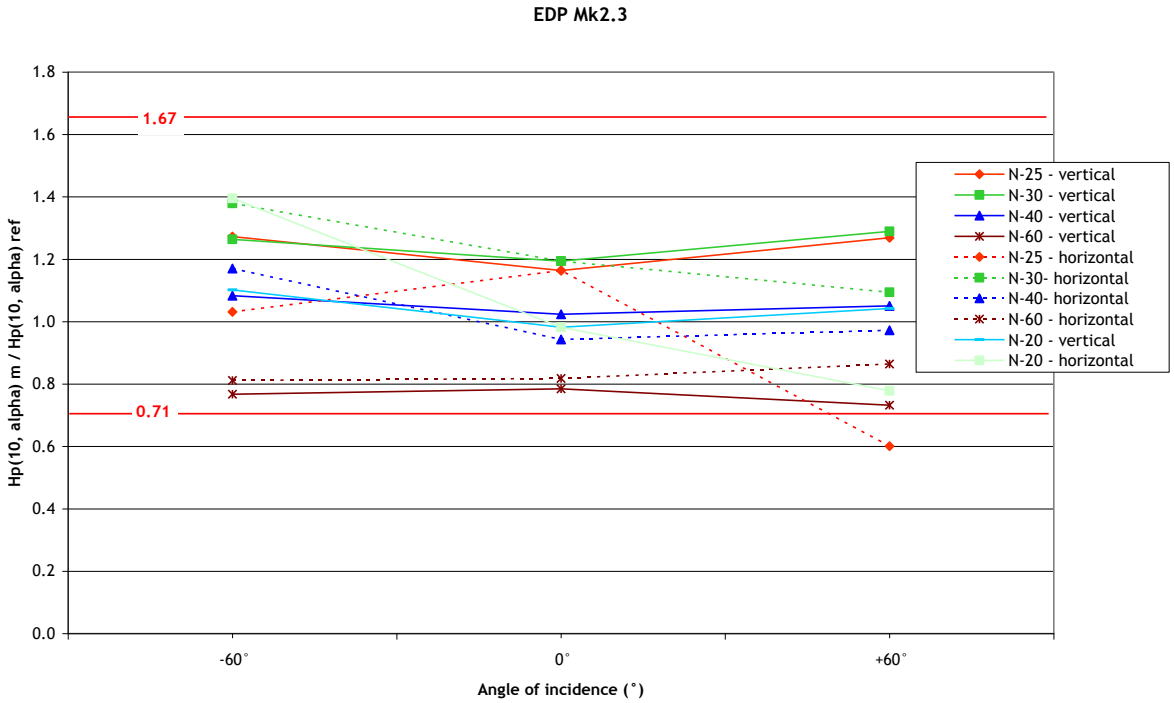


*Figure 3.7: Response of **EPDMk2.3**at different photon radiation energies and angles of incidence*

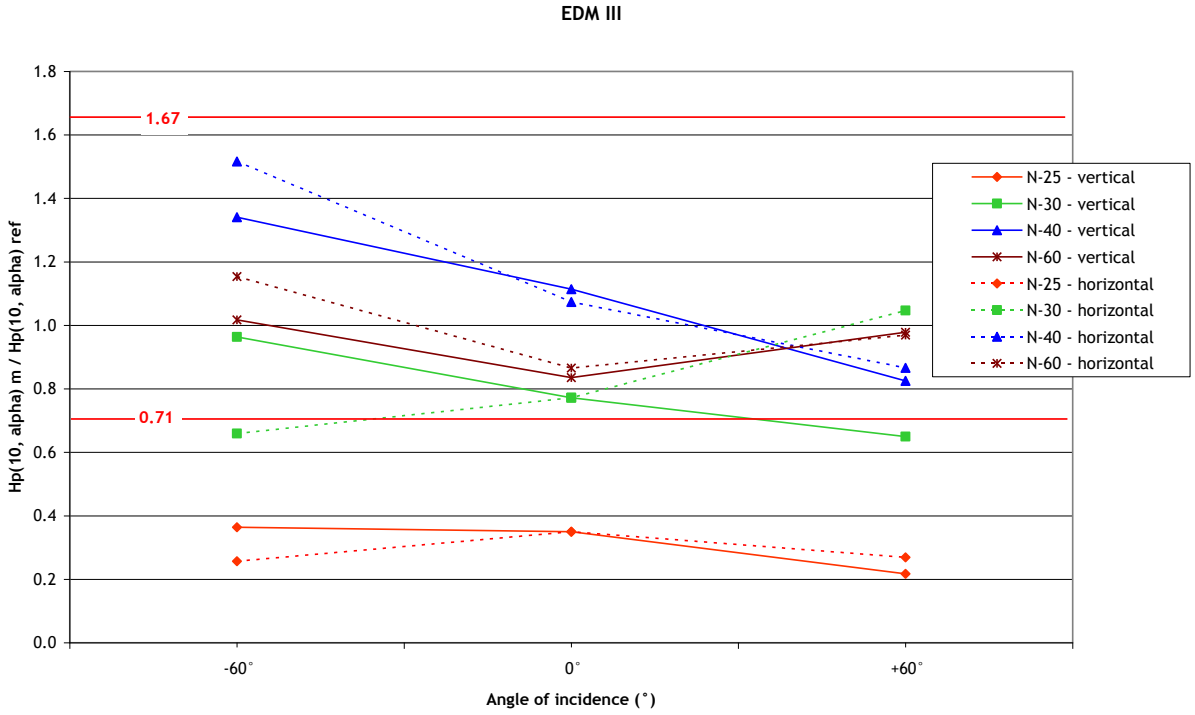


*Figure 3.8: Response of **EDMIII** at different photon radiation energies and angles of incidence*

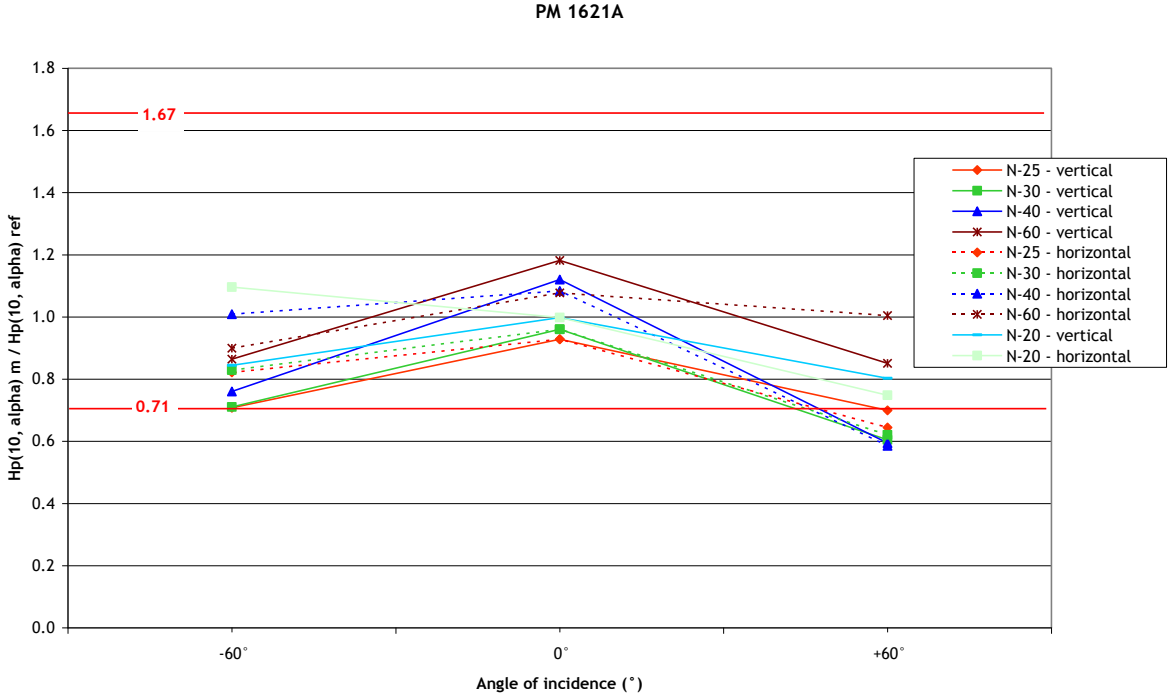


*Figure 3.9: Response of **PM1621A** at different photon radiation energies and angles of incidence*

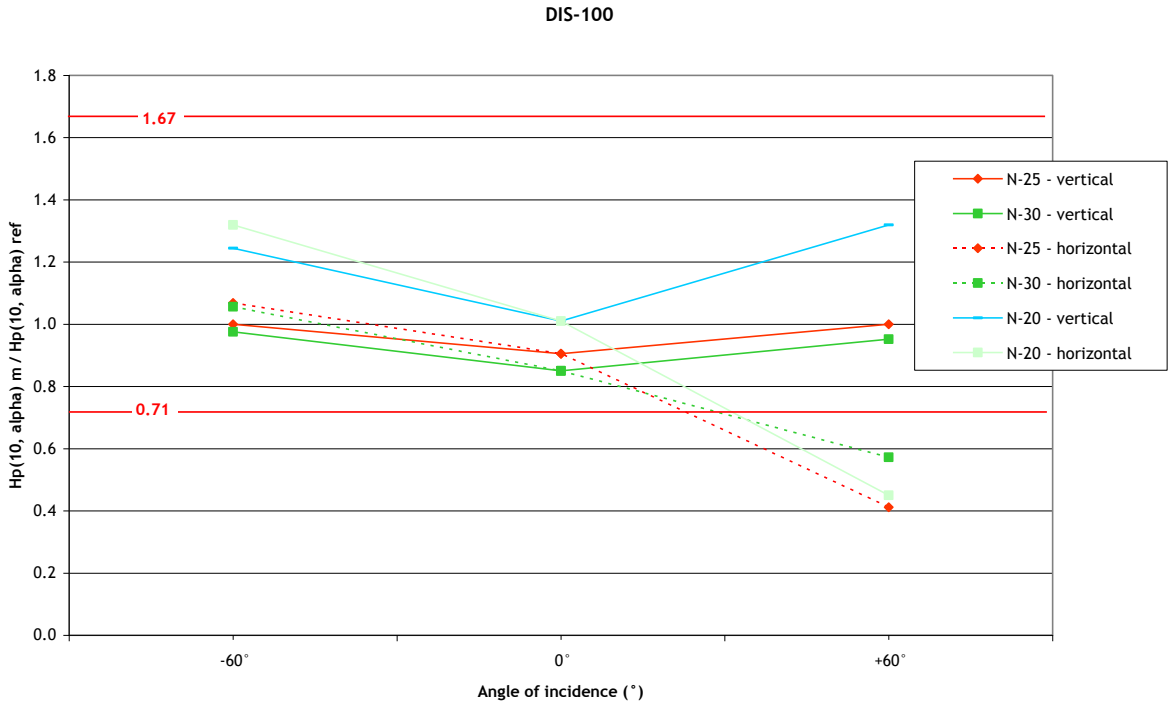


*Figure 3.10: Response of **DIS-100** at different photon radiation energies and angles of incidence*

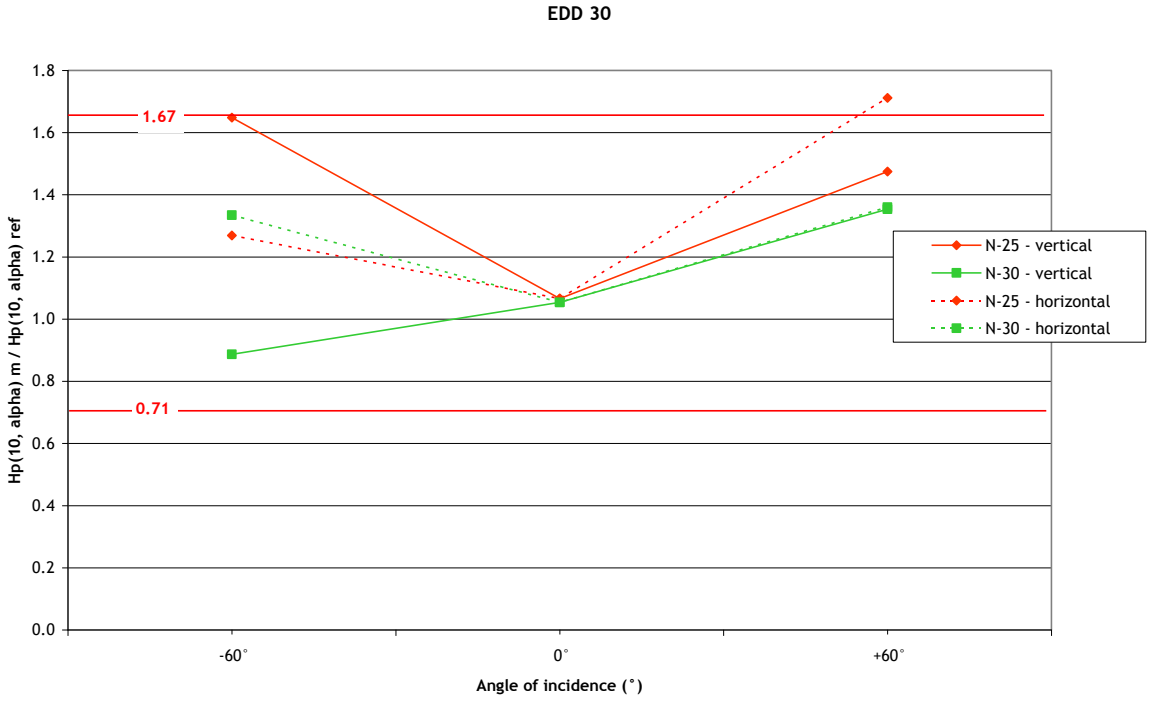


*Figure 3.11: Response of **EDD30** at different photon radiation energies and angles of incidence*

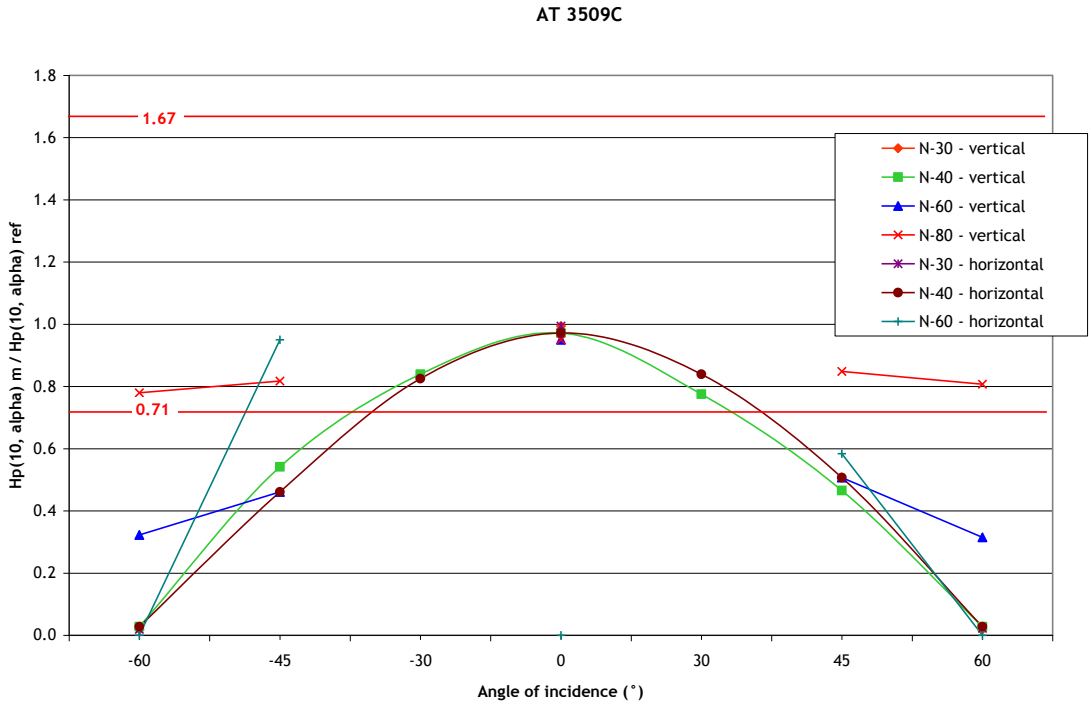


*Figure 3.12: Response of **AT3509C** at different photon radiation energies and angles of incidence*

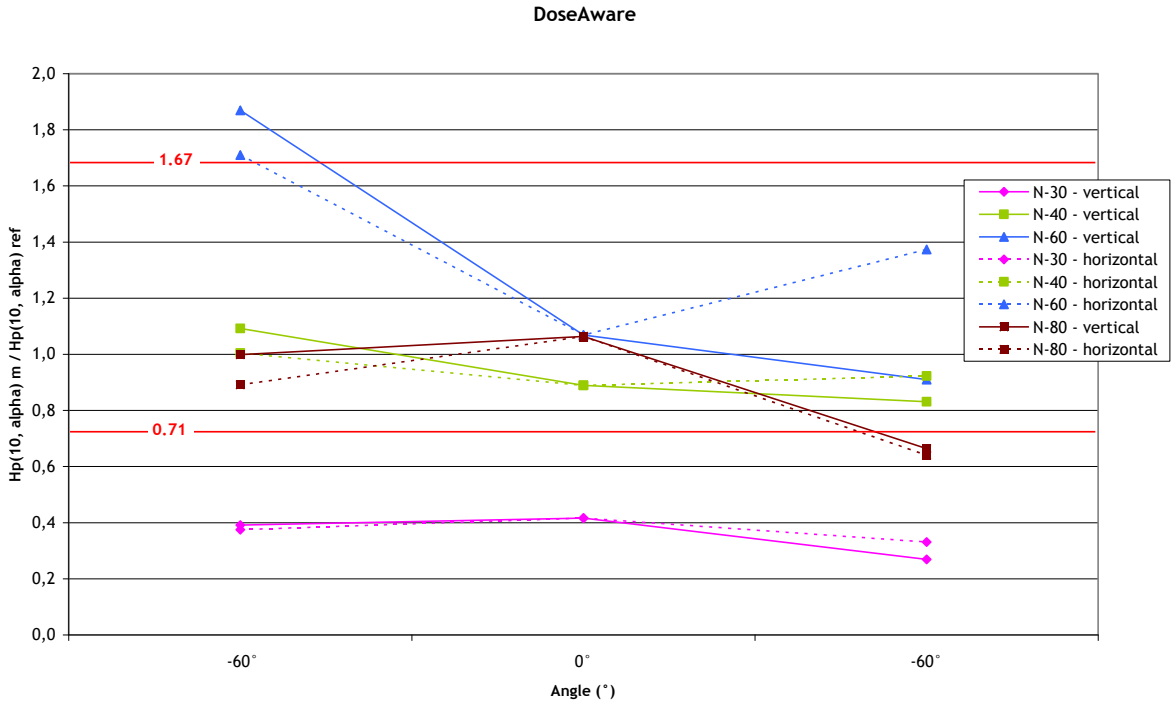


*Figure 3.13: Response of **DoseAware** at different photon radiation energies and angles of incidence*

3.2.3.3 Conclusions on laboratory tests in continuous mode - response of each APD

DMC2000XB

- Dose response: linear response with the dose up to 500 mSv
- Dose rate response: response varies between 1.3 and 0.7 up to 10 $Sv.h^{-1}$
- Energy response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard from ^{137}Cs energy down to N-30
- Angular response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard down to N-30 and for angles up to 60°

EPDMk 2.3

- Dose response: linear response with the dose up to 500 mSv
- Dose rate response: response decreases from 0.9 to 0.5 from 1 to 10 $Sv.h^{-1}$
- Energy response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard from ^{137}Cs energy down to N-20
- Angular response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard down to N-30 and for angles up to 60°

EDMIII

- Dose response: linear response with the dose up to 500 mSv
- Dose rate response: response decreases from 1 to 0.5 from 1 to 10 $Sv.h^{-1}$
- Energy response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard from ^{137}Cs energy down to N-30
- Angular response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard down to N-30 and for angles up to 60°

PM1621A:

- Dose response: linear response with the dose up to 500 mSv
- Dose rate response:the response is diverging rapidly from 1 $Sv.h^{-1}$. Moreover, the two PM1621A models tested behave completely different on dose rate response.
- Energy response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard from ^{137}Cs energy down to N-15
- Angular response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard down to N-30 and for angles up to 60°

DIS-100:

- Dose response: linear response with the dose up to 500 mSv
- Dose rate response: response very close to 1 from 1 to 10 $Sv.h^{-1}$
- Energy response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard from ^{137}Cs energy down to N-20
- Angular response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard down to N-40 and for angles up to 60°. For several points, the response is slightly outside the interval at N-30.

EDD30:

- Dose response: linear response with the dose up to 500 mSv
- Dose rate response: saturates for dose rates higher than 2 $Sv.h^{-1}$

- Energy response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard from N-80 down to N-20 (these results are consistent with the fact that this APD is calibrated at low energy, and not at ^{137}Cs)
- Angular response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard down to N-30 and for angles up to 60°

AT3509C:

- Dose response: linear response with the dose up to 500 mSv
- Dose rate response: response varies between 0.9 and 1.2 up to 10 Sv.h^{-1}
- Energy response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard from ^{137}Cs energy down to N-15
- Angular response: response is within the interval [1.67 – 0.71] as required in IEC 61526 standard at 60° only from N-80, the angular response is correct for 30° down to N-40

DoseAware:

- Dose response: linear response with the dose up to 500 mSv
- Dose rate response: response varies between 0.8 and 0.5 up to 4 Sv.h^{-1}
- Energy response: response within the interval [1.67 – 0.71] as required in IEC 61526 standard from N-120 energy down to N-40
- Angular response: response is within the interval [1.67 – 0.71] as required in IEC 61526 standard at 60° only down to N-40

All APDs have a linear response with the dose and most of them have a satisfactory response at low energies down to N-30, which is sufficient for IR/IC. Most APDs provide a satisfactory response for high dose rates up to 10 Sv.h^{-1}, except PM1621A for which the response is diverging rapidly from 1 Sv.h^{-1}as well as EDD30 and DoseAware which saturate for dose rates respectively above 2 and 4 Sv.h^{-1}. However, as indicated in Table 3.1, the dose rates in the direct beam can be much higher than those tested here. Therefore, the results of these tests in continuous fields do not deliver any conclusion that the APDs will correctly handle these very high dose rates in the direct beam. In addition, a problem of angular response at low energies was observed for AT3509C.

3.2.4 Tests of APDs with pulsed X-ray beams in laboratory conditions

3.2.4.1 Material and methods

The tests in pulsed mode (Denoziere et al., 2009) were performed at the French standard laboratory for ionizing radiation (Laboratoire National Henri Becquerel, CEA-LIST LNE-LNHB in France).

Three measurements per APD were performed. Two dosemeters of each type were tested. The influence of several parameters on the response of the APD in pulsed mode was studied. Table 3.3 presents the parameters considered for this study. The following radiation quality '70 kV, 4.5 mmAl + 0.2 mm Cu, HVL: 5.17 mmAl' was used. This radiation quality has been defined and used in previous work to match the characteristics of the radiation quality typically used in IR/IC (Bordy et al., 2007; CONRAD-EURADOS-WG9, 2009). The facility used for these tests is a commercially available medical X-ray generator for which the pulse duration is 20 ms when multi-pulse mode is used. The beam was monitored with a parallel flat chamber (PTW 233612) calibrated against the

primary standard made of a free air chamber (Denoziere et al., 2009). The reference dose equivalents $H_p(10)$ considered for the tests in pulsed mode are given with an uncertainty smaller than 6% (k=2).

Table 3.3: Parameters considered for the tests performed in pulsed radiation field (X-ray generator: GEHC PHASIX 80, 70 kVp, 4.5 mmAl + 0.2 mmCu, HVL 5.17 mmAl)

Test	Pulse duration (ms)*	Pulse frequency (s^{-1})	Personal dose equivalent rate ($Sv.h^{-1}$) integrated over the pulse
Effect of personal dose equivalent rate	20	10	0.1 to 50 (up to 1.8 for DoseAware)
Effect of pulse frequency	20	1, 10 and 20 (1 and 10 for DoseAware)	1.8 to 6.8 (0.9 and 1.8 for DoseAware)
Effect of pulse width	20 to 1000	Single pulse mode	1.8

*for technical reasons, tests with a pulse width lower than 20 ms were not possible

3.2.4.2 Results

A. Personal dose equivalent rate response

For most APDs, the response decreases when the personal dose equivalent rate increases (Figure 3.14). For personal dose equivalent rates lower than 0.2 $Sv.h^{-1}$, the deviation compared to the reference value is within 20%. For higher dose rates, the response falls down more or less rapidly, except the DIS-100 for which the deviation compared with the reference remains within 20% up to 55 $Sv.h^{-1}$. It was noticed that PM1621A, equipped with a Geiger-Muller tube, does not provide any signal at all in pulsed mode. DMC2000XB, EPDMk2.3, EDMIII, EDD30, AT3509C and DoseAware contain all silicon detectors. The difference of their response to the pulsed mode is probably due to the time response of their electronic systems which is a compromise solution between the electrical consumption (directly linked to the autonomy), the efficiency of the dead time correction and the complexity of the correction software. Unfortunately, information on the specific dead time compensation of each device was not available to the authors. The DIS-100 dosemeter (Kahilainen J., 1996), which has a "hybrid" technology between a silicon diode and an ionisation chamber, presents better results.

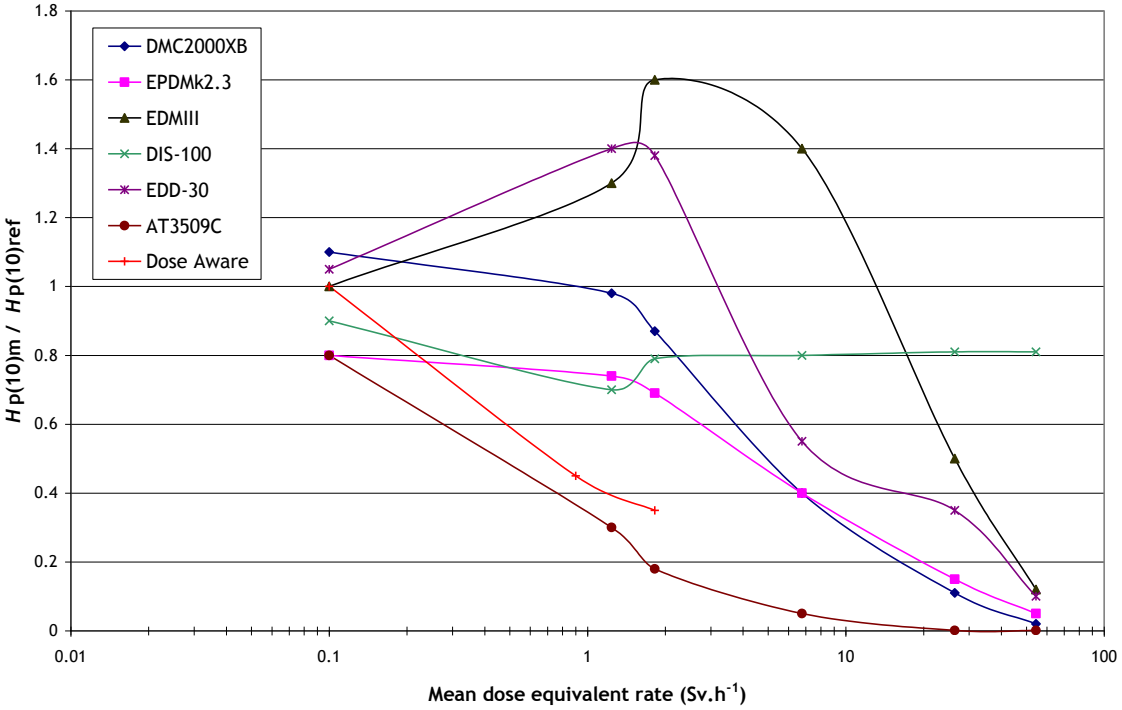


Figure 3.14: Personal dose equivalent rate response of APDs in pulsed modefor a pulse frequency equal to 10 s^{-1} and a pulse duration of 20 ms.

B. Pulse frequency response

For all APDs, the signal increases with the pulse frequency (Figures 3.15 to 3.21). Table 3.4 sums up the effect of pulse frequency as a percentage of variation in the APD response between 1 and 20 s^{-1}. This increase is roughly equal to 10% for EDMIII, EDD30 and DoseAware and to 30% for the other devices (except PM1621A that does not provide any signal in pulsed mode).

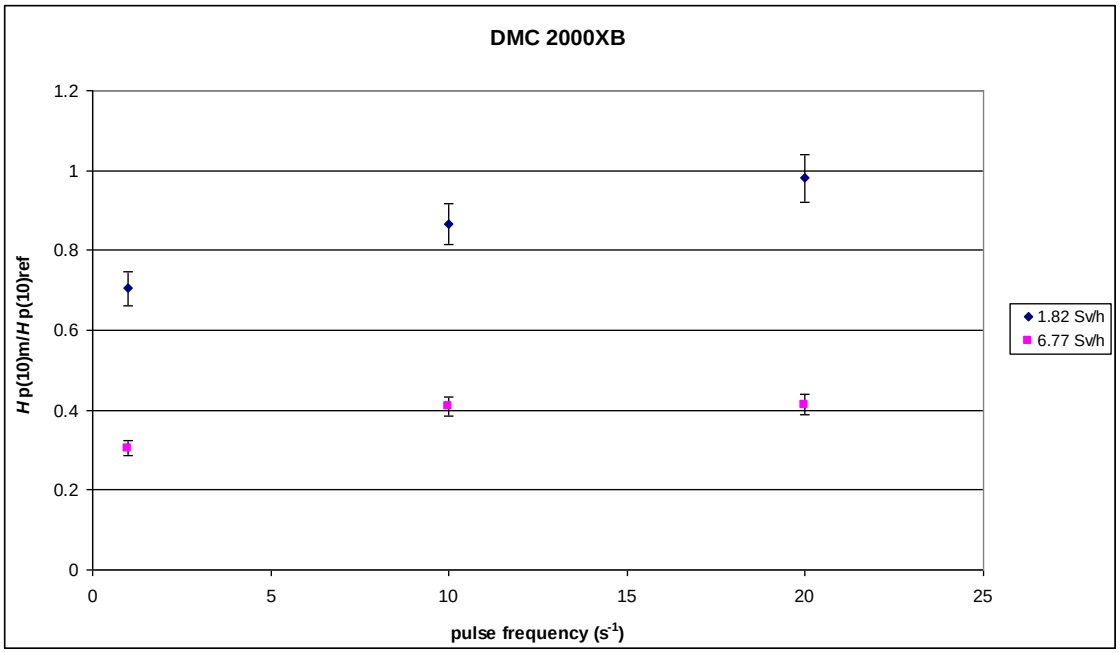


*Figure 3.15: Pulse frequency response of **DMC2000XB** in pulsed modefor a personal dose equivalent rate equal to 1.82 Sv.h^{-1} and 6.77 Sv.h^{-1} and a pulse duration of 20 ms.*

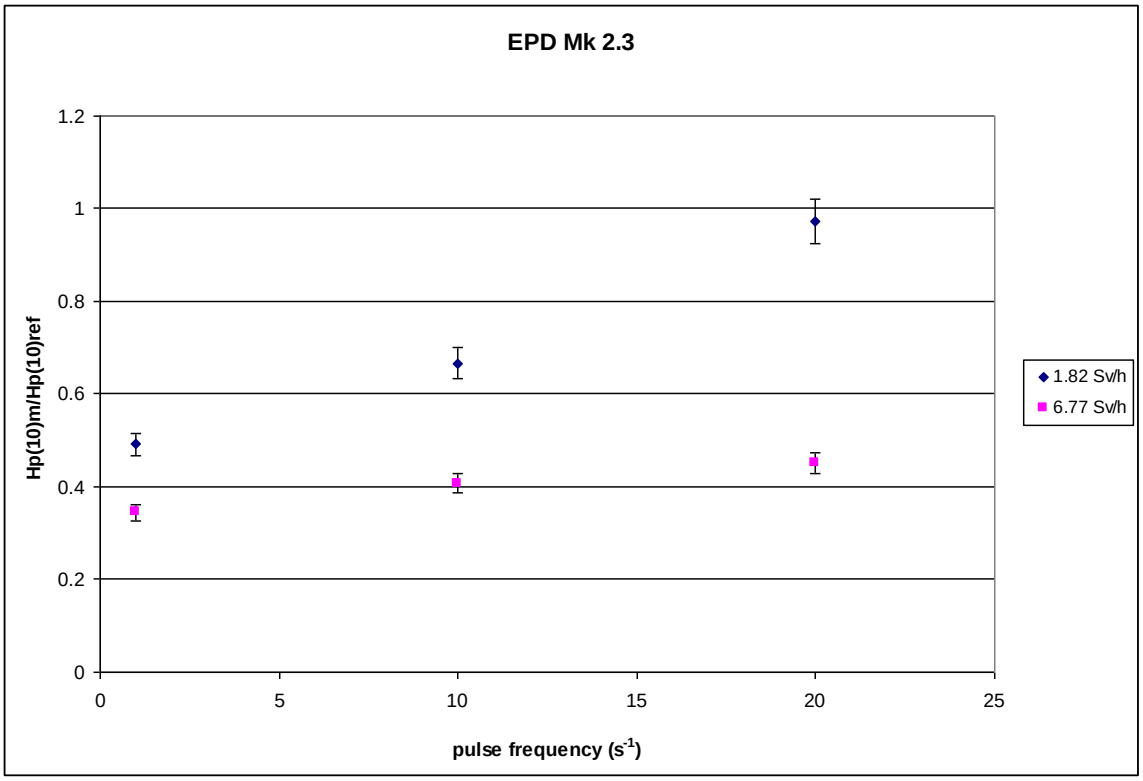


*Figure 3.16: Pulse frequency response of **EPDMk2.3** in pulsed modefor a personal dose equivalent rate equal to 1.82 Sv.h^{-1} and 6.77 Sv.h^{-1} and a pulse duration of 20*

ms.

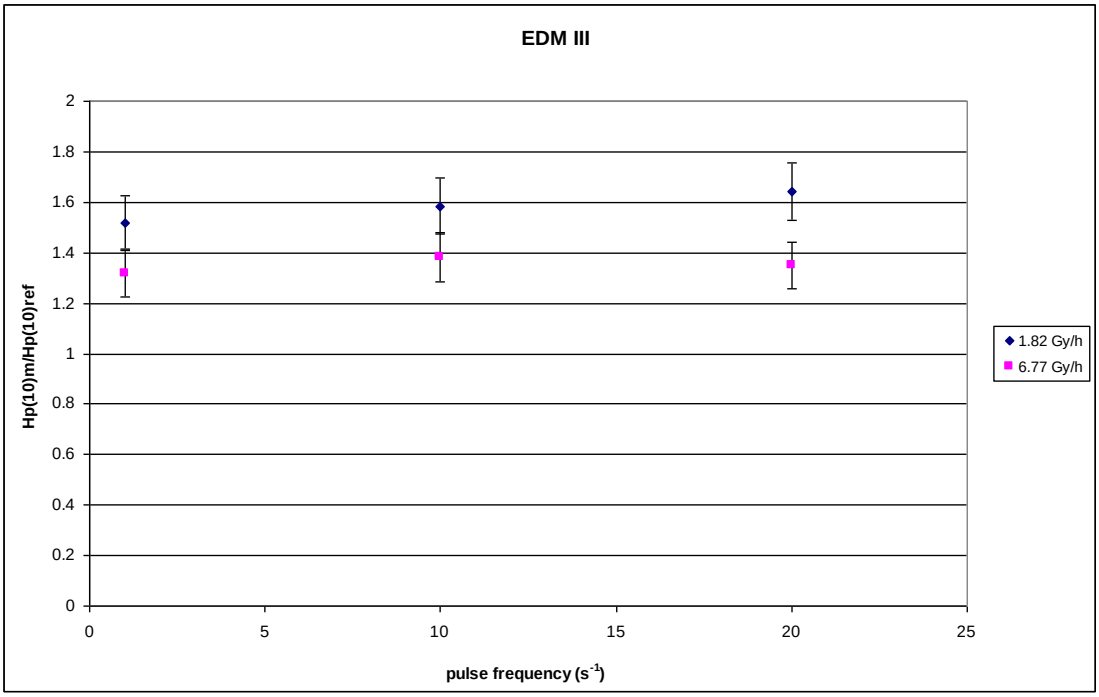


*Figure 3.17: Pulse frequency response of **EDMIII** in pulsed modefor a personal dose equivalent rate equal to 1.82 Sv.h^{-1} and 6.77 Sv.h^{-1} and a pulse duration of 20 ms.*

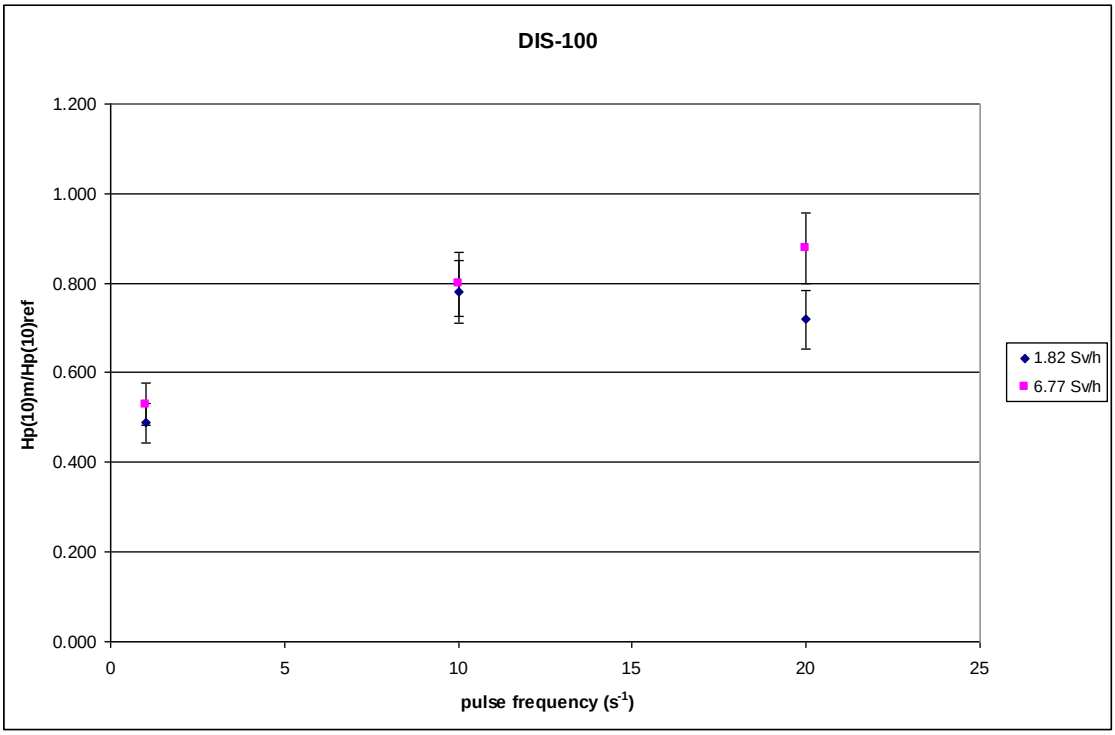


*Figure 3.18: Pulse frequency response of **DIS-100** in pulsed modefor a personal dose equivalent rate equal to 1.82 Sv.h^{-1} and 6.77 Sv.h^{-1} and a pulse duration of 20 ms.*

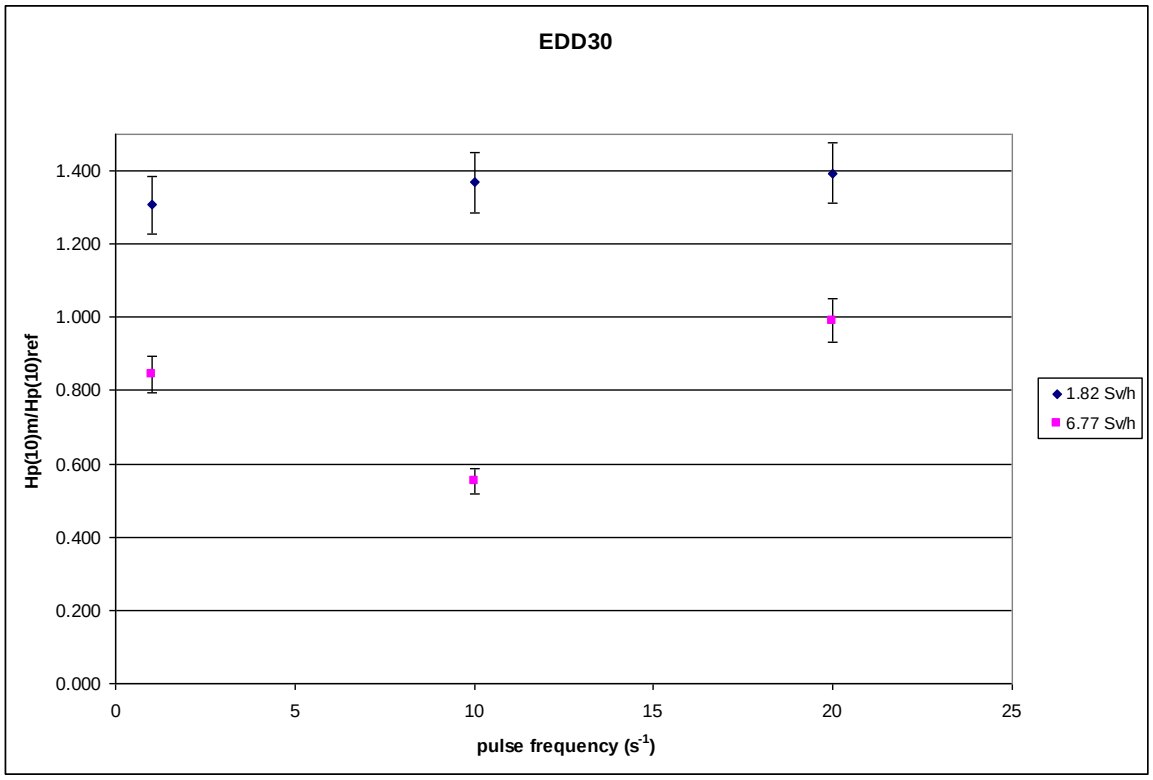


*Figure 3.19: Pulse frequency response of **EDD30** in pulsed modefor a personal dose equivalent rate equal to 1.82 Sv.h^{-1} and 6.77 Sv.h^{-1} and a pulse duration of 20 ms.*

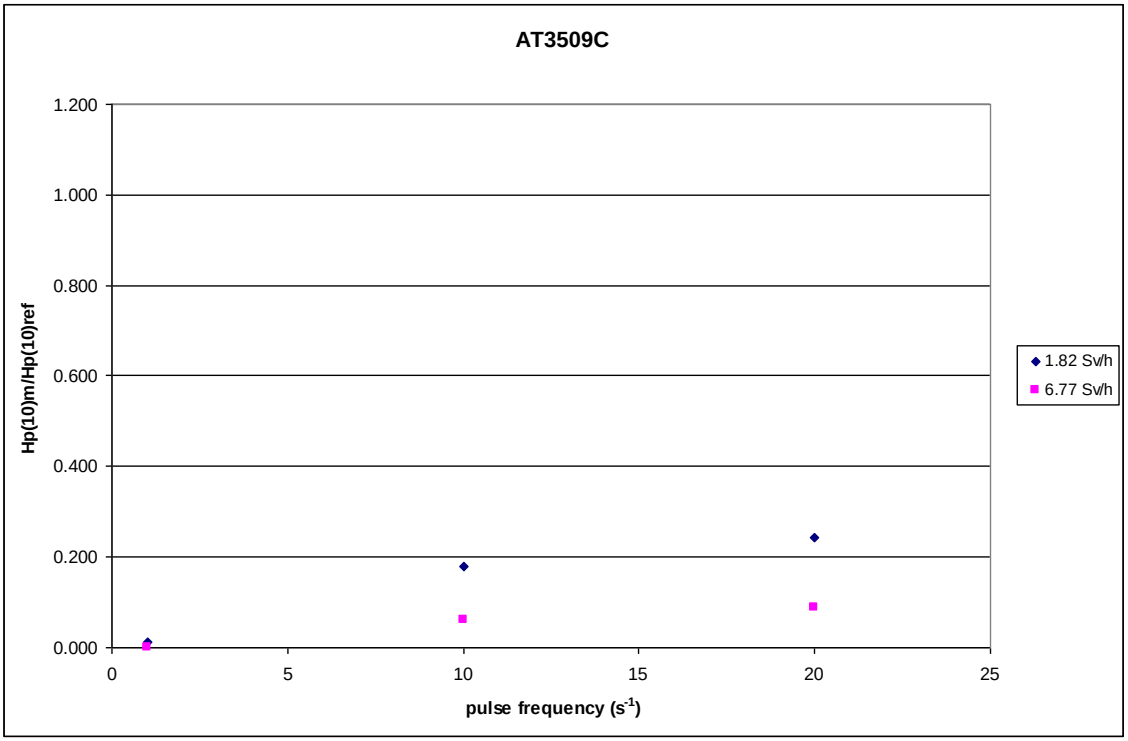


*Figure 3.20: Pulse frequency response of **AT3509C** in pulsed modefor a personal dose equivalent rate equal to 1.82 Sv.h^{-1} and 6.77 Sv.h^{-1} and a pulse duration of 20 ms.*

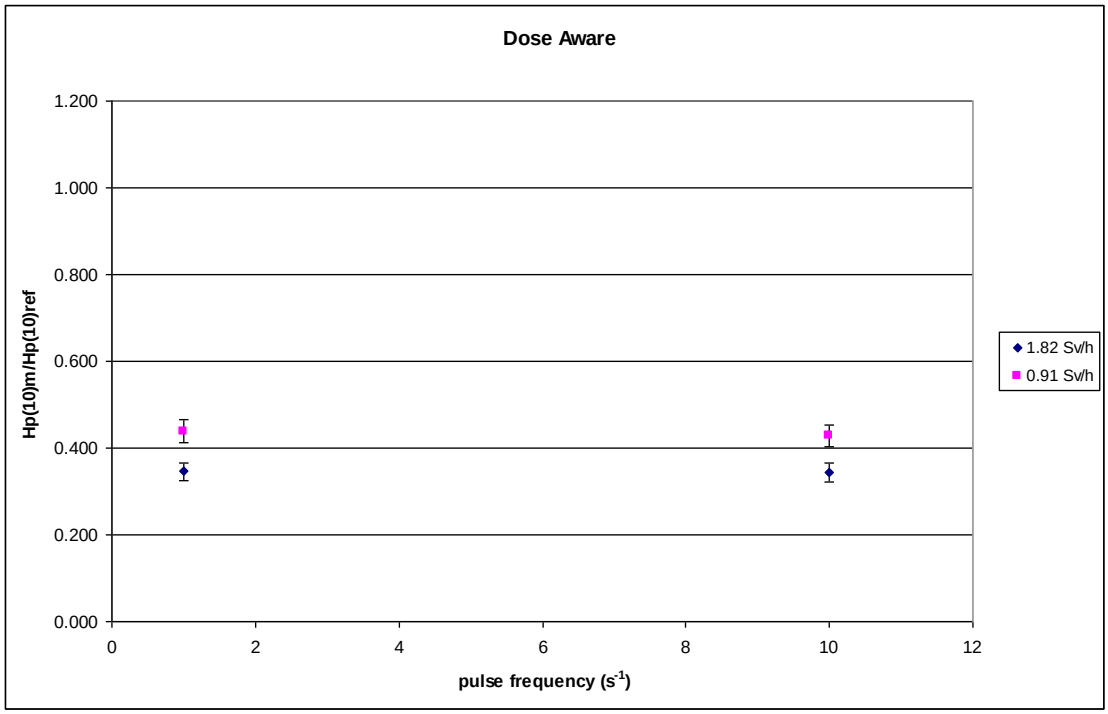


*Figure 3.21: Pulse frequency response of **DoseAware** in pulsed modefor a personal dose equivalent rate equal to 1.82 Sv.h^{-1} and 6.77 Sv.h^{-1} and a pulse duration of 20 ms.*

*Table 3.4**:** Effect of the pulse frequency (1 to 20 s^{-1}), percentage of variation on the APD responsefor a personal dose equivalent rate of 1.8 to 6.8 Sv.h^{-1} (0.9 and 1.8 for DoseAware) and a pulse duration of 20 ms*

APD	Increase of the APD response (%)
DMC 2000XB	25-30
EPD MK2.3	30-40
EDM III	<10
PM1621A	NO SIGNAL
DIS-100	30
EDD30	10 (1.8 Sv.h^{-1}) Saturation from 2 Sv.h^{-1}
AT3509C	30 (10- 20 s^{-1}) No signal at 1 s^{-1}
DoseAware	< 10 (between 1 and 10 s^{-1})

C. Pulse width response

No significant effect of pulse width was observed on the response of all APDs (Figures 3.22 to 3.27). When the pulse width is larger than 1 s, the responses in pulsed and continuous radiation field are quite similar.

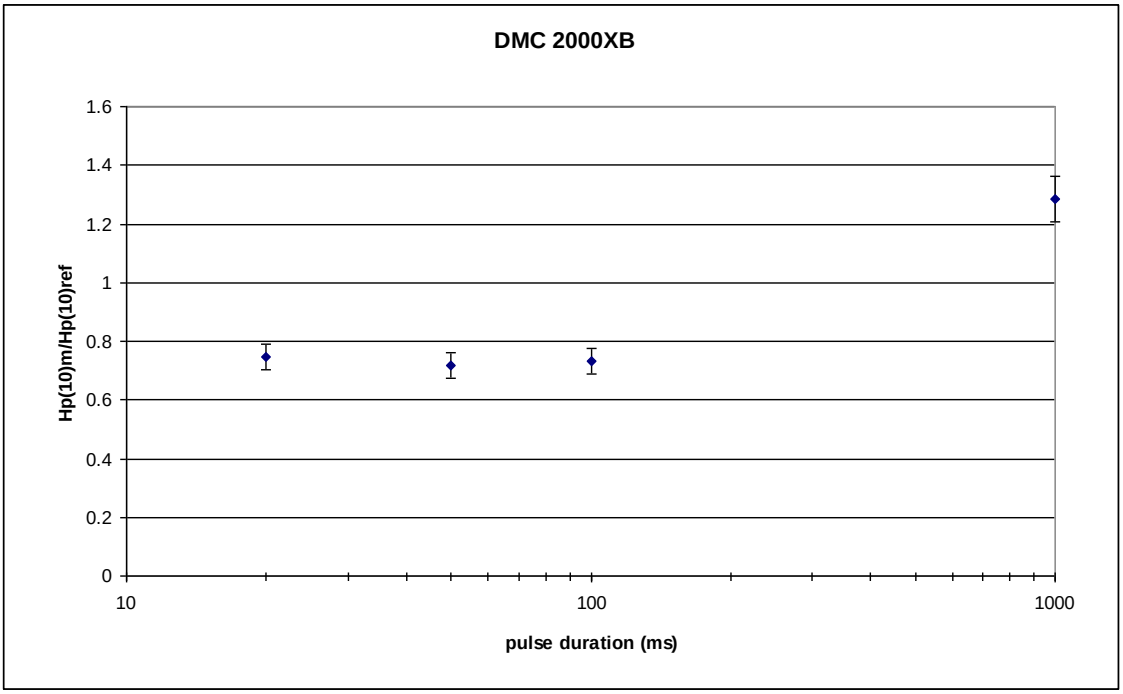


*Figure 3.22: Pulse widthresponse of **DMC2000XB** in single pulsed mode for personal dose equivalent rate integrated over the pulse of 1.8 Sv.h^{-1}.*

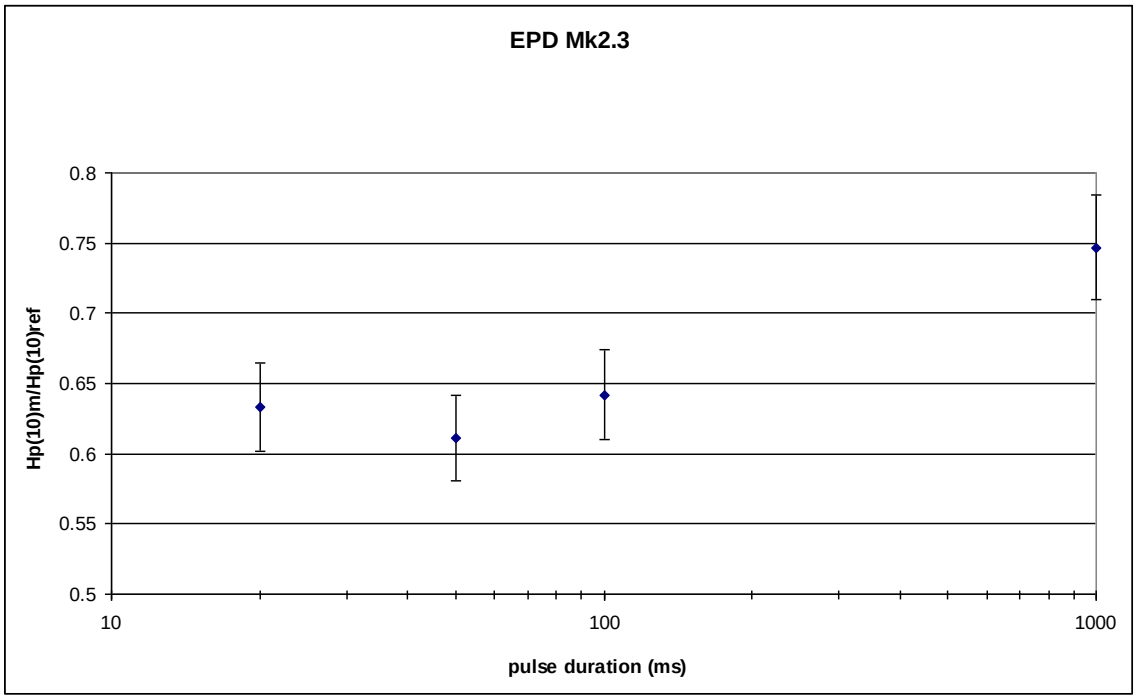


*Figure 3.23: Pulse widthresponse of **EPDMk2.3** in single pulsed mode for personal dose equivalent rate integrated over the pulse of 1.8 Sv.h^{-1}.*

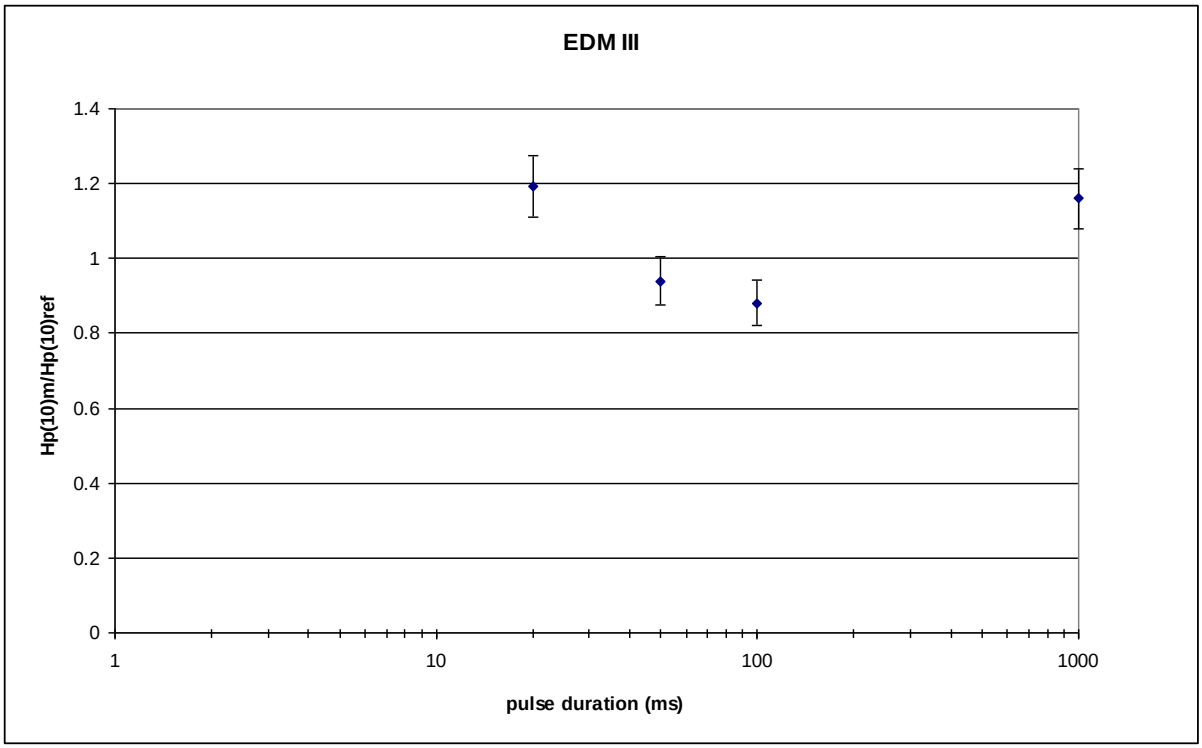


*Figure 3.24: Pulse width response of **EDMIII** in single pulsed mode for personal dose equivalent rate integrated over the pulse of 1.8 Sv.h^{-1}.*

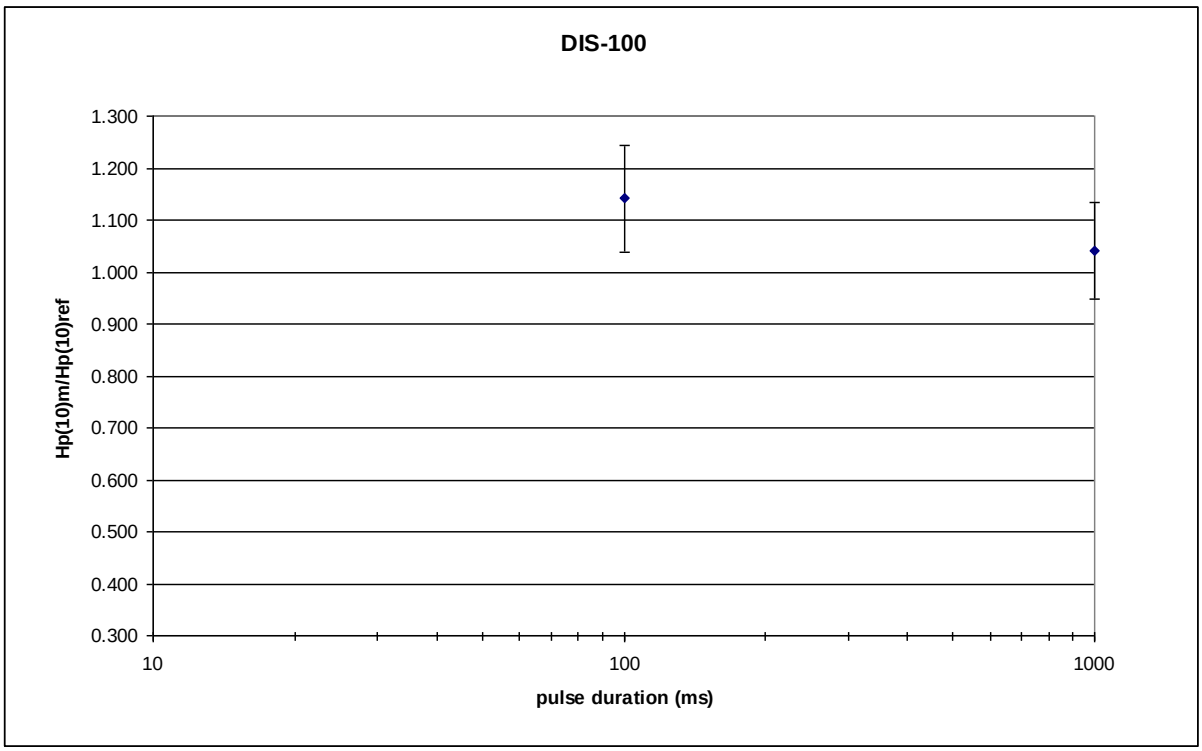


*Figure 3.25: Pulse width response of **DIS-100** in single pulsed mode for personal dose equivalent rate integrated over the pulse of 1.8 Sv.h^{-1}.*

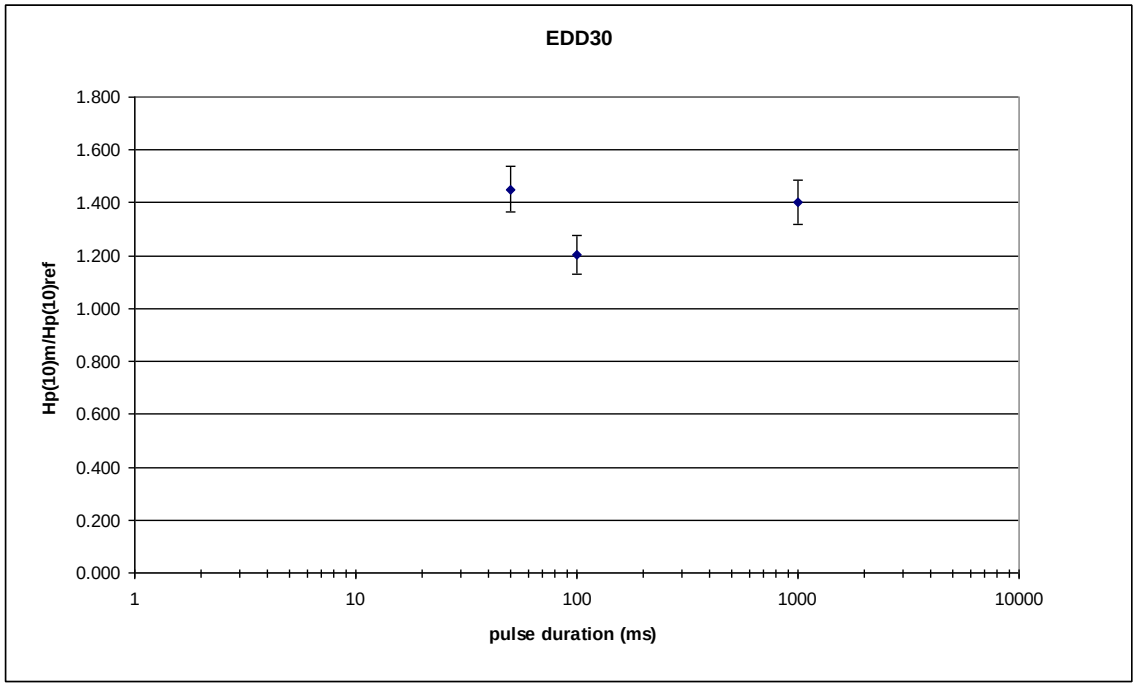


*Figure 3.26: Pulse width response of **EDD30** in single pulsed mode for personal dose equivalent rate integrated over the pulse of 1.8 Sv.h^{-1}.*

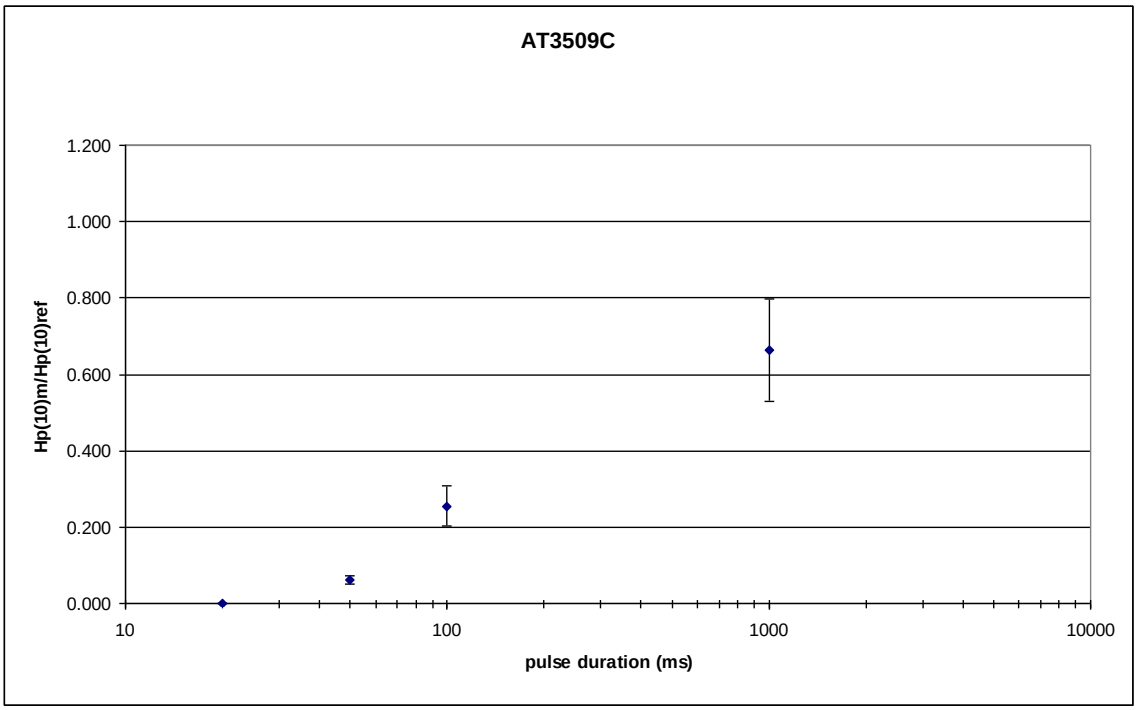


*Figure 3.27: Pulse width response of **AT3509C** in single pulsed mode for personal dose equivalent rate integrated over the pulse of 1.8 Sv.h^{-1}.*

3.2.4.3 Conclusion on tests in pulsed mode - response of each APD

All results from the pulsed field tests show that the longer the pulses and the higher the frequency, the better the behaviour of the devices tends to be.

DMC2000XB:

Effect of pulse frequency

- Variation of response : 25 to 30%
- Response better for 20 s^{-1} (close to 1) because conditions close to continuous field
- At 1 s^{-1}, the pulse frequency is low enough to give the same response in single pulsed mode
- 20% difference between 1 and 20 s^{-1} at 1.8 $Sv.h^{-1}$

Effect of personal dose equivalent rate

- Response within +/- 30% up to 1.8 $Sv.h^{-1}$
- Response decreasing with personal dose equivalent rate
- Response 0.5 at 5 $Sv.h^{-1}$ (extrapolated value) with respect to response in continuous mode
- Response 0.4 at 6 $Sv.h^{-1}$
- Response lower than 0.1 for dose rate higher than 20 $Sv.h^{-1}$

Effect of pulse width

- Response 0.7 from 20 ms to 100 ms and 1.2 for 1000 ms
- For 1000 ms: response consistent with continuous mode
- Increase of 40% between 100 and 1000 ms

EPDMk 2.3:

Effect of pulse frequency

- Variation of response : 40% at 1.8 $Sv.h^{-1}$and 25% at 6 $Sv.h^{-1}$
- 40% difference between 1 and 20 s^{-1} at1.8 $Sv.h^{-1}$

Effect of personal dose equivalent rate

- Response within +/- 30% up to 1.8 $Sv.h^{-1}$
- Response decreasing with personal dose equivalent rate
- Response 0.5 at 5 $Sv.h^{-1}$ (extrapolated value) with respect to response in continuous mode
- Response 0.4 at 6 $Sv.h^{-1}$
- Response lower than 0.1 for dose rate higher than 50 $Sv.h^{-1}$

Effect of pulse width

- Response 0.6 from 20 ms to 100 ms and 0.75 for 1000 ms
- For 1000 ms: consistent with continuous mode
- Increase of 20% between 100 and 1000 ms

EDMIII:

Effect of pulse frequency

- Variation of response : <10%
- Less than 10% difference between 1 and 20 s^{-1} at1.8 $Sv.h^{-1}$

Effect of personal dose equivalent rate

- Response within +/- 30% at 1.2 $Sv.h^{-1}$
- Over-response from 1.8 $Sv.h^{-1}$ to around 10 $Sv.h^{-1}$
- Response decreasing with personal dose equivalent rate from 1.6 to 0.1 from 1.8 to 50 $Sv.h^{-1}$
- Response 0.5 around 26 $Sv.h^{-1}$ with respect to response in continuous mode
- Response lower than 0.1 for dose rates higher than 50 $Sv.h^{-1}$

Effect of pulse width

- For 1.8 $Sv.h^{-1}$: response within +/- 30%
- For 1000 ms: consistent with continuous mode

PM1621A:

No signal in pulsed mode

DIS-100:

Effect of pulse frequency

- Variation of response : 30%
- 15% difference between 1 and 20 s^{-1} at1.8 $Sv.h^{-1}$

Effect of personal dose equivalent rate

- Response within +/- 30% for all personal dose equivalent rates up to 55 $Sv.h^{-1}$,

Effect of pulse width

- A large dispersion of the results is observed. It is probably due to the resolution of the reading (10 µSv). Indeed, the total dose equivalent received by the detector during the measurements was of about 80 mSv and as the annealing procedure of the detectors cannot be used between measurements, therefore one does not know which detector (among the three detectors which composed the DIS dosemeter) is used for measurements.

EDD30:

Effect of pulse frequency

- Variation of response : 10% at 1.8 $Sv.h^{-1}$and 40% at 6 $Sv.h^{-1}$

Effect of personal dose equivalent rate

- Response within +/- 30% up to 6 $Sv.h^{-1}$ for 20 s^{-1}
- Response decreasing with personal dose equivalent rate: the effect of saturation observed in continuous mode for dose rates higher than 2 $Sv.h^{-1}$ is confirmed
- Response 1 at 6 $Sv.h^{-1}$ for 20 s^{-1},

Effect of pulse width

- Response between 1 and 1.4 between 20 and 1000 ms
- Increasing of 10% between 100 and 1000 ms

AT3509C:

Effect of pulse frequency

- Variation of response : 30% for 10 to 20 s^{-1}
- No response at 1 s^{-1}

Effect of personal dose equivalent rate

- Response decreasing with personal dose equivalent rate
- Response 0.8 at 90 $mSv.h^{-1}$and0.3 at 1.2 $Sv.h^{-1}$
- Response 0.5 at 1 $Sv.h^{-1}$ (extrapolated value)
- Response lower than 0.1 for dose rates higher than 6 $Sv.h^{-1}$

Effect of pulse width

- Decreasing from 0.3 to 0 from 100 ms to 20 ms
- Response at 1000 ms: consistent with continuous mode

DoseAware:

Effect of pulse frequency

- No significant effect of pulse frequency

Effect of personal dose equivalent rate

- Response decreasing with personal dose equivalent rate
- Response 1 at 100 $mSv.h^{-1}$
- Response 0.5 at 900 $mSv.h^{-1}$

Effect of pulse width

- No test

PM1621A, equipped with a Geiger-Muller tube, does not give any reading in pulsed mode. The other APDs provide a response in pulsed mode, this means that they could be used in routine dosimetry with correction factors.

DMC2000XB, EPDMk2.3, EDMIII, EDD30, AT3509C and DoseAware contain all a silicon detector, the differences of their response is probably due to the time response of the electronics. The DIS has a "hybrid" technology between silicon and ionisation chamber which presents correct results, on the other hand the procedure for annealing the detector is a constraint.

3.2.5 Tests of APDs in hospitals

3.2.5.1 Introduction

Two different series of tests of APDs in real conditions in hospitals were done.

The first type of tests consisted in using a real IR facility and phantoms to simulate the operator and the patient, considering different realistic set-ups. The value of the reference dose equivalent $H_p(10)$ was measured with thermoluminescent dosemeters. The objective was to study the behaviour of APDs in realistic conditions with the possibility to select specific field parameters. The intention was to identify some trends in the behaviour of the APDs, and to compare the values with a typical passive dosemeter used in practice.

The second series of tests was made in different European hospitals in routine practice. The interventional radiologists and cardiologists were asked to wear an APD and an additional passive dosemeter above their lead apron during daily practice. The main objective of these tests was to have an overview of differences between active and passive dosimetry in routine practice in hospitals, where all kinds of procedures and parameter settings are used and without an accurate knowledge of the field parameters.

3.2.5.2 Tests on phantoms

3.2.5.2.1 Material and methods

A first series of tests in real conditions was performed by positioning APDs on an ISO slab phantom (International Organization for Standardization, 1999) representing the operator. The scattered irradiation was produced by an anthropomorphic Rando-Alderson (RA) phantom representing the patient (Figure 3.28). The tests were performed in the HUB (Hogeschool Universiteit Brussel), a teaching school in Medical Imaging in Brussels. The X-ray system was a Philips Optimus 50 generator and a Philips RO 1750 X-ray tube with an inherent filtration equivalent to 3.5 mm Al. Additional filtration of 1 mm Al + 0.2mm Cu was added. The tube voltage ranged from 40 to 150 kVp and the tube load ranged from 0.5 to 850 mAs. The X-ray system delivers single pulses.

The APDs tested were: DMC2000XB, EPDMk2.3, EDMIII, PM1621A, DIS-100 and EDD30.

The routine passive thermoluminescent dosemeter (TLD, LiF:Mg,Ti) from the Belgian Nuclear Research Centre was used as reference. The dosemeter service fulfils the technical requirements of IEC 61066 Standard (IEC, 2006).An expanded relative uncertainty of 20% (k=2) is estimated for the TLD measurements for the used dose ranges, taking into account the energy and angular response, the calibration and individual sensitivity. Two units were tested for each APD type, except for the EDD30 dosemeter, of which only one unit was available. For each irradiation, one or two APDs (of different types) and one TLD badge were positioned together on the ISO slab phantom. A sufficient number of pulses were applied for each irradiation to supply a minimum personal dose equivalent of the order of 15 to 20 µSv (from 5 to 40 pulses, depending on the X-ray system settings). To investigate the influence of the position of the detector on the ISO slab phantom, the dose uniformity on the surface of the phantom was determined and resulted in an uniformity within a maximum relative uncertainty of 20%. In general, each type of irradiation was not repeated for the same APD unit, but the repeatability of each APD system had been tested in laboratory and resulted in a dosemeter reading variability smaller than 5% (k=2), in addition the relative uncertainty due to the repeatability of the experimental set up was estimated in 5% (k=2). On the basis of the Guide to the Expression of Uncertainty in Measurement (ISO, 2008), the total expanded relative uncertainty of the APD response compared with the TLD measurement is 32% (k=2).

The thorax of the RA-phantom was irradiated and 4 realistic set-ups were considered:

- AP direct: tube above the RA phantom at 0°, ISO slab phantom at the level of the thorax (representing radial access)
- L direct: tube in lateral position at 90°, ISO slab phantom at the level of the thorax
- AP indirect: tube above the RA phantom at 0°, ISO slab phantom at the level of the pelvis (representing femoral access)
- L indirect: tube in lateral position at 90°, ISO slab phantom at the level of the pelvis

The effect of the variation of dose equivalent rate, kilo-voltage and pulse width was investigated for the four different clinical set-ups described above. A factor of 2 between the doses given by the two types of dosimeters was considered as acceptable.

Figure 3.28:General set-up (left) and positioning of APDs and TLD reference on ISO slab phantom (right)

3.2.5.2.2 Results

The influence of the dose equivalent rate was tested by varying the mAs value on the X-ray system. The tube voltage was kept constant at 80 kVp and additional filtration of 1 mm Al and 0.2 mm Cu was chosen. Changing the mAs-value resulted in a range of dose equivalent rates tested from 10 $mSv.h^{-1}$ to 1.08 $Sv.h^{-1}$. The response of the APD compared to the TLD for the 6 dosemeters tested is illustrated in Figure 3.29. It can be observed that the PM1621A does not give any signal, which is consistent with the laboratory tests in pulsed fields. In general we can observe that the APD response is within 50% for the range of dose equivalent rates tested, except for the EDM III for which the dose is general higher than the TLD dose.

The influence of the tube voltage was tested by changing it from 60 kVp to 100 kVp, with a tube current of 625 mA, pulse width of 20 ms and additional filtration of 1 mm Al and 0.2 mm Cu. This resulted in a dose equivalent rate range between 100 $mSv.h^{-1}$ and 1.5 $Sv.h^{-1}$. No important influence of the tube voltage was observed on the APD response compared to the TLD. Still no signal was observed on the PM1621A. An example of the APD response in function of tube voltage is given in Figure 3.30 for the EPDMk2.3 for the 4 different set-ups.

The influence of pulse width was tested by changing it from 5 ms to 2000 ms, with a tube voltage of 80 kVp, and additional filtration of 1 mm Al and 0.2 mm Cu. The tube current (mA) could not be kept constant, as tube current and pulse width cannot be set independently. No important influence of the tube width was observed on the APD response compared to the TLD. Still no signal was observed on the PM1621A. An example of the APD response in function of pulse width is given in Figure 3.31 for the DIS-100 for the 4 different set-ups. Depending on the combination of ms and mA, a maximum dose rate of 1 $Sv.h^{-1}$ was achieved.

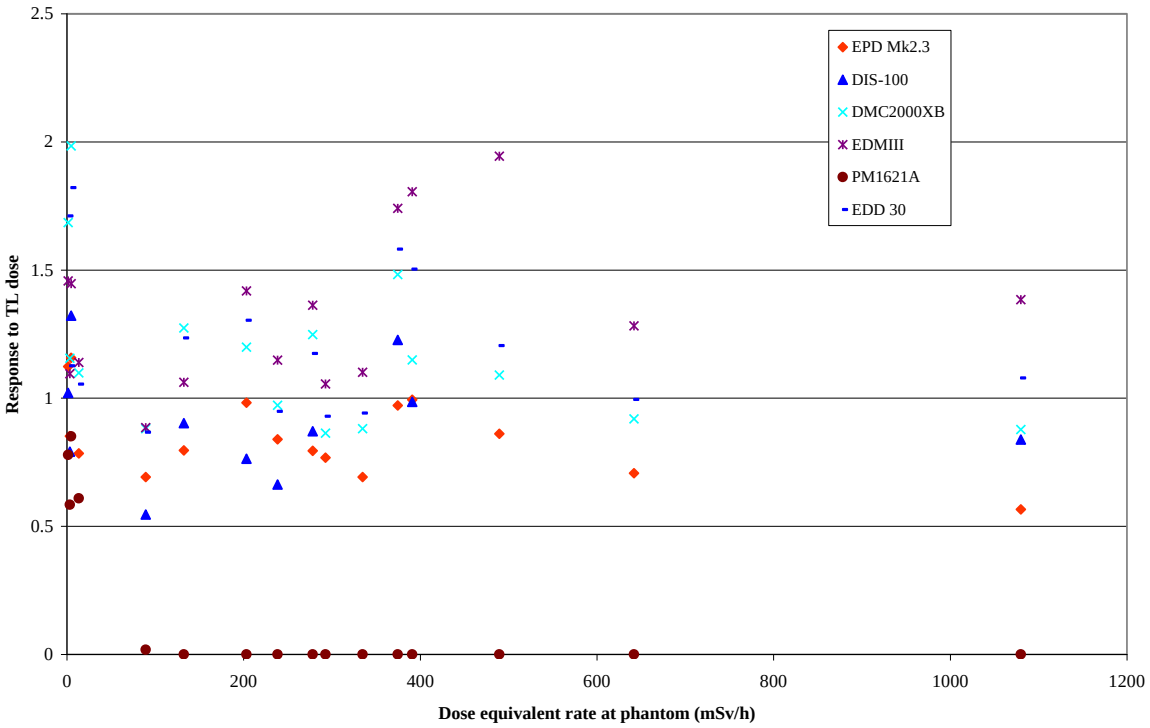


Figure 3.29: The influence of dose rate for different APDs tested compared to a passive TLD

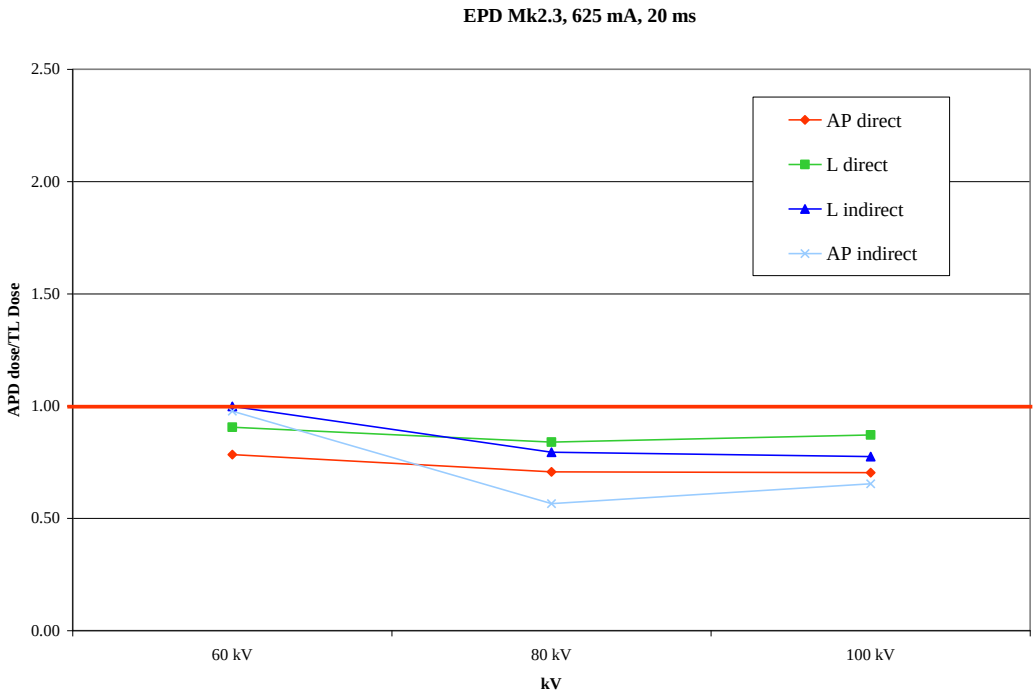


*Figure3.30: The influence of tube voltage for the **EPDMk2.3** compared to a passive TLD*

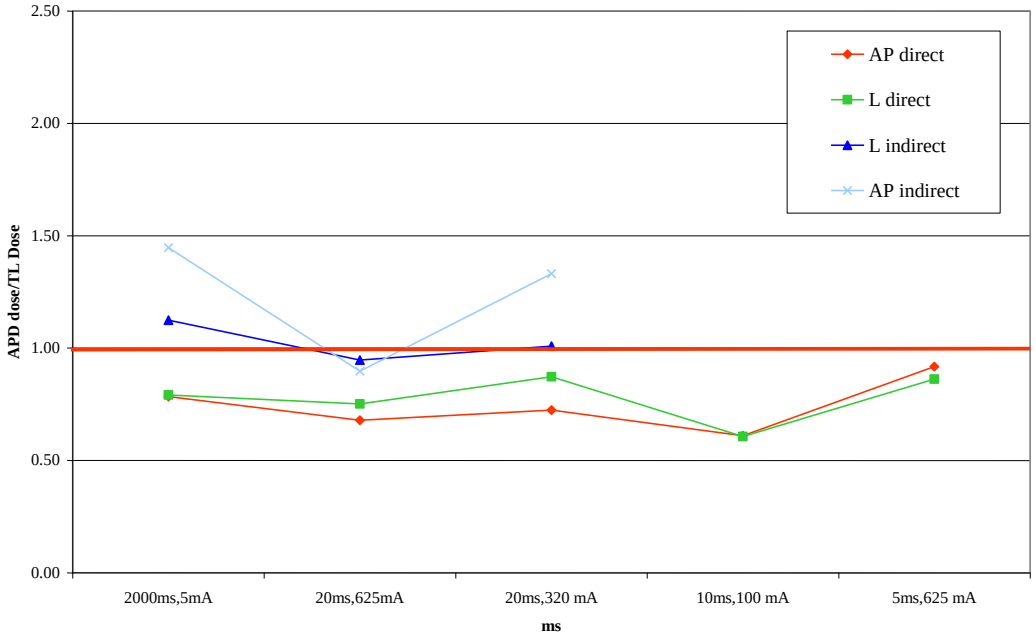


*Figure 3.31: The influence of pulse width for the **DIS-100** compared to a passive TLD*

3.2.5.3 Tests on operators

3.2.5.3.1 Material and methods

For these series of tests, operators wore, side by side, one APD and one passive dosemeter above the lead apron. The dosemeters were worn during several interventions to integrate doses of at least 300 µSv for several types of IR/IC procedures. The dose equivalent was provided by the passive dosemeter according to the routine measurement protocol of the respective partner that performed the measurements. For practical reasons only 5 APDs were tested: DMC2000XB, EPDMk2.3, EDMIII, DIS-100 and DoseAware. In total 102 measurements were performed in 7 different European hospitals. The main objective was to compare the measurements performed by the APD and passive dosemeter worn in routine practice where all kinds of procedures and parameter settings are used and without an accurate knowledge of these parameters.

3.2.5.3.2 Results

The results of the second series of tests performed on operators show that with respect to passive dosimeters, in general all 5 tested APDs under-respond. In Figure 3.32, a frequency distribution of the APD response related to the passive TLD is given. We can observe a large spread in the results, which might be explained by non-uniform irradiations or the shielding of one dosemeter by the other. The ratio of the APD Hp(10) reading to the TLD Hp(10) reading had a median value of 0.77 for the DMC2000XB, 0.77 for the EPDMk2.3, 0.86 for the DIS-100, 0.88 for the EDMIII and 0.61 for the DoseAware. The lower ratio of the DoseAware is similar as the under-response for lower energies in the laboratory tests.

3.2.5.4 Conclusions on tests of APDs in hospitals

The tests of the APDs on the phantoms in a clinical environment for different clinical set-ups with different tube voltages and pulse width compared to a TL dosemeter as reference showed that the APD response is roughly within +/- 30%. Only the EDMIII dosemeter gave a higher response within +/- 50%. The DMC2000XB and EDD30 resulted in doses slightly higher than the TLD dose, while for the EPDMk2.3 and the DIS-100 the doses are slightly lower than the TLD dose. The PM1621A active dosemeter had no response at all.

The problems encountered for the pulse field tests in laboratory conditions were not observed in the hospital tests as in these tests the APDs were irradiated in the scattered field with dose rates below 1 $Sv.h^{-1}$. For the same reason, the behaviour of the APDs is more satisfactory in hospitals than in laboratories with respect to the influence of tube peak high voltage and pulse width. For the 5 dosimeters tested on operators in routine practice we observed that all APDs had a median under-response around 20% compared to the TLDs.

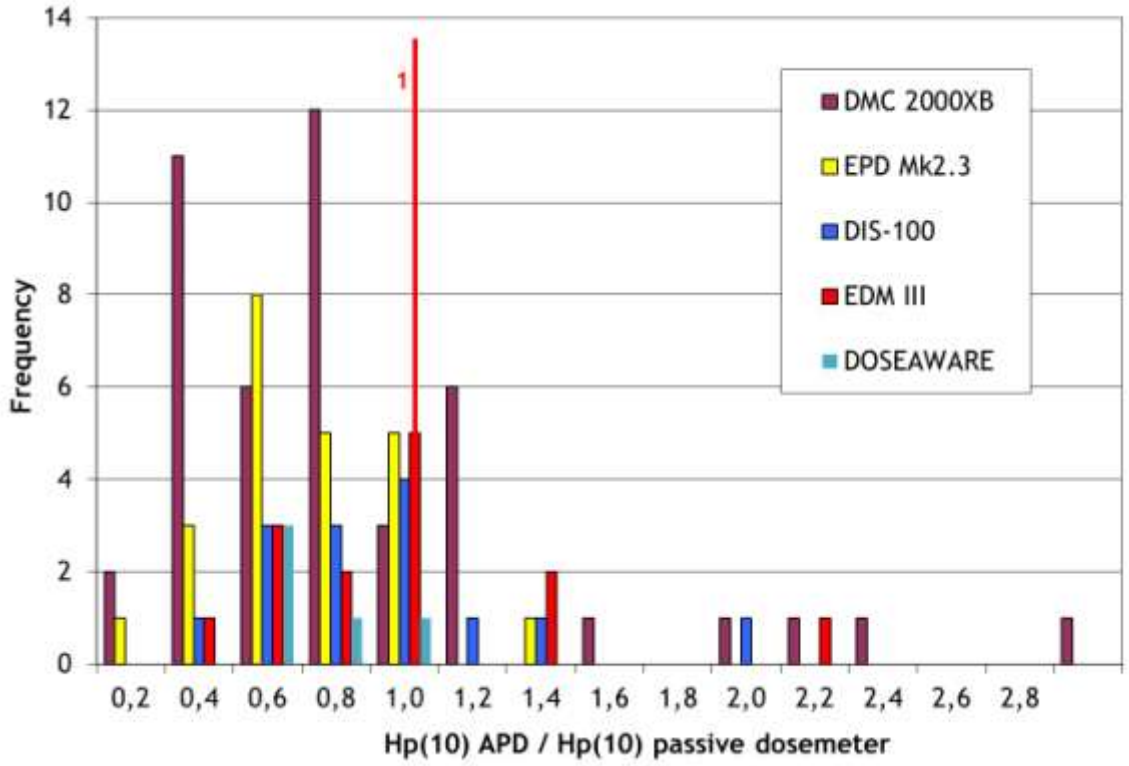


Figure 3.32: Frequency distribution of the APD response related to the passive TLD in routine practice

3.3 Guidelines for the use of APDs in interventional radiology

Some recommendations were prepared within the group to help in the selection and the use of APDs at IR/IC workplaces(see the three page leaflet in annex of this report).

3.3.1 Recommendations for the selection of an APD in IR/IC

- The APD has to fulfil the requirements of the IEC 61526 standard (International Electro technical Commission, 2010), and, in particular, the following specific points.
- The energy response has to be within the interval [0.71 – 1.67] for the energy range 20 – 100 keV.
- The angular response has to be within the interval [0.71 – 1.67] for angles from 0° to 60° from reference direction and for the energy range 20 - 100 keV.
- The maximum dose equivalent rate required by the IEC 61526 standard is 1 $Sv.h^{-1}$ but, since dose equivalent rates can be high when standing very close to the direct beam, if the APD can stand higher dose equivalent rates it should be taken into account as a positive characteristic. In any case, the APD should be able to give at least an alarm for dose equivalent rates higher than 1 $Sv.h^{-1}$.
- As pulsed radiation fields are not taken into account in existing standards, some information on the APD characteristics in pulsed field similar to those met at the workplace is needed (i.e. effect of pulse frequency and width on the dose equivalent response). Different sources of information can be used such as the results of the tests performed within the ORAMED project or those eventually performed by the manufacturer. It is also possible to perform his/her own tests using ISO slab phantoms to simulate the patient and the operator and placing the APD and a passive dosemeter side by side. A factor of 2 between the doses given by the two types of dosemeters can be considered acceptable.

3.3.2 Recommendations for the use of an APD in IR/IC

- The APD has to be periodically (according to local regulation) calibrated or verified in terms of $H_p(10)$ with X-ray beams in a calibration laboratory traceable to a primary standard, the conditions of calibration have to be as close as possible to those of use.
- The APD is considered, for this application in IR/IC, as a tool to optimize and reduce the exposure, it is then recommended to wear it over the lead apron.
- It is not recommended to use APD for the legal dose record in case of IR/IC, the reference $H_p(10)$ value should be given by the passive dosemeter
- The alarm should be switched ON (only visual alarm) in order to warn the operator when he/she is too close to the direct beam. The value to which the dose rate alarm shall be set depends on the characteristics of both the pulsed radiation field and the APD (Ambrosi et al. 2010).

3.4 Development of the prototype of an improved APD for interventional radiology

3.4.1 Context of development of the prototype

The objective of this part of the project was to propose technical solutions to improve the response of an APD for an application in IR/IC based on the results of the tests performed in laboratory conditions. The different technical solutions with continuous feedback, developed by MIRION Technologies, a partner of the ORAMED project, were tested in calibration laboratories.

A prototype of detection module was developed in order to improve the characteristics of detection of the APD "DMC2000XB" already distributed by MIRION Technologies.

In order to separate the detection considerations from the functionality and design requests of a whole dosimeter, the detection module developed regroups the main components involved in the detection: the ASIC[a], the detectors and the shielding.

3.4.2 The detection module

The components around the ASIC (Figure 3.33) have been re-designed in order to detect gamma and X-rays below 20 keV. It has a very low consumption in order to guarantee long battery life and has multi-channels amplifier/discriminator with independent counters. It integrates specific and dedicated counters on each detection channel in order to compensate the energy response and response at high dose rate.

Figure 3.33: Prototype of detection module with and without shielding

3.4.3 Improvements on the prototype

The improvements on the prototype have been done in two major directions: one to improve the main detection characteristics and the other one to improve the response at high dose rate in pulsed field.

The following items were analysed in details:

- energy response,
- angular response,

[a]Application-Specific Integrated Circuit

- personal dose equivalent rate response in continuous and pulsed photon fields.

3.4.3.1 Energy response

The first improvement on the detection module consisted in having a response that did not depend significantly on the energy. By selecting the materials in front of the detector (shape and composition) and adjusting the energy thresholds of the discriminators, it has been possible to reduce down to +/- 10% the deviation of the energy response all over the 20-100 keV energy range used in IR/IC procedures. In Figure 3.34, the energy response is compared for the DMC2000XB, the first version and the last version of the new detection module.

3.4.3.2 Angular response

The second task was to reduce the angle effect on the response. The position of the two detectors and the shape of the detection module have been re-designed in order to have a good angular response for irradiations angles up to +/- 60°. The angular response is now +/ 30% deviation for angles up to +/-65° for the 20-100 keV energy range (Figure 3.35).

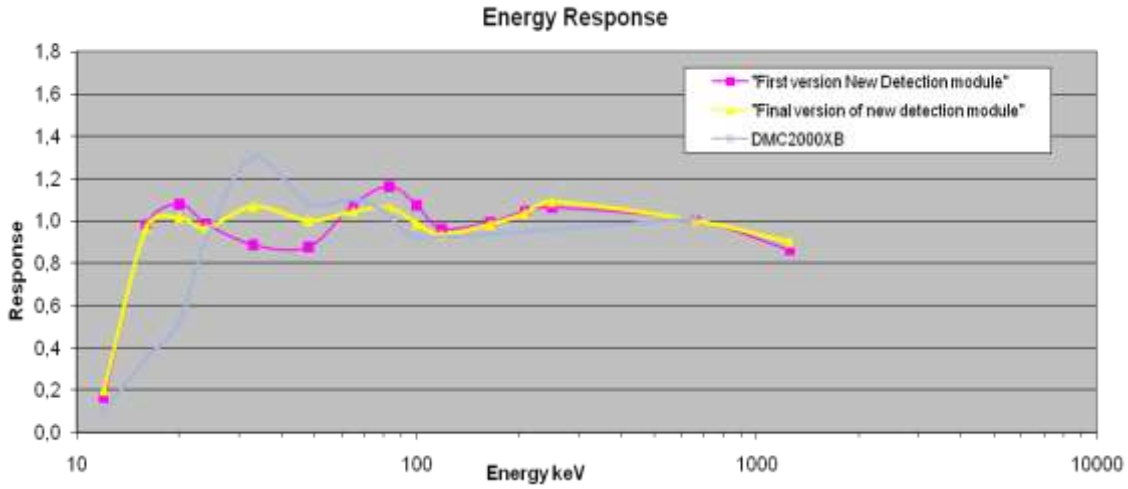
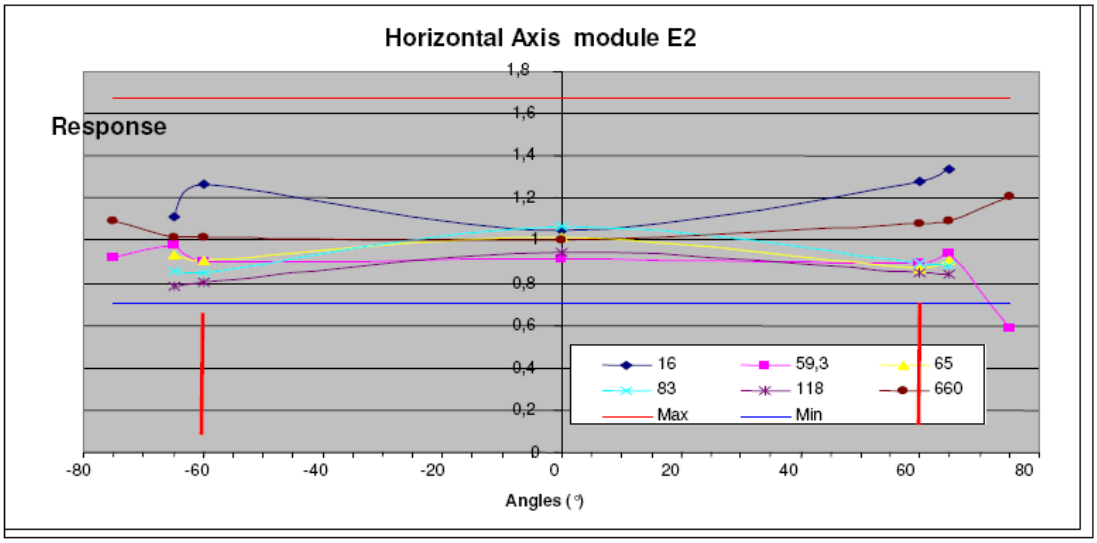


Figure 3.34: Energy response of DMC2000XB, first and final versions of the new detection module.



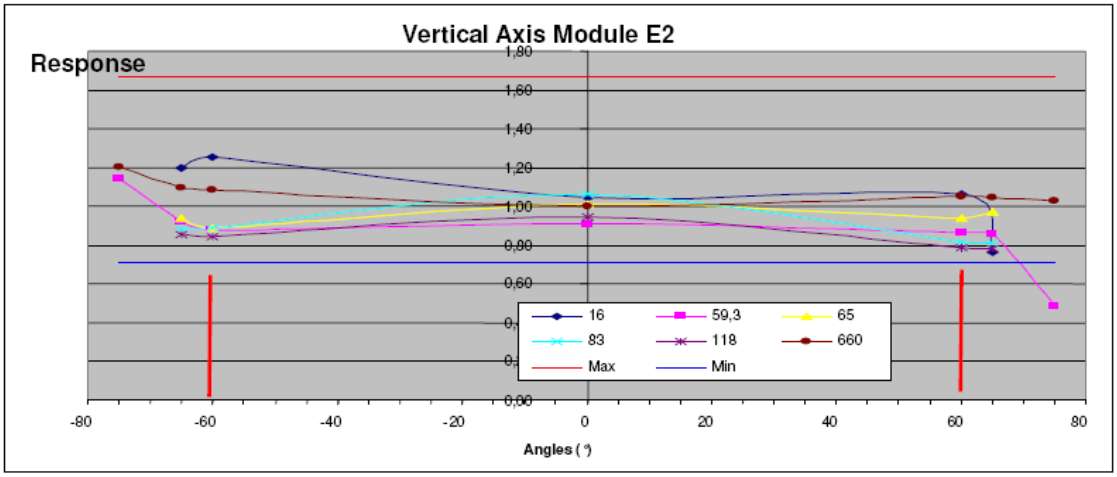


Figure 3.35: Angular response of final version of the new detection module

3.4.3.3 Personal dose equivalent rate response in continuous and pulsed photon fields

Finally, a study of the dead time compensation was conducted in order to reach dose rates as high as 10 $Sv.h^{-1}$. The response is now better than +/- 20% beyond 10 $Sv.h^{-1}$ in continuous mode (Figure 3.36). When exposed to pulsed fields, the response was not as good as in continuous irradiation and was similar to the response without correction (dead time correction).

The specific modification for pulsed X-ray field associated with a new dead time algorithm is expected to greatly improve response in high dose rate up to 50 $Sv.h^{-1}$with a flat response within +/- 20% deviation up to 20 $Sv.h^{-1}$ in pulsed mode (Figure 3.37).

This latest improvement will give a better assessment of doses in abnormal high dose rate situation.

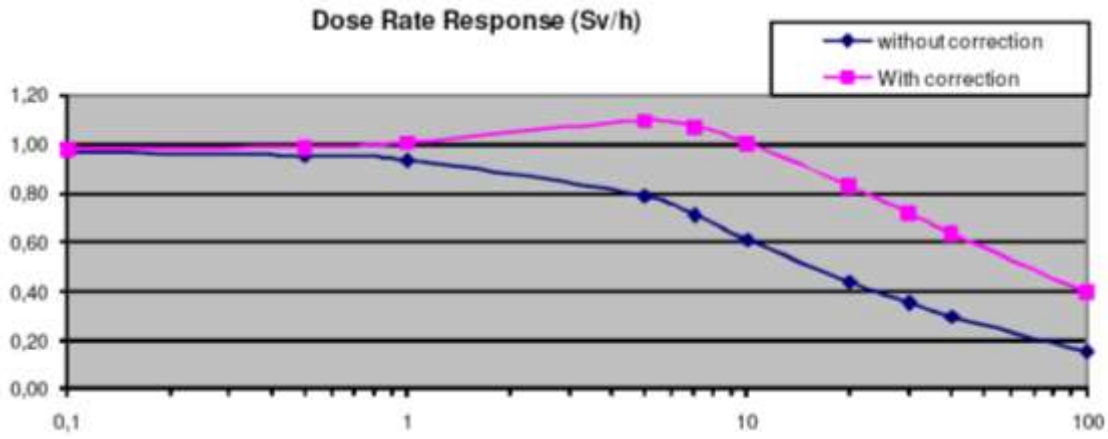


Figure 3.36: Personal dose equivalent rate response of the new detection module in continuous field.

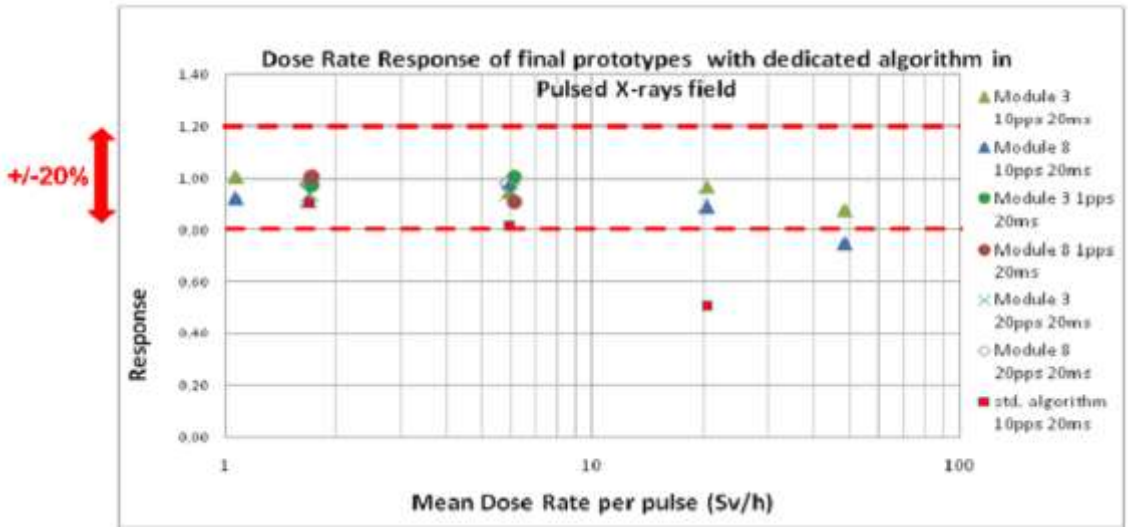


Figure 3.37: Personal dose equivalent rate response of the new detection module in pulsed field.

3.4.4 Conclusion on new APD prototype

The major detection characteristics (energy response, angular response and personal dose equivalent rate response) have been improved and will give a better assessment of occupational doses during IR/IC procedures.

3.5 Conclusion

Series of tests in laboratory conditions were performed on eight commercial APDs in order to evaluate their performances for use in IR/IC.

On the one hand, the tests performed with reference continuous X-rays showed that all APDs have a linear response with the personal dose equivalent and most of them have a satisfactory response at low energies down to N-30 radiation quality, which is sufficient for IR/IC. Most APDs provide a satisfactory response for high personal dose equivalent rates up to 10 $Sv.h^{-1}$. However, as indicated in table 3.1, the dose rates in the direct beam can be much higher than those tested here. So these tests in continuous fields do not mean that the APDs will correctly handle these very high dose rates in the direct beam. In addition, a problem of angular response at low energies was observed for AT3509C.

On the other hand, the influence of the frequency and duration of pulses on the APD responses was studied with reference pulsed X-ray beams. PM1621A, equipped with a Geiger-Muller tube, does not give any signal in pulsed mode. The other APDs provide a response in pulsed mode more or less affected by the personal dose equivalent rate, which means they could be used in routine monitoring provided that correction factors are introduced. These results emphasize the importance of adding tests in pulsed mode in type-test procedures for APDs.

The tests of these APDs in a clinical environment compared to a TLD as reference showed that their response is roughly within +/- 30%. For the 5 dosemeters tested on operators in routine practice, all APDs had a median under-response around 20% compared to the TLDs.

Some recommendations are given to help in selection and use of APDs at IR/IC workplaces. These recommendations are compiled on a three page leaflet presented in annex of this report and available on the ORAMED website http://www.oramed-fp7.eu/.

Finally, an APD prototype, improved for IR/IC procedures was developed. Performance of the prototype is promising and it is foreseen that shortly a new product will be available.

3.6 References

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3.7 Guidelines elaborated in the framework the ORAMED project for the use of active personal dosemeters in interventional radiology and cardiology.

GUIDELINES FOR THE USE OF ACTIVE PERSONAL DOSEMETERS IN INTERVENTIONAL RADIOLOGY/CARDIOLOGY

These guidelines were established in the framework the ORAMED project (2008-2011), a Collaborative Project supported by the European Commission within its 7th Framework Program.

General problematic

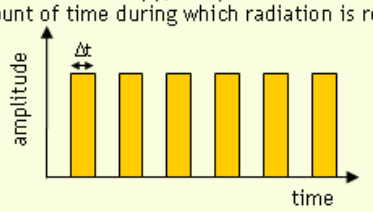
Active personal dosemeters (APD) are used in the context of operational radiation protection taking advantage of an immediate dose reading and an alarm at a pre-set dose and/or dose rate level [1-2]. In interventional radiology and cardiology (IR/IC), the possibility to assess the dose in real time is particularly interesting since operators can receive relatively high doses while standing close to the primary radiation field. In addition, the possibility to have an alarm when the personnel is accidentally exposed to the primary beam is very attractive.

Due to the specificity of the X-ray fields used in IR/IC (low energies and pulsed fields), the current technology of APDs can be inadequate. This problem was highlighted during two previous international intercomparisons [3-5]. These guidelines propose recommendations when selecting and using an APD in IR/IC based on the work performed in the framework of the European project ORAMED (2008-2011) [6].

Terms and definitions

BEAM CHARACTERISTICS IN PULSED MODE

In pulsed fluoroscopy, X-rays are delivered in pulses that follow in rapid succession. This reduces the amount of time during which radiation is released.



Pulse frequency: number of pulses per second = pps
Pulse width: Δt
Direct beam: beam directly delivered by the X-ray tube
Scattered beam: beam backscattered by the patient

TYPICAL FIELDS IN INTERVENTIONAL RADIOLOGY AND CARDIOLOGY

Table 1. Typical radiation field characteristics in interventional radiology and cardiology (data gathered through questionnaires sent to hospitals, literature and quality control outputs, calculations of dose rate at specific points of interest and typical scattered spectra were performed using Monte Carlo codes)

Parameter	Range
High voltage	60-120 kVp
Intensity	5-1000 mA
Inherent filtration	3 - 6 mm Al_{eq} (typically 4.5 mmAl_{eq})
Additional filtration	0.2 - 0.9 mmCu
Pulse duration	1 - 20 ms (typically 10-20 ms)
Pulse frequency	1 - 30 pps (typically 15 pps)
Dose equivalent rate in the direct beam (table)	2 to 360 $Sv.h^{-1}$
Dose equivalent rate in the scattered beam (operator - above the lead apron)	5.10^{-3} to 10 $Sv.h^{-1}$
Energy range of scattered spectra	20 keV - 100 keV

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Recommendations when selecting an APD in IR/IC

- The APD has to fulfil the requirements of the IEC 61526 standard (2010 - 07) [7] in particular for the following points:
  - energy response: correct* response within the energy range 20 keV - 100 keV
  - angular response: correct* angular response from 0° to 60° from reference direction within the energy range 20 keV - 100 keV
  - dose equivalent rate range: the maximum dose equivalent rate value required by the IEC standard is 1 $Sv.h^{-1}$ but, since dose equivalent rates can be high very close or inside the direct beam, if the APD can stand higher dose equivalent rates it is an interesting feature that has to be taken into account. In any case, the APD should be able to give at least an alarm for dose equivalent rates higher than 1 $Sv.h^{-1}$.

- As pulsed radiation fields are not taken into account in existing standards, some information on the APD characteristics in pulsed field are needed (i.e. effect of pulse frequency and width on the dose equivalent response). Different sources of information can be used:
  - results of tests performed within the ORAMED project (see annex of these guidelines and reference [6])
  - results of tests eventually performed by the manufacturer
  - perform tests using the following configuration:
    - ✓ place one ISO slab phantom on the table to simulate the backscattering created by the patient
    - ✓ place one ISO slab phantom at a representative position of the operator
    - ✓ place the APD and a passive dosemeter side by side on the operator phantom without lead apron
    - ✓ use a usual configuration for your facility in terms of kV, mAs, etc. and integrate at least 300 µSv
    - ✓ results: a factor of 2 between the doses given by the two types of dosemeters can be considered as acceptable.

**correct response: limit of variation of instrument parameter in the range -29% to +67%, as required in IEC 61526 standard (2010 - 07) [7]*

Recommendations when using an APD in IR/IC

- The APD has to be periodically (according to local regulation) calibrated or verified in terms of $H_p(10)$ with X-ray beams in a calibration laboratory traceable to a primary standard, the conditions of calibration have to be as close as possible as those of use.
- The APD is considered, for this application in IR/IC, as a tool to optimize and reduce the exposure, we then recommend to wear it the over the lead apron.
- It is not recommended to use APD for the legal dose record in case of IR/IC, the reference $H_p(10)$ is still given by the passive dosemeter
- The alarm should be switched ON (only visual alarm) in order to warn the operator when he/she is too close to the direct beam.

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ANNEX - Main results of tests performed in the ORAMED project

The work performed in the ORAMED project consisted in:
- making a selection of APDs deemed suitable for application in interventional radiology/cardiology
- defining, by measurements under laboratory conditions, the dose, the dose rate, the energy and the angular response of selected commercial APDs, with continuous X-ray beams.
- studying, by measurements under laboratory conditions and with tests in different hospitals, the effect of dose equivalent rate, pulse frequency and pulse width on the APD response, with pulsed X-ray beams.

Figure 1. APDs selected for tests (pre-requisite: the APD should respond to low photon energies starting from 20 keV)

TESTS DONE WITH CONTINUOUS X-RAY BEAMS IN CALIBRATION LABORATORY CONDITIONS

Dose equivalent response : S-Co, N-150 for DoseAware
Dose equivalent rate response from 0 to 10 Gy.h^{-1}: S-Co for all APDs, H-100 for EDD30 and N-150 for DoseAware
Energy response: N-15, N-20, N-25, N-30, N-40, N-60, N-80, N-100,N-120, S-Cs, S-Co for all APDs, from N-30 to N-300 for DoseAware
Angular response at +/- 60°: N-25, N-30, N-40 and N-60

All APDs have a linear response with the dose equivalent and most of them have a satisfactory response at low energies from N-30.
Most APDs can stand high dose equivalent rates up to 10 Sv.h^{-1}, except:
- PM1621A for which the response is diverging rapidly from 1 Sv.h^{-1}
- EDD30 which saturates for dose rates above 2 Sv.h^{-1}.
- DoseAware which saturates for dose equivalent rates above 4 Sv.h^{-1}

All APDs have a satisfactory angular response from the energy of N-30 (except AT3509C: satisfactory angular response only from N-80)

TESTS DONE WITH PULSED X-RAY BEAMS IN CALIBRATION LABORATORY CONDITIONS

① **Dose rate** (in multi-pulsed mode):
- pulse duration: 20 ms,
- pulse frequency: 10 pulse per second (pps)
- **dose equivalent rate variation from 100 mSv.h^{-1} to 50 Sv.h^{-1} (up to 1,8 Sv.h^{-1} for DoseAware)**

For most APDs the response decreases when the dose equivalent rate increases. For dose equivalent rates < 2 Sv.h^{-1} the responses are, in general, close to 1 and fall down for higher dose equivalent rates, except for DIS-100 that stands relatively high dose equivalent rates.

Table 2. Threshold in terms of dose rate (Sv.h^{-1}) for which the maximum APD response is divided by a factor 2.

APD	DMC 2000XB	EPD MK2.3	EDM III	PM1621A	DIS-100	EDD 30	AT3509C	DoseAware
Dose rate (Sv.h^{-1}) for APD response divided by 2	5	7	20	NO SIGNAL	Response within +/- 30% for all dose equivalent rates up to 55 Sv.h^{-1}	10	3.5	0.8

② **Pulse frequency** (in multi-pulsed mode) for all APDs:
- dose equivalent rate: 1.8 Sv.h^{-1} and 6.8 Sv.h^{-1} (908 mSv.h-1 and 1,8 Sv.h-1 for DoseAware)
- pulse duration: 20 ms,
- **pulse frequency variation: 1 pps, 10 pps and 20 pps (1 pps and 10 pps for DoseAware)**

The response of APDs decreases from 10% to 40% when the pulse frequency increases from 1 to 20 pps.

Table 3. Percentage of variation on the APD response from 1 to 20 pps.

APD	DMC 2000XB	EPD MK2.3	EDM III	PM1621A	DIS-100	EDD 30	AT3509C	DoseAware
Variation on the APD response %	25-30	30-40	<10	NO SIGNAL	30	10 (1.8 Sv.h^{-1}) saturation from 2 Sv.h^{-1}	30: 10- 20 pps; No signal at 1 pps	<10 (between 1 and 10 pps)

③ **Pulse width** (in single pulsed mode):
- **pulse width variation: 20, 50, 100 and 1000 ms at 1.8 Sv.h^{-1} (DoseAware not tested in this configuration)**

When the pulse width is larger than 1 s: the responses in pulsed and in continuous radiation field are similar. No significant effect of pulse width was observed on the response.

TESTS DONE WITH PULSED X-RAY BEAMS IN HOSPITALS

A series of tests was made in different European hospitals in routine practice. The interventional radiologists and cardiologists were asked to wear, side by side, an APD and an additional passive dosemeter above their lead apron during daily practice. The main objective of these tests was to have an overview of differences between active and passive dosimetry in routine practice, where all kinds of procedures and parameter settings are used and without an accurate knowledge of the field characteristics. Four dosemeters were tested in these conditions: DMC 2000XB, EPD Mk2.3, EDWIII and DIS-100.

All tested APDs present a slight under-response with respect to passive dosemeters.

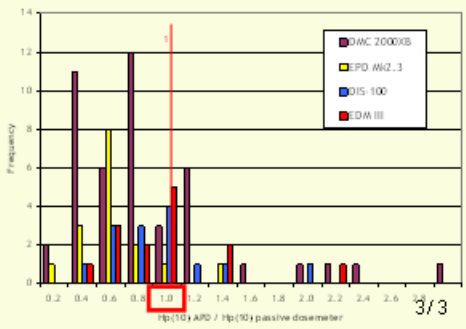

Figure 2. Distribution of APD response compared with passive dosemeter response in realistic conditions

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4 Extremity dosimetry in nuclear medicine

4.1 Introduction

Manipulation of unsealed sources in nuclear medicine (NM) may involve high skin doses to the hands of the staff during preparation (labelling/dispensing) and administration of the radiopharmaceuticals. In the framework of the FOP CONRAD project, Vanhavere et al. (2008) highlighted that the local skin doses can surpass the dose limit of 500 mSv per year averaged over an area of 1 cm^2(ICRP 2007, EC Directive 96/29/ERRATUM 1996). Also known is the high dose gradient across the hand, particularly for beta sources (Covens et al., 2010, Mansour et al., 2010). This fact complicates the routine monitoring since the maximum dose is usually received at the fingertips, and therefore is systematically underestimated by ring and wrist dosemeters (Doraville et al., 2008). The CONRAD study also showed a lack of use of these dosemeters or, when used, an inappropriate positioning of them. In addition, the information about this topic was poor due to the absence of systematic studies.

The objectives of WP4 (Extremity dosimetry in NM) can be summarized as follows:

- To evaluate maximum extremity doses and dose distributions across the hands of medical staff working in NM departments.
- To study the influence of protective devices such as syringe and vial shields and to improve such devices when possible.
- To propose “levels of reference doses” for each standard NM procedure and to use these for risk assessment and optimisation of working methods.
- To propose a methodology to reduce doses to NM workers.

For this purpose, an extensive measurement program was performed including 124 workers from 32 NM departments in 7 European countries, Belgium, France, Germany, Italy, Slovakia, Spain and Switzerland, representing the largest number of collected data on extremity dosimetry in NM. The purpose of this wide measurement campaign was to determine the maximum dose and dose distribution across the hands and to supply information on reference dose levels for each standard NM procedure. The experimental data were complemented with Monte Carlo (MC) simulations. MC calculations aimed at better determining the main parameters that influence extremity exposure, the effectiveness of different radiation protection measures, such as the design of shielding, and the degree of variability that could be “intrinsically related” to each monitored procedure.

4.2 Materials and methods

4.2.1 Radionuclides

For the ORAMED project, only those radionuclides most commonly used for diagnostic and therapy procedures have been considered. Concerning diagnostics, 80 to 90% of the scintigraphies are carried out using ^{99m}Tc(pure gamma ray source, emitting a photon of 140 keV (87%)), the rest being mostly associated with iodine, and to a lesser extend Thallium (^{131}I, ^{123}I and ^{201}Tl). The most common PET radiopharmaceutical is ^{18}F-FDG, ^{18}F is a positron emitter with a maximum energy of 634 keV (97%, the spectrum of the positron is shown in Figure 4.1) and the emission of annihilation photons of 511 keV (194%). Concerning therapy, nuclides that emit beta or mixed beta/gamma radiation are used, such as ^{131}I for metabolic therapy. ^{90}Y-labelled antibodies (e. g. ^{90}Y/Zevalin®) are used for treating Non-Hodgkin-lymphoma by radioimmunotherapy (RIT), and with ^{90}Y or ^{177}Lu labelled peptides (e. g ^{90}Y/DOTATOC) neuroendocrine tumors are treated by peptide receptor radiotherapy (PRRT). ^{90}Y is a pure high-energy beta radiation emitter with a maximum β-energy of 2.28 MeV. The spectrum is shown in Figure 4.2. Also ^{90}Y, ^{186}Re and ^{169}Er are included for radio-synoviorthesis (RSO).

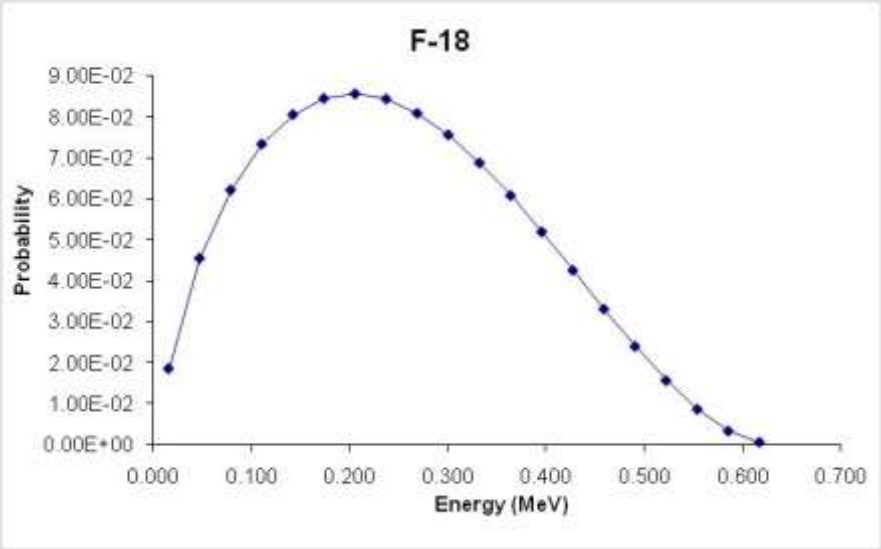

Figure 4.1: ^{18}F positron spectrum.

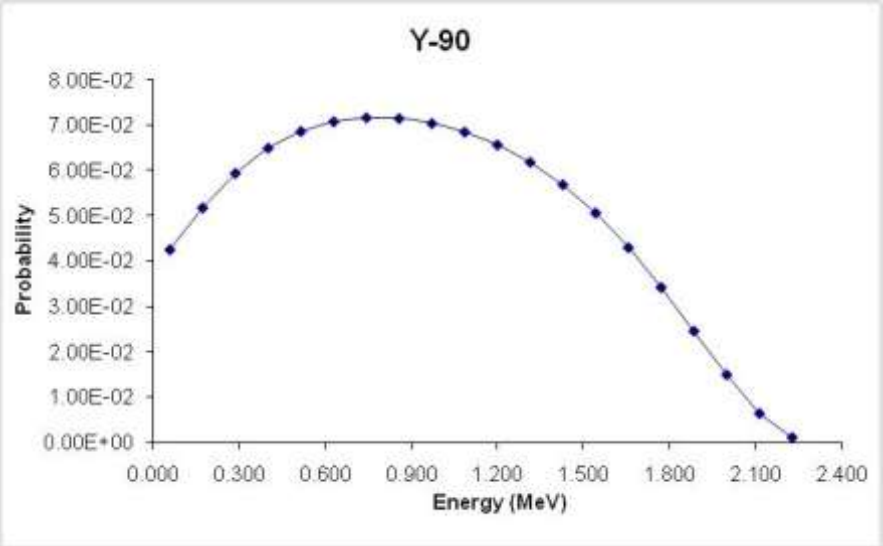

Figure 4.2: ^{90}Y β- spectrum.

Thus, ^{18}F and ^{99m}Tc for diagnostics and ^{90}Y-labelled Zevalin® and DOTATOC for therapy procedures were included in the ORAMED project. Metabolic therapy using ^{131}I even though more frequent than therapies using ^{90}Y was not chosen because in general there is no direct manipulation of the nuclide. More work was done to include further therapies, such as selective internal radiotherapy (SIRS) with ^{90}Y or RSO with ^{186}Re or PPT with ^{153}Sm. However, not enough data was collected to perform a statistically significant analysis.

Table 4.1, extracted from Delacroix et al., gives an overview of some important parameters of the different radionuclides studied within the project. Those parameters are essential to evaluate the exposure at different circumstances as: contact with a syringe, contamination of the skin and efficiency of the shielding.

Table 4.1: Radionuclide properties (Delacroix et al., 2002)

Nuclide	Skin dosedue to contactwith 5 ml syringe containing 1 MBq [mSv/(MBq.h)]	Skin dose due to contamination with 1 kBq in 50 μl [mSv/h]	Pb-shielding to lower transmission to 1/2 [mm]	1/10 [mm]
^{99m}Tc	0.354	0.00877	0.3	1
^{18}F	2.88	0.788	6	17
^{90}Y	43.5	1.35	Total β-absorption in 9.2 mm plastic	

4.2.2 Measurements

The operational quantity to be monitored, $H_p(0.07)$, was measured at 11 points on each hand (Figure 4.3), 8 on the palm side and 3 on the nail side, with thermoluminescent dosemeters (TLDs) attached (taped) to gloves or directly to the skin. When measuring extremity doses in nuclear medicine practices, the effective thickness of the dosemeter and the position to wear it are important matters of concern. In particular, the depth-dose curves in LiF for the typical nuclear medicine radiopharmaceuticals highlight the advantages of the use of thin-layer detectors for extremity dosimetry, in particular for ^{18}F and to a lesser extent, for ^{90}Y. However, standard TLDs are also acceptable for ^{99m}Tc measurements (Carnicer, Ginjaume et al., 2011).

Each ORAMED partner provided their own TLDs, mainly LiF:Mg,Cu,P except for one case (LiF:Mg,Ti). Thicknesses ranged from 7 to 240 mg·cm^2. Only thin-layer dosemeters (< 100 mg·cm^2) were used for ^{18}F measurements, whereas thick dosemeters were sometimes employed in ^{99m}Tc measurements. The dosemeters fulfilled ISO 12794 technical requirements (ISO, 2000) and were calibrated by each partner according to ISO 4037-3 and 6980-3 Standards (ISO, 1999; ISO, 2006). To ensure an appropriate response of all dosemeters, an internal intercomparison was organized before the beginning of the campaign. Two different reference standard irradiation fields were used in the intercomparison: ^{137}Cs and ^{85}Kr. The results showed the coherence among the partners' TLD responses, within 10% of the reference value.

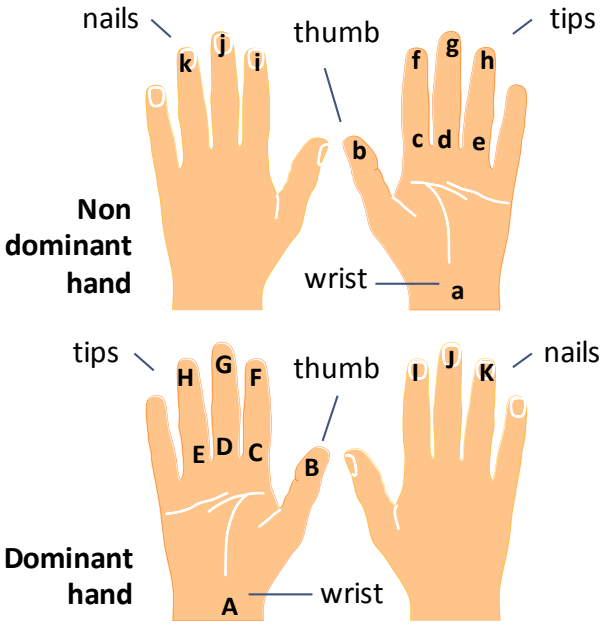

Figure 4.3:Standard skin dose measuring positions

A different pair of gloves was supplied for the preparation and for the administration of the radiopharmaceuticals, respectively, and for each considered radionuclide. The workers wore the gloves long enough to cumulate sufficient dose to ensure its adequate evaluation, typically from one day up to a week for ^{99m}Tc, from 1 to 2 days for ^{18}F and during a single procedure for ^{90}Y. For each radionuclide and hospital usually 2 workers participated in the preparation and 2 for the

administration. The goal for the diagnostic procedures was to perform 5 measurements per worker.However, since it was sometimes difficult to reach the 5 measurements, it was decided to also include workers with 4 measurements in the final database. For therapy procedures, no restriction was applied considering the limited amount of procedures performed.

A measurement protocol was developed for both administration and preparation procedures. The same protocol was used by all partners so that measurements were homogenized and all data could be compared and evaluated. The following information was collected for each single measurement:

- radionuclide (99mTc, 18F, 90Y),
- procedure (preparation and administration),
- hospital's ID,
- worker's ID,
- total manipulated activity,
- worker's dominant hand (right, left),
- worker's experience (beginner: ≤ 1 year, experienced: > 1 year),
- radiation protection devices used (vial or syringe shielding),
- Hp(0.07) values at each position.

Any additional information which could help to understand the results was also collected, such as a contamination event. Whenever possible, pictures and videos were recorded. All information was gathered in a common database.

$H_p(0.07)$, measured at each position, was normalized to the manipulated activity (µSv/GBq). For preparation of ^{99m}Tc, this activity was considered to be the total activity withdrawn from the elution vial, for ^{18}F the total activity withdrawn from the mono- or multi-dose vial and for ^{90}Y the whole activity withdrawn for the preparation. For the administration the total activity in the injection syringe was considered.

Table 4.2 summarizes all the data obtained and used for the analysis concerning diagnostic procedures. In total 734 measurements were performed, out of which 641 (87%) were used for the analysis.

Table 4.2: Number of measurements obtained and used for the analysis of diagnostic procedures.

Procedure	Number of measurements in database	Number of measurements considered for analysis	Number of workers considered for analysis	Number of NM services considered for analysis
^{99m}Tc preparation	202	178	36	21
^{99m}Tc administration	179	157	32	20
^{18}F preparation	184	160	30	17
^{18}F administration	169	146	30	17

An overview on the scope of measurements for therapy procedures is given in Table 4.3. In RIT with ^{90}Y-Zevalin®, 94 measurement series of 42 staff members, technicians, physicians or nurses, were performed and evaluated. Moreover, 33 measurement series of 12 staff members were made in PRRT during labelling and administration of ^{90}Y-DOTATOC.

Table 4.3. Data obtained for the therapy procedures. "P" stands for preparation and "A" for administration.

Therapy	Nuclide	Preparation/ administration	Number of workers	Number of data sets
RIT	^{131}I	P/A	1	4
PPT	^{153}Sm	P	1	2
RSO	^{186}Re	P	3	4
		A	3	4
SIRS	^{90}Y	P	4	20
PRRT Dotatoc	^{90}Y	P	5	16
		A	7	17
RIT Zevalin®	^{90}Y	P	20	49
		A	22	45

4.2.3 Statistical analysis

A common methodology was followed for the analysis of the data of each procedure with the aim of homogenizing the evaluation of all the important aspects of extremity dosimetry.

The statistical analysis was performed with the 641 measurements collected in diagnostics around 20 NM departments per procedure from 6 European countries (Belgium, France, Italy, Slovakia, Spain and Switzerland) (Table 4.2). Moreover, for therapy procedures the statistical analysis was carried out with 127 measurements concerning PRRT ^{90}Y-DOTATOC and RIT ^{90}Y-Zevalin® therapies. Those measurements comprise 54 workers from 6 European countries (Belgium, France, Germany, Italy, Spain and Switzerland).

For each radionuclide and procedure the analysis was performed independently. The normalized $H_p(0.07)$ (µSv/GBq) measured at each of the 22 monitored positions on both hands were averaged over the series of measurements for each worker, a minimum of 4 series for diagnostics and the number of available ones for therapy. These mean values were used for the analysis. Also, the maximum normalized local skin equivalent dose (from now on, maximum dose) was calculated as the highest of those 22 mean values.

The objectives of the statistical analysis were:

- To classify the workers according to their maximum dose.
- To estimate the annual maximum dose.

- To identify good and bad practices and relate them to working habits and parameters of influence.
- To analyze the dose distribution across the hands.
- To determine the frequency of the position where the maximum dose is received.
- To determine the best position for placing the extremity dosemeter and the possible underestimation at the available routine monitoring positions.

Many parameters and steps affect the local skin dose at hands, especially for preparation. In addition, not all the information on potential parameters of influence, such as the operation time, was considered. Furthermore, the tools to reduce finger doses (shields, forceps…) were sometimes used in some steps and not in others during a single measurement, or were either used differently from one measurement to another. The number of times that the activity was manipulated was not taken into account (e.g. number of tries to draw the radioactive liquid into a syringe to obtain the right volume). In general, the fact that the measurements were not systematically watched or recorded on video could result in some important details that were missed. Despite this, the study provides a good overview of the level of finger exposure from a wide range of working habits and working procedures.
In order to identify the parameters to be studied that could have an influence on the skin dose, workers were classified into categories for those parameters for which information was available and whenever the data available in each category was at least 10% of the total data. Three different non-parametric tests (Mann Whitney-U, Kruscall-Wallis and Wilcoxon test) were applied (SPSS v.17.0) to analyze the differences between the skin doses received by workers within different categories. The Mann Whitney-U test is a non-parametric statistical hypothesis test for assessing whether one of two samples of independent observations tends to have larger values than the other. The Kruscall-Wallis test is a non-parametric method for testing whether samples originate from the same distribution. It is used for comparing more than two samples that are independent, or not related. The Wilcoxon test is a non-parametric statistical hypothesis test used when comparing two related samples or repeated measurements on a single sample to assess whether their population mean ranks differ.

4.2.4 Simulations

A sensitivity analysis was carried out through MC simulations employing voxel models, representing operator's hands during the considered practices. The goal of the calculations was to quantify the influence of several parameters separately on the skin dose such as the effectiveness of the shielding adopted, the variability of doses when increasing the distance to the sources or when shielding is used. More than 200 MC simulations have been performed in order to understand better the parameters influencing the dose. Furthermore, with the MC simulations it was possible to study the appropriateness of the shielding usually utilized in these practices.

MC simulations have been performed in 5 typical scenarios selected as the most common manipulations performed by workers when preparing and administrating radiopharmaceuticals. Those scenarios are divided in two categories, those concerning the administration and those concerning the preparation of the radiopharmaceutical.

For what concerns the administration, the scenarios have been labeled as follows:

- injecting scenario (I1): corresponds to the administration of the radiopharmaceutical to the patient with a syringe. In particular the hand which pushes the piston is studied.
- holding the syringe when injecting (I2): represents the moment when the technician holds a filled syringe. This scenario is found both in the administration of the dose but also in the preparation. For instance, right before the administration of the radiopharmaceutical, one hand – non dominant hand – holds the syringe while the technician tries to feel the vein with the other hand.

For what concerns the preparation of the radiopharmaceutical the scenarios have been labelled as follows:

- transport of vial (PTR): represents the step within the preparation of radiopharmaceuticals in which the vial is transported with forceps.
- syringe manipulations (PSM): this scenario is repeated several times for the preparation of the radiopharmaceutical. It represents the manipulation of the syringe from the piston or from the needle when capsulating the syringe.
- shielded vial manipulations (PVM): represents the step within the preparation of radiopharmaceuticals in which the vial, with shield, is transported by direct contact with the hand.

A selected number of wax hand phantom of realistic human dimension were prepared for the project representing the chosen scenarios (Figure 4.4).

Figure 4.4. Wax hand phantoms employed for the project (from left to right the models represent the scenarios called I1, I2, PTR, PSM, PVM).

These phantoms were scanned by a CT scanner, segmented using the DOSIsoft tool (www.dosisoft.com) and converted in a MCNPX input file with the SESAME software (Huet et al., 2009) exploiting the standard repeated structure cell feature of the MC code (lattice card). For the calculations, the hand phantoms were assumed to be made of soft tissue (ICRU, 1989). The voxel size was $0.222 \times 0.222 \times 0.425$ cm^3.

Two hand models were used for the injection procedure (Figure 4.5) representing: the hand pushing the piston (model I1) and the hand holding the syringe (model I2).

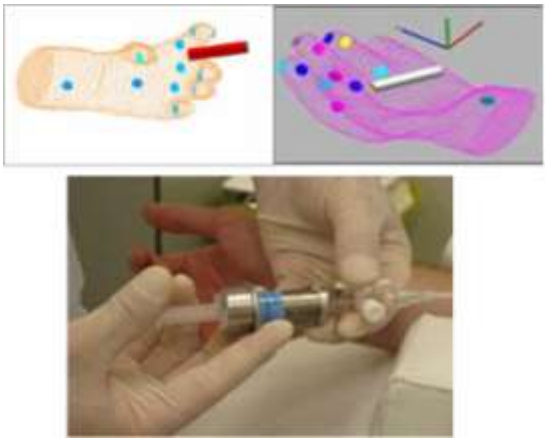

Figure 4.5.The two voxel models representing the injection phase compared with a clinical image of the same procedure. Models I1 and I2 on the left and right side, respectively.

For the preparation of radiopharmaceuticals, four models were used representing the hand at several steps during the preparation procedure (Figure 4.6): manipulating the syringe (PSM model, two positions), employing forceps for vial transport (PTR model) and manipulating the vial (PVM model).

Figure 4.6. The four voxel models (upper row) represent the selected steps of preparation of radiopharmaceuticals (figures from the lower row).

For each model, a set of 12 scoring soft tissue cylindrical regions, 140 μm thick, of 1 cm^2 cross-section, were defined on the voxel hand surface. Their positions on the voxel hand model correspond to the TLD positions during the ORAMED measurement campaign. The dose was calculated in those regions at 70 μm depth in a cell of 10 μm thickness. Charged particle equilibrium was studied (Mariotti and Gualdrini 2009) and a small amount of tissue simulating the

gloves was added on top of the cylindrical regions(simulating the TLDs), when necessary (Table 4.), to ensure equilibrium.

Three radionuclides were considered in the simulations: ^{99m}Tc, ^{18}F and ^{90}Y, the same as those of the measurement campaign. In the case of ^{99m}Tc only photons were transported (mode P), whilst for ^{18}F (without shielding) and ^{90}Y full photon/electron transport (mode PE) was followed. Table 4.4.describes in detail the specific parameters considered for each simulation scenario. The source was simulated as a water cylinder, of the proper volume, filling the syringe or the vial and surrounded by the eventual shielding.

Table 4.4. Specific parameters considered for each simulated scenario.

Radionuclide	Shielding (Y/N)	Mode used	Source	Extras
^{99m}Tc	Y/N	Mode P	^{99m}Tc spectra 18.25keV (2.17%) 18.37keV (4.12%) 20.61keV (0.98%) 140.47keV(87.2%)	No need to add gloves
^{18}F	Y	Mode P	photon source 511keV (193.8%)	No need to add gloves
	N	Mode PE	Positron source (96.9%) E_{max}=633.5keV	Gloves should be used (thickness of gloves 200 µm)
^{90}Y	Y/N	Mode PE	Electron source (100%) E_{max}=2280keV	Gloves should be used (thickness of gloves 200 µm)

To better understand the experimental results and to comprehend the influence of a given perturbation to the dose distribution, a sensitivity analysis was done using the above mentioned phantoms and scenarios. The following parameters have been considered for this purpose:

- Active volume of the source.
  For the same activity, the volume of the source was modified (adding water to the source geometry) to check the sensitivity of the volume on the doses obtained at the different positions of the hands. For those geometries involving unshielded syringes, the volume of the source was changed between 1ml and 10ml. For those geometries involving a close contact with the vial (essentially PVM) the volume of the active solution was changed between 2.5ml and 10ml.
- Displacement of the source along its axis.
  For those geometries involving unshielded syringes, those were displaced along their axis to a maximum distance of 2.7cm. For those involving unshielded vials, the displacement was between 3 and 8 cm.
- Rotation of the source.

For those geometries involving unshielded syringes, those were rotated with respect to their axis at an angle of 10 or 30 degrees, depending on the case. For those involving unshielded vials, only the scenario of PTR case allowed a rotation of 90 degrees.

- Shielding thickness and material.
  After consultation with all NM departments where measurements have been performed, a compilation of the most frequently used shielding material and thickness was done. The shielding parameter was changed in the simulations accordingly to this information, this is summarized in Table4.5 (Pb stands for lead, W for tungsten and PMMA for polymethylmethacrylate).

Table 4.5: Shields considered for the simulations

Radionuclide	Syringe shields considered	Vial shields considered
^{99m}Tc	2mm or 3mm (Pb or W)	1-4mm (Pb or W)
^{18}F	2-8mm (W)	1-4cm (Pb)
^{90}Y	5mm (W) or 7-10mm (PMMA) or 1cm (leadglass)	1cm or 2cm (PMMA) + 0.5cm or 1cm (Pb) or 1cm (leadglass)

The MC sensitivity analysis was performed for the same points on the hand used in the measurements and, as in the case of the measurements, the maximum dose was considered to be the highest dose calculated among these positions.

The relative standard deviation of all the results obtained from the MC simulations is generally lower than 5% (10% in the case of electron transport).

Since the maximum skin dose could be found in other positions, for the models representing the injection, a dose mapping across the voxel hand external surface was produced. The 12 scoring regions were removed from the geometry file, and the dose was calculated at all the voxels of the hand surface. The simulation parameters were maintained (geometry, source specification, transport mode and tallies) to allow comparison between the dose calculated in the scoring regions from the sensitivity study and the dose in the nearest voxels from the dose mapping, as well as to identify the voxel with the highest dose (both the dose and the position).

Before launching the simulation program and in order to ensure the consistency between measurements and simulations, doses were measured by means of TLDs in some of the selected scenarios using the wax phantoms, and also calculated by simulation with the simulation code MCNPX (Carnicer at al. 2009). The results of both measurements and simulations were compared and used to prove the validity of the methodology followed to prepare MCNPX input files for the type of simulations needed.

The accuracy reproducing the experimental results using MC simulations depends on how good the experimental configuration was modelled in the geometry of the simulation. The placement of the dosemeters was done by the observation of some pictures. This method can lead to the introduction of significant errors on the positioning of the dosemeters and of the source with respect to the hand.Taking into account the uncertainties in the methodology of the simulations,

the individual ratios for each position and scenario were considered acceptable. Moreover, the weighted mean ratios for every case (the mean is 0.99) demonstrated a good concordance between measurements and calculations. Hence, the methodology of the simulations, as earlier described was considered satisfactory for thepurpose of this work.

4.3 Results and discussion

4.3.1 Classification of workers

In order to evaluate the exposure for each participant and to compare their maximum skin dose, the individual maximum skin dose $H_p(0.07)$, normalised to the activity, was determined. As indicated in paragraph 4.2.3, first the mean value of the set of 4 or 5 measurements was calculated for each monitoring position and then the maximum value of the 22 data was assigned as maximum dose. In the case of therapy, the mean value was calculated with the available data, independently of the number of repetitions. Workers were classified per procedure with respect to their maximum dose in increasing order. Figure 4.7, Figure 4.8 and Figure 4.9 show the maximum dose for each worker (each worker is represented by a vertical bar) for diagnostics, ^{90}Y Zevalin® and ^{90}Y Dotatoc procedures respectively. In Figure 4.7 and Figure 4.8 the first coloured values correspond to the 1st quartile (green), then the 2nd (blue), 3rd (yellow) and 4th (red) quartiles. In Figure 4.9 the different colours represent workers working with (blue) and without (orange) shielding.

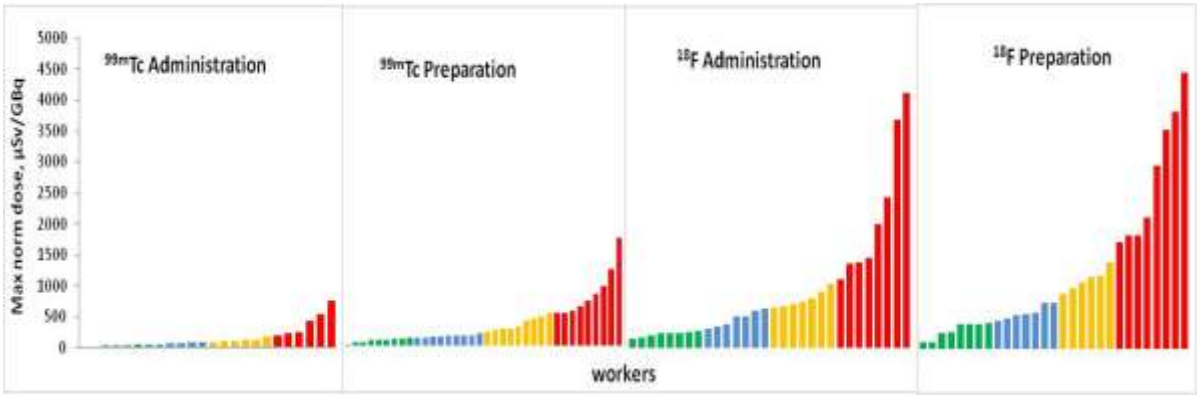

Figure 4.7: Maximum dose for each worker for all diagnostic procedures.

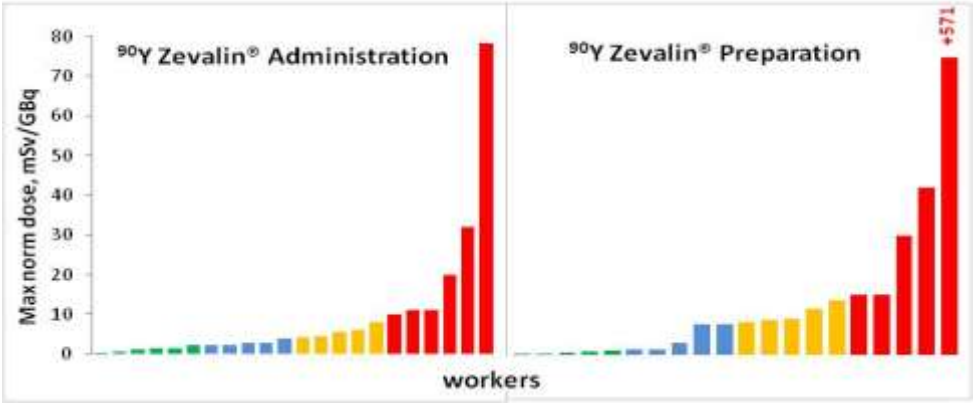

Figure 4.8. Maximum dose for each worker for ^{90}Y-Zevalin® procedures.

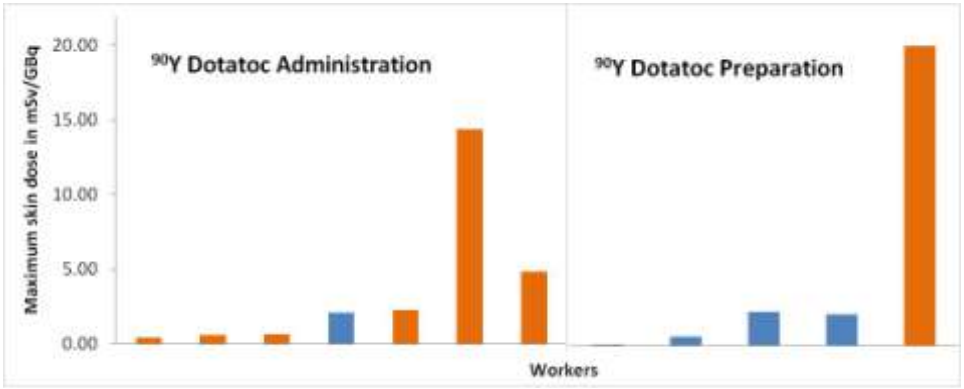

Figure 4.9. Maximum dose for each worker for ^{90}Y-Dotatoc procedures. Workers working with shielding are represented in blue and those working without shielding in orange.

First, the extremely wide range of maximum doses measured for the same procedure indicates that good and bad practices were monitored and thus those workers who are more exposed could potentially optimize their working procedures or habits. Some workers associated with very low exposure were found to be related to well-optimized procedures or use of advanced techniques, including semi-automatic dispensing tools, or the use of appropriate shields for syringes and vials

(Figure 4. a,b,e and f). As an example, Figure 4.10b shows a shielding device developed for the administration of ^{18}F used in one of the NM departments visited. On the contrary, Figure 4.10c, d, g and h illustrate examples where protection means are not used properly. In Figure 4.10.c some parts of the hand touch directly the unshielded regions such as the needle and the bottom of the syringe. These cases clearly demonstrate that there is a potential to further decrease hand doses by optimizing procedures, not only by using the appropriate tools but also by correctly using them.

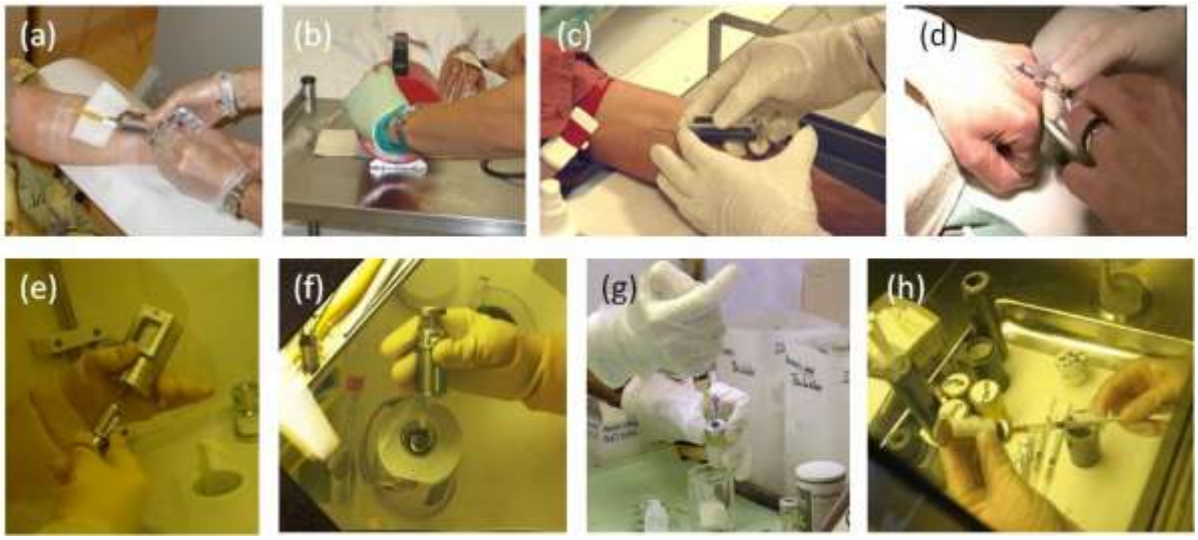

Figure 4.10 Examples of good administration (a) (b) and preparation (e) (f) practices, and examples for bad administration (c) (d) and preparation (g) (h) practices.

4.3.2 Values of maximum doses per procedure

The range, mean and median values of the maximum doses for all workers were calculated for each procedure and have been summarized in Table 4.6. The outliers concern those workers with values which exceed 1.5 times the inter-quartile range.Those workers have not been included in the calculation of the mean and median. Neither have been included those workers for whom contamination occurred during the procedure. In those cases, high dose values can be achieved as demonstrated by Covens et al.,2011.

Table 4.6. Range, mean and median values of the maximum dose of all workers monitored, excluding outliers, per procedure.

Procedure	Maximum normalized dose (mSv/GBq)		
	Range	Mean	Median
^{99m}Tc Administration	0.01 – 0.95	0.23	0.12
^{99m}Tc Preparation	0.03 – 2.06	0.43	0.25
^{18}F Administration	0.14 – 4.11	0.93	0.64
^{18}F Preparation	0.10 – 4.43	1.20	0.83
^{90}Y Zevalin® Administration	1.0-11.9	4.8	2.9
^{90}Y Zevalin® Preparation	1.2-43.9	11.0	9.5
^{90}Y Dotatoc Administration	0.4 – 4.9	1.9	1.5
^{90}Y Dotatoc Preparation	0.1 – 7.4	2.1	1.1

As shown in Table 4.6 very large ranges of maximum doses were found for the same procedure. The preparation of radiopharmaceuticals involves higher finger doses per activity than the administration. There are several reasons for that:

- the procedures are longer
- there are more steps requiring manipulations of the vials/syringes
- higher activities are manipulated and some of them without shielding.

It is shown that preparation of ^{18}F is the most critical of the studied procedures in diagnostic, which is in agreement with other authors' findings (Chiesa et al., 1997; Vanhavere et al., 2006; Covens et al., 2010).

On the other hand, ^{90}Y involves higher skin doses per activity than ^{18}F and much higher than ^{99m}Tc because of the different dose rate factors of the three radionuclides (Table 4.1). Figure 4.11 illustrates these differences for the specific situation of being at contact with a 5 ml unshielded syringe filled with the typical administered activities of 500 MBq, 400 MBq and 1 GBq of ^{99m}Tc, ^{18}F and ^{90}Y, respectively. The time needed to reach the annual skin dose limit (500 mSv) is also illustrated on the right side of the figure. Nevertheless, it should also be considered that diagnostic procedures are performed with a much higher frequency than therapy procedures.

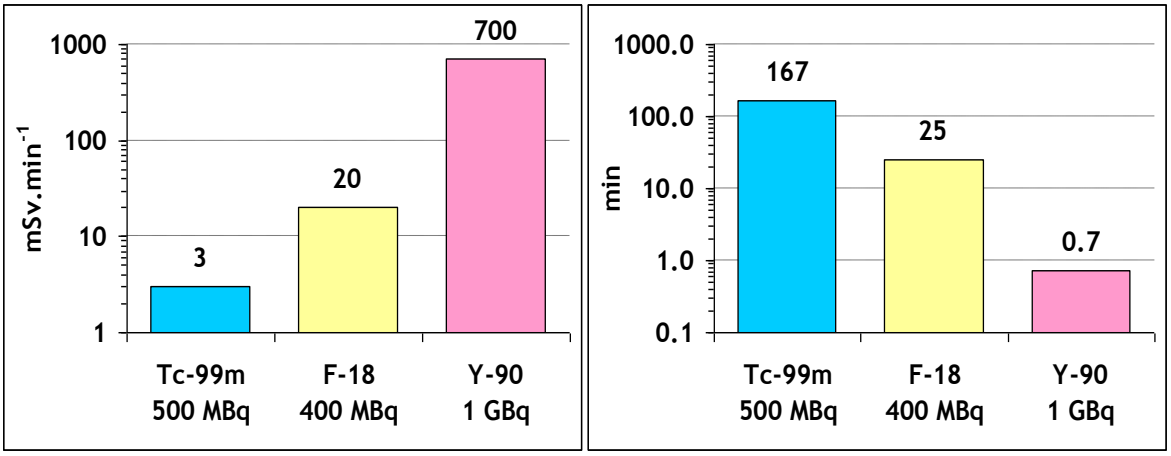

Figure 4.11. Dose rates at contact of a 5 ml unshielded syringe for typical administered activities of 99mTc, 18F and 90Y (left figure) and time to reach the annual dose limit for the same cases (right figure) (data derived from Delacroix et al. 2002).

4.3.3 Annual dose estimation

With the intention of finding out whether the measured maximum doses represent a matter of concern from the point of view of radiation protection, the annual maximum dose was estimated for all workers involved in diagnostic procedures. The estimation was based on the maximum dose

of each worker and the assumption that all workers were only involved in the procedure for which they were monitored. Two different ways of estimating the annual dose were employed. The first estimation was based on a workload of 1000 patients per year and the common activity manipulated for each of the procedures were considered. Results are shown in Table 4.7, where the percentage of workers exceeding the annual dose limit and the percentage of those exceeding 3/10th of this limit (150 mSv), together with the data used in the estimation is presented.

Table 4.7. Estimation of workers exceeding the annual dose limit and 3/10th of the annual dose limit.

Procedure	Patients per year	Activity per patient (MBq)	% workers exceeding annual dose limit	% workers exceeding 3/10 of the annual limit
99mTc Administration	1000 (5 patients per day, 10 months)	500	0%	28%
99mTc Preparation		500	8%	47%
18F Administration		400	23%	66%
18F Preparation		500	40%	87%

According to the results, the annual dose limit for the extremities would be surpassed for all procedures except for administration of ^{99m}Tc. In addition, the fraction of workers surpassing the limit is significant for ^{18}F (from 20 to 40%). The percentage of workers exceeding 3/10th of the limit is also very considerable and ranges from 30 to 90% depending on the procedure. Other authors have also reported cases of workers who could surpass the annual dose limit (Chruscielewski et al., 2002; Wrzesién et al., 2008).

The second method to estimate the annual skin dose considered the actual annual workload for each worker together with the measured normalized maximum dose for each radionuclide. Similar results were found as for the previous estimation, with 20% of the workers exceeding the annual dose limit and 51% exceeding 3/10th of the annual dose limit.

It has to be noticed that the real situation is more complex since usually a given worker will not perform only one but several differentprocedures, the workload being shared among different operators.

4.3.4 Parameters of influence

Table 4.shows the results of the Mann Whitney-U test (SPSS v.17.0) applied to analyse the influence on the measured maximum doses of the vial shield, syringe shield and the experience of the worker in the monitored diagnostic procedures. Workers with less than one year experience are considered as “low experienced". Other parameters, such as time or use of automatic devices, could not be analysed because of a lack of data. For therapy, the number of data was also insufficient for a complete inference statistics analysis. In Table 4.8, Table 4.9andTable 4.10, the parameter of interest, the different categories and the number of cases in each category are

indicated together with the result of the test. The mean maximum normalized dose Hp(0.07) of the different categories is statistically significant when the p-value is below 0.05. Whenever a difference was found to be significant for a certain parameter, the test applied on the next parameter was performed separately to the categories of the former significant parameter, in order to eliminate the influence of that parameter. The order of the parameters was chosen such that the potentially most important parameters were analysed first and those withless importance at the end. The following order was considered: influence of vial shield, influence of syringe shield and experience.

The tests were applied both for preparation (Table 4.8) and administration (Table 4.9), for the two radionuclides separately and together. Finally the test was applied again to all diagnostic procedures together (Table 4.10).

Table 4.8. Results of the Mann Whitney-Utest for preparation in diagnostic procedures

		Parameter	Category		N	Differences?	p-value
Preparation	^{99m}Tc	Vial shield	Yes		32	Yes	0.004
			No		4		
		Syringe shield	Shielded vial	Yes	14	No	0.649
				No	18		
		Experience		Low	7	No	0.480
				High	25		
	^{18}F	Vial shield	Yes		30	Not enough data	
			No		0		
		Syringe shield	Yes		18	Yes	0.010
			No		12		
		Experience	Unshielded syringe	Low	4	No	0.394
				High	7		
			Shielded syringe	Low	3	No	0.450
				High	14		
	^{99m}Tcand ^{18}F	Vial shield	Yes		62	Yes	0.039
			No		4		
		Syringe shield	Unshielded vial	Yes	1	No	0.180
				No	3		
			Shielded vial	Yes	32	No	0.398
				No	30		
		Experience	Unshielded vial	Low	0	Not enough data	
				High	4		
			Shielded vial	Low	14	No	0.416
				High	46		

Table 4.9 Results of the Mann Whitney-Utest for administration in diagnostic procedures

		Parameter	Category		N	Differences?	p-value
Administration	^{99m}Tc	Syringe shield	Yes		24	Yes	0.001
			No		8		
		Experience	Unshielded syringe	Low	2	No	0.355
				High	4		
			Shielded syringe	Low	4	No	0.215
				High	20		
	^{18}F	Syringe shield	Yes		29	No	0.094
			No		1		
		Experience	Low		6	No	0.195
			High		24		
	^{99m}Tc and ^{18}F	Syringe shield	Yes		53	No	0.150
			No		9		
		Experience	Unshielded syringe	Low	2	No	0.699
				High	5		
			Shielded syringe	Low	10	No	0.633
				High	43		

Table 4.10. Results of the Mann Whitney-U test for all diagnostic procedures

	Parameter	Category		N	Differences?	p-value
All diagnostic procedures	Vial shield	Yes		62	Yes	0.039
		No		4		
	Syringe shield	Unshielded vial for preparation	Yes	54	Yes	0.019
			No	12		
		Shielded vial for preparation	Yes	85	Yes	0.048
			No	39		
	Experience	Unshielded vial for preparation	Low	12	No	0.667
			High	52		
		Shielded vial for preparation	Low	26	No	0.262
			High	94		

Based on these results, the influence of the different parameters is discussed on the following pages.

4.3.4.1 Experience

Although in general experienced workers received lower doses, as demonstrated in some studies (Hildith et al., 1990), it was observed that some very experienced workers had deeply rooted inappropriate habits whereas some beginners worked with extra carefulness. The results of the Mann Whitney-U test did not show statistically significant differences between the doses received by experienced workers and beginners. For therapy procedures when feedback was given to workers after a measurement series and when they were informed on their exposures with a discussion of possible bad practices, a decreased dose was observed in the subsequent measurements, in general. Obviously, the outcome of this is an improvement of the individual operational procedures, resulting in an optimisation of the radiation protection standard, e.g. by using shielding and tools to avoid any direct contact of the fingers to the source. The results are illustrated in Figure 4.12, which shows the dose history of staff with three or more sets of measurements performing ^{90}Y-Zevalin procedures.

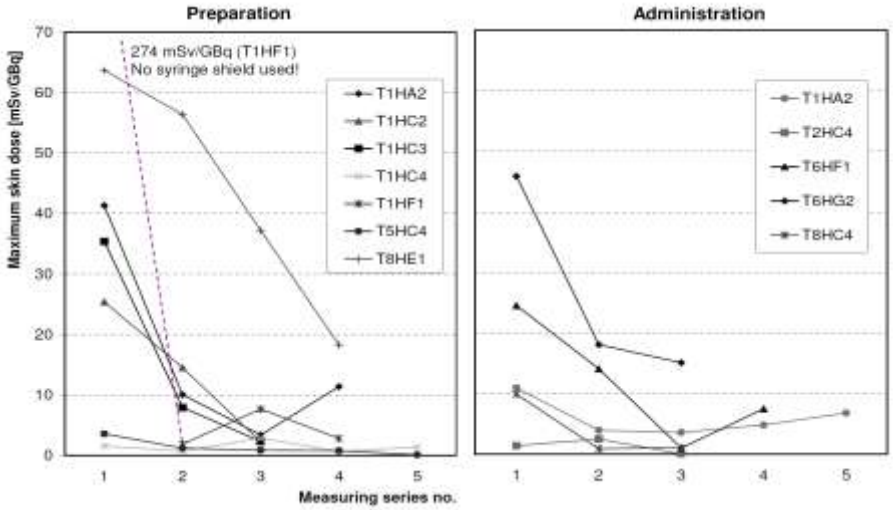

Figure 4.12. Dose history for staff with more than three subsequent measurements in ^{90}Y-Zevalin® RIT.

To contribute to the risk awareness of the staff in NM a dose estimation tool (Figure 4.13) has been developed. This dose estimation tool provides values for the expected doses at 11 different points in each hand when preparing or administering one of the radionuclides studied within the ORAMED project (^{99m}Tc, ^{18}F or ^{90}Y Zevalin®), for a given activity.

Figure 4.13 illustrates the output of the programme associated to the preparation of 1 GBq of ^{99m}Tc. The values given are based on the ORAMED results. Nevertheless outliers, workers who did not use shielding and data coming from contamination have not been considered. The tool is available via the ORAMED web site (http://www.oramed-fp7.eu/).

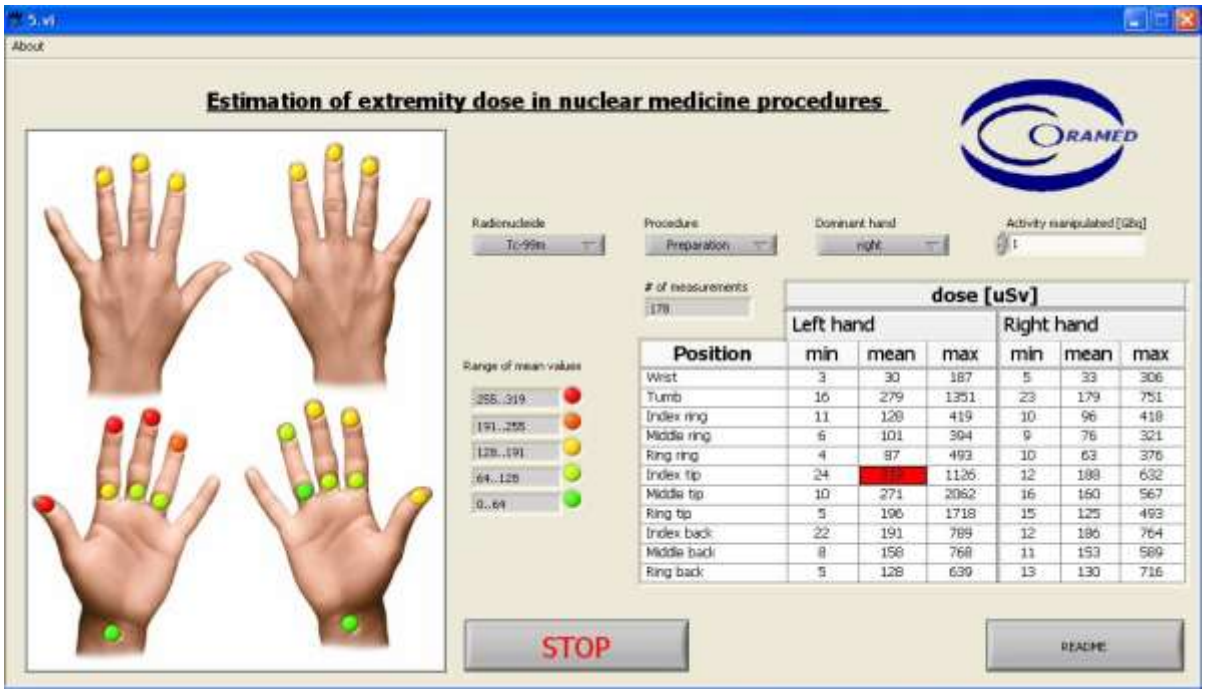

Figure 4.13 Dose estimation tool.

4.3.4.2 Shielding

According to the results of the statistical analysis, the shielding of the vial is, for preparation of ^{99m}Tc, the most important parameter of influence. Although for ^{18}F it could not be analysed (all workers handled shielded vials), the result is likely to be the same for this radionuclide. The shielding of the syringe was also found to be an important parameter of influence: the differences whether or not syringe shielding is used arefound statistically significant for preparation of ^{18}F and for administration of^{99m}Tc. Considering all procedures together, the tests showed a significant influence of shielding on the maximum skin doses, both for the vial and the syringe shields.

The identification of the shield as one of the most important parameters for dose reduction is in agreement with the conclusions of the ICRP review (ICRP, 2008) and other authors (Montgomery et al., 1999; Tsopelas et al., 2003; Smart, 2004; Whitby and Martin, 2004). The use of adequate shields reduces significantly the exposure to the hands thus should be used whenever it is possible. The study demonstrated that 89% of the workers use shielded vials when manipulating ^{99m}Tcradiopharmaceuticals and all of the workers use shielded vials when manipulating ^{18}F.

Concerning the use of syringe shields, 73% of the workers employed the shield during ^{99m}Tcadministration. For^{18}F procedures only 57% of the workers utilized a proper shielding during the preparation phase.

MC simulations also provided very valuable information in the study of the influence of shielding. The simulations were used to determine what type of material and which thickness represented the best skin dose reduction. Figure 4.14, illustrating the case of ^{99m}Tc administration, represented by scenario I1, shows that a 2 mm oftungsten (W) syringe shield provides more than 2 orders of magnitude in dose reduction to the hand. Moreover, little differences are observed between Pb and W, even if W is better performing because of its density of 19.3 g/cm^3 compared to that of lead (11.35g/cm^3).

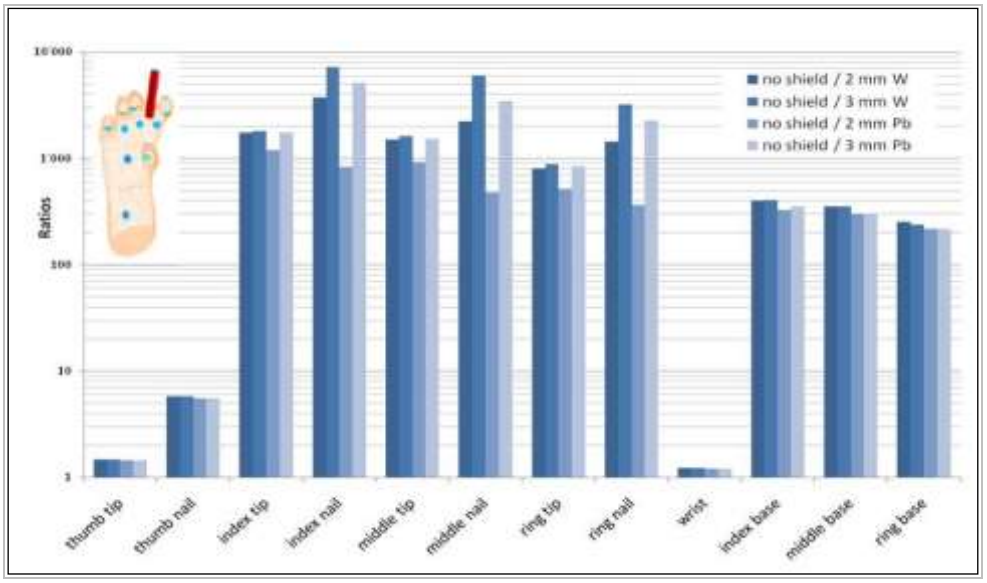

Figure 4.14. Administration scenario for a ^{99m}Tc source (model I1). Ratios between $H_p(0.07)$ for an unshielded syringe and for four different shields.

The effectiveness of the shielding is only valuable for those parts of the hand really protected by the shielding. As shown in Figure 4.15, the doses to the thumb and the wrist are not reduced significantly when shielding is used. These positions are not adequately protected by the shielding. However it should be mentioned that the simulations represent a "static scenario", which means a fixed geometry where the hand of the operator is like "frozen" in space, therefore the lateral shielding simulated may not correctly represent the real protection offered to these parts of the hand during the manipulation of the syringe.

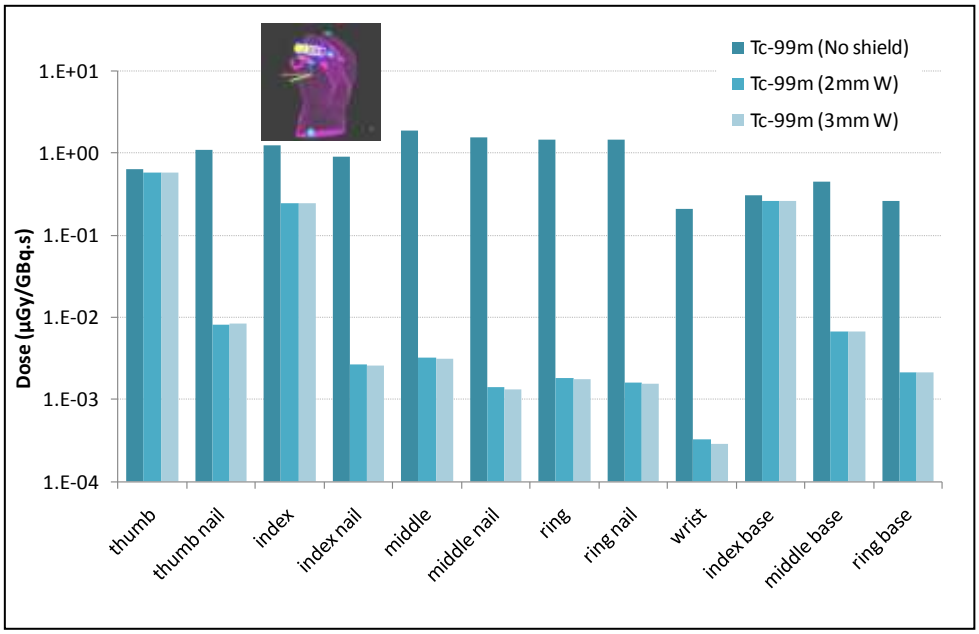

Figure 4.15 Preparation scenario for ^{99m}Tc (PSM1 model).Ratios between calculated $H_p(0.07)$ for the unshielded syringe and for a 2mm and 3mm W shielding.

Working with a different radionuclide implies different shielding to be used (Figure 4.15-4.17). As shown in Figure 4.16, thicker shielding is needed when manipulating a ^{18}F source. In this case, 8 mm of W for a syringe is very effective in reducing doses during the administration phase (scenario I1) but already 5mm of W can reduce doses up to a factor of 10 for the same scenario. Taking also other considerations into account, such as the weight and cost of the shielding, 5mm of tungsten is considered a more convenient solution.

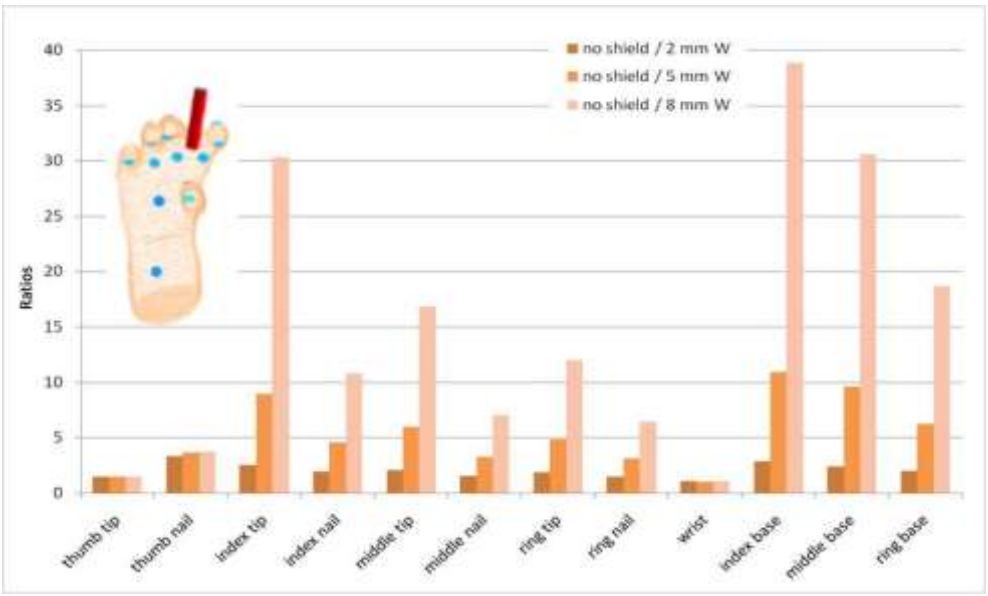

Figure 4.16 Injection scenario for ^{18}F (I1 model)-Ratios between $H_p(0.07)$ for an unshielded syringe and for three increasing W shielding thicknesses.

Figure 4.17 shows the influence of shielding when manipulating ^{90}Y sources. For ^{90}Y, 5 mm W is slightly better than 10 mm PMMA providing more than 3 orders of magnitudes of attenuation as illustrated in Figure 4.18.

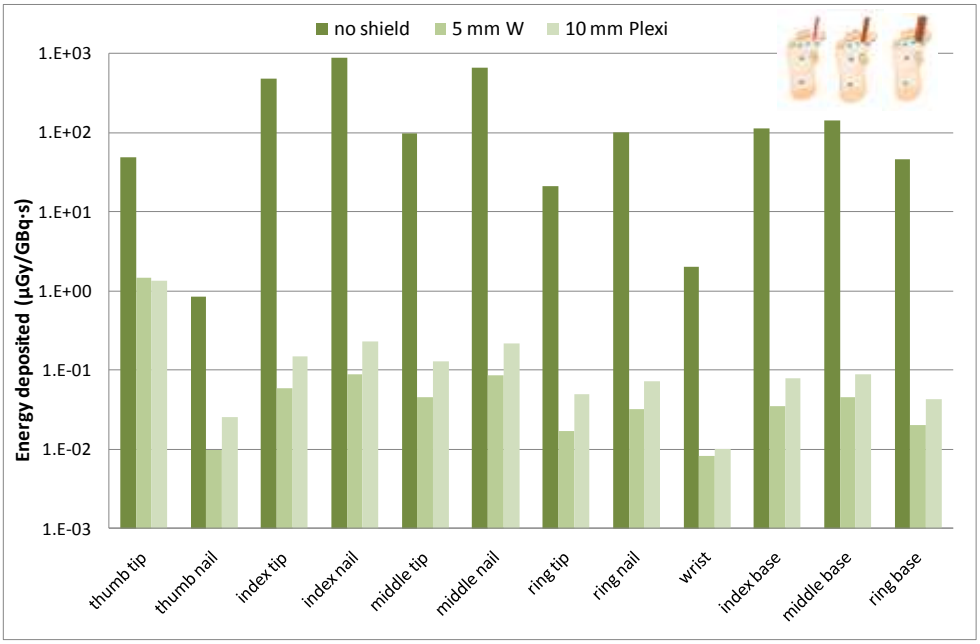

Figure 4.17 Injection scenario for ^{90}Y (I1 model)- calculated $H_p(0.07)$ for an unshielded syringe and for 5 mm W and 10 mm PMMA shielding.

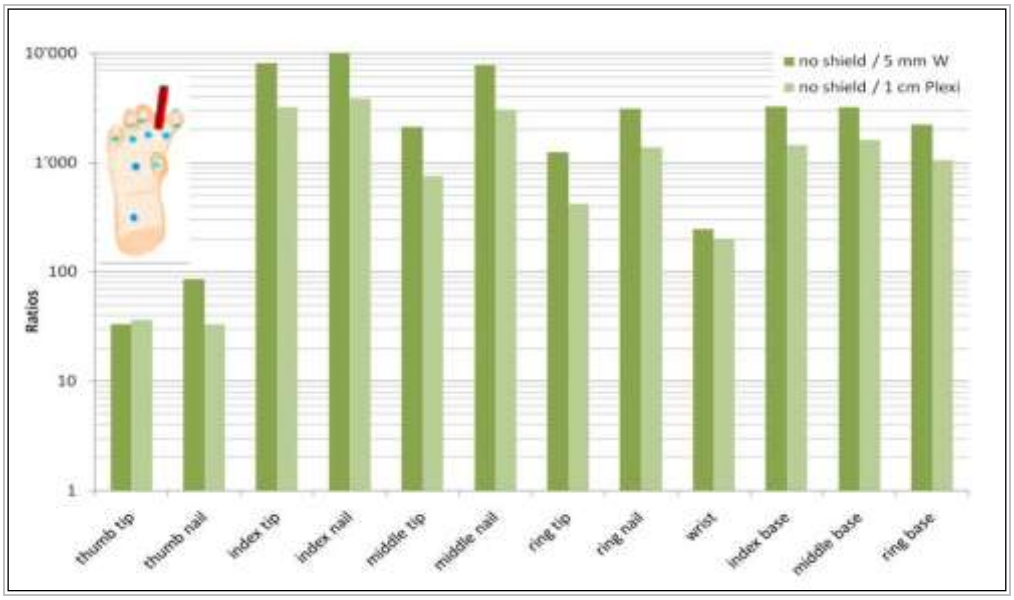

Figure 4.18. Injection scenario for ^{90}Y (I1 model)- ratios between $H_p(0.07)$ for an unshielded syringe and for several W and PMMAshielding conditions.

The influence of the vial shielding was also studied. When manipulating a vial containing ^{99m}Tc, 3 mm Pb provides more than 3 orders of magnitude in dose reduction, for the scenario PTR, as shown in Figure 4.19.

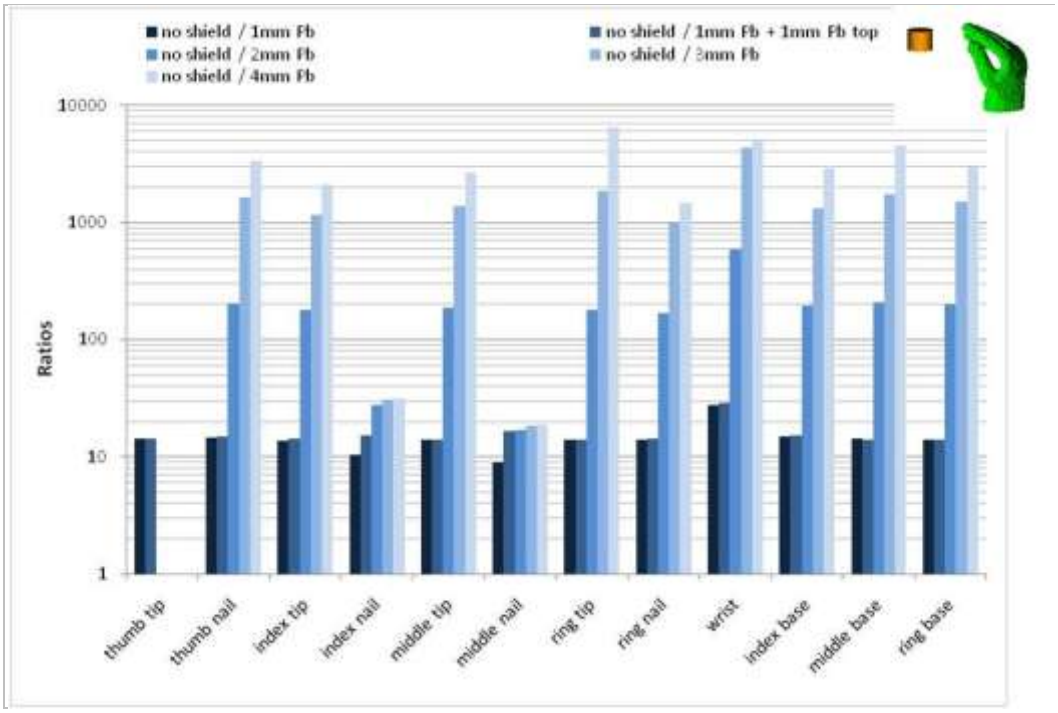

Figure 4.19. Preparation scenario for ^{99m}Tc(PTR model)-Ratios between calculated Hp(0.07) for an unshielded syringe and for different shielding thicknesses.

For a vial containing ^{18}F, thicker shielding is needed. Typically, as shown in Figure 20 for PTR scenario, 3cm Pb provides 2 orders of magnitude in dose reduction.

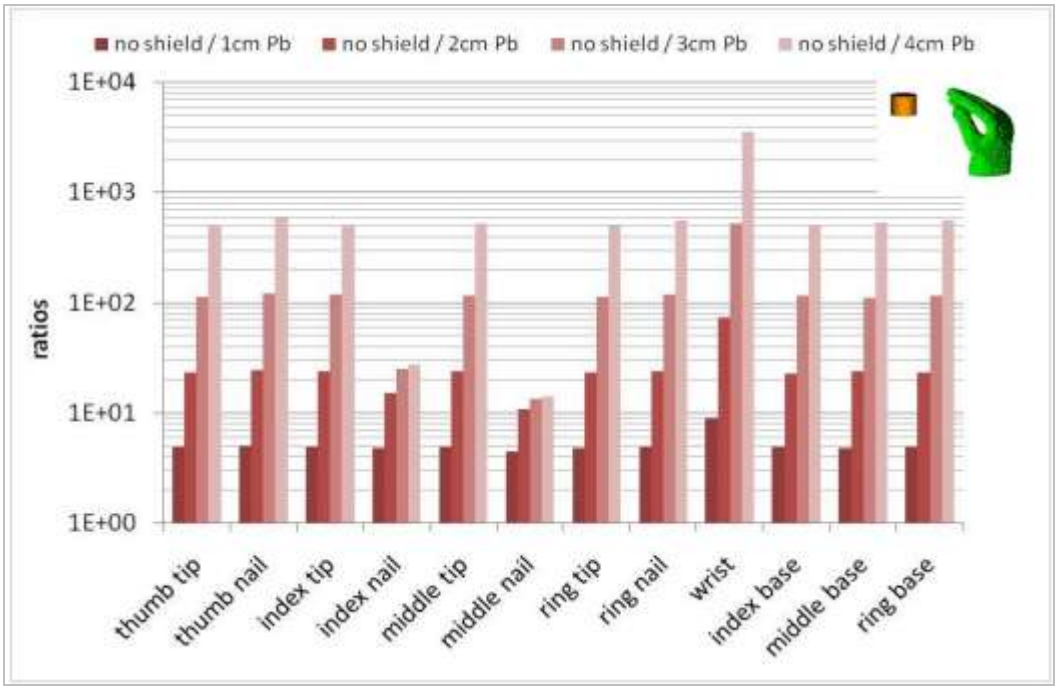

Figure 4.20. Preparation scenario for ^{18}F (PTR model)-ratios between doses evaluated with different shielding thickness and unshielded case doses.

For ^{90}Y sources, it has been shown that 10 and 15mm of PMMA provide almost the same attenuation, 5mm being less effective as shown in Figure 4.21. In order to absorb the Bremstrahlung contribution and to further reduce the doses, it is recommended to add some mm of Pb to the PMMA shielding.

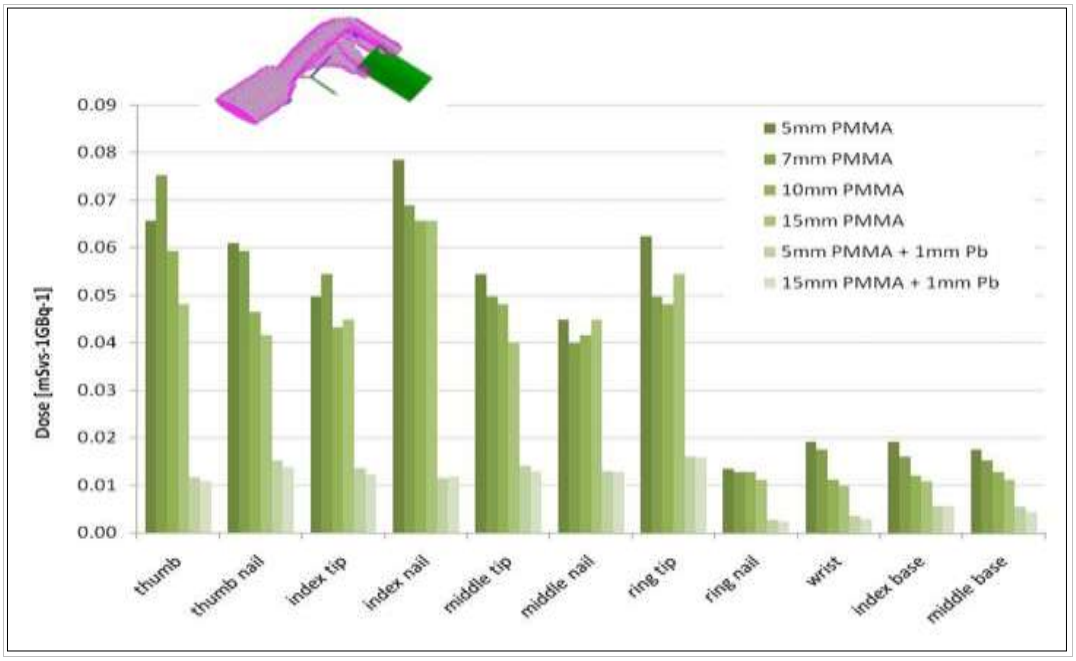

Figure 4.21. Dose distribution for different shielding thickness and material for an ^{90}Y source in the geometry corresponding to the scenario PVM.

Moreover, additional strategies can be used to optimize the protection. Figure 4.22 illustrates an additional dose reduction if the distance between the hand and the source is increased by using tools, for example forceps. For a vial containing a ^{18}F source and shielded by 8 mm W, an additional reduction of the doses, of approximately a factor of 10, is obtained when the distance is increased by 5 cm.

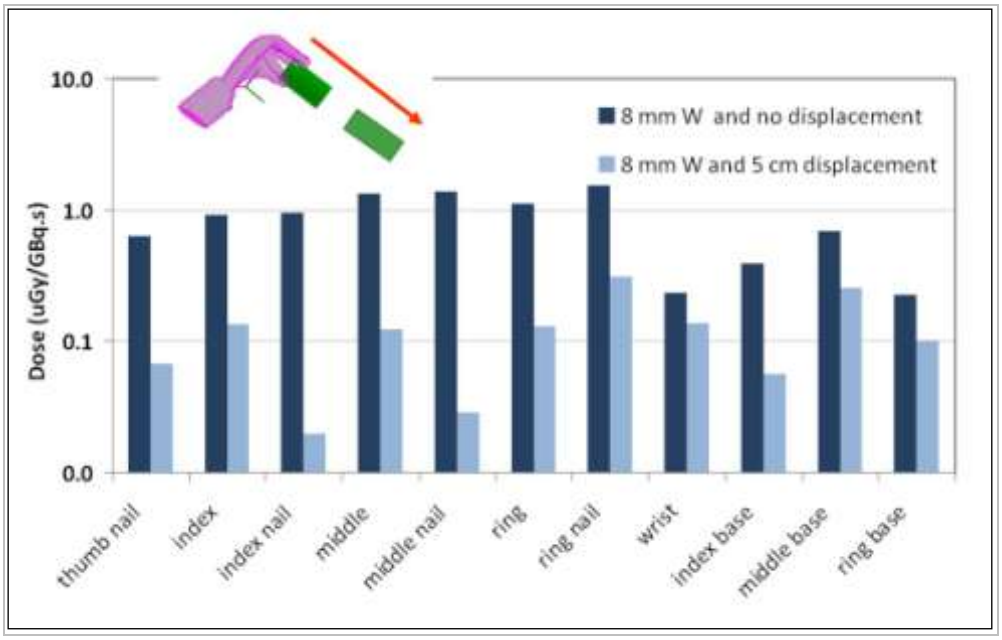

Figure 4.22. Preparation scenario for ^{18}F (PVM model) doses evaluated with 8 mm W shielding at two different distances from the hand.

The MC results on the recommended shielding for the different scenarios, with the limitations of the study above mentioned (static scenario), can be summarized as follows:

1. For the injection (concerning the syringe shielding):
- 2 mm W (or Pb) for ^{99m}Tc give a dose reduction of at least 2 order of magnitudes;
- 5 mm W provides up to a factor of 10 in dose reduction for ^{18}F (8 mm W up to a factor 40).
- For ^{90}Y 10mm PMMA completely shield beta radiation, nevertheless 5mm shielding of W provides a slightly better shielding cutting down bremsstrahlung radiation too.

2. For the preparation (concerning the vial shielding):
- For ^{18}F, 3cm of Pb provides 2 orders of magnitude on dose reduction. The same attenuation for ^{99m}Tc is obtained with 2 mm Pb.
- For ^{90}Y an acceptable shielding is obtained with 10 mm PMMA with an external layer of a few mm of lead or alternatively 5 mm of W.

4.3.4.3 Source displacement

Concerning the position of the syringe in the hand, a small change could imply a large variation in the skin doses. Figure 4.23 shows the effect caused by a syringe displacement of 1.4 cm and 2.7 cm along its axis, towards the centre of the palm, for the model I1 employed for the injection of ^{18}F. The results show that the smaller is the displacement towards the palm side the smaller is the increase of the doses; but the effect is different depending on the position of the scoring cells. In the case of the index and middle tips a factor of about 3 was found for a 2.7 cm shift. On the contrary for the wrist a sort of "shielding" effect (ratio lower than 1) was produced for 1.35 cm. This is probably due to the position of the thumb providing a "natural shield", with respect to the shifted source, for the detector placed at wrist position. It is worth to emphasize that this effect is generated by the particular form of the hand phantom and has to be taken with care in the analysis.

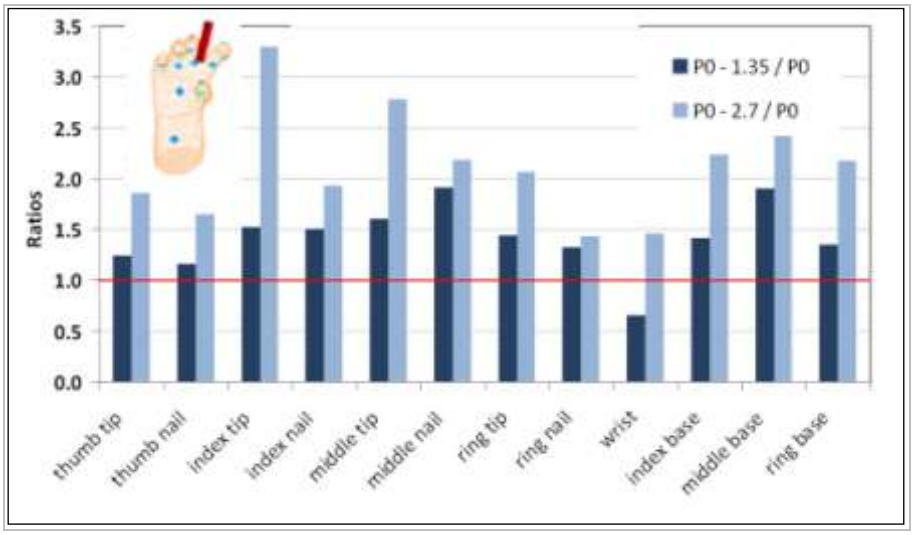

Figure 4.23. Administration scenario for ^{18}F (I1 model)- ratios between $H_p(0.07)$ evaluated with the source shifted for 1.35 and 2.7 cm towards the centre of the palm, and $H_p(0.07)$ estimated at the original position (P0) estimated doses.

One of the possible causes of the variability of the measured data can be attributed to the variation in distance between the source and the measurement positions which is obviously intrinsically different for different operators. This is particularly important when using unshielded syringes or vials. Such variations are intrinsic to the scenario and have been studied in the case of the injection of ^{99m}Tc with an unshielded syringe. Eight workers performed ^{99m}Tc administration with an unshielded syringe. Table 4.11 shows the minimum, maximum and mean value of the corresponding mean normalised dose, for the dosemeters placed at the base of the index and the middle fingers for the non-dominant hand. Figure 4.24 compares the ratio between minimum and maximum to the mean in Table 4.11 with the effect of a shifting of +/- 1 cm of the source for the voxel model I2, representing the hand supporting the syringe during injection. The spread in the measurements and the variation in the simulation are comparable.

Table 4.11. Minimum, maximum and mean value of the mean normalised skin doseHp(0.07) at the base of the index and the middle fingers for the non-dominant hand for the 8 workers performing 99mTc administration with an unshielded syringe.

	Index base	Middle base
Min (µSv/GBq)	24	11
Max (µSv/GBq)	92	77
Mean (µSv/GBq)	44	32
Min/Mean	0.56	0.34
Max/Mean	2.08	2.37

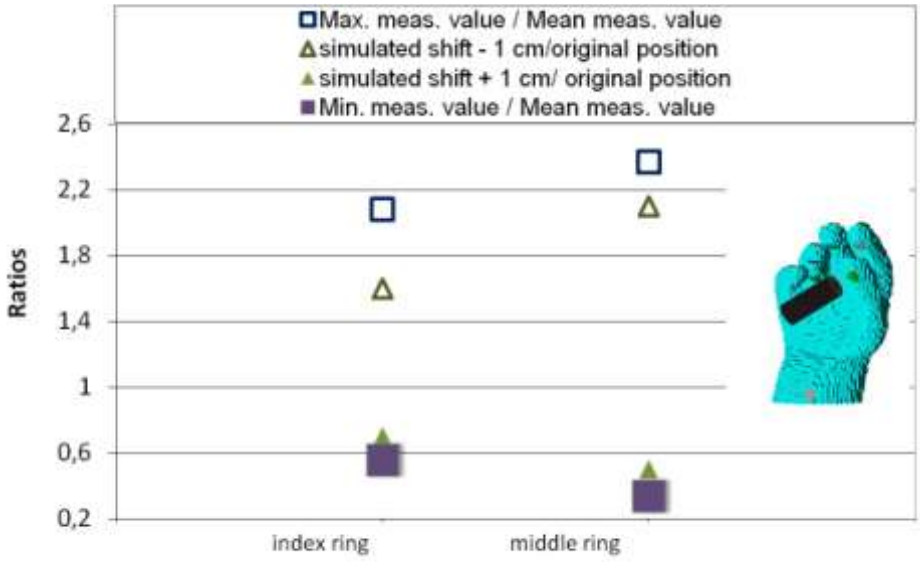

Figure 4.24. Comparison between selected measurements for injection of ^{99m}Tc without shielding, non-dominant hand data, and the sensitivity analysis for a shifting of the source along its axis of +/-1 cm in Model I2.

4.3.4.4 Volume of the source

Changing the volume of the source for the same absolute activity can increase or decrease the dose depending on the positions where the dosemeters are placed with respect to the source. For the injecting scenario, as illustrated in Figure 4.25, increasing the active volume solution for the same activity means approaching the source to the monitoring positions. Therefore when increasing the volume, the doses increase at all positions. Nevertheless these changes remain relatively small for ^{99m}Tc and ^{18}F, with a maximum of a factor of 2, but it can be much larger for ^{90}Y. For the case illustrated in Figure 4.25, a maximum factor around 1.9 is found when manipulating a 4ml syringe for ^{99m}Tc and ^{18}F instead of a 1ml syringe. This factor is much higher for certain

positions when the source is ^{90}Y, going up to 170 (in case of using a 10ml syringe instead of a 1ml syringe).

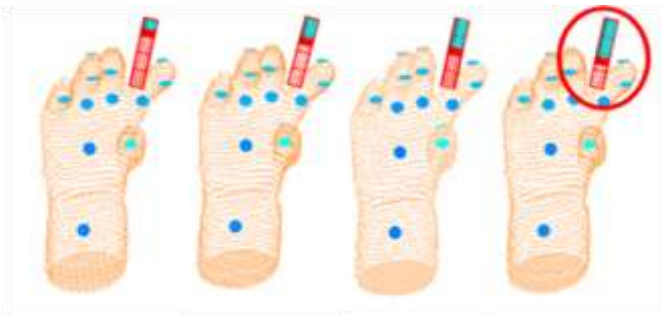

Figure 4.25. Voxel model representation, when increasing the volume of the active solution, 1ml, 2ml, 3ml and 4ml.

4.3.5 Dose distribution

The dose distribution across the hands was also studied for all diagnostic procedures and for ^{90}Y Zevalin® therapeutic procedures. For each monitored position the range of measured normalised doses for all workers are shown inFigure 4.26, for each radionuclide and separately for the preparation phase (top) and administration phase (below). For all these procedures it was observed that the non-dominant hand usually receives higher doses than the dominant hand.

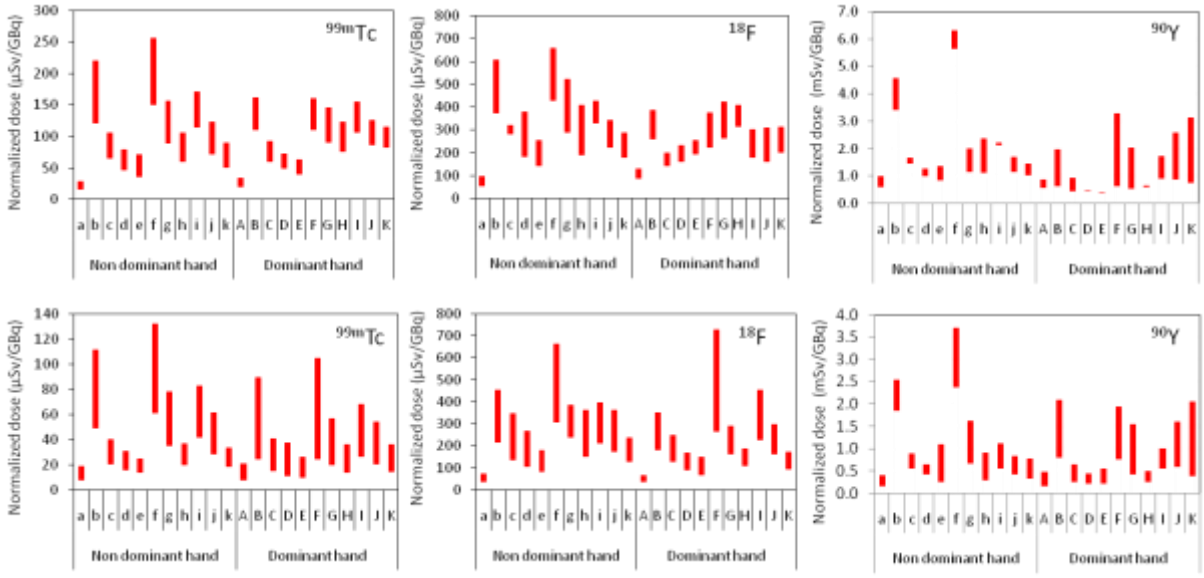

Figure 4.26. Dose distribution across the hands for the three radionuclides, the upper row concerns the preparation and lower row the administration procedures. For each monitoring position the mean and median of normalized doses is shown (the monitored position is identified by the notation indicated in Figure 4.3).

For diagnostic procedures, the difference between the dominant and the non-dominant hand was evaluated. The quantity to be analysed was the relative difference between the mean maximum normalized $H_p(0.07)$ of the non-dominant hand and of the dominant hand (i.e., the quantity $\langle H_p(0.07)/A\rangle_{max}$ ND - $\langle H_p(0.07)/A\rangle_{max}$ D, in %).

For each type of procedure, this difference was calculated and the Kruscall-Wallis test was applied to find out whether this difference is statistically the same for the different procedures (Tabel 4.12).

Table 4.12. Results of the Kruscall-Wallis test to investigate if the difference between the mean maximum dose to the non-dominant hand and dominant hand is the same for all type of procedures.

	Parameter	Category	N	Kruscal-Wallis test	
				Differences?	p-value
All data	Procedure	Preparation of ^{99m}Tc	36	No	0.259
		Administration of ^{99m}Tc	32		
		Preparation of ^{18}F	30		
		Administration of ^{18}F	30		

Because the test showed no differences between dominant hand and non-dominant hand among the procedures, all data was treated together in one group in following analyses. In a second step, the Mann Whitney-U test was applied to see if the distributions were significantly different or not because of the use of shield (Table 4.13). For the syringe shield no differences were found, but for the vial shield differences between the distributions were found (p-value of 0.004). The 4 cases of unshielded vial were removed from the rest of data and the test was applied again to see if, without these data, the influence of the syringe shielding was highlighted.

Table 4.13. Mann-Whitney test.

Data	Parameter	Category	N	Mann-Whitney	
				Differences?	p-value
All data	Vial shield	Yes	34	Yes	0.004
		No	4		
	Syringe shield	Yes	47	No	0.426
		No	24		
Shielded vial	Syringe shield	Yes	85	No	0.761
		No	39		

Since no differences were found, the last step was to apply the Wilcoxon test, to all data except the 4 cases of the unshielded vial, to the differences between the maximum dose at each hand. The result is given in Figure 4.27.

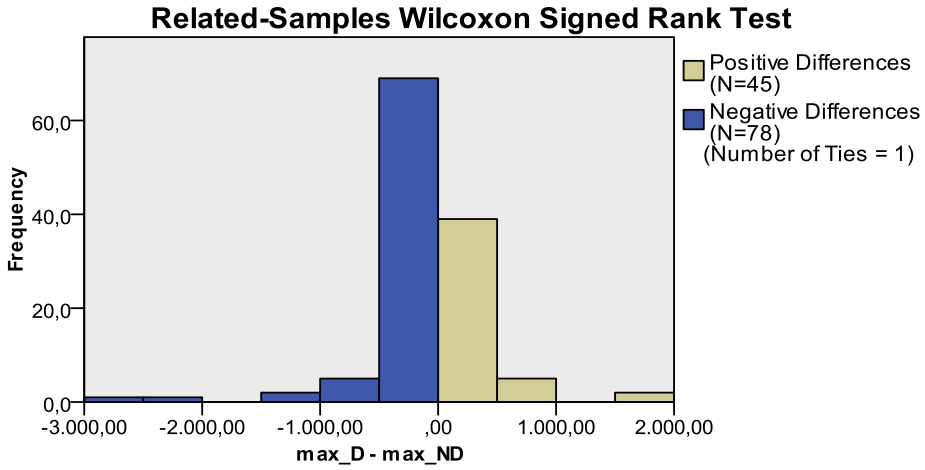

Figure 4.27. Wilcoxon test

The p-value for the Wilcoxon test is 0.06, close to the proposed p-value of 0.05. Figure 4.27illustrates the tendency to receive higher doses on the non-dominant hand.

The frequency of the position where the maximum dose was received was also calculated for each procedure, considering the 22 positions of both hands. The results are shown in Figure 4.28 and Figure 4.29.

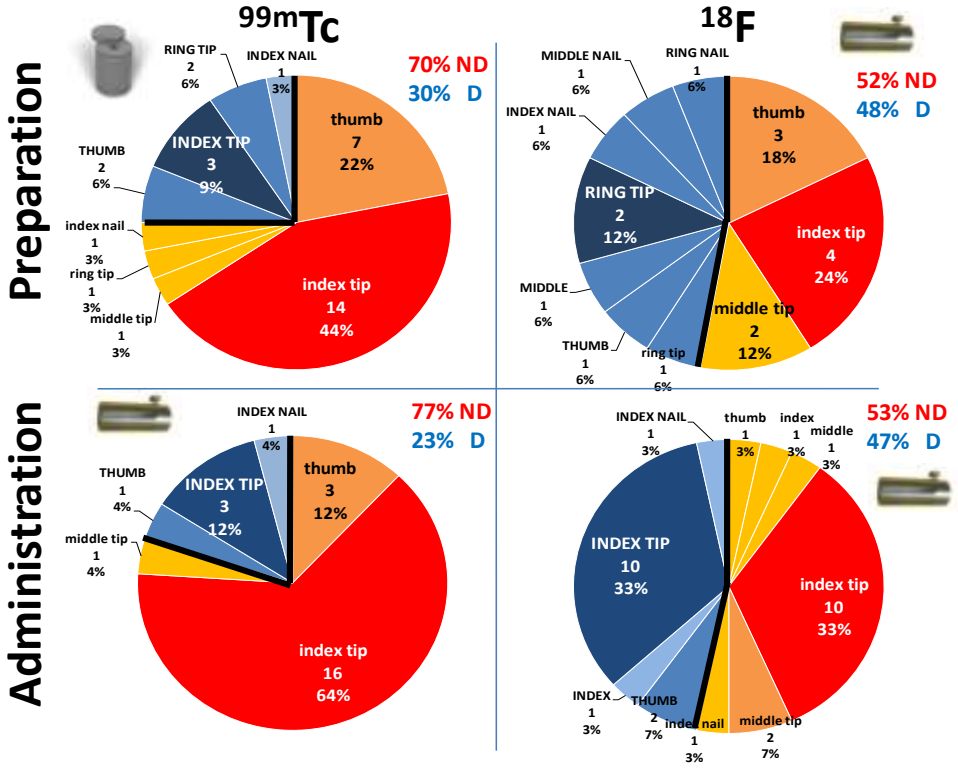

Figure 4.28. Frequency of the position where the maximum dose was received for each diagnostic procedure when using vial and syringe shielding.

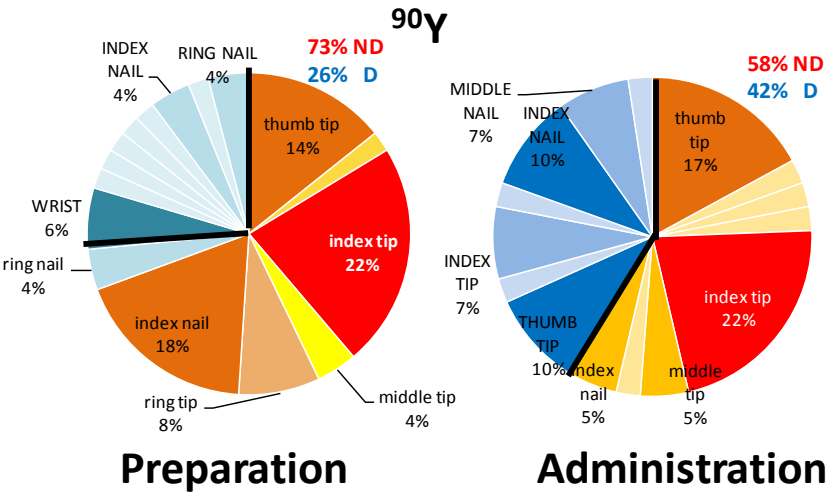

Figure 4.29.Frequency of the position where the maximum dose was received for ^{90}Y Zevalin® procedures.

For all procedures and when manipulating with shields, the index finger tip of the non-dominant hand is the position where the maximum dose is most frequently received (from 22% to more than 60% over all procedure types), followed by the thumb of the same hand for almost all procedures (from 7% to 20%) (Sans-Merce et al., 2011; Carnicer, Sans-Merce et al. 2011). Less frequently, the same positions of the dominant hand received the maximum dose (up to 10% for most procedures).

There is a general agreement that the fingertips are the most exposed part of the hands (Jankowski et al., 2003; Vanhavere et al, 2006; Covens et al., 2010). However, there is no consensus on which hand and which particular positions. When looking at specific cases in this study it was observed that the higher exposure of one of the hands is something strongly linked to the individual working habits, as reported in other works (Vanhavere et al., 2006, Brasik et al. 2007). Nevertheless, this study, based on a large measurement campaign, showed that the fingertips of the non-dominant hand are the most exposed positions, whereas ICRP, based on a thorough literature review, reports that the same fingers of the dominant hand are the most exposed (ICRP, 2008).

4.3.6 Routine monitoring

Wrist or ring dosemeters are typically used for routine monitoring. Although there is not a harmonized criterion for the position of the ring dosemeter, in practice it is usually placed at the base of the index, middle or ring fingers since these positions do not hamper work. This fact will cause the maximum dose to be largely underestimated. The order of underestimation was assessed, in a first step, by calculating the correlations (linear correlation coefficients) between the dose at all measuring positions and the maximum dose independent of the location where it was measured. The skin dose was found to be well correlated to the maximum dose at all the positions (R^2 >0.6). The tips of the fingers, especially those of the non-dominant hand, present the highest correlations (R^2 >0.8), whereas the least correlated positions are the two wrists (R^2 around 0.6). In

between, the ring positions present correlation coefficients of the order of 0.7 and 0.8 for the dominant and non-dominant hands, respectively. Thus, although the routine monitoring positions do not correspond to the position of the maximum skin dose, they can be used to estimate this quantity.

To quantify the impact of placing the routine dosemeter at a specific position different than that corresponding to the maximum hand dose, the ratios between the maximum dose and the dose at relevant monitoring positions and at the index tip were calculated. The calculation was made for each single measurement and then averaged over the set of measurements of each worker. The mean values for all workers and for each procedure are given in Table 4.14.

Table 4.14. Mean values of the ratios between the maximum dose and the dose at the base of the index, base of the ring and tip of the index fingers for each procedure. "Prep" stands for preparation and "Adm" for administration.

	Non-dominant hand				Dominant hand			
Procedure	Max / wrist	Max/base index	Max/base ring	Max/index tip	Max/ wrist	Max/base index	Max/base ring	Max/index tip
^{99m}Tc Prep	21	5	8	2	19	6	8	3
^{99m}Tc Adm	26	9	15	3	23	8	13	4
^{18}F Prep	15	4	6	2	12	5	7	2
^{18}F Adm	21	5	9	2	19	6	10	3
^{90}Y Prep	15	6	12	4	15	24	34	16
^{90}Y Adm	27	7	19	3	26	21	27	10

NM workers are usually involved in more than one diagnostic procedure. The ratios were also calculated by including all data from all diagnostic procedures together and separately for all therapy procedures. There is a large spread on the values obtained for the ratios as shown in Figure 4.30 and Figure 4.31 for diagnostic and therapy procedures respectively.

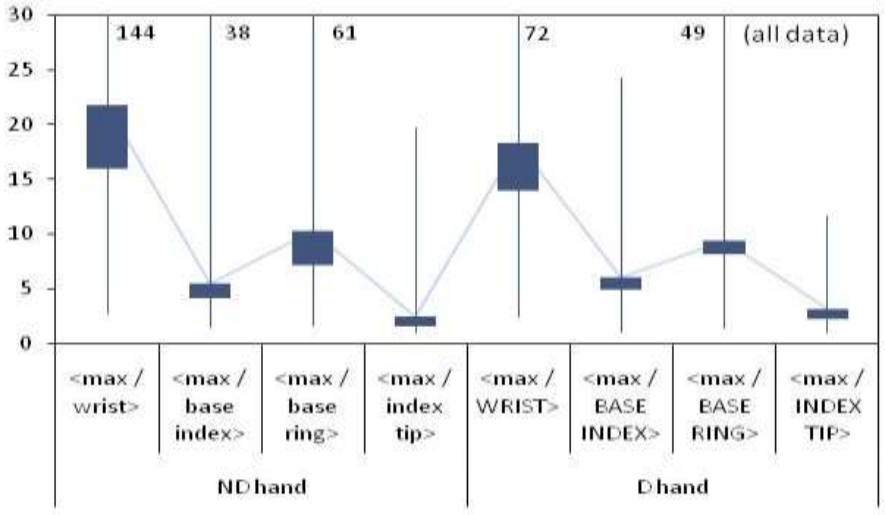

Figure 4.30. Ratios between maximum dose and dose at some specific positionsfor all diagnostic procedures. "ND hand" stands for non-dominant hand and "D hand" for dominant hand.

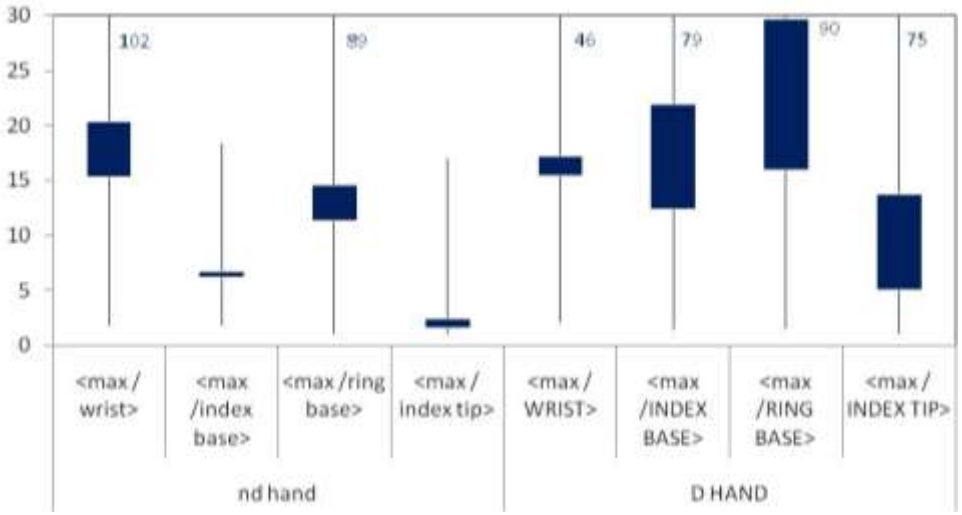

Figure 4.31.Ratios between maximum dose and dose at some specific positionsfor all therapy procedures. "nd hand" stands for non-dominant hand and "D hand" for dominant hand.

The mean values of the ratios presented in Figure 4.30 and Figure 4.31 are summarized in Figure 4.32.

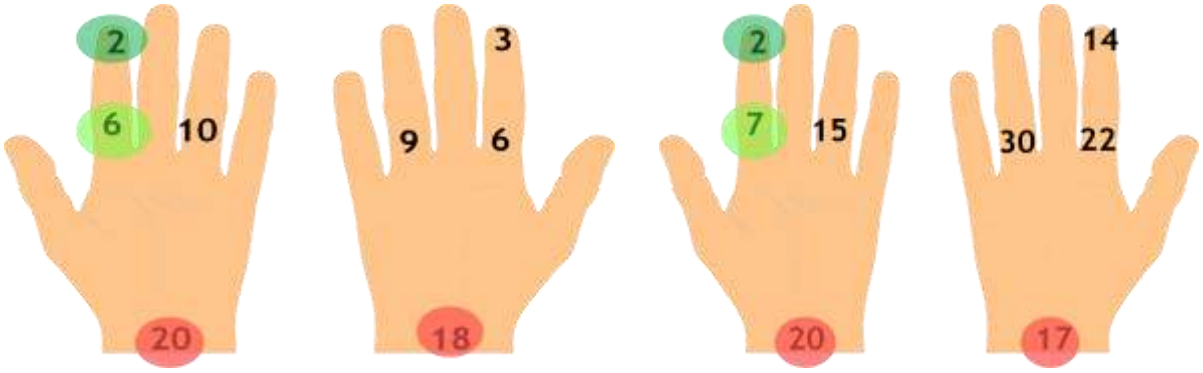

Figure 4.32. Mean ratios between maximum dose and dose at some specific positions for diagnostic procedures (left) and therapy procedures (right).

The mean ratios are significantly higher for the wrist positions (around 20). This value is in good agreement with that reported by Jankowsky for the wrist, which is also near 20 (Jankowsky et al., 2003). The lowest mean ratios were found for the index tip position of the non-dominant hand, usually around 2. The ratios are also lower for the base of the index finger than for the base of the ring finger, and lower for the non-dominant hand than for the dominant one. At the base of the middle finger ratios are in between. Thus, according to these results, the use of wrist dosemeters should be avoided because of a very high underestimation and a lower correlation to the maximum dose ($R^2 = 0.6$). Ring dosemeters are recommended instead. Since for practical reasons, the dosemeter cannot be placed at the finger tip, the most appropriate position is the base of the index finger of the non-dominant hand. In this position the mean underestimation is around a factor of 6. The same value was reported by Jankowsky for the index nail and the base of the ring finger (Jankowsky et al., 2003), and also close to the value of 5 reported by Wrzesién, considering the fingertips and the base of the middle finger of the right hand (Wrzesién et al., 2008). The TLD must always be arranged on the palm side of the hand. Other authors (Stuardo, 1990, Koback and Plato, 1985,Covens et al., 2007) show much lower ratios, typically from more than 1 to 4. Of course these values are strongly operator and procedure-dependent, as revealed by the large range of ratios observed in Figure 4.30 and Figure 4.31. This was also highlighted by other authors: Mebhah reported ratios ranging from 5 to 56 (Mehbah et al., 1993). ICRP recommends for the estimation of $H_p(0.07)$ a dosemeter placed on the base of the middle finger with the detector positioned on the palm side, whenever monitoring the dose to the most exposed fingertip is not possible. For this position ICRP recommends a factor of 3 to derive an estimate of the dose to the tip, and of 6 if the dosemeter faces the back of the hand (ICRP, 2008). The results of ORAMED highlight that this correction is too low.

4.3.7 Dose mapping

The dose mapping was performed for the injection scenario (model I1). This scenario provides an easier comparison with the measurements for the administration procedures, since the steps involved are much less and much more simple than in the case of preparation. Dose maps were made for the 3 radionuclides included in the sensitivity study (^{18}F, ^{99m}Tc and ^{90}Y) using MCNPX and their results were visualized using Voxler, a 3D Data Visualization software. Figure 4.33 shows the dose maps obtained for the administering scenario when manipulating an unshielded source.

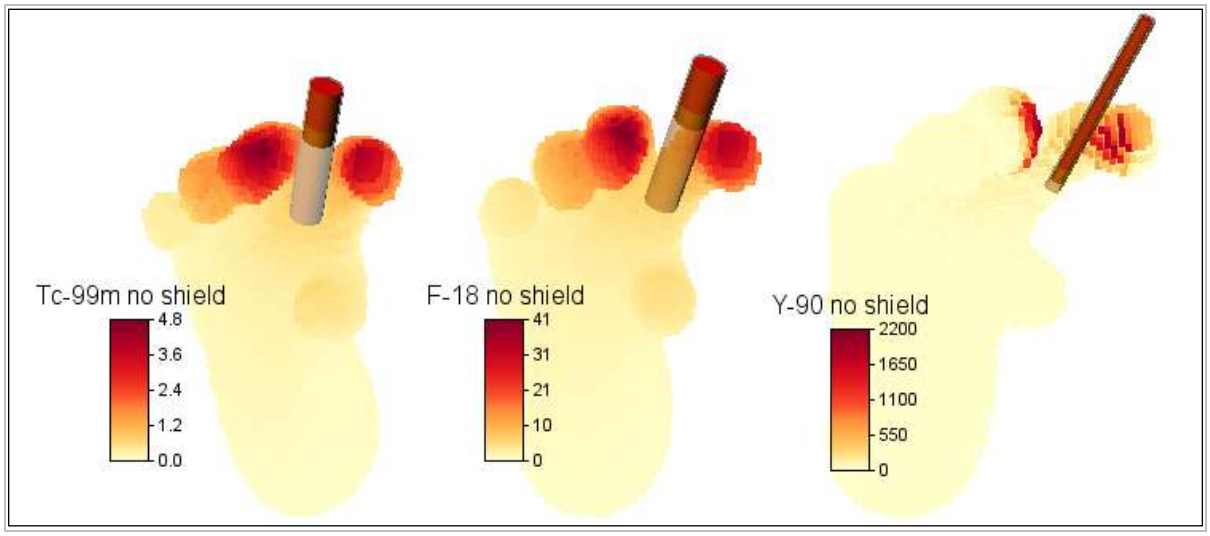

Figure 4.33. Dose maps (dose rates in µSv/GBq.s) obtained for scenario I1 (injection) for ^{99m}Tc, ^{18}F and ^{90}Y sources with unshielded syringes. For ^{99m}Tc and ^{18}F, syringes of 5ml are filled with 2ml solution and for ^{90}Y a 1ml syringe is filled with 1ml solution.

Similar dose maps were made for the case of a shielded source as shown in Figure 4.34.

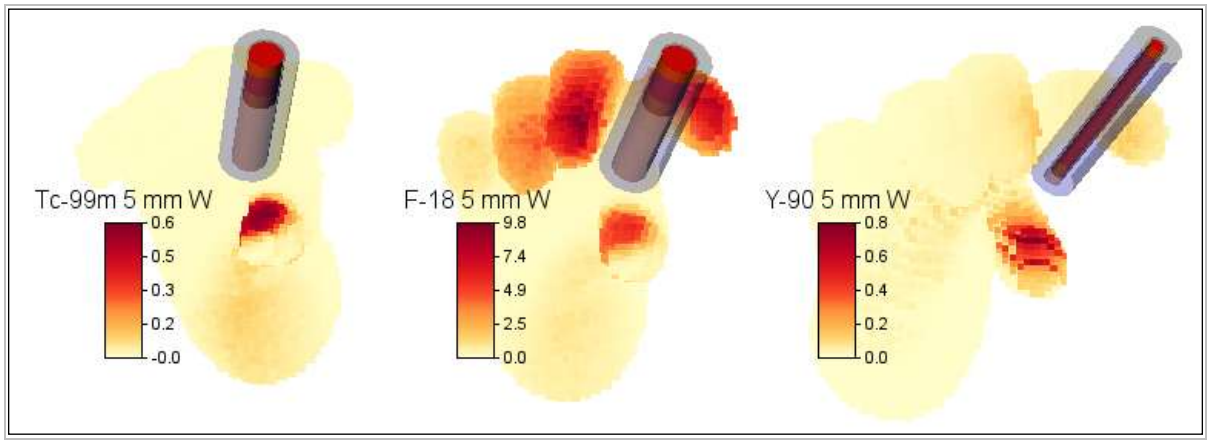

Figure 4.34. Dose maps (dose rates in µSv/GBq.s) obtained for scenario I1 (injection) for ^{99m}Tc, ^{18}F and ^{90}Y sources with shielded syringes with 5mm W. For ^{99m}Tc and ^{18}F, syringes of 5ml are filled with 2ml solution and for ^{90}Y a 1ml syringe is filled with 1ml solution.

The dose distribution (unshielded syringe cases) is very similar for ^{18}F and ^{99m}Tc. The distribution obtained for ^{90}Y is much more inhomogeneous. The most exposed positions to the unshielded syringe are the back of the index and middle fingers, and the maximum dose is found in the latter position in all cases. When the syringe is shielded, the thumb is not protected because it is located on the axis of the syringe, and thus the maximum dose is received at this position, as it was also observed in the sensitivity study.

The maximum dose obtained from the dose mapping was compared to the highest dose among the dosemeters used for the sensitivity study. It must be taken into account, though, that the shape and the mass of the voxel and of the simulated dosemeter are very different. The voxel mass is about 20 times higher than the mass of the tally cell in the dosemeter. For scenario I1 and the shielded ^{99m}Tc syringe the maximum dose is found at the same position, with the dose from the dose mapping a 35% higher than the one obtained in the sensitivity study. For the unshielded ^{99m}Tc syringe, though, it can be observed how the sensitivity study fails from finding the real maximum dose because it was located on the side of the tip of the middle finger rather than on the nail, where the dosemeter was located. In this case the differences between the maximum doses are not high (20%) because for a source like ^{99m}Tc the dose is distributed quite uniformly in the most exposed area if the source is not very close to the hand. For ^{18}F and especially for ^{99m}Tc sources, the fact that the maximum dose is not located in one of the pre-defined measuring positions is only critical if that measuring position is far from the place where the maximum dose is really located, and if the source is very close to the hand. If this is not the case, differences will not be high because the dose is uniformly distributed in this area. For ^{90}Y the situation is more delicate because the dose distribution is highly inhomogeneous even if the source is not very close and even if the measuring position is not far from the location of the maximum dose. Thus, the difference between the maximum doses could be higher.

4.4 Recommendations

The results of the WP4 measurements campaign highlight large variations of doses among procedures and workers. To some extent, the spread of the doses, even within the same procedure, has been partially verified by the Monte Carlo sensitivity analysis, as being due to the influencing parameters. Nevertheless some general trends have been observed:

- There is a wide range of individual exposures (min/max) for similar procedures due to the fact that different equipment is used, radiation protection means and tools;
- The annual skin dose limit (500 mSv averaged over 1 cm^2) can be exceeded by numerous workers in hospitals where radiation protection standard is low;
- There is potential to further improve radiation protection and decrease exposures;
- Adequate skin dose monitoring is urgently needed in nuclear medicine.

The interpretation of the analysis of the data and the simulations lead to the following points:

- The choice of the dosemeter type and the wearing position is important for an accurate dose assessment;
- Shielding of vials and syringes are essential and a precondition but not a guarantee for low exposures;
- Other RP tools and measures (e.g. pincers, forceps, time etc.) can significantly reduce the exposure;
- Subjective factors e.g. risk awareness and training affect exposures. Especially in therapy, participants have reduced extremity dose during the project due to the feedback of the measurement results on the radiation protection standard;
- Working fast is useful but not sufficient.

From the observations done and the analysis and interpretation of the data obtained from the measurement campaign as well as from the simulations, recommendations have been derived:

- Extremity monitoring is essential in nuclear medicine.
- To determine the position for routine monitoring, the most exposed position on the hand for each worker should be found by individual measurements. If these measurements are not possible, the base of the index finger of the non-dominant hand with the sensitive part of the dosemeter placed towards the inside of the hand is the recommended position for routine extremity monitoring in nuclear medicine.
- To estimate the maximum dose, the reading of the dosemeter worn at the base of the index finger of the non-dominant hand should be corrected by a factor of 6.
- Shielding of vials and syringes is essential. This is a precondition but not a guarantee for low exposure.
- The minimum acceptable thickness of shielding for a syringe is 2 mm of tungsten for ^{99m}Tc and 5 mm of tungsten for ^{18}F. For ^{90}Y, 10 mm of PMMA completely shields beta radiation, but a shielding of 5 mm of tungsten provides better protection, as it additionally cuts down bremsstrahlung.
- The minimum acceptable shielding required for a vial is 3 mm of lead for ^{99m}Tc and 3cm of lead for ^{18}F. For ^{90}Y, acceptable shielding is obtained with 10 mm of PMMA with an external layer of a few mm of lead.
- Any tool increasing the distance (e.g. forceps, automatic injector) between the hands/fingers and the source is very effective for dose reduction.
- Training and education in good practices (e.g. procedure planning, repeating procedures using non-radioactive sources, estimation of doses) are more relevant parameters than the worker's experience level.
- Working fast is not sufficient, the use of shields and tools for increasing the distance are more effective than working quickly.

The ORAMED recommendations agree with most of the ICRP (ICRP, 2008) recommendations for nuclear medicine. Two main differences have been found concerning the routine monitoring. ICRP recommends placing the routine dosemeter on the base of the middle finger of the dominant hand with the detector positioned on the palm side when the tip can't be used, whereas ORAMED results show that the base of the index finger of the non-dominant hand with the palmar positioned detector is a more appropriate position. A second difference is related to the correction factor proposed to estimate the maximum dose. ICRP recommends to apply a correction factor of 3 (6 if the dosemeter faces the back) whereas ORAMED suggests a factor of 6.

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4.6 Guidelines elaborated in the framework the ORAMED project to reduce hand exposure for standard nuclear medicine procedures.

ORAMED: Extremity dosimetry in nuclear medicine (Work Package 4)

Practical guidelines to reduce hand exposure for standard nuclear medicine procedures

Marta Sans Merce*, WP4 leader, Institute of Radiation Physics, University Hospital Center of Lausanne (CHUV), Switzerland
Sébastien Baechler, Institute of Radiation Physics, University Hospital Center of Lausanne (CHUV), Switzerland
Ilona Barth, Bundesamt für Strahlenschutz (Bfs), Berlin, Germany
Adela Carnicer, Institute of Energy Technology, Universitat Politècnica de Catalunya (UPC), Spain
Laurent Donadille, Institut de Radioprotection et de Sûreté Nucléaire (IRSN), France
Paolo Ferrari, Ente per le Nuove Tecnologie, l'Energia e l'Ambiente (ENEA), Bologna, Italy
Marki Fulop, Slovak Medical University (SMU), Bratislava, Slovakia
Mercé Ginjaume, Institute of Energy Technology, Universitat Politècnica de Catalunya (UPC), Spain
Gianfranco Gualdrini, Ente per le Nuove Tecnologie, l'Energia e l'Ambiente (ENEA), Bologna, Italy
Sabah Krim, Belgian Nuclear Research Centre (SCK•CEN), Belgium
Francesca Mariotti, Ente per le Nuove Tecnologie, l'Energia e l'Ambiente (ENEA), Bologna, Italy
Xavier Ortega, Institute of Energy Technology, Universitat Politècnica de Catalunya (UPC), Spain
Arndt Rimpler, Bundesamt für Strahlenschutz (Bfs), Berlin, Germany
Natacha Ruiz, Institute of Radiation Physics, University Hospital Center of Lausanne (CHUV), Switzerland
Filip Vanhavere, ORAMED coordinator, Belgian Nuclear Research Centre (SCK•CEN), Belgium

*Corresponding author

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GUIDELINES FOR REDUCING DOSE TO THE HANDS DURING STANDARD NUCLEAR MEDICINE PROCEDURES

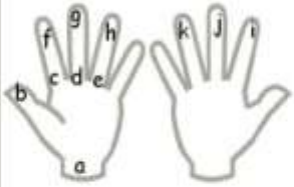
These guidelines were established in the framework the ORAMED project (2008-2011), a Collaborative Project supported by the European Commission within its 7th Framework Program.

General problematic

Since the dose limit for the skin (500mSv/year) must be applied to 'the dose averaged over any area of 1 cm^2 regardless of the area exposed' it is advisable to measure the local skin dose at the location with the highest presumed exposure. This consideration is the central dilemma of extremity dosimetry and causes severe practical difficulties. In the daily practice of nuclear medicine, the part of the hand receiving the highest dose is often unknown. Moreover, the dose distribution over the hand may vary during a single process as well as when different operators perform the same procedure.

Description of the work

Skin dose equivalents $H_p(0.07)$ at different positions (see Figure 1) on the hands were measured for several nuclear medicine procedures using appropriate dosemeters. Measurements were based on a unified protocol that included all relevant information for radiation exposure. Procedures were selected according to their frequency and their potential level of hand exposure, and they covered the most commonly used radionuclides in nuclear medicine: ^{99m}Tc, ^{18}F, ^{90}Y. Furthermore, Monte Carlo simulations were performed to analyse the sensitivity of hand doses to different parameters. Based on the results of this work performed within the framework of the ORAMED project, these guidelines were established in order to propose recommendations regarding the positioning of dosemeters for routine monitoring as well as practical tools and techniques to reduce exposure.



Meas points	Description
a	wrist
b	thumb tip
c	index base
d	middle base
e	ring base
f	index tip
g	middle tip
h	ring tip
i	index nail
j	middle nail
k	ring nail

Figure 1. Location of the measuring points on the hands.

MEASUREMENT CAMPAIGN

Diagnostic procedures considered:
- ^{99m}Tc preparation and administration
- ^{18}F preparation and administration

Therapeutic procedures considered:
- ^{90}Y Zevalin® preparation and administration
- ^{90}Y DOTATOC preparation and administration

The aim was to evaluate hand doses and dose distributions across the hands of medical staff.
Data comes from:
- 34 hospitals across Europe
- 7 different European countries
- 124 monitored workers

SIMULATION CAMPAIGN

- Simulation code: *MCPNX*
- 6 scenarios : 2 for the injection procedure and 4 for the preparation of the radiopharmaceutical.
- 3 hand phantoms moulded out of wax were scanned and voxelized to be introduced into the simulation input files

Figure 2. Hand model used for the simulations representing the injection scenario

The aim was to evaluate the efficacy of different radiation protection measures by comparing hand dose distributions according to various parameters such as:
- active volume of the source,
- displacement and/or rotation of the source,
- shielding thickness and material.

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Recommendations for positioning dosemeters for accurate monitoring

The dose distribution over the hand depends on:

- the physical properties of the radionuclide (highly inhomogeneous dose distribution with ^{90}Y, less inhomogeneous with ^{18}F and homogeneous with ^{99m}Tc),
- the distance between the source and the hand,
- the use of shields,
- the nature of the manipulations performed,
- the workers individual habits; even performing the same procedure with the same devices, it may vary significantly from one worker to another.

General trends observed among the monitored workers for all procedures

- Doses to the non-dominant hand are usually higher than doses to the dominant hand.
- The tip of the index finger is generally the most exposed position on the hand but not a comfortable position for routine monitoring.
- Good correlations are found between the maximum dose to the hand and the dose in usual monitoring positions for ring dosemeters (e.g. ring finger).
- The correction factor for the base of the index finger of the non-dominant hand as regards the position of the maximum dose has lower values and smaller variability than those factors corresponding to other positions for the different diagnostic procedures.

1) **Extremity monitoring is essential in nuclear medicine.**
2) **To determine the position for routine monitoring, the most exposed position on the hand for each worker should be found by individual measurements for a short trial period. If for practical reasons, these measurements are not possible, the base of the index finger of the non-dominant hand with the sensitive part of the dosemeter placed towards the inside of the hand is the recommended position for routine extremity monitoring in nuclear medicine.**
3) **To estimate the maximum dose, the reading of the dosemeter worn at the base of the index finger of the non-dominant hand should be corrected by a factor of 6.**

Recommendations regarding the parameters influencing the hand dose

General trends

- In several case the estimation of annual dose to hands exceeded the annual dose limit.
- The extremely wide range of maximum doses measured for an identical procedure indicates that good and bad practices were performed and thus, that workers who received larger doses could potentially optimize their working procedures or habits.
- Three main factors are associated with workers receiving higher doses: working without shield, direct contact with the source container and skin contamination.
- Some workers associated with very low doses use advanced techniques, including semi-automatic dispensing tools.
- A worker's experience level was not decisive of reduced hand exposure.
- Training and the use of appropriate radiation protection measures can reduce doses to acceptable levels.
- In absence of good practices (no use of appropriate shielding and tools, lack of training...) the annual maximum dose is likely to exceed the annual limit of 500 mSv.

1) **Shielding of vials and syringes is essential. This is a precondition but not a guarantee for low exposure, since sometimes shielding is not properly used.**
2) **The minimum acceptable thickness of shielding for a syringe is 2 mm of tungsten for ^{99m}Tc and 5 mm of tungsten for ^{18}F. For ^{90}Y, 10 mm of PMMA completely shields beta radiation, but a shielding of 5 mm of tungsten provides better protection, as it cuts down bremsstrahlung radiation.**
3) **The minimum acceptable shielding required for a vial is 3 mm of lead for ^{99m}Tc and 3 cm of lead for ^{18}F. For ^{90}Y, acceptable shielding is obtained with 10 mm of PMMA with an external layer of a few mm of lead.**
4) **Any tool increasing the distance (e.g. forceps, automatic injector) between the hands/fingers and the source is very effective for dose reduction.**
5) **Training and education in good practices (e.g. procedure planning, repeating procedures using non radioactive sources, estimation of doses to be received) are more relevant parameters than the worker's experience level.**
6) **Working fast is not sufficient, the use of shields or increasing the distance are more effective than working quickly.**

This study has received funding from the European Atomic Energy Community's 7th Framework Program (FP7/2007-2011 - grant agreement n°211361).

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APPENDIX - Main results of WP4

MAXIMUM DOSES FOR THE DIFFERENT PROCEDURES

Table 1. Mean, median, maximum and minimum values of the maximum doses, normalized to the manipulated activity, for all workers and procedures (P stands for preparation and A for administration).

	Mean values of maximum doses from all workers (mSv/GBq)	Median values of maximum doses from all workers (mSv/GBq)	Minimum values of maximum doses from all workers (mSv/GBq)	Maximum values of maximum doses from all workers (mSv/GBq)
P- ^{99m}Tc	0.43	0.25	0.03	2.06
A- ^{99m}Tc	0.15	0.09	0.01	0.76
P- ^{18}F	1.31	0.88	0.10	4.55
A- ^{18}F	0.72	0.62	0.14	2.42
P- ^{90}Y Zevalin®	9.62	8.87	0.90	32.06
A- ^{90}Y Zevalin®	5.25	2.92	0.32	32.05

For a given procedure, the mean, median, maximum and minimum value have been determined considering the maximum doses registered among all 22 measured positions for each worker for a specific procedure

- Preparation usually delivers higher doses than administration
- Dose values for diagnostics remain much lower than those measured for therapeutic procedures.

POSITION OF DOSEMETER FOR ROUTINE MONITORING

Table 2. Mean values for the correction factors for the different positions and for each procedure (P stands for preparation and A for administration). Correction factors are evaluated by considering the ratios between $H_{p,max}$, the maximum of the mean $H_p(0.07)$ (µSv/GBq) when both hands are considered simultaneously, and $H_{p,base\ ring}$, $H_{p,wrist}$, $H_{p,base\ index}$ and $H_{p,index\ tip}$ the mean dose at the base of the ring finger, the wrist, the base of the index and the tip of the index, respectively, for the non dominant and dominant hand.

	Non dominant hand				Dominant hand			
	Max/ wrist	Max/ base index	Max/ base ring	Max/ index tip	Max/ wrist	Max/ base index	Max/ base ring	Max/ index tip
P - ^{99m}Tc	27	5	11	2	20	6	9	3
A - ^{99m}Tc	15	5	10	2	15	7	10	4
P - ^{18}F	14	4	6	2	12	5	7	2
A - ^{18}F	30	7	12	4	27	7	12	4
P - ^{90}Y	16	7	11	4	16	22	30	16
A - ^{90}Y	26	8	17	5	23	20	17	10

- Doses are statistically higher in the non-dominant hand than in the dominant hand.
- The highest dose is often found to be received by the index tip of the non-dominant hand.
- Dose distribution over the hand is inhomogeneous.
- The ratios between the maximum skin dose and the dose at the possible monitoring positions in the non-dominant hand are smaller than those in the dominant hand, except for the wrist.
- The smallest ratio between the dose at the maximum and the dose at a given position is found in the tip of the index finger of the non-dominant hand. However, this is not a practical monitoring position.
- The second smallest ratio is found for the index base of the non-dominant hand and thus the index base, on the inner side of the hand, is the recommended monitoring position.

ANNUAL HAND DOSE ESTIMATION FOR DIAGNOSTIC PROCEDURES

The annual dose of 60% of the workers monitored for the ORAMED project has been estimated **only considering the procedures from which real measured values were available** and only for those whom their workload was known.

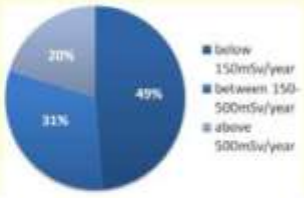

Figure 3. Percentage of workers with a given annual hand dose estimation.

- The annual dose estimation is above 150 mSv (3/10 of the annual limit) for 51% of the workers.
- 20% of the workers exceed the annual dose limit of 500mSv.

N.B. considering only the procedures measured within the ORAMED project.

PARAMETERS INFLUENCING THE HAND DOSE

- A dose reduction between 1 and 3 orders of magnitude is achieved when using the appropriate shielding.
- The participants in therapy measurements achieved a reduced hand dose during the project due to feedback received on their measurement results and therefore, on radiation protection standards.
- Radiation protection tools, such as forceps, significantly influence the doses (when manipulating a ^{18}F shielded vial with 5 cm long forceps doses are reduced by a factor of 6).

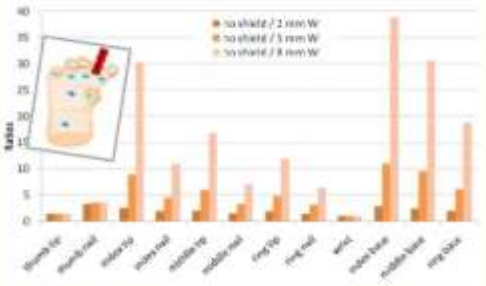

Figure 4. Ratios between unshielded syringes and shielded syringes of ^{18}F with 2, 5 and 8 mm of tungsten (W).

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5 ORAMED training and knowledge dissemination

1.1 5.1 Introduction

Previous chapters describe the main methodologies that have been developed within the framework of the ORAMED project for better assessing and reducing exposure to medical staff in interventional radiology and nuclear medicine.

An additional concern of ORAMED was to ensure correct dissemination of the main milestones and conclusions of the study and to guarantee a practical impact on medical staff of the findings. These actions have been coordinated through a specific workpackage, WP5, whose main objective was to develop a teaching and knowledge dissemination program to make sure that the conclusions and recommendations of the project are communicated to stake-holders, mainly medical staff, radiation protection officers, dosimetry services and authorities in the field.

One of the main tools to make the developed knowledge both accessible and usable to stakeholders has been the project website, www.oramed-fp7.eu.

The website includes an open part which provides the description of the research objectives and main results, abstracts or transparencies of the given presentations at international meetings, in particular at the ORAMED 2011 workshop, training material and the proposed guidelines. Also all the deliverables from the project are available at the website.

The main activities of WP5 can be divided into two categories: i) training, ii) dissemination of results through participation at scientific conferences.

1.2 5.2 Training

Education and training is a key factor in establishing effective radiation protection programmes. The use of ionizing radiation in medical applications constitutes the major field of non-natural exposure to the worldwide population, mainly as patients, while about 50% of radiation-monitored workers belong to the medical field (UNSCEAR, 2000). Thus, any training initiatives can result in important improvements in radiation protection practice. In addition, new developments in medical technology and the increasing complexity of medical radiation techniques require new skills and continuous up-dated training of personnel.

The training proposal that has been developed within ORAMED has a much more specific scope and intends to provide practical skills as well as disseminating knowledge developed within the project.

First of all, stakeholders for chosen topics were identified. For these stakeholders the best channels and type of material to be prepared were selected in order to achieve the expected radiation protection education objective.

Three main stakeholders were considered: the occupationally-exposed medical staff, the medical staff trainers and calibration laboratories together with dosimetry services. Different approaches

were proposed depending on the targeted user. A short summary of the contents and methodology of each category is presented.

5.2.1 Medical staff modules:

For medical staff, two specific modules on occupational radiation protection for interventional radiology and nuclear medicine, respectively, were prepared. The main emphasis was to provide practical understanding on how to improve radiation protection practices in medical applications where, at present, ORAMED results showed that doses are sometimes high, and can even exceed dose limits.

Some of the problems which are presented are usually not included in other available radiation protection training courses.

The two modules have a similar outline, structured in five chapters. Chapter One is a general introduction on occupational radiation protection in the field. Chapter Two reviews the main critical procedures from the radiation protection point of view and the corresponding organs at risk. Chapter Three describes the main dosimetric devices available in order to monitor medical staff. Technical characteristics, advantages and limitations, together with new developments are provided. Chapter Four is devoted to radiation protection means. Their effectiveness is illustrated with practical examples obtained from ORAMED measurement campaigns or calculations. Chapter Five provides a conclusion and summary of the main recommendations and lessons learned from the ORAMED project.

In preparing the material, special attention has been given to the type of audience that was targeted. The content of the course has been carefully studied to meet the needs and interests of the participants. As mentioned above, one of the main features is the use of information obtained directly from both practical and realistic situations.

After the training participants should be able to know:

- the physical characteristics of the different sources of exposure in nuclear medicine and interventional radiology,
- the limits of exposure,
- how to identify the organs at risk for the different diagnostic/ therapy procedures,
- how to apply radiation protection means to ensure an adequate protection of staff,
- how to select the best dosimetric system and how to implement the best monitoring procedure (type of dosemeter, position of use, interpretation of dosemeter reading) and,
- how to identify good and bad practices, in order to improve, if needed, their daily practice.

In addition, the training modules have been prepared to be used with new interactive tools (www.powervote.com/uk/; www.educlick.com/portal/), which allow questions to be answered online. Several companies have provided the software and key-pads to register audience voting and most of the programs can be easily integrated in PowerPoint presentations. These new interactive systems have been used in innovative education programmes and are recognised as favouring student participation and ensuring immediate knowledge feedback both for trainers and trainees. The systems encourage active attitudes and promote discussions, in particular on topics which need further explanation.

The training modules are available on the project website as a PowerPoint 97-2003 slide show: www.oramed-fp7.eu/en/Training%20material: Module 1: Interventional radiology (prepared by E. Carinou (GAEC) and L. Struelens (SCK)), Module 2: Nuclear medicine (prepared by M. Sans-Merce (CHUV) and M. Ginjaume (UPC)).

Examples of transparencies of the two modules are shown below. Questions on the main topics are proposed and collectively answered using interactive systems. After reviewing the participants' answers, solutions based on the ORAMED project results are shown. In addition, some short videos are included to illustrate both practical and realistic situations.

During the ORAMED 2011 Workshop, two 45-min lectures were given using a selection of the two training specific modules. The feedback of the participants was very positive and, in general, the lectures were very much appreciated. Some of the main lessons learned were related to the importance and differences between protection measures, such as syringe shielding, lead apron, ring dosemeter. Participants also mentioned they were interested in confirming the importance of individual skill to reduce personal doses. It was shown that different practices had direct consequences in the doses received. These considerations were useful both for those doing the actual work and for those responsible of the service and its radiation protection.

Characteristics of the most frequently used radionuclides

✓ **Diagnosis** with Tc-99m and F-18

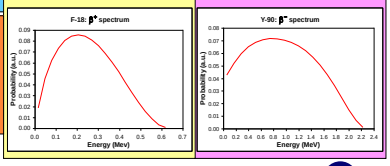
✓ **Therapy** with Y-90 (RIT with Zevalin®, PRRT with Dotatoc®), I-131

Tc-99m
Pure γ-emitter
E_γ = 140.5 keV (87%)

F-18
Mixed γ- and β^+-emitter
E_γ = 511 keV (194%)
$E_{\beta+max}$ = 634 keV (97%)

Y-90
Pure β^--emitter
$E_{\beta-max}$ = 2280 keV (100%)

I-131
Mixed γ and β emitter
E_γ = 365 keV (82%)
$E_{\beta-max}$ = 606.3 keV(89%)



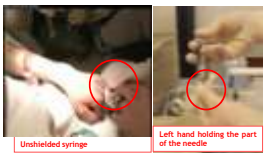
Examples of bad practices

Preparation of Tc-99m

Preparation of F-18

Administration of Tc-99m

Administration of F-18



Staff monitoring

The ring dosemeter should be worn as close as possible to the most exposed part of the hand. However this is not easy to do in practice.

Q8. How much do you underestimate the maximum skin dose when monitoring it with a ring dosemeter worn in the base of the index (palm side) non-dominant hand?

A. You don't underestimate

B. Up to a factor of 2

C. Around a factor of 6

D. Around a factor of 10

E. Up to a factor of 100 when you manipulate beta sources.

Staff monitoring

Q6. Why is double dosimetry better than single dosimetry?

A. A single dosemeter below the lead apron overestimates the effective dose

B. A single dosemeter above the lead apron underestimates the effective dose

C. Better estimation of the effective dose

D. Because the dose to the gonads and thyroid are better estimated

Radiological risks: Sources of exposure of workers involved in interventional procedures

Medical staff involved in interventional procedures work next to the patient ⇒ close to the X-ray beam

Tests in pulsed mode

MGPi DMC2000XB | Siemens EPD Mk2.3 | Dosilab EDM III | Polimaster PM1621A

Rados DIS-100 | Unfors EDD 30 | Atomtex AT3509C | Philips DoseAware

Polimaster PM1621A does not respond in pulsed mode.

All other APDs provide a reading. Limitations of some APDs are mostly due to high dose rates rather than to pulse frequency.

5.2.2 Medical staff trainer guidelines:

There are several available national and international training programmes which aim at ensuring appropriate radiation protection both for patients and workers. Among others, we can outline the IAEA radiation protection programmes, which provide Member States with training material and have a very active website that is frequently up-dated with new information on radiation protection of patients, videos and new training material (IAEA, 2011). The European Commission has promoted several projects under the topic Education and Training. These projects deal with radiation protection in various work sectors (EC, 2003; ENETRAP, 2008). Finally, it is also worth mentioning ICRP work in this field and, more specifically, the training material available on radiation protection in medicine, which is freely downloadable from the website (ICRP, 2011).

For trainers, ORAMED material includes some guidelines on the topics that an occupational radiation protection course for IR and NM should contain. The proposal has been prepared by I. Clairand and L. Donadille from IRSN and provides free internet links of interest for the different chapters. It is mainly based on IAEA modules available at:

http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/index.htm.The ORAMED medical staff modules are also recommended.

5.2.3 Videos to complement training:

In order to complement the training material presented in the previous paragraphs (5.2.1 and 5.2.2), two videos were produced:

SMU prepared a video for interventional radiology, showing how ORAMED measurements were performed (English version available).

BfS prepared a video on Y-90 DOTA therapy. It includes good recommendations on radiation protection measures (English and German versions available).

Both videos are available on the ORAMED website (www.oramed-fp7.eu/en/Training%20material) and were shown during the ORAMED 2011 workshop in Barcelona in January 2011.

As mentioned above, the combination of audiovisual and digital systems with traditional techniques improves both the concentration and participation of trainees.

5.2.4 Calibration laboratory and Dosimetry service module:

Many ORAMED participants are involved in metrology and dosimetry. Furthermore, the project has studied some topics related with personal dosemeter calibration, which have not yet been introduced in the corresponding international standards, namely, the calibration of electronic personal dosemeters in pulsed fields and the calibration of eye-lens dosemeters. The proposals and recommendations derived from the study have been incorporated in a specific training module *"Main features for calibrating dosemeters"* prepared by J.M. Bordy, CEA, which is mainly addressed to calibration laboratories, but can also be useful for personal dosimetry services.

This module on calibration is also available on the project website as a PowerPoint presentation. The main topics presented include: revision of standards applicable to personal dosemeter calibration, definitions of interest, recommendations for positioning dosemeters for calibration and for the simultaneous irradiation, information about the new Standard ISO DIS 29661 (2011). Moreover, advices to help laboratories in performing calibration of active personal dosemeters and eye lens dosemeters are provided.

5.3 Dissemination of results

The International Workshop on Optimization of Radiation Protection of Medical Staff, ORAMED 2011, was organized from the 20thto 22nd January 2011, in the School of Industrial Engineering of Barcelona at UPC (Spain).

The workshop, chaired by Mercè Ginjaume, was organized by the UPC with the collaboration of the ten other ORAMED partners. Together with the ORAMED consortium partners, the Programme Committee, chaired by the ORAMED coordinator, Filip Vanhavere from SCK•CEN, had the collaboration of the Directorate General of R & D of the European Commission, the International Atomic Energy Agency (IAEA), the European Radiation Dosimetry Laboratory Consortium (EURADOS), the Spanish Nuclear Safety Council (CSN), the Spanish Radiation Protection Society (SEPR) and the School of Industrial Engineering of Barcelona (ETSEIB).

The proposed topics attracted considerable interest internationally. There were 155 participants from 31 countries, 18 from Europe, the United States, Canada, Japan, Costa Rica and Sudan. 70 papers were submitted of which 20 were presented in the form of posters and 25 as invited papers. Among the oral and invited presentation papers, 30 papers have been peer-reviewed and publishedin a special issue of the Radiation Measurement Journal. Oral presentation slides are available at the ORAMED project website.

5.4 Conclusions

The main objectives of WP5, ensuring a correct dissemination of the main milestones and conclusions of ORAMED and developing novel training tools and materials to guarantee a practical impact on medical staff of the project findings, have been fully achieved.

The composition of the consortium with representatives from research institutes, universities, hospitals, government bodies and commercial companies, as well as the coupling of experimental dose measurements and high accuracy modelling capabilities, have been very useful to reach those objectives.

The radiation protection recommendations and calibration guidelines developed within the framework of the project summarize the main findings and have been distributed to medical staff but also to regulators and policy makers. In addition, the development of a new eye-lens dosemeter should be a useful tool to monitor the eye-lens doses in interventional radiology and cardiology.

The new training materials will surely improve training on radiation protection for medical staff. They should help to enhance the awareness of personnel about the organ at risks and the procedures which better guarantee a dose reduction.

There have been more than 40 oral presentations and lectures in international scientific meetings and training courses during the project, and more will be delivered in the following years.

Last but not least, the ORAMED website, hosted by the SCK•CEN, will be maintained up to 5 years after completion of the project. It will, thus, contribute to continue the dissemination of the project achievements even beyond the project duration. Training material, guidelines, ORAMED 2011 presentations and list of publications will be available.

5.5 References

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