EMAN Project

Optimisation of patient and occupational exposure in interventional radiology

Synthesis document on the impact of interventional radiology on medical exposures and the state of the art of optimisation for patients and staff

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SUMMARY

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Medical procedures using ionising radiation constitute by far the largest contribution to people by man-made sources. Moreover, the increasing use of ionising radiation in the medical sector has also an impact on occupational exposures, and there are concerns that practices such as interventional procedures may cause high individual doses. There are more and more different applications in a wide range of medical specialties using such techniques, which represent huge advantages for patients over invasive surgical procedures (lower risk of infection, shorter recovery time, etc.

Angiography and interventional procedures involve relatively high patient doses and the latter have been increasing in frequency in European countries over recent years. Both of these procedures contribute from 10% (Norway, 2002 data) to 26% (The Netherlands, 2002 data) of the total population dose (UNSCEAR, 2010). Moreover, interventional radiology and cardiology (IR and IC) procedures are responsible for more than 0.3 mSv per caput effective dose in Germany and Luxembourg, which is for example equivalent to about 80% of the total per caput dose from all X-ray procedures in the UK (reference!!). A survey of developing countries conducted by the IAEA revealed that about 30% of the 20 participating countries demonstrated a 100% increase in workload in the interventional departments in the 3-year period from 2004 to 2007 (Tsapaki et al., 2009). Moreover, large differences in the patient dose from all medical exposures have been observed between developed countries. This was one of the reasons to set up an EU-funded project called Dose Datamed.

The stochastic effects are always present in interventional procedures but there is also a possible risk for patient skin injuries (Miller, 2008). Though, these injuries are not observed normally in interventional diagnostic examinations, during therapeutic procedures the threshold value of 2 Gy for deterministic effects could be reached (e.g. maximum surface doses of up to 5.4 Gy were observed during cerebral embolizations, (Struelens, 2005; O'Dea, 1999)). In addition, large differences are observed depending on the complexity of the different lesions and interventions but also on the physician and the institution). Despite the fact that the number of these radiation injuries remains relatively small, they have a major impact on the patients who are affected. Moreover, complex cases may be treated in repeated procedures, which increase the risk of skin injury especially when performed within a short period of time. Children sensitivity to cancer induction by radiation is considered to be higher than in adults by a factor of three to five, (Valentin 2003). Follow-up studies in children showed that cancer risks were greatest for children irradiated early in life; risks for solid tumors persisted at least until the age of 50 years (Kleinerman 2006).

According to the Council Directive 97/43/Euratom (EC, 1997), patient radiation doses need to be estimated. The Directive has been implemented in national legislations such as shown in France (Cordoliani 2004). Other existing regulations recommend dose recording only when entrance surface dose exceeds 1-2 Gy for a procedure (Miller et al., 2003). There is a clear need to monitor whether the threshold doses for deterministic effects are being reached or even exceeded for the specific procedure. No patient databases exist in most of the hospitals where interventional procedures are performed. No clear directives for the patient follow up and accident handling exist though in its guideline for patient radiation dose management, the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) and the Society of Interventional Radiology (SIR) have defined criteria to organize the follow-up of patients after an interventional procedure (Stecker, 2009).

Concerning optimization of patient and staff doses, CIRSE and SIR recently published joint guidelines respectively on patient radiation dose management (Strecker, 2009) and on occupational radiation protection in interventional radiology (Miller, 2009). In order to optimize medical exposures, the concept of diagnostic reference levels (DRLs) was developed for common diagnostic purposes. The definition and implementation of such levels for IR and IC procedures are much more controversial, mainly due to the specificities

of these procedures, which make difficult to define a standard examination associated with a standard patient. In that context, many national or international studies have been performed in the last years to establish and/or propose DRLs for interventional procedures, but no specific recommendation and/or regulation have been established yet.

The above mentioned procedures often imply high radiation doses to occupationally exposed personnel. Workers exposed in ionizing radiation in medical fields constitute a significant percentage of the European workforce that is occupationally exposed to radiation. During IR and IC procedures, staff radiation doses can be high as physicians need to stay close to the patient. Moreover, advanced technologies (e.g biplane systems that are lately used) imply an additional source of staff doses.

For the estimation of the effective dose for staff involved in IR and IC procedures, double dosimetry is recommended. Double dosimetry is the use of two dosemeters, one located above and one under the protective apron. Many algorithms exist today for the calculation of the effective dose (Järvinen et al., 2008). Many national legislations clearly mention how many, when and where the dosimeters should be worn, and how the effective dose should be estimated. However, no European harmonization exists on the subject of the positioning of the dosemeters and the proper algorithm to use for the estimation of the effective dose.

Many of the data kept at the specific dose databases where the radiation protection regulatory bodies can have access to, do not give reliable data on occupational exposures. The data are often not detailed enough to provide the required information distinction between the various specialties (e.g cardiology and radiology). A further complicating factor is that recorded doses may underestimate true occupational exposure because compliance of IR and IC personnel can be poor, and because an individual's exposures from different facilities may not be summed (Padovani et al., 2011)

Other areas of major concern in the occupationally exposed personnel are the ones involving new methodologies especially IR and IC, resulting in high extremity doses (Vanhavere, 2008) to hands and legs, as well as to the eye lens of the physicians. It should be stressed that there are many parameters that affect the whole body and extremity dose of workers in IR and IC departments. If proper protective equipment is used then the whole body doses can be considerably low. The extremity doses can be as high as 1 mSv per procedure for complex procedures. If no proper protective shields are used then doses can be as much as 3-9 times higher. The doses to the lower limbs of physicians can also be high if no lead protection is used.

Moreover, interventional radiologists and cardiologists are categories of professionals, who can receive high doses to the eye lens possibly approaching the actual deterministic threshold for cataracts after some years of regular practices without protection of the eye (Ciraj-Bjelac, 2010; Hidajat, 2006; Vano, 2008a). Within the ORAMED (Optimization of Radiation Protection of Medical Staff) project, a lot of data on eye-lens doses have been collected and measurements with new types of dosemeters have been performed. The measurements showed that the present dose limit of 150 mSv per year for Hp(3) is generally not reached, but doses can be sufficiently high. If the dose limit will be reduced to 20 mSv, as it is proposed by ICRP in its latest statement (ICRP, 2011) many physicians will surpass this limit, and monitoring and the proper use of radiation protection equipment will even be more important (Vanhavere, 2011).

The average annual individual dose, for all workers that are monitored and receive a measurable dose, varies from country to country by a factor up to 10 (ESOREX database, http://www.esorex2010.cz/, Frasch and Petrova 2007). ESOREX (European Study on Occupational Radiation Exposure) project assesses how radiation protection monitoring, recording and reporting is arranged within Europe. However, in these databases/projects there are no references about the storage of extremity and eye lens doses which are very important for the target group that this network is addressed to.

From the ORAMED project (http://www.oramed-fp7.eu/) it was seen that the majority of the operators wear protective apron and thyroid collar. However, there is a 2% of the operators

in IR who do not use any personal protective equipment. Protective eye glasses are used in 30% of the cases in the IR and IC procedures. A 2% of the operators use protective gloves in IR procedures. For the room protective equipment, there is a percentage of more than 24% who does not use any room protective equipment.

Concerning the equipment used to perform interventional procedures, IEC defines the essential performance of X-ray equipment to be declared by the manufacturer so that are suitable for radioscopically guided interventional procedures (IEC, 2010). The dosimetric indications that will be provided by the equipment are also defined. The WG members agree that it is more and more difficult for the physicians to intervene on the basic parameters of the equipment. In fact before installing the machine the manufactures usually define particular presets depending on the procedures that will be performed with the use of machine. This limits the user to adjust and adopt the protocols required for specific patients.

Quality assurance of the equipment, acceptance testing and maintenance programmes are mandatory and well defined by international agencies. The role of medical physicist has to be highlighted.

According to EC guidelines on Clinical Audit for Medical Radiological Practices (EC, 2009) the aim of clinical audit is to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures. The EC guidelines were published in order to improve implementation of Article 6.4 of Council Directive 97/43/EURATOM (EC, 1997) on Clinical Audit. Despite all the EC efforts clinical audit is terms of EC directive 97/43/Euratom is only implemented according the synthesis report in Poland, Finland, Italy, United Kingdom, The Netherlands and Czech Republic.

The Euratom Directive 97/43 on radiation protection related to medical exposure (EC, 1997) requires an appropriate training in radiation protection of the medical professional using ionising radiation on patients. In 2011, ICRP has published a report on “Education and training in radiological protection for diagnostic and interventional procedures” (ICRP, 2009). One of the main findings made in this report is that it is accepted that RP education and training is deficient in many countries for almost all types of medical professionals requesting or performing diagnostic and interventional procedures. As a consequence, there is a need to provide an adequate education and training to all the medical staff and stakeholders playing a role in the medical procedures using ionising radiation. A process for the revision of the above Directive has been launched by the European Commission following the publication of the last general recommendations of ICRP in 2007. As far as education and training for professionals in the medical sector is concerned, the requirements in the latest Basic Safety Standards (EC, 2010) are not different from the existing ones.

Preliminary recommendations

1) Patient radiation dose reports should be produced at the end of the procedures, and archived. A relevant quantity for the patient dosimetry is the absorbed dose in the skin at the site of maximum cumulative skin dose. Various dose indicators can be used for this purpose. The best one is the kerma-area product (KAP), stored at the Digital Imaging and Communications in medicine (DICOM) header entrance. The fluoroscopy time (FT) is an additional useful parameter as a performance index for the quality of the procedure.

   KAP meters should be mandatory, included in all equipment and properly calibrated. An harmonised and unique dose unit should be adopted by the manufacturers.

   To deal with international and national professional communities.: ECR, ESR, ESC, CIRSE, regulatory bodies and manufacturers.

   To deal with HERCA in order to introduce obligation of registering the patient dose and KAP meters in all equipment.

2) Many national and international studies have been performed in the last years to estimate DRLs for interventional procedures. These data should now be analysed and international recommendations and national regulations should be proposed to implement diagnostic reference levels for interventional procedures. Specific DRLs should also be developed for interventional procedures concerning children.

   Action for EC: concerted action to propose DRLs for interventional procedures

   To deal with: professionals (physicians and medical physicists), national authorities, and regulatory bodies.

3) Patient follow-up should be organised to detect skin injuries (deterministic effects). This follow-up should be done at the Department where the procedure was performed, in collaboration of a dermatologist. The doses received by the patient should be communicated to the dermatologist

   To deal with professional societies (ESR, ECR, Dermatologists, …)

4) European guidelines should be formulated about the number of the dosemeters that should be worn and their position in IR and IC. A proper algorithm must be used to avoid over- or under-estimation of the effective dose when one or two dosimeters is used. The monitoring and evaluation of doses to the lens should be particularly addressed.

   Recommendations to have an EC concerted action to elaborate guidelines adapted to IR and IC procedures.

5) When using an APD in IR and IC, the requirements of the IEC 61526 standard and, in particular the points about the energy and angular response should be fulfilled. When selecting APDs, the characteristic of the pulsed fields met in IR and IC should be taken into account as some APDs do not have any response to these fields.

6) About the use of personal protective equipment:
   a. All personnel in the procedure room should wear a wrap-around protective apron of at least 0.25 mm lead-equivalence (so that when worn the double thickness anteriorly provides 0,5 mm lead-equivalence) and a protective collar of at least 0,35 mm lead-equivalence.
   b. The radiation protection glasses of at least 0.5 mm lead-equivalence thickness effectively attenuate radiation transmission. They should have side panels to block scatter radiation. However, they are heavy and uncomfortable (bad acceptance). The glasses are recommended especially in over-couch systems.
   c. Despite the fact that Protective gloves can attenuate the X-rays by 15%-30%, there is an international consensus to not recommend their use because of a series of drawbacks (risk to increase patient dose, uncomfortable for practitioners, cost, etc.). In any case, best practice is to keep hands out of the X-ray beam (Martin, 2009, Miller (CIRSE), 2010, Dumonceau (ESGE), 2012).

7) About the use of room protective equipment:
   a. 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.
   b. 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.

c. If biplane systems are used, the proper use and positioning of a ceiling shield is very important for the protection of the eyes.

d. Mobile floor shield should be used for the assisting personnel that need to be in the irradiation room.

To deal with national / European professional societies

Recommendation to the manufacturers to provide better protection devices for the eyes

8) Quality control of X-ray units is mandatory and acceptance testing needs to be carried out before the first use of the equipment and thereafter on a regular basis.

To deal with for regulatory bodies

9) The physicians and the medical physicists should be involved in the specification list of the equipment to be purchased. They should determine in advance the desired performance and radiation protection requirements for patient and staff as well.

To deal with professional societies (EFOMP, ESR, ESC, …)

10) Manufacturers of interventional procedure equipment should work with the medical physicist, radiographers and health physicians to determine the optimised protocols in terms of dose rates and image quality adapted to the different IR procedures. In choosing an X-ray equipment, the availability of experienced technical personnel in a given centre should also be taken into consideration, so as a prompt service is secured in the event of technical problems. At the time of installation, equipment performance evaluations should be conducted in order to ensure that the purchase specifications meet regulatory requirements. The records of the acceptance testing should be retained throughout the lifetime of the equipment for comparison with monitoring results in order to assess continued acceptability of performance.

To deal with manufacturers, national authorities and the professional societies

11) The implementation of the requirements described in EC directive 97/43/Euratom concerning the quality audit should be enhanced within all European countries.

To deal with national radiation protection authorities and national professional community should be addressed to help towards this direction.

12) Appropriate education and training in radiation protection should be required for all healthcare professionals performing interventional procedures. The level of education and training should be adapted to the radiation risk and to the specificities of the procedure. Training of the outside workers involved in the maintenance of the facilities should also be taken into account. These data should be written in the related documents (passbook) and checked by the radiation protection officer of the operator facility.

The accreditation of radiation protection training programs should be established by regulatory authorities at a national or a regional level, with the help of academic institutions, scientific and/or professional societies.

Development of training material, distance learning tools, posters, etc, can support this aim.

To deal with international organizations, regulatory bodies and national radiation protection authorities.

For EC: Update of the present EC Radiation Protection Guideline 116 on training is also necessary.

1. INTRODUCTION

Medical procedures using ionising radiation constitute by far the largest contribution to people by man-made sources. This fact has again been confirmed by UNSCEAR in its annex A of the 2008 report to the General Assembly published in 2010 (UNSCEAR, 2010). Although the benefit for patients exposed will normally outweigh the risk associated with the radiation, there is concern that patients may undergo radiological examinations that will not have any impact on their health, or that unnecessary high dose could be delivered with regard to the diagnostic outcome. Moreover, the increasing use of ionising radiation in the medical sector has also an impact on occupational exposures, and there are concerns that practices such as interventional procedures may cause high individual doses.

As part of the medical procedures using ionising radiation, interventional radiology and cardiology (IR and IC) procedures are performed in increasing large numbers worldwide. There are more and more different applications in a wide range of medical specialties using such techniques, which represent huge advantages for patients over invasive surgical procedures (lower risk of infection, shorter recovery time, etc). However, these procedures often imply high radiation doses to patients, but also to the healthcare personnel. This is reinforced by the fact that many of the specialists performing interventional procedures do not have proper education and training on radiation protection tasks. As a consequence, there are more and more concerns about radiation protection of patients and healthcare personnel using such techniques.

Patient exposure

Large differences in the population dose from all medical exposures have been observed between developed countries. This was one of the reasons to set up a EU-funded project called Dose Datamed (2004-2007). In spite of these differences, the relative distribution with respect to imaging modalities and types of examination in European countries was found to be similar. In particular, CT, angiography and interventional procedures give the largest contribution to the total collective dose from all X-rays examinations:

- CT is the major contributor with nearly 60%,
- Angiography and interventional procedures also involve relatively high patient doses and the latter have been increasing in frequency in European countries over recent years. Both of these procedures contribute from 10% (Norway, 2002 data) to 26% (The Netherlands, 2002 data) of the total population dose. Moreover, angiography and interventional radiology are responsible for more than 0.3 mSv per caput effective dose in Germany and Luxembourg, which is for example equivalent to about 80% of the total per caput dose from all X-ray procedures in the UK. A survey of developing countries conducted by the IAEA revealed that about 30% of the 20 participating countries demonstrated a 100% increase in workload in the interventional departments in the 3-year period from 2004 to 2007 (Tsapaki et al., 2009).

Occupational exposure

Workers exposed in medicine constitute a significant percentage of the European workforce that is occupationally exposed to radiation. For example, in France, they represent 60% of the occupationally exposed workers, receiving about 30% of the total occupational dose (IRSN, 2010). Moreover, in Greece the vast majority of occupationally exposed workers belong also to the medical sector (Kamenopoulou, 2000).

The average annual individual dose, for all workers that are monitored and receive a measurable dose, varies from country to country by a factor up to 10 (European Study on Occupational Radiation Exposure, ESOREX project).

Major areas of concern are the ones involving new methodologies especially interventional radiology and cardiology, resulting in high extremity doses (Vanhavere, 2008) to hands and legs, as well as to the eye lens of the physicians. Recent data on the effects of eye lens exposure (Ciraj-Bjelac, 2010; Hidajat, 2006; Vano, 2008a, Chodick, 2008) increase the concerns about possible late effects such as lens injuries or cataracts for the medical staff.

EMAN Working Group on optimisation of patient and occupational exposure in IR and IC

In this context, within the EMAN project, a working group has been set up to investigate IR and IC practices within the European Medical ALARA Network including relevant stakeholders with the aim to exchange information and improve the optimisation of radiation protection in these practices.

This report summarizes the work performed by the WG. It proposes an inventory of interventional procedures of interest for radiation protection, including data on patient and staff exposures. It also includes discussions on equipment used for interventional procedures, including quality control, as well as discussions on training and education. The state of the art of radiation protection optimization during interventional procedures is also presented.

2. INVENTORY OF PROCEDURES

This section introduces, identifies and classifies procedures depending on the level of radiation risk. It includes data on the numbers of procedures and data on both patient and staff exposure.

2.1 Criteria for inclusion and selection of procedures of interest

Identification of interventional procedures of interest for radiation protection of patients and staff is based on literature information, the experience of international or European scientific societies and European projects (e.g. ORAMED) and networks (e.g. EURADOS). Patient and staff exposure data are mainly derived from available literature data or from scientific societies.

Main criteria for the selection of procedures of interest are the following: KAP values, annual frequency of the procedures (only for staff), fluoroscopy time, number of images and, if relevant, possible patient complications (in particular deterministic effect). Staff exposure is given in literature in different ways: annual effective dose, personal dose equivalent, Hp (10) over or below the protective apron per single procedure. Moreover, in similar ways the dose to the extremities is also presented using annual estimation of personal dose equivalent of Hp(0.07), or per procedure at different locations: wrists, fingers, feet, eye lens etc.

2.2 Identified specialities and procedures, both diagnostic and therapeutic

2.2.1 Patient exposure

In its 2008 report (UNSCEAR, 2010), UNSCEAR proposes an important analysis of the literature providing data on patient exposure for different interventional radiology and cardiology procedures. For many procedures, UNSCEAR extracted the mean KAP values and number of patients from different papers.

The Table 1 below summarizes these data by indicating for each main type of procedures the minimum KAP, the maximum KAP, the main KAP weighted by the number of patients for each study and the total number of patients. Additional patient dose survey results have also been included. Complete data are available in Annex A.

Table 1. Patient dose data for different interventional radiology and cardiology procedures

Procedures	Mean KAP (Gy cm^2)			Total number of patients	References
	Observed minimum	Weighted mean [a]	Observed maximum		
Percutaneous [b]	1	43.2	150	872	(1)
IJV [c]	77	324.5	524	297	(2)
Angioplasty [d]	44.5	73.6	233.6	394	(3)
Embolization [e]	30.6	273.0	560.4	1 808	(4)
Angiogram [f]	77.3	204.3	347.6	200	(5)
Vertebroplasty	41	75.1	118.8	109	(6)
Stent [g]	18	166.3	344	539	(7)
Coronary angiography	12.7	30.2	147.43	32 121	(8)
PTCA	11.8	43.4	145.0	13 323	(9)

a. Mean weighted by the number of patient from each reference.

b. Biopsy, small bowel biopsy, bile duct drainage, biliary intervention, bile duct stone extraction, lithotripsy, nephrostomy.

c. TIPS.

d. Renal/visceral angioplasty (no stent), central venous reconstruction, aortic fenestration, iliac angioplasty (no stent), pulmonary angiogram (with IVC filter), IVC filter placement only, insertion of caval filters.

e. Hepatic chemoembolization, management of varicocele, neuroembolization, peripheral AVM embolization, bronchial artery embolization, other tumor embolization, pelvic vein embolization, pelvic arterial embolization, uterin fibroid embolization, GI haemorrhage (therapy), stroke therapy

f. GI haemorrhage (diagnosis), pulmonary angiogram (no IVC filter)

g biliary drainage/stenting, biliary duct dilatation/stenting, ureteric stenting, kidney stent insertion, renal/visceral angioplasty (with stent), iliac angioplasty (with stent), vascular stenting, iliac dilatation/stenting, carotid stent

(1) Hart (2002)a; Marshall (2000); McParland (1998); Miller (2003); Ruiz-Cruces (1997); Ruiz-Cruces (1998); Vano (1995); Vehmas (1991)

(2) McParland (1998); Miller (2003); Zweers (1998)

(3) Hart (2002)a; Miller (2003)

(4) Andrews (2000); Aroua (2007); Bergeron (1994); Hart (2002)a; Chalmers (2000); Johnson (2001); Marshall (1995); Marshall (2000); McParland (1998); Miller (2003); Ruiz-Cruces (1997); Ruiz-Cruces (1998); Williams (1997)

(5) Miller (2003)

(6) Fitousi (2006); Miller (2003); Tappero (2009)

(7) Aroua (2007); Hart (2002)a; McParland (1998); Miller (2003); O'Driscoll (1998); Williams (1997)

(8) Aroua (2000); Betsou (1998); Broadhead (1997); Delichas (2005); Efstathopoulos (2003); Fransson (2000); Hart (2002)a; Hart (2002)b; Kuon (2003)a; Kuon (2003)b Leung (1996); Padovani (1998); Paisley (2004); Van de Putte (2000); Vano (1995); Vano (2001)a; Vano (2001)b

(9) Aroua (2000); Aroua (2007); Balter (2006); Broadhead (1997); Delichas (2005); Efstathopoulos (2006); Fransson (2000); Hart (2002)b; Hunold (2003); Kuon (2003)a; Kuon (2003)b; Neofotistou (2003); Padovani (1998); Paisley (2004); Tsapaki (2005); Van de Putte (2000); Vano (1995); Vano (2001)a; Vano (2001)b

2.2.1.1 Neurointerventions

Neuroradiological interventions deserve particular attention regarding radiation protection. Especially during the last few years a continuous increase in neurointerventions has been presented. . Endovascular interventions have become a safe alternative in the treatment of selected cerebrovascular diseases or they are even considered as the treatment of choice, such as in the case of cerebral aneurysms. A prospective randomised study - the ISAT study - which compared endovascular coiling using detachable platinum coils with surgical clipping for acutely ruptured aneurysms had to be terminated prematurely, since the outcome data on patients undergoing endovascular treatment were significantly better compared to surgical treatment (Molyneux, 2002). In parallel, a considerable increase of stent implantations has also been observed with respect to the treatment of stenosis of the carotid artery. Arteriovenous malformations (AVM) or intracranial stenosis are areas of endovascular treatment as well. Since these procedures are rather complex, they may be accompanied by high exposure times, in particular for embolization of arteriovenous malformations (see also Table 2).

Table 2. Examples of mean fluoroscopy times during various neurointerventions

Mean fluoroscopy time (min)	Author
110	Huda (1994)
59.8	Berthelsen (1991)
43.3	Bergeron (1994)
44.7	EU (1993)
20-60	Giacomuzzi (1995)
39	Norbash (1996)
Mean fluoroscopy time: 16 min (lat), 12 min (pa) (indiv. Cases up to 50 min)	Theodorakou (2003)

The published data on radiation exposure during neurointerventions, which constitute the main source of information on the probability of deterministic damage, are extremely heterogeneous. Balter et al. (Balter et al., 2010) made a review of the literature concerning the effects on patient skin and hair following X-ray exposure in interventional radiology. For most patients, there is no observable effect at short or long-term below 2 Gy; clinically important skin and hair reactions occur only when the skin dose is higher than 5 Gy.As far as hair loss is concerned, these effects have been reported in the literature in patients who underwent cerebral endovascular treatments, such as aneurysm (Foroozan et al.,2008; Marti et al., 2008, Nannapanemi et al., 2005, Lee et al., 2004; D'incan et al., 2002,) and arteriovenous malformations (Wen,et al., 2003). The maximum surface dose determined during AVM embolizations with the help of thermoluminescent dosimeters amounted in these cases up to 6 and 4Gy, respectively. Fluoroscopy times of up to 100 minutes (29 image series) were reached in individual cases. Similar results were obtained by Struelens *et al.* (Struelens, 2005), who measured the surface dose to the head during diagnostic and interventional neuroradiological procedures with the help of thermoluminescent dosimeters. While the threshold value of 2 Gy for deterministic effects was far from being reached in diagnostic examinations (surface doses of less than 320mGy), maximum surface doses of up to 5.4 Gy were observed during cerebral embolizations. In addition, large differences were observed, depending on the examiner and the institution, which are, of course, also due to the complexity of the different lesions and interventions.

Table 3. Surface dose in mGy and effective dose in mSv during neurointerventions

Author	Surface dose (mGy)	Effective dose (mSv)
Bergeron (1994)	615 (187 - 1,335)	1.67 (0.44 - 3.44)
Chopp (1980)	159 ± 45	-
Feygelman (1992)	-	16.6
Berthelsen (1991)	660 - 1,400	6 - 43
Huda (1994)	6,600 *	30 *
Habermaas (1995)	-	23.8 (8.5 - 61.2)
Norbash (1996)	1,510 ± 880 960 ± 640 **	-
Theodorakou (2003)	770 (pa) 780 (lat)	
Mooney (2000)	up to 4,000	
Struelens (2005)	up to 5,400	
O'Dea (1999)	up to 5,400	
Marshall (1995)		3.6 (diagn. 4-vessel angiography)

** selected case*

*** with added filtration*

Looking at neuroradiological interventions, particular consideration should be given to possible delayed reactions of critical organs such as the eye and thyroid gland. Thus, for patients undergoing neurointerventional procedures, the dose to the eye should be kept as low as possibly achievable by positioning the patient accordingly (i.e. PA projections). A simple, but effective way for dose reduction of the examiner is to place the lateral X-ray tube on the opposite side of the table.

Theodorakou and Horrocks (Theodorakou, 2003) found the average dose to the patients' right eye (i.e. the eye nearest the X-ray tube) amounted up to 60 mGy (lateral and PA projection summarized); the dose to the thyroid gland amounted up to 24 mGy, respectively. The dose to the examiner's eye was also measured during 17 treatments and was found to be no more than 0.13 mGy on average (maximum value of 0.47 mGy). A rather weak correlation was observed between total kerma area product and fluoroscopy time. Monitoring of fluoroscopy time will thus not disclose the full potential of possible skin damage. A strong correlation, however, was found between kerma area product and the number of image series.

Since neurointerevntional devices such as microcatheters and guidewires, tiny coils and microstents are small and sometimes hardly visible (i.e. at the skull base or temporal bone) image quality during fluoroscopy must fulfil very high requirements.

Biplane systems are currently considered as standard for neurointerventions. Another important option is the 3D rotational angiography, which has considerably enlarged the capabilities of diagnostic angiography. This technique allows three-dimensional visualization for the more complex vascular pathology thereby facilitating endovascular therapy planning especially in the case of cerebral aneurysms. Comparative studies on 3D rotational angiography and conventional cerebral angiography have shown considerably lower dose values for 3D rotational angiography (maximum skin entrance dose in rotational angiography of 15 mGy versus 58 mGy in conventional angiography; cumulative entrance dose in rotational angiography of 33 mGy versus 53 mGy in biplanar angiography (Schueler, 2005)).

Patients with acutely ruptured cerebral aneurysms may receive a cumulative radiation dose which should not be underestimated, if they are diagnosed on the spot with the help of CT and CT angiography and immediately afterwards undergo endovascular treatment (coiling). For reasons of radiation protection, the total number of angiographic image series should be kept as low as possible. Rotational angiography or even 3D visualization of the CT angiography may be very helpful to quickly find the "working projection" for subsequent endovascular therapy and can thus help to significantly reduce the amount of series and radiation dose.

In general, if interventions are performed in appropriate neurological centres by an examiner who is experienced in radiation protection, no deterministic effects are expected. However, the published data show that the threshold values for deterministic effects were reached or even exceeded in individual cases during neurointerventional embolizations. It is therefore necessary to monitor the surface dose received by these patients and to inform them about the potential reactions. It is in any case recommendable to have (elective) neurointerventions performed in centres treating a large number of cases, where a high level of expertise and experience can be expected.

2.2.1.2 Vertebroplasty

Vertebroplasty and kyphoplasty are increasingly applied as minimally invasive treatment of osteoporotic vertebral body compression fractures, osteolytic metastases and for symptomatic vertebral body haemangiomas. Long fluoroscopy times have been found in individual cases, which led to an increased exposure of the patients undergoing this treatment (Fitousi, 2006; Ortiz, 2006). The average fluoroscopy time for kyphoplasty, for example, amounted to 10 ± 2 minutes. The average effective dose was in these cases between 8.5 and 12.7 mSv, the average gonadal dose (depending on the site of the vertebral body under treatment) was between 0.04 and 16.4 mGy. In total, skin damage caused by vertebroplasty and/or kyphoplasty is unlikely to appear as long as the distance between tube and skin is greater than 35 cm.

The dose to the physician should not be underestimated either. Measurements have shown that dose values of up to 3.2 mGy over the lead apron and 0.47 mGy under the lead apron may occur. The dose to the hands was considerably higher with up to 8.5 mGy. Special bone cement injectors make it possible to reduce the radiation dose to the examiner considerably (Mehdizade, 2004; Kallmes, 2003; Komemushi, 2005; Perisinakis, 2004).

2.2.1.3 Frequencies of interventional procedures in different European countries

Through the Global Survey of Medical Radiation Usage and Exposures, UNSCEAR collects data on the number of various medical examinations, including interventional procedures, in different countries. A survey of developing countries conducted by the IAEA revealed that about 30% of the 20 participating countries demonstrated a 100% increase in workload in the interventional departments in the 3-year period from 2004 to 2007 (Tsapaki et al., 2009). Table 4 presents the data of different European countries extracted from the UNSCEAR 2008 report (UNSCEAR, 2010).

Figure 1 and Figure 2 illustrate data for PTCA and cardiac angiography.

According to Faulkner and Werduch (Faulkner, 2008), there have been increases in the frequency of both diagnostic and therapeutic X-ray guided procedures, mainly due to advances in the equipment used for interventional cardiology, combined with the introduction of more cost-effective devices. Table 5 presents the calculated average annual rate of increase in PTCA procedures for various European countries. These values have been extrapolated using statistical data published by the British Heart Foundation for the period

1990-2003: the annual increase varies from 3.78% (The Netherlands) per year to 11.82% (Finland) per year.

Table 4. Annual number of various interventional procedures and angiographies per 1,000 population in different European countries - Data from the UNSCEAR Global Survey of Medical Radiation Usage and Exposures

Country	Interventional procedures				Angiography	
	PTCA	Cerebral	Vascular	Others	Non-cardiac	Cardiac
Austria	3.66	0.37	1.95	2.80	8.90	0.85
Belgium	1.90	--	0.90	--	13.00	1.90
Bulgaria	--	0.66	0.67	--	0.20	--
Croatia	3.34	--	--	--	2.70	--
Czech Rep.	0.78	0.44	0.31	0.12	0.43	8.96
Finland	1.88	0.08	1.39	2.75	2.37	3.15
France	1.71	0.20	5.74	6.81	--	--
Germany	2.30	1.67			12.70	15.52
Greece	--	--	--	--	3.18	3.18
Iceland	1.97	--	0.66	0.41	2.70	7.21
Luxembourg	1.54	0.07	1.40	0.52	7.00	3.42
Malta	1.45	0.00	0.19	0.73	0.93	5.13
Netherlands	--	1.21	--	--	5.12	--
Norway	0.54	0.08	2.36	--	6.19	3.67
Romania	0.73	--	--	--	1.57	0.89
Spain	0.65	0.17	1.53	3.00	1.70	1.28
Switzerland	1.05	0.09	1.27	0.47	2.95	2.68
UK	0.44	0.03	1.09	1.63	2.66	2.74

-- No data available

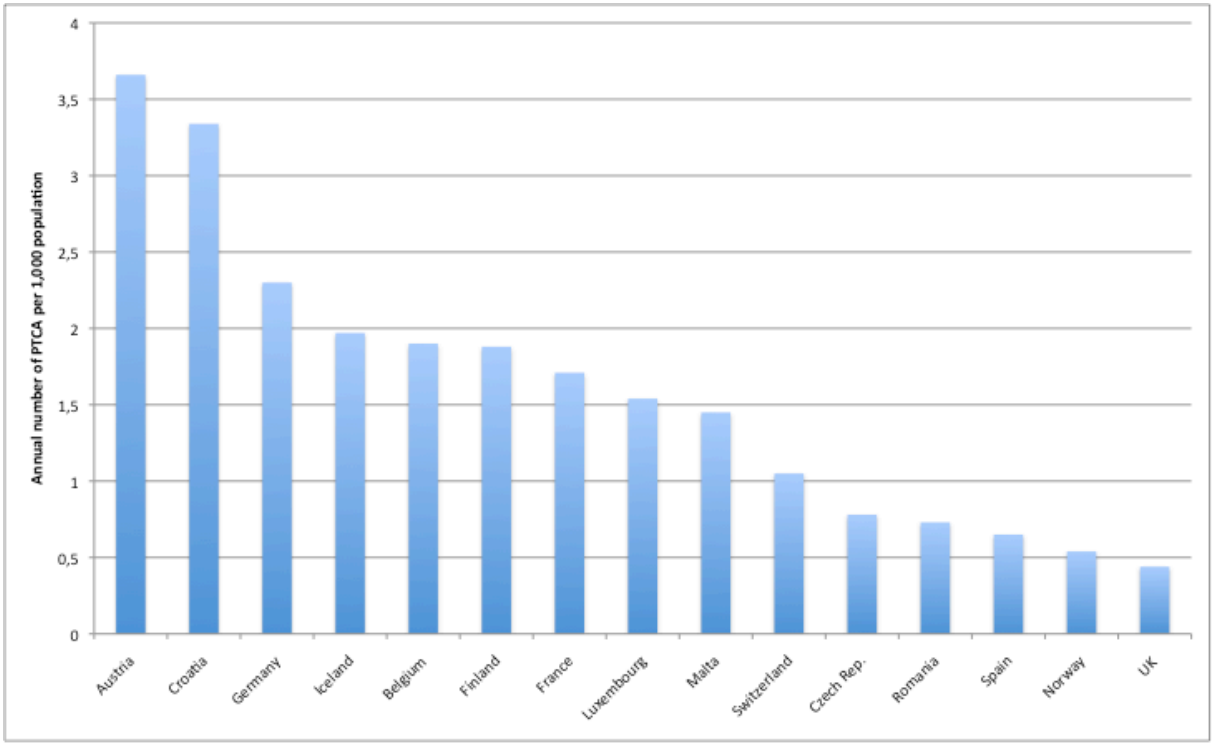

Figure 1. **Annual number of PTCA per 1,000 population in different European countries - Data from the UNSCEAR Global Survey of Medical Radiation Usage and Exposures (UNSCEAR, 2010)**

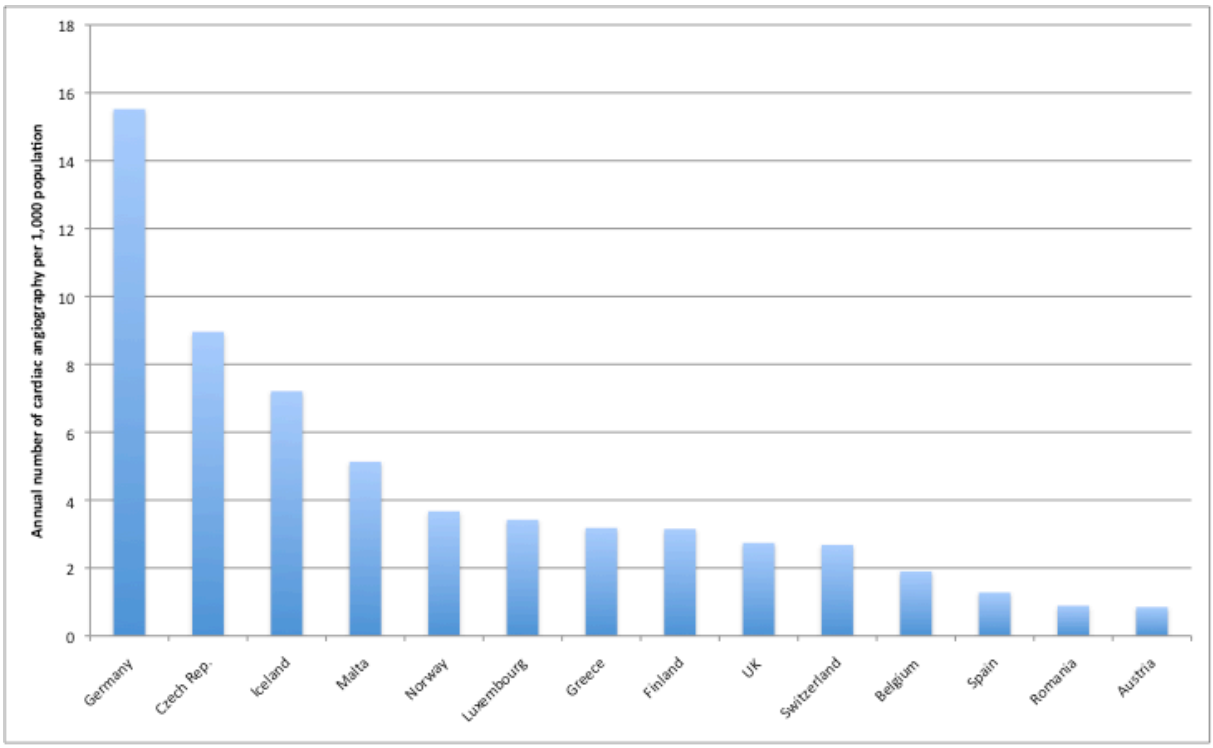

Figure 2. **Annual number of cardiac angiography per 1,000 population in different European countries - Data from the UNSCEAR Global Survey of Medical Radiation Usage and Exposures (UNSCEAR, 2010)**

Table 5. **Calculated average annual percentage rate of increase in PTCA procedures for various European countries (Faulkner, 2008)**

Country	PTCA average increase (%)/year
Austria	6.18
Belgium	4.20
Croatia	9.23
Czech Republic	7.55
Finland	11.82
France	5.37

Country	PTCA average increase (%)/year
Germany	5.52
Iceland	5.33
The Netherlands	3.78
Romania	9.36
Spain	5.82
Switzerland	5.02

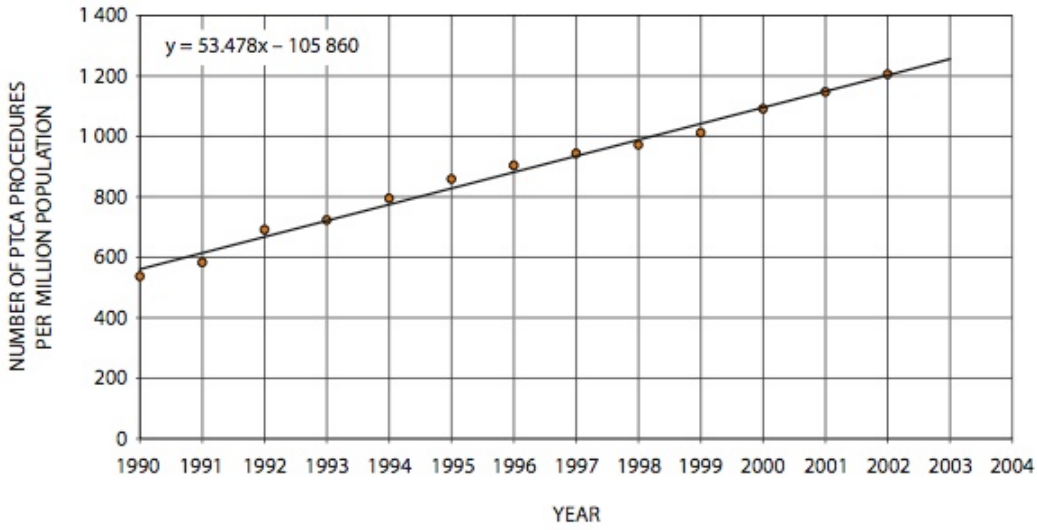

Figure 3. Frequency of PTCA procedures in the Netherlands for the period 1990-2003 (UNSCEAR, 2010)

France

French agencies, IRSN (Institute for Radiation Protection and Nuclear Safety) and INVS (Institute for Public Health Surveillance) are involved in monitoring patient medical exposures through the ExPRI information system. Based on the 2009 ExPRI data, a report has been published that gives the type and frequency of interventional procedures. In 2009, 277 901 diagnostic coronarography procedures and 161 712 non cardiac diagnostic vascular procedures were performed. The number of therapeutic procedures is not indicated in this report.

Greece

The Figure 4 illustrates the evolution of the number of some interventional radiology and cardiology procedures from 2002 to 2004 in Greece.

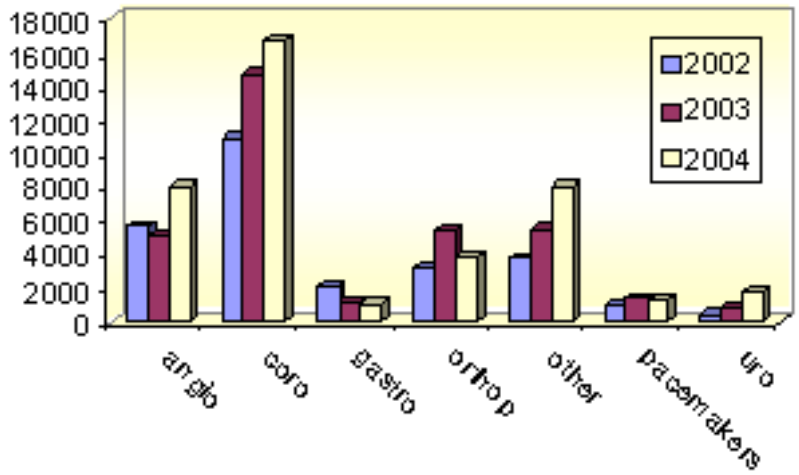

Figure 4. Evolution of the number of some interventional radiology and cardiology procedures from 2002 to 2004 in Greece

2.2.2 Staff exposure

IR and IC procedures require the operator and assisting personnel to remain close to the patient, and thus to the primary radiation beam. While the body area can be individually shielded by protective lead aprons, the hands, legs and the eye lenses remain practically unshielded. The unsuitable use of protective tools or bad practice (e.g. placing the hands in the direct X-ray beam) could lead to high doses at unexpected positions.

The ICRP Publication 85 (ICRP, 2000) has given examples of the doses of the monitored workers for various X-ray interventions. The dose ranges for the same kind of procedures vary a lot, since there are many factors affecting the extremity doses like the protective devices, the X-ray geometry and spectra, the irradiated area of the patient, etc.

Another important issue in radiation protection of the staff involved in IR and IC procedures is the fact that their hands, legs and eyes remain often unshielded entailing to a high radiological risk. As far as extremity monitoring is concerned the following Table 6 is presented as a result of the CONRAD project. As it can be seen the annual extremity doses above 50 mSv are found in very few cases only. However, in IR/IC, there are references where higher doses than the respective limits have been found. These observations are in apparent contradiction with the annual reported doses from the seven European countries considered previously. These discrepancies are probably due to the fact that (i) the dosemeters may not be systematically worn; (ii) the most exposed workers may not be monitored; and (iii) the dosemeters may be worn at not adapted positions.

Table 6. Mean annual extremity doses in IR/IC and number of workers with annual doses above 5 mSv and 50 mSv in 2005 - Data from 7 European countries (Donadille, 2008a)

Type of extremity dosimeter	Country	Number of workers wearing extremity dosimeter	Reporting level (mSv)	Mean annual doses (mSv)	Number of annual doses > 5 mSv		Number of annual doses > 50 mSv	
RING	F	1279	0.1 to 0.3	10.9	--	--	--	--
	D	7155	1	2.5	--	--	--	--
	IE	188	0.1	2.3	0	0%	0	0%
	PL	585	1	8.2	--	--	0	0%
	E	50	0.1	19.2	25	50%	10	20%
	CH	407	1	3.6	39	10%	9	2%
WRIST	F	5302	0.1 to 0.2	1.5	--	--	--	--
	GR *	133	1	17.9	7	5%	2	2%
	E	2799	0.1	8.9	654	23%	144	5%

F: France - D: Germany - GR: Greece - IE: Ireland - PL: Poland - Spain: E - Switzerland: CH

** For Greece the mean annual dose is reduced to 1.85 mSv when two cases of bad-practices are not considered*

-- Indicate no data available

In the following two tables (Table 7 and Table 8), doses per procedure are presented from Vano (1998) for radiology and cardiology procedures.

Table 7. Doses per procedure in vascular radiology (Vano, 1998)

Position of the dosemeter	Number of procedures monitored	Average dose (μSv)	Median Dose (μSv)	Range (μSv)
Left Shoulder	21	283	182	45-1214
Right Eye	18	296	122	45-2103
Left Eye	19	284	95	40-1683
Head	19	22	159	19-1013
Neck	19	325	138	48-2104
Right hand	23	260	120	47-974
Left hand	23	396	184	40-2150
Left forearm	22	326	225	40-1886

Table 8. Doses per procedures in interventional cardiology (Vano, 1998)

Position of the dosemeter	Number of procedures monitored	Average dose (μSv)	Median Dose (μSv)	Range (μSv)
Left Shoulder	55	252	185	30-1031
Right Eye	53	167	140	39-742
Left Eye	54	294	193	53-1005
Head	53	236	178	40-934
Neck	54	269	214	43-816
Right hand	54	191	144	45-921
Left hand	58	364	256	60-1500
Left forearm	54	646	445	88-2890

Moreover, doses from various IC and IR procedures are presented in the following tables (Table 9 and Table 10).

Table 9. Reported doses for interventional cardiology procedures

Procedure	Extremity dose/procedure (μSv)
CA	13(S) 10(A) 60(S) 70(F)
PTCA	20(S) 20(A) 350(H) 100(S) 200(F)
ICD	30(S) 60(A)
RF	10(S) 5(A) 75(FH) 260(H)

CA: coronary angiography, PTCA: percutaneous transluminal coronary angioplasties, ICD: implantation of defibrillators, RF: ablation.

The position of the dosemeter is shown at the parenthesis - S: shoulder, A: ankle, F: foot, H: hand, FH: forehead

References: Trianni (2006), Tsapaki (2004), McFadden (2002), Martin (2003), Whitby (2005), Whitby (2003), Harstall (2005)

Table 10. Reported doses for interventional radiology procedures

Procedure	Extremity dose/procedure (μSv)
Percutaneous	920[1](H) 820(H)-biliary procedure 620(F)-biliary procedure
IJV	630*(H) 900(H)-TIPS 2670(F)-TIPS
Angioplasty	210*(H) 100(H) 320(F)
Embolisation	140*(H) 1200(H) 940(F)
Angiogram	50*(H) 100(H)
Vertebroplasty	210-450(R)
Stent	300(H) 690(F)

IJV: internal jugular vein, TIPS: transjugular intrahepatic portosystemic shunts

The position of the dosemeter is shown at the parenthesis - S: shoulder, A: ankle, F: foot, H: hand, FH: forehead, R: ring

References: Trianni (2006), Tsapaki (2004), McFadden (2002), Martin (2003), Whitby (2005),

Within the ORAMED project coordinated measurements were performed in 34 hospitals in 6 European countries in order to obtain a set of standardized data on extremity and eye lens doses for staff in IR and IC. Furthermore, simulations of the most representative workplaces in IR and IC were performed to determine the main parameters that influence the extremity and eye lens doses. In Table 11 the mean Hp(0.07) values and mean Hp(0.07) values normalized by the respective KAP values, Hp(0.07)/KAP, are shown at the different measurement positions for CA/PTCA, RFA and PM/ICD procedures. Data extracted from the review made by Kim et al. (2008) are summarized here as the range of mean or median doses, as appropriate. It can be seen that for all positions the left-side part of the operator received higher doses than his right side. This is due to the fact that in the very large majority of the cases the X-ray tube and consequently the scattering centre of ionizing radiation were located at his left side. The location of the maximum mean doses is mostly observed at the left finger for CA/PTCA, with close values for left wrist and left leg, at the left leg for RFA and at the left finger for PM/ICD. It is also worth noticing that maximum doses, i.e. 6.6 mSv for the finger, 4.9 for the wrist, 5.0 for the leg and 1.1 mSv for the eye, were all registered for the same PM/ICD procedure with a high KAP value of 37054 μGy.m² and no room protective equipment used, with the exception of the left wrist dose which corresponded to a KAP equal to 9236 μGy.m² and only a table shield used but also for PM/ICD. More details can be found in Donadile et al., 2011.

[1] Dose from the hand nearest to the X-ray tube

Table 11. Statistics of the Hp(0.07) distributions (minimum, 1st quartile, median, mean, 3rd quartile, maximum and standard deviation SD) and mean normalized Hp(0.07) per KAP values for the IC procedures monitored in this work, and reviewed ranges of mean or median, as appropriate, hand and eye doses (Kim et al., 2008 and references therein).

			Donadile et al., 2011								Kim et al., 2008	
			L Finger	R Finger	L Wrist	R Wrist	L Leg	R Leg	L/R Eye	M Eye	Hand*	Eye*
CA/PTCA	mSv	Minimum	0.008	0.008	0.008	0.008	0.006	0.004	0.004	0.004	CA: 0.005-0.787 PTCA: 0.033-0.47 CA/PTCA: 0.235-0.514	CA: 0.005-1.12 PTCA: 0.009-0.17 CA/PTCA: 0.17-0.439
		1st quartile	0.029	0.018	0.032	0.022	0.016	0.013	0.017	0.013		
		Median	0.066	0.032	0.083	0.047	0.037	0.029	0.032	0.023		
		3rd quartile	0.154	0.063	0.192	0.082	0.191	0.059	0.054	0.042		
		Maximum	5.000	0.503	1.775	0.579	1.567	1.232	0.820	0.644		
		Mean	0.176	0.057	0.163	0.070	0.163	0.062	0.052	0.042		
		SD	0.406	0.073	0.239	0.083	0.288	0.115	0.077	0.068		
	mSv $\mu Gy^{-1} m^{-2}$	Mean	3.30E-05	1.27E-05	3.35E-05	1.58E-05	2.97E-05	1.18E-05	1.02E-05	8.47E-06		
RFA	mSv	Minimum	0.005	0.004	0.004	0.004	0.005	0.004	0.004	0.004	0.04-0.993	0.047-0.281
		1st quartile	0.010	0.008	0.024	0.012	0.013	0.008	0.008	0.008		
		Median	0.028	0.017	0.053	0.029	0.033	0.031	0.018	0.016		
		3rd quartile	0.057	0.032	0.137	0.058	0.156	0.057	0.039	0.032		
		Maximum	0.896	0.446	1.838	0.880	1.819	0.780	0.880	0.633		
		Mean	0.059	0.034	0.124	0.056	0.159	0.055	0.044	0.030		
		SD	0.115	0.054	0.211	0.093	0.302	0.093	0.082	0.057		
	mSv $\mu Gy^{-1} m^{-2}$	Mean	2.27E-05	1.64E-05	3.76E-05	2.43E-05	3.77E-05	2.03E-05	1.61E-05	1.78E-05		
PM/ICD	mSv	Minimum	0.005	0.008	0.004	0.004	0.004	0.004	0.004	0.004	0.255-1.05	0.039-?
		1st quartile	0.060	0.034	0.032	0.032	0.020	0.018	0.008	0.008		
		Median	0.167	0.106	0.099	0.083	0.067	0.064	0.029	0.022		
		3rd quartile	0.405	0.278	0.234	0.219	0.233	0.258	0.062	0.061		
		Maximum	6.564	4.328	4.852	3.825	4.996	4.046	1.083	0.810		
		Mean	0.418	0.281	0.309	0.237	0.250	0.241	0.060	0.051		
		SD	0.916	0.531	0.695	0.468	0.572	0.497	0.122	0.094		
	mSv $\mu Gy^{-1} m^{-2}$	Mean	2.29E-04	1.74E-04	1.53E-04	1.48E-04	1.29E-04	1.30E-04	5.52E-05	5.46E-05		

*Mean or median dose, as appropriate, per procedure. Dose rate measurements, phantom simulations and MC calculations were not considered

In Table 12 the extremity doses in terms of $H_p(0.07)$ and $H_p(0.07)$/KAP, measured at different positions for some IR procedures are summarized (Nicodemova et al., 2011). It can be seen that in most cases the operator received higher normalized doses at the left side than at the right one. Among the IR procedures special attention should be given to embolisations due to high doses received in all measured positions. Operators are also significantly exposed during therapeutic procedures such as angioplasties of the lower limbs and the renal arteries.

Table 12. Normalized $H_p(0.07)$ values to the respective KAP ones at different measurement positions for DSA PTA Ca/Ce*, DSA PTA LL*, DSA PTA Re*, and Embolisation procedures

	$H_P(0.07)$/KAP	Position					
	mSv/µGy.m^2	R Finger	L Finger	R Wrist	L Wrist	R Leg	L Leg
DSA PTA Ca/Ce	min	3.7E-08	4.1E-08	3.3E-08	3.3E-08	3.3E-08	3.3E-08
	max	2.0E-04	2.3E-04	9.0E-05	1.1E-04	1.1E-04	1.2E-04
	1st quartile	6.9E-07	8.3E-07	8.3E-07	1.1E-06	8.4E-07	8.4E-07
	3rd quartile	3.3E-06	75E-06	5.0E-06	8.7E-06	2.9E-06	3.0E-06
	mean	7.5E-06	1.2E-05	5.6E-06	9.2E-06	7.4E-06	9.2E-06
	median	1.6E-06	1.8E-06	2.8E-06	3.2E-06	1.7E-06	1.8E-06
DSA PTA LL	min	1.9E-07	2.3E-07	1.5E-07	1.7E-07	6.6E-08	5.8E-08
	max	1.9E-02	4.8E-02	1.4E-02	4.1E-04	6.0E-03	1.7E-03
	1st quartile	1.7E-06	4.0E-06	2.3E-06	3.7E-06	1.6E-06	1.7E-06
	3rd quartile	2.4E-05	4.2E-05	1.8E-05	2.8E-05	1.7E-05	2.2E-05
	mean	1.5E-04	3.7E-04	1.0E-04	2,.5E-05	5.6E-05	2.7E-05
	median	7.2E-06	1.5E-05	5.0E-06	1.0E-05	3.2E-06	3.4E-06
DSA PTA Re	min	2.1E-07	5,.4E-07	2.3E-07	7.5E-07	7.2E-08	7.4E-08
	max	8.2E-05	3.7E-04	2.1E-04	2.0E-04	1.6E-04	2.1E-04
	1st quartile	1.7E-06	4.4E-06	2.1E-06	3.8E-06	1.1E-06	1.5E-06
	3rd quartile	8.8E-06	2.1E-05	9.8E-06	1.7E-05	1.2E-05	2.9E-05
	mean	1.1E-05	2.6E-05	1.3E-05	1.8E-05	1.7E-05	2.6E-05
	median	4.1E-06	8.7E-06	6.1E-06	7.8E-06	4.5E-06	7.2E-06
Embolisation	min	6.0E-08	1.2E-07	4.5E-08	7.4E-08	2.8E-08	2.8E-08
	max	2.1E-04	7.3E-04	3.5E-04	3.6E-04	3.4E-04	2.9E-04
	1st quartile	1.2E-06	2.1E-06	1.5E-06	2.5E-06	9.4E-07	1.1E-06
	3rd quartile	1.2E-05	3.1E-05	1.1E-05	3.1E-05	6.8E-06	1.0E-05
	mean	1.2E-05	5.1E-05	1.2E-05	3.7E-05	1.1E-05	1.2E-05
	median	3.5E-06	6.1E-06	3.6E-06	6.4E-06	2.5E-06	3.0E-06

*DSA – Digital Subtraction Angiography and PTA – Percutaneous Transluminal Angioplasty of carotids (Ca) brain (Ce), lower limbs (LL) and renal arteries (Re)

Within the ORAMED project a lot of work was done on eye lens doses (Vanhavere et al., 2011). In general, the doses to eye lens are low, but with great variability. An overview of all the measured eye lens doses can be seen in

Table 13. The highest doses are found in embolizations, with an average value of about 60 µSv per procedure. The values for the other procedures are on average lower. However, one can see that the range of measured values is large, and that much larger values can be found. In most of the procedures monitored, values up to 1 mSv per procedure were measured in a few cases.

Table 13. Results of the measurements for the eyes (left/right) per the respective KAP values for the different procedures.

$H_p(0.07)$/KAP [mSv/µGym²]	1st quartile	Median	3rd quartile	Maximum	Average
CA/PTCA	4.2E-6	7.3E-6	1.3E-5	7.7E-5	1.0E-5
RF Ablations	3.3E-6	8.2E-6	2.0E-5	1.6E-4	1.7E-5
PM/ICD	9.1E-6	1.9E-5	5.0E-5	8.8E-4	5.4E-5
DSA/PTA Lower limbs	1.6E-6	4.1E-6	1.3E-5	5.8E-3	4.7E-5
DSA/PTA Renal	1.0E-6	2.0E-6	4.2E-6	1.1E-5	3.0E-6
DSA/PTA Ca&Ce	1.9E-6	2.8E-6	6.8E-6	4.4E-5	5.8E-6
Embolizations	2.1E-6	5.2E-6	1.9E-5	2.1E-4	2.3E-5

To check if the annual limits are exceeded, an effort was made to extrapolate the measured eye lens values per procedure to annual doses This was estimated from the logbook of the hospital/room or from personal contacts/interviews. In the following Table 14 and Table 15 the number of procedures that each operators performs is shown as well as the respective annual dose

Table 14. Extrapolated annual doses for different operators

Operator CA/PTCA	# procedures	Annual dose [mSv]	Operator embolizations + angiographies	Annual dose [mSv]
1	260	10	1	27
2	230	28	2	23
3	750	47	3	6
4	1200	69	4	4
5	1000	46	5	15
6	710	10	6	4
7	900	26	7	11
8	600	11	8	31
9	630	11	9	14
10	630	12	10	10
11	500	5	11	7
12	1000	27	12	14
13	500	30	13	20
14	600	9	14	49
15	1100	9	15	85
			16	9

Table 15. Extrapolated annual doses for different operators doing PM/ICD and RFA

Operator	procedure	#	Annual dose [mSv]	Operator	procedure	#	Annual dose [mSv]
1	PM/ICD	44	1.1	1	RFA	180	1.7
2	PM/ICD	400	31	2	RFA	60	1.1
3	PM/ICD	100	6.1	3	RFA	100	1.8
4	PM/ICD	100	1.6	4	RFA	70	0.6
5	PM/ICD	110	0.1	5	RFA	100	6.3
6	PM/ICD	100	0.2	6	RFA	65	0.2
7	PM/ICD	144	1.2	7	RFA	160	2.0
				8	RFA	210	8
1	PM/ICD+RFA	150+60	88+63	9	RFA	60	4
2	PM/ICD+RFAabl	190+190	24+13				
3	PM/ICD+RFA	90+190	25+7				
4	PM/ICD+RFA	110+50	0.8+1.5				
5	PM/ICD+RFA	40+20	4+0.1				
6	PM/ICD+RFA	40+20	7+0				
7	PM/ICD+RFA	80+350	1+5				

Concerning the eye lens dose limit, a recent ICRP statement recommends to reduce 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 lower proposed limit, the requirements for eye lens dose monitoring and radiation protection measures will be even higher. For the procedures that are mentioned above the 3/10th of the limit can be surpassed easily without the proper protection measures. As an example, in Table 13 it can be seen that for CA/PTCA half of the monitored persons would exceed the new proposed limit.

In conclusion it should be stressed that there are many parameters that affect the whole body and extremity dose of workers in interventional radiology and cardiology departments. If proper protective equipment is used then the whole body doses can be considerably low. The extremity doses can be as high as 1 mSv per procedure for complex procedures . If no proper protective shields are used then doses can be as much as 3-9 times higher. The doses to the eyes and the lower limbs of physicians can also be high if no proper lead protection is used.

2.2.3 Data and experience from international and European societies

The following classifications are based on personnel opinion of experts from the respective professional organizations.

Classification for procedures of interest for CIRSE

High dose (hundreds of mGy)

1. TIPS
2. Biliary rendez-vous
3. SFA/PTA/stenting
4. BTK interventions/limb salvage
5. Hepatic Chemoembolization
6. Thoracic and/or abdominal EVAR
7. Pelvic arterial embolization
8. Neuroembolization/head (AVM, Aneurysm, Tumour)
9. Neuroembolization/spine (AVM, Aneurysm, Tumour)

Medium dose (tens of mGy)

1. Biliary drainage (PTC)/Gallbladder drainage
2. Collection drainage
3. Ureteral stent placement
4. Vertebroplasty
5. Carotid artery stenting
6. Bleeding embolization
7. Venous sampling
8. Bronchial artery embolization
9. Stroke terapy
10. Non-vascular stent placement
11. Foreign body removal
12. Uterine fibroid embolization

Low dose (less than tens mGy)

1. Port-a-cath placement
2. PICC-line placement
3. Pelvic vein embolization
4. Nephrostomy
5. Exchange ureteral stent
6. IVC filter placement
7. Coagulation therapy (RF ablation, microwave coagulation, ethanol injection, laser ablation, cryosurgery)
8. Renal PTA/stenting
9. Iliac PTA/stenting

10. Peripheral AVM embolization
11. Needle biopsy
12. Gastrostomy

Classification for procedures of interest for European Society of neuroradiology
To be included

Classification for procedures of interest for cardiology by ESC

High dose (hundreds of mGy)
1. Multivessel PCI (stent)
2. CTO (Chronic Total Occlusions)
3. Percutaneous aortic valve implantation
4. Percutaneous mitral clip procedure

Medium dose (tens of mGy)
1. Other electrophysiologic Interventions
2. Complex PCI

Low dose (less than tens of mGy)
1. Simple PCI (one vessel)

2.3 Classification

In the final report, the WG expects to prepare a detailed table indicated for the main IR and IC procedures the level of risk for both patients and staff. As it was concluded that this classification needs to be strongly argued, the WG wishes to work further on it.

3. EQUIPMENT

3.1 Equipment used for interventional radiology and cardiology procedures

European Council Directive 97/43/EURATOM of 30 June 1997 (EC, 1997) establishes in its article 9 that:

> "*Member States shall ensure that appropriate radiological equipment, practical techniques and ancillary equipment are used for the medical exposure*
>
> - *of children,*
> - *as part of a health screening programme,*
> - *involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.*"

In a 2010 report, the IEC defines the essential performance of X-ray equipment declared by the manufacturer to be suitable for radioscopically guided interventional procedures (IEC, 2010).

It is important to underline the recommendation of not using conventional fluoroscopic units with image-intensifier/detector over the table for interventional procedures due to staff radiation protection reasons. A similar warning could be applied to C-arm mobile X-ray units without all the functionalities of an X-ray equipment declared by the manufacturer to be suitable for interventional procedures. Appropriate collective RP devises should be used in connection with the equipment. This will be discussed in the section 5.

Moreover, in the IEC report (IEC, 2010), the dosimetric indications that will be provided by the equipment are defined as follows:

Interventional X-ray equipment specified for either radioscopy or radioscopy and radiography shall satisfy the following requirements.

- The value of the mean reference air kerma rate shall be displayed during radioscopy and during serial radiography in mGy/min together with this unit. This value shall be continuously displayed at the working position of the operator during the actuation of the irradiation switch and updated at least once every second.
- The value of the cumulative reference air kerma resulting from radioscopy and radiography since the last reset operation shall be continuously displayed at the working position of the operator in mGy together with this unit and updated at least once per 5 seconds.
- The values of the cumulative reference air kerma shall be displayed within the 5 seconds following the interruption or termination of loading in radioscopy or radiography.
- During radioscopy, the values for the reference air kerma rate and the cumulative reference air kerma shall be displayed simultaneously while remaining clearly distinguishable from each other.
- The reference air kerma rate and the cumulative reference air kerma shall not deviate from their respective displayed values by more than ± 35 % over the range of 6 mGy/min and 100 mGy to the maximum values.

Interventional X-ray equipment shall be provided with an indication of the cumulative dose area product resulting from radiography and from radioscopy since the last reset operation. The dose area product may be measured or calculated. The value should be expressed in

Gy·cm^2. The overall uncertainty of the displayed values of the cumulative dose area product above 2,50 Gy.cm^2 shall not exceed 35 %.

This dose area product indication need not be provided at the working position of the operator.

If part of the interventional X-ray equipment, dose area product meters shall comply with IEC 60580.

The indications of cumulative reference air kerma and reference air kerma rate shall be clearly legible 2,5 meter from the display in the procedure room. This display may be included on an image monitor or it may be on a separate device.

The display label for the cumulative reference air kerma and reference air kerma rate at the patient entrance reference point shall not be designated as “skin dose” and “skin dose rate” respectively.

When the cumulative reference air kerma displayed on the interventional X-ray equipment exceeds a threshold expected to produce skin injury, the interventional X-ray equipment should display a visual warning to the operator. When such a display is provided, the threshold value shall be adjustable.

Finally, the Guidelines for Patient Radiation Dose Management of the SIR indicates that *“as of 2008, no manufacturer sells fluoroscopic equipment capable of providing real-time monitoring of peak skin dose[2], although aftermarket methods for estimating peak skin dose are available. However, all equipment used in the United States provides total fluoroscopy time, and many systems manufactured within the past 15 years have kerma-area-product[3] measurement capability. All equipment manufactured after June 10, 2006, and sold in the United States must also provide air kerma rate at the interventional reference point[4] and cumulative air kerma[5]. For several reasons, fluoroscopy time correlates poorly with peak skin dose, but if it is the only measurement available, it is better than not monitoring at all. Reference point air kerma correlates with peak skin dose better than does kerma-area-product, although both reference point air kerma and kerma-area-product have wide variability for different instances of the same procedure.*

Finally, clinically available dose and kerma-area-product measurements ignore the effect of backscatter from the patient. Backscatter can increase skin dose 10%–40%, depending on the beam area and energy. Estimated skin doses may differ from actual skin dose by a factor of two or more. Users of dose data should be aware of these uncertainties.”

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2 ***Peak Skin Dose:*** *The highest dose at any portion of a patient’s skin during a procedure. Peak skin dose includes contributions from both the primary X-ray beam and from scatter. Peak skin dose is measured in grays (to soft tissue)* - Extract from the glossary (Stecker, 2009).

3 ***Kerma-Area-Product:*** *The integral of air kerma across the entire X-ray beam emitted from the x-ray tube. Kerma-area-product is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. Kerma-area-product is measured in Gy·cm². Kerma-area-product is usually measured without scatter. This quantity was previously called dose-area-product. Earlier publications used the abbreviations ‘KAP’ and ‘DAP’ for this quantity* - Extract from the glossary (Stecker, 2009).

4 ***Interventional Reference Point:*** *For isocentric fluoroscopic systems, the interventional reference point is located along the central x-ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot. The interventional reference point is close to the patient’s entrance skin surface. The FDA prescribes the location of the interventional reference point for several non-isocentric geometries* - Extract from the glossary (Stecker, 2009).

5 ***Kerma:*** *Kinetic energy released in matter; the energy extracted from an X-ray beam per unit mass of a specified material in a small irradiated volume of that material (e.g. air, soft tissue, bone). Kerma is measured in grays. For the x-ray energies covered in this report, the kerma produced in a small volume of material delivers its dose to the same volume (which is not true in high-energy radiation therapy)* - Extract from the glossary (Stecker, 2009).

3.2 Roles of the manufacturers and users

The WG members agree that it is more and more difficult for the physicians to intervene on the basic parameters of the equipment. In fact before installing the machine the manufactures define particular presets depending on the procedures, which will be performed with the machine. This limits the user to adjust and adopt the protocols required for individual patients.

The members of the WG note that the standardization and the automation of the X ray equipment restrict the abilities of the user to try and better adapt the radiation exposure to the demands of the image quality. In particular, it is then difficult to take into account the physical parameters and condition of the patient (body weight, body size and the specific anatomical part that is being examined). The consequence is that the user has sometimes to use tricks to obtain correct images and these can have a negative impact on the exposure.

It may be a recommendation of the WG that the manufactures allow more freedom to the user to adjust the programs manually. In turn this requires the users to be well trained/educated and with a wide knowledge on technology issues.

3.3 Quality assurance and quality control

Quality assurance begins with appropriately selected, properly functioning X-ray equipment. Equipment should be appropriate to the intended clinical use and properly installed and configured prior to clinical use (ACR, 2006).

3.3.1 Results of the EFRS survey on Quality Assurance in interventional radiology and cardiology departments

In order to gain a better understanding of what is happening in the interventional departments across Europe, a questionnaire was distributed to the radiographer experts of the EFRS network in interventional radiology and cardiology departments in 12 countries. 9 responses were received from the United Kingdom, Ireland, Norway (3 responses), Greece, Germany, the Netherlands and Sweden. The detailed results of the survey can be found in Annex B. The main findings of the answers are as follows:

1. About half of the responding departments run a QA programme, the other half do not.
2. 8/9 of the departments keep records of patient doses, 7/9 record the fluoroscopy time and 4/9 record the number of the fluoroscopic images per patient.
3. 7/9 of the responding departments record the anthropometric patient values (height-weight).
4. All the departments (9/9) keep doses of the personnel.
5. 6/9 have threshold values[6] for the doses recorded in their departments.
6. 5/9 of the departments have reference levels of the radiation.
7. In 8/9 of the departments the radiographer monitors the dose during the procedure, and also in 3/9 of the departments the medical doctor, too.
8. 9/9 of the departments perform quality control checks to the peripheral accessories/ equipment also, like lead aprons, thyroid collars, lead screens, etc. 8/9 keep records of those tests.
9. It seems that 9/9 of the departments do not have organized meetings for QA.
10. All departments (9/9) have in their working culture for all the staff to recognize unsafe practice and to bring this to the attention of others who can correct this situation.
11. Only 1/9 has an informed consent policy with special information to the patient about the radiation risks.

[6] For the purpose of the questionnaire, a threshold was a specific level of an indicator that should prompt a review.

12. 9/9 of the departments perform monitoring/maintenance of their equipment for its stability, safety and adequate performance by qualified staff, but only 3/9 have it as part of the departmental QC checks.
13. 8/9 have a contract with the manufacturer for the monitoring/maintenance programme of the equipment/machine.
14. There is a variety of annual frequency for the maintenance of the machine: 4 times a year (1/9), 2 times a year (2/9), 1 time a year (3/9).

Having all the above in mind, a search in the most recent literature showed that there is a quiet good number of papers dealing with the subject of QA and QC in the interventional departments.

For the purpose of this project it was decided to follow only the very official papers and reviews issued from the international bodies like IAEA, ICRP and EU.

3.3.2 Quality assurance of the equipment

With age and time, radiation output and image quality of fluoroscopic equipment change. If they are left unmonitored, radiation outputs can be too low. Together with ageing image intensifiers, this is usually brought about by fading image quality that is compensated by increased dose delivery. While routine service on equipment is necessary to maintain its functionality, it is important to independently verify the performance of equipment to assure proper dose management and high image quality in all operational modes (IAEA, 2010).

Quality assurance begins with appropriately selected, properly functioning X-ray equipment. Equipment should be appropriate to the intended clinical use and properly installed and configured prior to clinical use (ACR, 2006).

3.3.3 Acceptance testing (EU Directive)

It is a requirement of the Medical Exposures Directive that acceptance testing shall be carried out on radiological equipment before its first use for clinical purposes and performance testing performed on a regular basis thereafter (EC, 1997).

Acceptance tests should be performed by the manufacturer's representative in the presence of authorized local personnel (e.g. a qualified expert in radiology physics) representing the user to decide on acceptance. It involves verification of all specifications and features of the equipment, in particular, protection and safety features.

After acceptance, commissioning is carried out, usually by the qualified expert in radiology physics, and should include all parameters and conditions of use that are expected in clinical use. At commissioning, the baseline for constancy tests is established (IAEA, 1996).

3.3.4 Maintenance programme

In order for a QA programme to be effective, it is important to have a maintenance programme in place that ensures that any malfunction of equipment, revealed by Quality Controls, is rectified. Tests may need to be performed after maintenance or repairs that may affect its imaging and/or radiation characteristics (IAEA, 2006).

Both the technical performance of the equipment and its expected clinical uses will change over time. A qualified medical physicist should test the equipment on at least an annual basis (AAPM, 2002).

The NCRP recommends a semiannual interval (NCRP, 1988).

There are three possible outcomes to this acceptability review, beyond compliance with local regulatory standards: The equipment is acceptable for all intended uses, acceptable for a limited range of intended uses, or not acceptable until repaired or replaced.

3.3.5 Role of medical physicists

As stated in the Policy Statement Nr. 2 of EFOMP (EFOMP, 1984):

> "*The clinical medical physicist must be responsible within this area of competence for the standardization and calibration of medical physical equipment and for the accuracy and safety of physical methods used in routine clinical applications in close co-operation with medical doctors and other personnel. He has also a responsibility in research and in the development of new techniques and physical methods and equipment. Further he has a responsibility for providing education and training in applied physics for doctors, nurses, medical technical assistants, etc., and student physicists and technical staff.*
>
> *The clinical medical physicist is a member of a team of personnel responsible for diagnosis and treatment of patients. The clinical medical physicist will have an influence on the diagnosis, treatment and safety procedures for the patient and thus his decisions will have consequences for the patient.*"

In the Guidelines for Patient Radiation Dose Management of the Safety and Health Committee of the SIR (Stecker, 2009) the following role appears:

> "*Appropriate review of image quality in relation to radiation dose should be performed at least annually as part of a comprehensive quality control program, as performed by a qualified medical physicist.*"

3.4 New developments: interventional radiology using CT

In the recent years interventional radiology has witnessed the introduction of new imaging techniques that have become basically essential for having several procedures correctly performed. A steady technical development has involved TC equipment and specifically acquisition velocity, imaging quality, 3D reconstruction. In addition the "flat panel" technology, only lately applied to digital angiography, has allowed TC technology to enter the angiographic world producing new 3D angiographic equipment. Conventional digital subtraction angiography (DSA) can be combined with rotational digital subtraction angiography (3D-DSA).

The first clinical application of CT Fluoroscopy (CTF) dates back to 1993 and CTF using multidetector CT (MDCT) was introduced in 1999. Their main characteristic is the possibility to generate images that are used to guide interventional procedures. The number of clinical indications for CTF using MDCT is still growing steadily. Relatively new clinical applications are guidance of radiofrequency ablations, vertebroplasty, drainage, biopsy and percutaneous ethanol injections of tumors.

The new CTF and CT angiographic equipment(s) show to be greatly advantageous to the patient's benefit. Before their introduction, in fact, the patient's specific area of interest was punctured under CT guidance and then the patient was moved into the angio-suite to have the catheter positioned or to complete the second phase of the procedure that required a constant monitoring under fluoroscopic guidance.

Nowadays, instead, the new CTF equipment allows the entire procedure to be carried out in the CT section where, under continuous fluoroscopic guidance, a precise positioning of the needle can be achieved through axial images, where the correctness of the needle position as well as of any other device can be exactly checked and controlled. Besides increasing the

patient's comfort, another advantage is that the risk of infections or of peri-procedural complications is highly reduced.

Such good outcomes are negatively affected by a too high exposure to radiation especially of the medical staff.

Flat panel detectors (FPD) mounted on dedicated gantry systems or interventional C-arms are currently used also for CT scanning. These scanners are used for interventional radiology and angiography or image-guided radiation therapy units and offer large coverage of up to 200 mm. Volumetric imaging provided in the operating room has proved to be valuable for intraoperative procedures and is available for navigation and fusion with other preoperative or postoperative imaging modalities.

Real time CT is generally performed at a low tube current, e.g. 30-70 mA. Images are usually reconstructed on a 256×256 matrix, with frame rates of up to 12 per second. For CTF, additional hardware is required to initiate exposures and to move the table, usually this consists of a foot switch, or bed mounted control. A monitor for viewing the CT fluoroscopy output is also required in the scanner room. Real time CT and CTF are often sold as separate packages, so the purchase of a system with real time capabilities does not necessarily imply that CTF will also be available.

The image quality of modern C-arm scanners has improved, especially with respect to low-contrast detectability. The first C-arms with use of CT functionality were equipped with image intensifier tubes and had their application, especially in the very-high-contrast angiographic imaging, working with contrast differences of more than 1000 HU. Current systems are equipped with FPDs and offer a significant improvement in low-contrast resolution. Contrast differences of down to 10HU can be detected, which is a qualitative highlight.

Special attention to patient and staff dosimetry and risk assessment is needed for CT-guided interventions because exposure times during CTF-guided procedures can be long compared with diagnostic CT acquisitions. Saving dose during interventional procedures is very important for the patient, but also for the interventionalist and the staff in the room during the examination. General recommendations for improving radiation protection in CTF include the following:

- raise workers awareness about the need for proper radiation protection by supplying workers frequently (e.g., every 2 weeks) with a new legally required personal dosimeter and updated dose reports;
- use the gantry laser lights and a laser goniometer to accurately position needles because it helps to reduce CTF time and radiation exposure;
- use appropriate shielding (lead apron, thyroid shield) to reduce radiation exposure to the workers;
- select a low tube current that results in reduced but adequate image quality due to an increase in image noise, because it also reduces radiation exposure for workers and patients;
- apply a quick check acquisition instead of dynamic CTF because it helps to reduce radiation exposure for the workers and patient;
- maintain as much distance as possible from the gantry during CTF because it is a simple and efficient measure to reduce radiation exposure for workers.

It is not surprising that this concern has led to increased scrutiny with regard to the accuracy of radiation dose assessment to patients who undergo CT examinations. C-arm FPCT again has substantial changes in geometry, providing collimations by far higher than the 100-mm recommended integration length of the CT dose index (CTDI) standard. In addition, the systems use partial rotation scanning, which is expected to result in inhomogeneous dose distributions in the patient. It is also questionable if the common phantoms are sufficient for dosimetry with use of wide-beam fields. The use of C-arm CT can be compared with

standard CT in exposure and can vary from very low to high dose depending on the protocols used and cannot be ignored. Of course, this dose application has to be regarded with respect to the total exposure during intervention in which additional fluoroscopy or DSA scans (2D) are often necessary.

3.4.1 Dose to Patient

For the patient, the dosimetry associated with real time CT is broadly the same as conventional CT. However, there are differences in two main areas; firstly, the tube current is low, at around 50 mA, compared to 150-300 mA for a conventional abdomen scan; secondly, the irradiation is concentrated in a smaller area than for a conventional CT examination. This concentration of the dose can give rise to larger local skin doses.

A study of published papers on real time CT found a typical scanning time for a CT fluoroscopy biopsy or drainage procedure to be approximately 120 seconds. Reported screening times vary widely, from 5 to a maximum of 660 seconds. This wide variation is due to differing techniques, levels of operator experience and workloads studied, as well as the levels of difficulty of individual procedures.

The skin dose rate for real-time CT is in the range of 4-5 mGy/s. Using the typical CT fluoroscopy scan time of 120 s produces a total skin dose of approximately 500-600 mGy. The maximum reported scan time of 660 seconds would give a skin dose of up to 3 Gy. Bearing in mind that the thresholds for skin erythema and temporary epilation are approximately 2 and 3 Gy respectively, there is a potential for deterministic radiation effects from lengthy CT fluoroscopy procedures. The effective dose from a typical CT fluoroscopy procedure is in the region of 6-8 mSv, which is in the same range as a typical conventional CT abdomen examination.

Audible alarms that sound after a pre-set time limit are included with all real time scanners, although the time limit is not standardized. For conventional image intensifier fluoroscopy systems, the time limit is 5 minutes, with a maximum skin dose rate of 100 mGy/min. As the skin dose rate from real time CT is 2-3 times higher than this, a similar skin dose limit for CT fluoroscopy would imply an alarm that sounded after 100 seconds.

The peak entrance skin dose can be estimated for deterministic skin effects. A peak entrance skin dose of 2 Gy is a safe and pragmatic warning level for relatively high skin dose in the context of radiation-induced acute skin reactions. Temporary skin injury originating in the epidermis is not expected at a peak entrance skin dose of 6 Gy. Serious skin effects originating in the dermis may occur at a peak entrance skin dose of 10 Gy or higher.

Patient dose (effective dose, peak entrance skin dose) and occupational dose (occupational dose equivalent, effective dose) in CTF using single-detector CT has been evaluated in various studies.

The median value of 15 μSv for the measured occupational dose equivalent is between the average values that were reported by Teeuwisse *et al.* (7 μSv for drainage, 5 μSv for biopsy, and 2 μSv for treatment of osteoid osteoma) and Paulson *et al.* (25 μSv).

3.4.2 Dose to Operator

CT scanning does not normally involve dose to the equipment operator, who is in a separate control room. However, CTF procedures are interactive, and require the operator to be in the scanner suite. Considerable doses can be accumulated, especially to the skin of the hands, when conducting multiple procedures. A variety of techniques can be employed to avoid these doses, the most important of which is to ensure that the hands are out of the beam when the scanner is operating. The tightly collimated x-ray beam on a CT scanner means that the dose rate drops very rapidly away from the scan plane, and the use of a pair of

forceps to manipulate the biopsy or drainage needle from a distance will greatly reduce the dose rate to the hands.

The dose rates are obviously highly dependent on the position of the operator relative to the scanner. M. Ozaki (Ozaki, 1995) states that the use of a lead apron reduces the dose rate by a factor of 14 for 120kV exposures, which would mean that dose to the skin and the body become equally important in order to keep within dose limits.

In a study performed by ImPACT (St. George's Hospital, London: Real Time CT and CT Fluoroscopy V 1.11) during the procedures, workers were predominantly facing the source of scattered radiation (the patient), so there is no significant effect due to the angular response of the dosimeter. The interventional radiologist received the highest median occupational dose equivalent per procedure (median, 14 μSv; maximum, 1,636 μSv), followed by the assisting radiologist (median, 5 μSv; maximum, 1,884 μSv) and the radiologic technologists (median, 1 μSv; maximum, 133 μSv). Note that these values were measured outside the lead apron and thus do not represent effective dose for the worker. The actual median effective dose was 3 μSv for the interventional radiologist and less than 0.4 μSv for the assisting radiologist and radiologic technologists.

C-arm CT combined with suitable software (e.g. navigation) may support the clinical workflow and can result in a lower dose by simply reducing the overall exposure time. In addition, CT-guided interventions have the potential to minimize the additional fluoroscopic time in the operating room needed for control scans and, perhaps, also additional postoperative CT scans. Additional developments regarding the improvement of image quality for these systems will potentially result in a dose reduction for the same image quality. The use of thin-collimated scans or advanced methods such as multi-resolution local tomography could also help to maintain image quality in a volume of interest while reducing patient dose.3,6 Furthermore, more sophisticated AEC methods as well as spectral optimization (e.g. tube filtration) combined with improved reconstruction algorithms could lead to additional improvements.

The important and rational aim of reducing exposure to radiation makes for the operator mandatory to be continually aware, during the procedure, of the exact radiation dose. In order to vary the acquisition parameters and maintain a lower exposure.

To monitor the patient dose constantly while treating patients, the dose values are displayed on the monitors in the examination and the control room.

Some angiographic equipment of the latest generation (Angio-CT) allows the patient dose to be constantly monitored while treating patients. The dose values are displayed on the monitors in the examination and in the control room. For instance the ArtisZee (Siemens, Erlangen, Germany) is equipped with a “careguard” system from which the interventionalist receives a warning on the live display in the examination room as well as a popup message on the table side ECC (Examination Control Console), which indicates that a certain predefined skin dose level has been reached. Three skin dose levels can be defined by the institution. Physicians can treat their patients without constantly worrying about radiation and still meet clinical requirements. At the end of the procedure, an examination or patient protocol is stored together with the acquired images. All information on each run is stowed and listed in the protocol with the number of exposures, total fluoro time, total dose area product and total dose at IRP. This protocol can also be sent to a PACS system, printed, stored or sent as a DICOM structured report for further evaluations.

Performance of several interventional procedures is today being greatly facilitated by real time CT and CT-angiography that can reduce possible complications and extend their practical applications to the many fields of interventional radiology.

Monitoring the doses to patients and operators groups is important. Measures to reduce the doses to both the patient and operator are: exposure time kept to a minimum for patient’s and operator’s benefit, as well as the use of lead aprons, needle holders, thyroid shields and lead glasses for the operator should be carefully considered.

4. EXPOSURE MONITORING

4.1 Monitoring of patient dose

The following paragraphs are extracted from the Guidelines for Patient Radiation Dose Management of the SIR (Stecker, 2009). Information on equipment used for monitoring of patient dose is available in the section 3 of the document.

4.1.1 Introduction

In Interventional Radiology both biological effects (deterministic and stochastic) have to be considered:

- *Deterministic injuries[7] occur only after the radiation dose to the tissue exceeds a given threshold dose. In interventional fluoroscopy procedures, the issue of concern is the skin although the lens of the eye is another consideration. The skin at the site where radiation enters the body receives the highest radiation dose of any body tissue. Once the threshold dose is exceeded, the injury becomes progressively more severe with increasing dose, although the true severity of major injuries will only become apparent weeks to months after the procedure. Very high doses usually produce some symptoms within 24 hours of the procedure.*
- *Stochastic effects[8] must also be considered. The likelihood of stochastic effects increases with the total radiation energy applied to the patient. The principal injury is the induction of a malignancy. The probability of a radiation-induced malignancy caused by an invasive procedure is small compared to the "natural" frequency of malignancies. Based on published data, the frequency of fatal malignancy in the U.S. population is about 21%. With use of the linear no-threshold model, a typical interventional procedure is estimated to increase the risk of developing a fatal cancer by less than 0.5% in adults (estimating a worst-case effective dose[9] of 100 mSv, which is multiplied by a risk of 5% per Sv), assuming a normal life span. The probability of a new (non-radiation-induced) malignancy being diagnosed in the next 10 years is about 16.5% for a 60-year-old man.*

4.1.2 Dose documentation

Estimated radiation dose is recorded in the medical record, preferably the formal procedure report, for every procedure. Existing SIR guidelines for recording patient radiation dose detail that ideally the peak skin dose and kerma-area-product are recorded, as they are the most useful predictors for deterministic and stochastic effects, respectively. If peak skin dose is not

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7 ***Deterministic Effect:*** *Detrimental health effect for which the severity varies with the dose of radiation, and for which a threshold usually exists (i.e. causally determined by preceding events). The effect is not observed unless the threshold is exceeded, although the threshold dose is subject to biologic variation. Once the threshold dose is exceeded in an individual, the severity of injury increases with increasing dose. Examples of deterministic effects include skin injury, hair loss, and cataracts* - Extract from the glossary (Stecker, 2009).

8 ***Stochastic Effect:*** *A radiation effect whose probability of occurrence increases with increasing dose but whose severity is independent of total dose. Radiation induced cancer is an example* - Extract from the glossary (Stecker, 2009).

9 ***Effective Dose (E):*** *The sum, over specified tissues, of the products of the dose in an organ and the tissue weighting factor for that tissue. Current techniques for estimating effective dose use computer simulation based on a "model" body and statistical simulations of radiation exposure. This yields only a gross approximation of effective dose. The stochastic risk to an average member of an irradiated population is expressed in terms of sieverts (Sv). Effective dose is often used in the literature to roughly estimate the radiogenic risk to an individual. Age and sex modifiers, appropriate to the irradiated individual, should be applied to such calculations* - Extract from the glossary (Stecker, 2009).

available on a fluoroscopic system, reference point air kerma[10] is an acceptable substitute. If none of these other parameters is available and fluoroscopy time is used as the radiation dose metric, recording the total number of fluorographic images acquired during the procedure is also helpful for reconstructing the estimated dose. However, fluoroscopy time should not be used as the only metric of estimated radiation dose if any of the others are available.

4.1.3 Procedural Radiation Monitoring

Radiation dose is monitored throughout the procedure. This responsibility may be delegated to a technologist, nurse or other personnel depending on the institution's policy and needs and in accordance with relevant laws and regulations. The following rules should be applied in order of availability of radiation monitoring technology:

- *For fluoroscopy units that can provide estimates of peak skin dose, the operator is notified when this reaches 2,000 mGy, then every 500 mGy after that.*
- *For units with reference point air kerma capability, initial notification is given at 3,000 mGy and then every 1,000 mGy thereafter.*
- *For units with kerma-area-product capability, the notification level is based on a procedure-dependent nominal x-ray field size at the patient's skin. With use of a 100 cm² field, the initial report would be at 300 Gy·cm² and subsequently at increments of 100 Gy·cm². Note that different brands of fluoroscopes report kerma-area-product using different units.*
- *For units that can only monitor fluoroscopy time, the operator is notified when the total fluoroscopy time has reached 30 minutes and then in increments of 15 minutes or less. Notification intervals should be reduced for procedures that involve a relatively large number of fluorographic images (including digital subtraction angiography and cineangiography). All fluoroscopes display fluoroscopy time. However, because of poor correlation with other dose metrics, it should be used with caution to monitor patient irradiation.*

4.2 Patient follow-up

The Diagnostic Reference Levels (DRLs) are not an appropriate tool to manage the deterministic radiation risks from interventional procedures, in particular radiation-induced skin injuries. To limit the occurrence of such effects after an interventional procedure, there is a need to monitor in real time parameters whose interpretation could be used to determine if deterministic effects could occur or not. This should of course be accompanied with an appropriate follow-up of the patient after the procedure to detect the eventual occurrence of such effects.

In its Guideline for patient radiation dose management, the SIR has defined criteria to organize the follow-up of patients after an interventional procedure (Stecker, 2009): adult patient who received a significant radiation dose during an interventional radiology procedure should be followed-up depending on the criteria defined in Table 16. According to the SIR, the follow-up is organized as follows if one or more of the criteria was exceeded:

- The patient is given written radiation follow-up instruction on its discharge sheet: the irradiated zone should be inspected for sign of redness or rash two weeks from the time of the discharge,

[10] ***Reference Point Air Kerma (Ka,r):*** *The air kerma accumulated at a specific point in space relative to the fluoroscopic gantry (see interventional reference point above) during a procedure. Reference point air kerma does not include backscatter and is measured in grays. Reference point air kerma is sometimes referred to as reference dose, cumulative dose, or cumulative air kerma. Earlier publications used the abbreviations 'CD' and 'RPDose' for this quantity* - Extract from the glossary (Stecker, 2009).

- The patient is asked to notify the operator and/or a qualified medical physicist of the results of self-examination of the irradiated area (even if the result is negative),
- If the result of the self-examination is positive, clinical follow-up is then arranged for findings of deterministic radiation effects.

Table 16. Thresholds for patient follow-up as recommended by SIR (Stecker, 2009)

Parameter	Threshold
Peak skin dose (PSD)	3,000 mGy
Reference point air kerma	5,000 mGy
Kerma area product (KAP)	500 Gy.cm^2
Fluoroscopy time	60 min

This issue of patient follow-up after an interventional procedure has also been treated in a 2005 joint document of the US National Cancer Institute and the US Society of Interventional Radiology (NCI-SIR, 2005). After an interventional procedure, the radiation dose delivered should be reviewed and according to the results appropriate steps should be taken to insure the follow-up of the patient. The following criteria are defined:

- Schedule a follow-up visit 30 days after the procedure for all patients who received a radiation skin dose of 2 Gy or more or a cumulative dose of 3 Gy or more,
- Send the interventional fluoroscopy procedure description, operative notes, doses and information about possible short-term and long-term effects to the patient's primary care provider,
- The patient and primary care physician should be specifically requested to notify the operator and a dermatologist if observable skin effects occur.

As a conclusion, an adequate procedure should be defined to organize the follow-up of patients after an interventional radiology or cardiology procedure with the objective to detect and to treat as soon as possible the occurrence of deterministic effects. The analysis of the parameter measured during the procedure in function of pre-determined specific parameters can help to define the appropriate follow-up strategy.

4.3 Monitoring of staff dose

For the estimation of the effective dose for staff involved in IC and IR procedures, double dosimetry is recommended. Double dosimetry is the use of two dosemeters, one located above and one under the protective apron. The algorithms that exist for the determination of the effective dose are presented in the review paper by Järvinen (2008) (see Table 17). Tasks related to the national practices and recommendations in many European countries are also presented. It was found out, through a circulation of a questionnaire, that regulations for double dosimetry almost do not exist and there is no firm consensus on the most suitable calculation algorithms. The calculation of effective dose is mainly based on the single dosemeter measurements, in which either personal dose equivalent, directly, (dosemeter below the apron) or a fraction of personal dose equivalent (dosemeter above the apron) is taken as an assessment of effective dose. The most recent studies suggest that there might not be just one double dosimetry algorithm that would be optimum for all interventional radiology procedures.

Table 17. Algorithms for the calculation of the Effective Dose using one or two dosemeters

Authors	Algorithm	Place of dosemeters	Remarks
1. Wambersie (1993)	**E = Hu + 0.1Ho**	Hu: chest Ho: neck or shoulders	
2. Rosenstein (1994)	**E = 0.5Hu + 0.025Ho**	Hu: waist Ho: neck	Based on Faulkner (1993) Not supported by Mateya and Claycamp tests=underestimation 1.4-3.3 times
3. NCRP (1995)	Double: same as No. 2	Ho: neck	Based on data published until (including) 1993
4. Huyskens (1994)	Single: E = Ho/D or E= H_uM		D=5 and M=3 for fluoroscopic interventional practice
5. Niklason (1994)	Double without TS: **E = 0.06(Hos - Hu) + Hu** Double with TS: **E = 0.02(Hos - Hu) + Hu**	Hu: waist Hos: collar *os: over collar shallow dose-* $H_p(0.07)$	Single algorithm: *Recommended by Padovani (2001); assuming Hu ~0.01Hos Tested by Mateya (1997) and Kicken (1999)
6. Swiss ordinance (1999)	**Hp(10) = Hu + aHo** a = 0.1 without TS a = 0.05 with TS **Hp(0.07) = Hu + Ho**	Not defined	Without TS same as No.4.
7. McEwan (2000)	Double without TS: **E = 0.71Hu + 0.05Ho**	Hu: trunk Ho: collar	Based on E/Hp(10) ratios for AP exposures published by NRPB (1993)
8. Franken (2002)	Double without TS: **E ≤ Hu + Ho/10** Double with TS: **E ≤ Hu + Ho/30**	Ho: mid front (1) Hu: mid front (2) Ho: mid front (3)	Lead apron: at least 0.25 mm lead (1) At collar or chest level (2) At waist level (3) At collar level
9. Sherbini (2002)	**E = 1.0Hu + 0.07Ho**	Hu: waist Ho: neck	Used MC but with direct exposure from point source and not scatter
10. Boetticher et (2003) and Lachmund (2005)	Double without TS: **E = 0.65Hu + 0.074Ho** Double with TS: **E = 0.65Hu + 0.017Ho**	Hu: anterior thorax Ho: neck	
11. Clerinx (2008)	Double without TS: **E = 2.25Hu + 0.120Ho[1]** Double with TS: **E = 2.25Hu + 0.097Ho[2]** <u>Worker-tube distance<50cm</u> Double without TS: **E = 1.64Hu + 0.075Ho[3]** Double with TS: **E = 1.64Hu + 0.058Ho[4]**	Hu: thorax Ho: neck	Variable under couch geometry, [1]Max overestimation 146% [2]Max overestimation 235% [3]Max overestimation 60% [4]Max overestimation 105% Estimation within a 10% underestimation margin for all formulas

Table 17 (continued). Algorithms for the calculation of the Effective Dose using one or two dosemeters

12. Boetticher (2010)	Double without TS: **E = 0.79Hu + 0.1Ho** Double with TS: **E = 0.84Hu + 0.051 Ho**		Conservative approach taking into account ICRP 103 (ICRP, 2007a)

Hu: under apron dose - Ho: over apron dose - E: effective dose - Hos: overcollar shallow dose - TS: thyroid shield.

As it has already been mentioned extremity doses can be as high as 1 mSv per procedure in the IR and IC fields. 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" according to ICRP recommendations (ICRP, 2007) cannot easily be found. In most cases only finger or hand doses are reported; doses to the eye lens or legs are not usually evaluated. Even when ring/hand dosimetry is used for extremity monitoring the position of the dosemeter is not clear. There is evidence that eye lens doses are high in interventional radiology, and cases of cataracts 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. Up to now, there was no suitable dosemeter available and the standards for the operational quantity measurements were not complete. This situation is partly due to the lack of conversion coefficient and 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.

ORAMED project raised the above issues. One of the main goals of the ORAMED project was to obtain extensive extremity dose data for staff in IR/IC departments, with special attention to eye lens doses in order to give recommendations for the monitoring of the extremities and eye lens doses and the protection of the medical staff. The personal dose equivalent, Hp(3), is considered as the proper operational quantity to control the eye dose limits. A proper dosemeter was developed within the project, as well as, a suitable phantom for its calibration and respective conversion coefficients from air kerma to Hp(3). Finally recommendations on the selection and use of APDs in IR and IC fields were given.

About the position of the maximum in IC procedures figure 5 (a) shows the frequency of the position where the maximum dose was recorded. It can be seen that most frequently the maximum dose was recorded at Left Finger, Left Wrist and Left Leg positions. Clear preeminence of Left 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. However, since the annual limit for hands and legs (500 mSv) is different to that for eyes (150 mSv), it has to be taken into account (ICRP, 2007). This is done on figure 5 (b) which shows the frequency of the position where the maximum ratio of the dose to the annual limit for the corresponding position is seen. It is observed that the eyes become more important, with a frequency level similar to that of the other positions. Moreover, the position of the maximum dose of operators in IR procedures has been studied. In figure 6a it is clear that the highest frequency of the position of the maximum dose is on the left finger (23%) and left wrist (22%). However, since the annual limits for the hands and legs (500 mSv) are different from the respective limits for the eyes (150 mSv), the relative contribution is not the same. Figure 6b shows the frequency of the position where the maximum ratio of the dose to the respective annual limit for the corresponding position was recorded. In this case it is seen that the maximum contribution comes from the Left eye (34%).

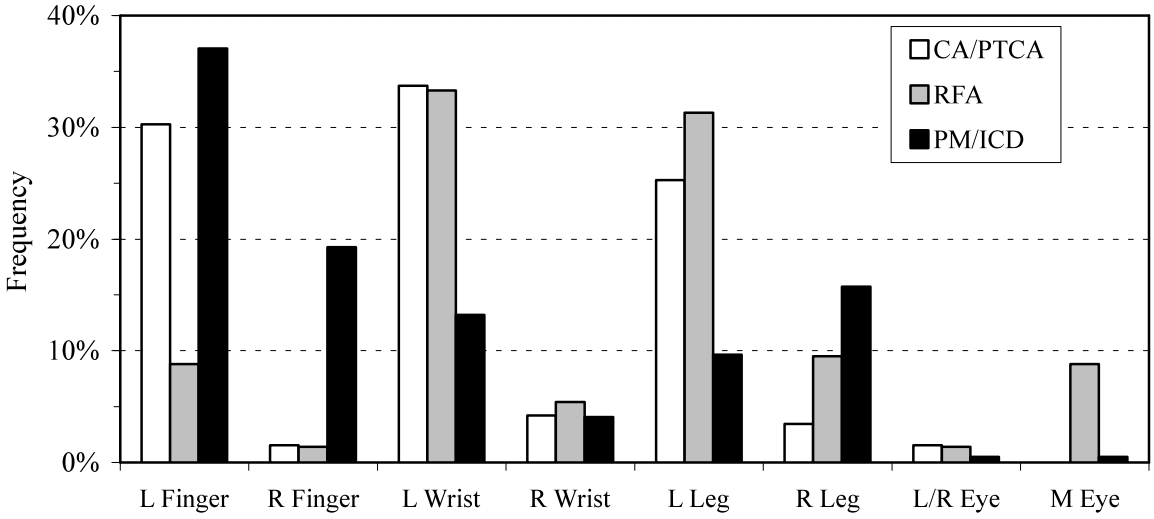

Figure 5a. Position of the maximum dose in IC procedures

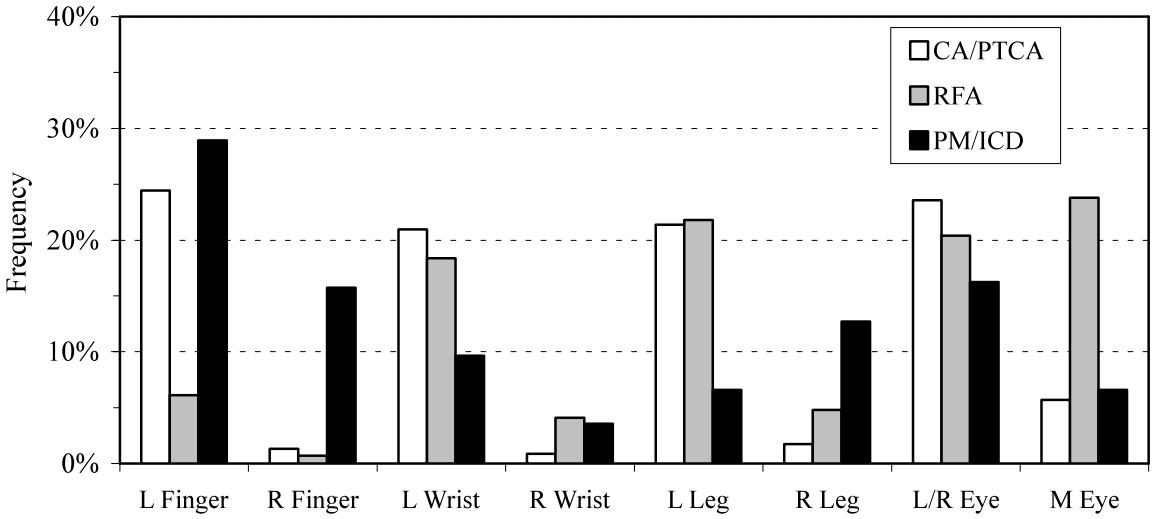

Figure 5b. Position of the maximum dose normalized to the respective annual limit

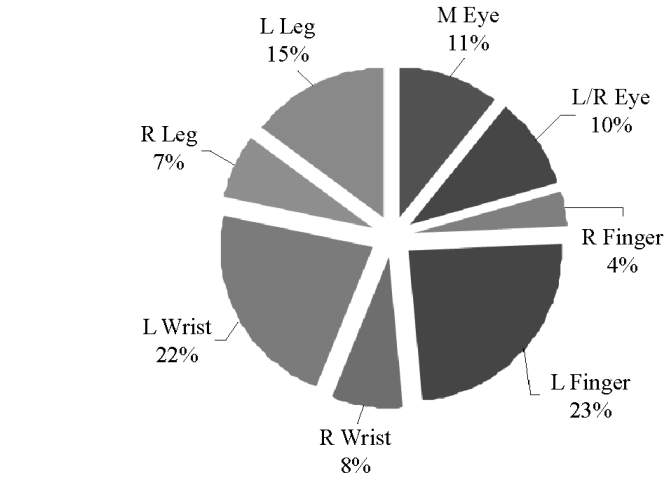

Figure 6a. Position of the maximum dose in all IR procedures

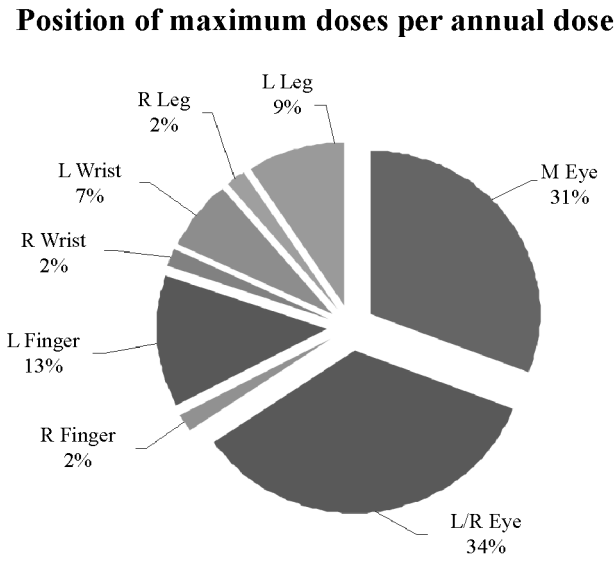

Figure 6b. Position of the maximum dose normalized to the respective annual limit

The names for the measurement points that are used in the above figures are: L Finger and R Finger (for the left and right finger respectively), L Wrist and R Wrist (for the left and right wrist respectively), L Leg and R Leg (for the left and right leg respectively), and L/R Eye and M Eye (for the left or right eye and the region between the eyes respectively).

Furthermore, the annual eye lens doses depend vary a lot and largely on the workload and the protection measures used (Figure 7). The present dose limit of 150 mSv per year for $H_p(3)$ is generally not reached, but doses can be sufficiently high so that monitoring is recommended for all IR and IC procedures (Vanhavere et al. 2011). 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.

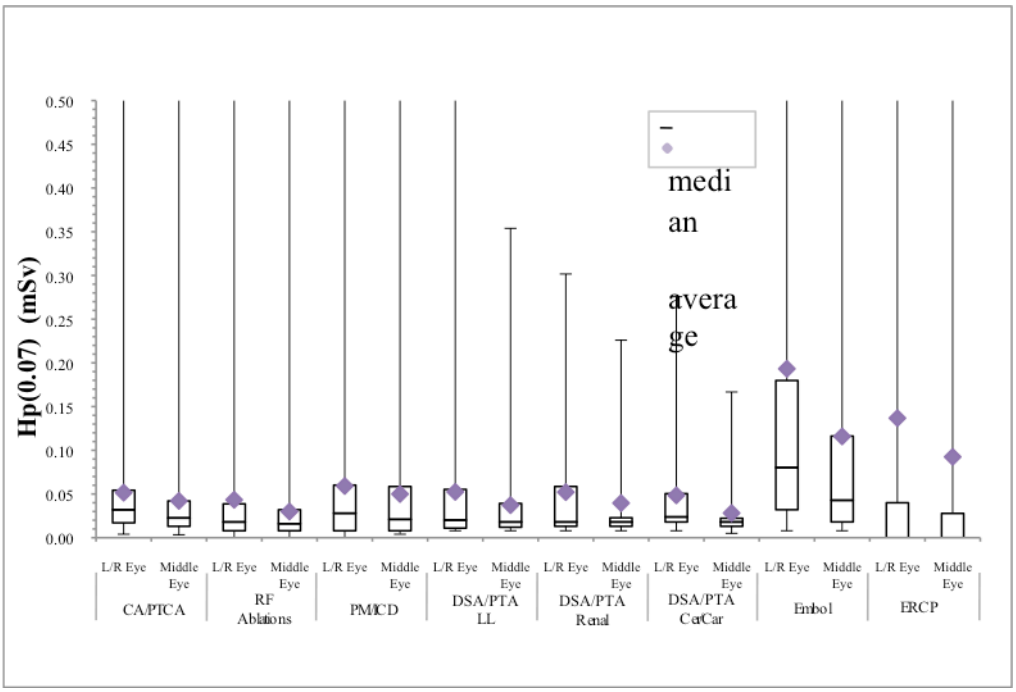

Figure 7. Measured $H_p(0.07)$ values at the eyes during the different procedures. The minimum, 1st quartile, median, 3rd quartile, mean (diamond) and maximum values are shown

Finally the APDs that are used in IR and IC fields has to fulfil the requirements of the IEC 61526 standard, 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 $Sv.h^{-1}$.

One important thing about the APDs is that they should be able to measure low-energy photons and pulsed radiation with relatively high instantaneous dose equivalent rates ususlly encountered in IR and IC fields.

References: Balter (2004), Balter (2008), Donadille (2008)b, Duran (2010), IAEA (2010), ISEMIR (2010), Järvinen (2008), Miller (2003), Padovani (2005), Soye (2008)

5. RADIATION PROTECTION OPTIMIZATION DURING INTERVENTIONAL PROCEDURES

In 2005, the US National Cancer Institute and The US Society of Interventional Radiology published a joint document on the reduction of radiation risks for patients and staff in interventional fluoroscopy (NCI-SIR, 2005). The immediate and long-term strategies to optimize both patient and staff exposure were synthesized (Table 18).

Quite recently, the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) and the Society of Interventional Radiology (SIR) published joint guideline on patient radiation dose management (Strecker, 2009) on one hand and on occupational radiation protection in interventional radiology (Miller, 2009) on the other hand. Occupational radiation protection should not only include interventional radiologists, radiographers and nurses, who spend a substantial amount of time in a radiation environment, but also other professionals such as anaesthesiologists, who may work occasionally in such an environment. According to this publication key points to optimize exposure to professionals are the following:

- Minimize fluoroscopy time,
- Minimize the number of fluorographic images,
- Use available patient dose reduction technologies,
- Use good imaging-chain geometry,
- Use collimation,
- Use all available information to plan the interventional procedure,
- Position the professional in a low-scatter area,
- Use protective shielding,
- Use appropriate fluoroscopic imaging equipment,
- Obtain appropriate training,
- Wear the dosimeters and be aware of the dose received.

Of course, many of the above key points to optimize occupation exposure also contribute to optimizing exposure of patients (equipment should be operated at the lowest fluoroscopic dose rates that yields adequate images; pulsed fluoroscopy should be used at the lowest pulse rate that yields adequate quality image; minimize fluoroscopy time and number of fluoroscopic images; use of appropriate collimation). Some other technical choices will also favour reduction of patients exposure: maximization of source-to-image receptor distance; minimization of object-to-image receptor distance; use if image magnification only when essential clinically; variation of C-arm angles from time to time if this does not interfere with the conduct of the clinical procedure. Most of these techniques for both staff and patients are in accordance with US societies' recommendations.

However, apart from the technical means to reduce patient exposures, the CIRSE-SIR guidelines on patient dose management also insist on the importance of staff training, information and consent of the patient before the procedure, dose documentation and patient follow-up after the procedure.

Moreover, during the ORAMED project the following guidelines (Carinou et al., 2011) were drawn for the optimization of staff protection:

• 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 during the ORAMED project it was observed that the majority of the operators wear protective apron and thyroid collar. However, there is a 2% of the operators in IR who do not use any personal protective equipment.
- 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.
- 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.
- 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.
- 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 measurement 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 beam 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 7 times for the various positions that were monitored. Figure 4 shows the median Hp(0.07) values divided by the respective KAP ones for all monitored positions. The results refer to CA/PTCA procedures for femoral and radial access of the catheter. As it is shown from the figure, the doses received at the various positions when the femoral access is used, are lower than the ones for the radial access. Moreover, it is observed that the left finger is more affected by the use of the femoral access since it is the part of the operator closer to the irradiation field.
- The use of an automatic image injector can reduce the doses to the various monitored positions significantly (4 to 16 times), especially to the hands.
- The operators should avoid direct exposure of hands to primary radiation. Many bad practices were observed within the ORAMED project where the hands of the operators were displayed on the monitors of the systems.

- Monitoring of the eyes and fingers (or wrists) should be performed on routine basis.

Table 18. Immediate and long-term strategies to optimize both patient and staff exposure as recommended by the US National Cancer Institute and the US Society of Interventional Radiology

Immediate	Long-term
Optimize dose to patient	
Use proper radiologic technique: • Maximize distance between X-ray tube and patient, • Minimize distance between patient and image receptor, • Limit use of electronic magnification. **Control fluoroscopy time:** • Limit use to necessary evaluation of moving structures, • Employ last-image-hold to review findings. **Control images:** • Limit acquisition to essential diagnostic and documentation purposes. **Reduce dose:** • Reduce field size (collimate) and minimize field overlap, • Used pulsed fluoroscopy and low frame rate.	**Include medical physicist in decisions** • Machine selection and maintenance. **Incorporate dose-reduction technologies and dose-measurement devices in equipment** **Establish a facility quality improvement program that includes an appropriate X-ray equipment quality assurance program, overseen by a medical physicist, which includes equipment evaluation/inspection at appropriate intervals**
Minimize dose to operators and staff	
Keep hands out of the beam **Use movable shields** **Maintain awareness of body position relative to the X-ray beam** • Horizontal X-ray beam - operator and staff should stand on the side of the image receptor, • Vertical X-ray beam - the image receptor should be above the table. **Wear adequate protection** • Protective well-fitted lead apron • Leaded glasses	**Improve ergonomics of operator and staff** • Train operator and staff in ergonomically good positioning when using fluoroscopy equipment; periodically assess their practice, • Identify and provide the ergonomically best personal protective gear for operators and staff, • Urge manufacturers to develop ergonomically improved personal protective gear, • Recommend research to improve ergonomics for personal protective gear.

5.1 Procedure performance

5.1.1 Quality Assurance

Even when equipment safeguards are in place, users may not have received adequate training in the proper use of these features and the importance of optimizing radiation dose. Additionally, imaging facilities may not have adequate quality assurance practices in place, such as regular evaluation of their study protocols and equipment.

Some steps have been taken to address these issues (FDA, 2010).

5.1.2 Quality indicators

Although fluoroscopy time is not a good predictor of patient dose, it is a very good indicator of quality in procedure performance; at least as far as radiation use is concerned. The same is true of KAP. These two quantities should be monitored routinely and reviewed to assess whether there exists any procedures for which these dose surrogates appear to exceed the normal range. The reasons for the aberration should be identified. Feed back to the interventionalist can assist in maintaining or improving dose management skills (IAEA, 2010).

5.2 Diagnostic Reference levels

The concept of diagnostic reference levels (DRLs) was developed as a tool for optimization of protection in the exposure of patients for common diagnostic purposes. As stated by ICRP (ICRP, 2007a), DRLs "*are used to indicate whether in routine conditions, the levels of patient dose from […] a specified imaging procedure are unusually high or low for that procedure*". "*In practice, the values are selected on the basis of a percentile point on observed distribution of doses to patients or to a reference patients*". Thus, DRLs are defined based on the feedback experience on observed data and are generally specific to a country or a region. The DRLs are well established for common, simple and standardized procedures in many countries. Their implementation produced an increased awareness among professionals and stimulated corrective actions by facilities which has finally implied reduction in the radiation dose to patients.

However, the definition and implementation of such diagnostic reference levels in interventional radiology and cardiology are much more controversial, mainly due to the specificities of these procedures, which make difficult to define a standard examination associated with a standard patient. In particular, interventional radiology and cardiology procedures can be diagnostic, therapeutic or a combination of both. Individual procedures can have a wide range of complexity accompanied by a wide range of exposure levels for instance due to patient sizes and diseases. Moreover, as underlined by IAEA (IAEA, 2009), philosophical and ethical question are raised in relation with the definition of DRLs for interventional therapeutic procedures if the concept of DRL is misunderstood: it is inappropriate to curtail an uncompleted procedure on the basis of radiation exposure exceeding the DRL. It is important to systematically remind that DRLs must be applied "*with flexibility to allow higher exposures if these are indicated by sound clinical judgement*".

In that context, many national or international studies have been performed in the last year to establish and/or propose DRLs for interventional procedures. The definition of the DRLs is usually based on the 75th percentile of the appropriate distribution. The Table 19 and Table 20 summarize the DRLs proposed respectively for interventional cardiology procedures and for different interventional radiology procedures.

In a pilot study performed within the scope of IAEA, the complexity of the procedure was taken into account to propose DRLs for PCI (Balter, 2008; IAEA, 2009). The complexity is defined as a parameter which differentiates individual cases of the same procedures depending on the patient's anatomy, the location and severity of the pathology. A complexity index for PCI procedures was then defined as follow:

$$Complexity\ index = NV + NLT \times 0.51 + NO \times 0.73 + NST \times 0.69 + NBF \times 0.58$$

where *NV* is the number of vessels treated during the procedure; *NLT* is the number of lesions with an ACC/AHA complexity greater than B2; *NO* the number of occlusions > 3 months; *NSV* is the number of vessels with severe tortuosity; and *NBF* is the number of bifurcation stents placed during the procedure. The DRLs defined depending on the complexity index for PCI can be found in Table 21.

Table 19. Diagnostic Reference levels for interventional cardiology procedures

Type of examination	Diagnostic Reference levels			Reference
	Fluoroscopy time (min)	Number of images	KAP (Gy cm^2)	
CA	5.6	/	36	Hart (2000)
	5.0	/	42	D'Helft (2009)
	9	1,000	50	Balter (2008)
	6.0	/	57	Neoffotistou (2003)
	/	/	71.3	Bogaert (2009) [a]
	7	1,400	80	Aroua (2007)
PCI	14.6	/	63.4	Hart (2000)
	18.0	/	84	D'Helft (2009)
	16.0	/	94	Neoffotistou (2003)
	/	/	106.0	Bogaert (2009) [b]
	20	1,500	110	Aroua (2007)
	22	1,700	125	Balter (2008) [c, d]
CA + PCI	20	2,800	260	Aroua (2007)
PPI	10.7	/	27	Hart (2000)
	7.7	/	21	D'Helft (2009)

a. Diagnostic coronary angiography, possibly combined with measurement of pulmonary capillary wedge pressure

b. Single or multiple percutaneous transluminal coronary angioplasty with or without single or multiple consecutive stenting, single or plural direct stenting and combined procedures

c. Include all forms of interventional procedures on the coronary arteries and associated vein grafts with or without a diagnostic component

d. Moderate complexity

Table 20. Diagnostic Reference levels for both diagnostic and therapeutic interventional radiology procedures

Type of examination	Reference levels			Reference
	Fluoroscopy time (min)	Number of images	KAP (Gy cm^2)	
Cerebral angiography	15	480	125	Aroua (2007)
Hepatic embolisation	30	160	620	
Biliary drainage and stent insertion	25	30	240	
Cerebral embolisation	50	800	440	
Iliac dilatation and stent insertion	25	200	460	
Transjugular intrahepatic portosystemic shunt creation	60	300	525	Miller (2009)
Biliary drainage	30	20	100	
Nephrostomy for obstruction	15	12	40	
Nephrostomy for stone access	25	14	60	
Pulmonary angiography	10	215	110	
Inferior vena cava filter placement	4	40	60	
Renal or visceral angioplasty without stent	20	210	200	
Renal or visceral angioplasty with stent	30	200	250	
Iliac angioplasty without stent	20	300	250	
Iliac angioplasty with stent	25	350	300	
Bronchial artery embolisation	50	450	240	
Hepatic chemoembolisation	25	300	400	
Uterine fibroid embolisation	36	450	450	
Other tumor embolisation	35	325	390	
Gastrointestinal hemorrhage localization and treatment	35	425	520	
Embolisation in the head for AVM	135	1,500	550	
Embolisation in the head for aneurysm	90	1,350	360	
Embolisation in the head for tumor	200	1,700	550	
Vertebroplasty	21	120	120	
Pelvic artery embolisation for trauma or tumor	35	550	550	
Embolisation in the spine for AVM or tumor	130	1,500	950	

Table 21. Diagnostic Reference levels for simple, medium and complex PCI procedures (Balter, 2008)

Complexity group	Diagnostic Reference levels		
	Fluoroscopy time (min)	Number of images	KAP (Gy cm^2)
Simple - CI = 1	15	1,500	100
Medium - 1 < CI ≤ 2	22	1,700	125
Complex - CI > 2	32	2300	200

CI - Complexity Index

6. EDUCATION AND TRAINING - CLINICAL AUDIT

6.1 International recommendations and guidelines

6.1.1 ICRP recommendations on education and training for healthcare and students

In 2011, ICRP has published a report on "Education and training in radiological protection for diagnostic and interventional procedures" (ICRP, 2009).

The ICRP has already published recommendations related to education and training of medical staff and healthcare professional (ICRP, 2007a; ICRP, 2007b). The main aim of this new publication is to expand on these basic recommendations with regard to various categories of medical practitioners and other healthcare professionals. This is the first ICRP report specifically addressing these issues.

One of the main findings made in this report is that it is accepted that RP education and training is deficient in many countries for almost all types of medical professionals requesting or performing diagnostic and interventional procedures. Moreover the lack of knowledge on the hazards induced by ionising radiation may create unnecessary risks to the population as a whole. In one hand this lack of knowledge may result in more imaging tests being requested when other non-radiation tests could be performed or when different lower dose imaging tests could be carried out. In the other hand it may also lead to persons not receiving the medical care they need because of exaggerated fears of the risks induced by ionising radiation.

As a consequence, there is a need to provide an adequate education and training to all the medical staff and stakeholders playing a role in the medical procedures using ionising radiation. These also include regulators and individuals with responsibilities for maintaining X-ray equipments.

In this report, ICRP underlines that "*a key component in the success of any training programme is to convince the engaged personnel about the importance of the principle of optimization in RP so that they implement it in their routine practice. In order to achieve this, the material must be relevant and presented in a manner that the clinicians can relate to their own situation"*. Priority topic and the level of knowledge for each topic must depend on the involvement of the different professionals in medical exposure. For example, knowledge on deterministic effects and their occurrence is of high importance for interventional operators so they will act to manage the doses to patients and the staff in such a way that they are kept well below the threshold values for each effect.

ICRP proposes different groups of topics and associated level of training for different professionals, based on existing guidelines in particular EC guideline RP116 (EC, 2000). In particular the following professional must follow a specific training in RP:

- Medical Physicists "*working in RP and diagnostic radiology should have the highest level of training in RP as they have additional responsibilities as trainers in RP for most of the clinicians*",
- Radiographers and X-ray technologists require "*substantial training in RP as this represents a core aspect of their work*",
- Maintenance engineers performing work on X-ray systems require specific training in RP of patients "*so that they understand how the settings of the X-ray systems and adjustments that they make influence the radiation doses to patients*",

- "*Nurses and other healthcare professionals assisting in fluoroscopic procedures require knowledge of the risks and precautions to minimize their exposure and that of other. There is particular evidence of a risk of lens opacities among those working in cardiac catheterization laboratories where RP has not been optimized*".

The Table 22 summarizes this information. The grey columns correspond to healthcare professionals who could be involved in performing interventional procedures.

Table 22. Recommended RP training requirements for different categories of healthcare professionals

Training Area / Type of professional	DR	NM	CD	MDX	MDN	MDA	DT	MD
Atomic structure, X-ray production and interaction of radiation	M	H	L	L	L	L	L	-
Nuclear structure and radioactivity	M	H	L	-	M	-	-	-
Radiological quantities and units	M	H	M	L	L	L	L	L
Physical characteristics of the X-ray machines	M	L	M	M	L	L	L	-
Fundamentals of radiation detection	L	H	L	L	M	-	L	-
Fundamentals of radiobiology, biological effects of radiation	H	H	M	M	M	L	L	L
Risks of cancer and hereditary disease and effective dose	H	H	M	M	M	L	M	M
Risk of deterministic effects	H	M	H	M	L	L	L	L
General principles of RP	H	H	H	M	M	M	M	L
Operational RP	H	H	H	M	H	M	M	L
Particular patient RP aspects	H	H	H	H	H	M	M	L
Particular staff RP aspects	H	H	H	H	H	M	M	L
Typical doses from diagnostic procedures	H	H	L	L	L	L	L	M
Risks from foetal exposure	H	H	L	M	M	L	L	L
Quality control and quality assurance	M	H	M	L	L	-	L	-
National regulations and international standards	M	M	M	M	M	L	M	L
Suggested number of training hours	30-50	30-50	20-30	15-20	15-20	10-15	10-15	5-10

L - low level of knowledge M - medium level of knowledge H - high level of knowledge

DR - Diagnostic Radiology Specialists
NM - Nuclear Medicine Specialists
CD - Interventional Cardiologists
MDX - Other Medical Doctors using X-ray systems
MDN - Other Medical Doctors using radiopharmaceuticals
MDA - Other Medical Doctors assisting with fluoroscopy procedures such as anaesthetists and occupational health physicians
DT - Dentists
MD - Medical Doctors prescribing medical exposures and medical students

Table 22 (continued). Recommended RP training requirements for different categories of healthcare professionals

Training Area / Type of professional	RD NM	ME	HCP	NU	DN	RL	REG
Atomic structure, X-ray production and interaction of radiation	M	M	L	-	L	M	L
Nuclear structure and radioactivity	M	M	-	-	-	M	L
Radiological quantities and units	M	M	L	L	L	M	M
Physical characteristics of the X-ray machines	M	H	M	-	L	L	L
Fundamentals of radiation detection	M	H	L	L	L	M	L
Fundamentals of radiobiology, biological effects of radiation	M	L	M	L	L	M	L
Risks of cancer and hereditary disease and effective dose	M	L	M	L	M	M	M
Risk of deterministic effects	M	-	L	L	L	L	M
General principles of RP	H	M	M	M	M	M	M
Operational RP	H	M	M	M	M	H	M
Particular patient RP aspects	H	M	H	M	M	-	M
Particular staff RP aspects	H	M	H	M	M	H	M
Typical doses from diagnostic procedures	H	L	L	-	L	-	L
Risks from foetal exposure	H	L	M	L	L	M	L
Quality control and quality assurance	M	H	L	-	M	L	M
National regulations and international standards	M	H	M	L	L	M	H
Suggested number of training hours	40-100	40-60	15-20	10-15	10-15	20-40	15-20

L - low level of knowledge M - medium level of knowledge H - high level of knowledge

RD NM - Radiographers, nuclear medicine physicists and technologists, medical physics technologists
ME - Maintenance engineers
HCP - Healthcare professional involved in X-ray procedures
NU - Nurses assisting in procedures
DN - Dental nurses or assistants
RL - Radionuclide laboratory staff
REG - Regulators

Interventional procedures can involve high doses of radiation and one of the particular risks to take into account is deterministic effect on skin. In its Publication 85 (ICRP, 2000), ICRP has proposed a second level of RP training for interventional radiologists and cardiologists:

"(50) Interventional procedures are complex and demanding. They tend to be very operator dependent with each centre having slightly different techniques. It is particularly important in these circumstances that individuals performing the procedures are adequately trained in both the clinical technique and in knowledge of RP. A second, specific, level of training in RP, additional to that undertaken for diagnostic radiology, is desirable. Specific additional training should be planned when new X-ray systems or techniques are implemented in a centre. A quality assurance programme for interventional radiology facilities should include RP training and assessment of dose control technique."

Annex C and Annex D present examples of proposed content of training courses for professional working respectively in interventional radiology and in interventional cardiology.

In its report, ICRP recommends that specialists performing interventional procedures other than interventional radiologists and cardiologists (for instance, vascular surgeons, urologists, etc.) require a lower level of RP training, but the duration of this E&T should be at least 15 hours.

ICRP also discusses the accreditations of organization providing RP training for healthcare professional and the need for certification for the trainees, who followed the courses.

6.1.2 Training material of the International Atomic Energy Agency

The IAEA has launched a specific website dedicated to the radiation protection of patients[11]. This website gives information on all medical procedures using ionising radiation addressed to both health professionals and patients. A specific section is dedicated to training. In particular, training materials is freely available to download on the following topics:

- Diagnostic and Interventional Radiology (see the complete list of topics in Annex E),
- Radiotherapy,
- Nuclear Medicine,
- Prevention of Accidental Exposure in Radiotherapy,
- Cardiology (see the complete list of topics in Annex F),
- PET/CT.

6.2 European Directives and guidelines

6.2.1 Education and training in the European Directives

The Euratom Directive 97/43 on radiation protection related to medical exposure (EC, 1997) requires an appropriate training in radiation protection of the medical professional using ionising radiation on patients (Article 7 - Training): "*Member States shall ensure that practitioners and those individuals mentioned in Articles 5(3) and 6(3)* [professional performing the procedure with a delegation of the practitioner; medical physic expert] *have adequate theoretical and practical training for the purpose of radiological practices, as well as relevant competence in radiation protection. For this purpose Member States shall ensure that appropriate curricula are established and shall recognize the corresponding diplomas, certificates or formal qualifications*". This article also states that the professionals must follow continuous refreshing course in radiation protection, in particular if new techniques are used. No specific detail is given on the content and duration of education and training.

Moreover, as exposed workers, the medical professionals using ionising radiation, including those involved in interventional radiology procedures, must receive under the Euratom Directive 96/29 (EC, 1996), information and training on the health risks involved in their tasks and on the general procedures and precaution to be taken to reduce the risks.

A process for the revision of the above Directives has been launched by the European Commission following the publication of the last general recommendations of ICRP in 2007. As far as education and training for professionals in the medical sector is concerned, the requirements in the February 2010 draft version of the BSS (EC, 2010) are not different from the existing ones.

[11] http://rpop.iaea.org

6.2.2 Radiation Protection 119 - MARTIR

In 2001, the European Commission published the results of the MARTIR project (Multimedia and Audio-visual Radiation Protection Training in Interventional Radiology), which aims to promote a consistent high level of practice in radiological protection and quality assurance.

The result is an interactive course composed of all useful knowledge for every individual working in interventional radiology. Different levels of courses (basic courses, intermediate course and advance course) are proposed in order to adapt the training depending on the needs of education. This courses is split into different thematic chapters:

- General introduction on interventional radiology and radiation protection,
- Fundamentals of radiation physics and introduction to radiation protection,
- Technology,
- Radiation protection in interventional radiology,
- Quality assurance in interventional radiology.

The complete table of content can be found in Annex G. This training material can be freely downloaded from the European Commission website[12] and is available in English, French, German, Italian and Spanish.

6.3 National experience on education and training requirements

6.3.1 France

In France, the requirements related to the training in RP for healthcare professional are directly derived from the EC Directives in particular the Euratom Directive 97/43 (EC, 1997). The French Code of Public Health states in its legislative part (Article L.1333-11) that the professionals playing a role in medical procedures using ionising radiation (diagnostic procedures, radiotherapy, nuclear medicine, etc.) must follow a theoretical and practical training related to the protection of patients. These professionals include persons performing the procedures as well as those participating to the procedures and persons in charge of the maintenance and quality control of the equipments.

In 2004 a specific order was published by the Ministry of Health to complete the Code of Public Health. This specific order specifies in particular the objectives and the content of the training. The content must be adapted to the different types and specialties of the professionals according to the annexes of the order. All the professionals mentioned in that order should have received this training by 2009. The training must be organized by the employer and must be renewed every 10 years. The participants must receive a document attesting that they have followed the training. An evaluation of the professionals is not mandatory at the end of the course. The order does not specify the duration of the training. Moreover, organisation delivering the training to the professional does not need an accreditation.

6.3.2 Greece

In Greek Radiation Protection Regulations it is mentioned that all scientific, technical and ancillary staff participating in any activity which involves danger from ionizing radiation must be suitably trained and contribute to implementing these Regulations. Greek Atomic Energy

[12] http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm

Commission, which is the regulatory authority for radiation protection matters in Greece, shall provide radiation protection training for ancillary, technological, technical and scientific staff employed in various fields of nuclear science. It also provided continuing training in radiation protection to the staff of special groups for emergency situations.Practically this is done only for technologists and not for physicians and nurses who work in IC and IR departments.

6.3.3 Spain

In 2011 in Spain, the structure of the training in RP for physicians is the following (see also Figure 8).

- **Pre-grade** (regulated by the Spanish Ministry of Education):
  - In the first cycle of the degree in Medicine (habitually in the 1st course) there is a compulsory subject on medical physics with a total of 6 ECTS (European Credit Transfer System), where about 0.15 ECTS are devoted to radiation protection principles.
  - In the second cycle of the grade in Medicine (from 3rd to 6th course) there is an optional subject on radiation protection with 6 ECTS.

- **Post-grade:**
  - **Petitioners**: When the physicians begin their specialization at a hospital as a resident physician they receive a theoretical training in radiation protection of 6 - 8 hours mainly regarding to the justification principle. In the third year as resident physician there is a 2 - 4 hours practical exercise about their own implementation of the principle of justification, when they are prescribing radiological examinations. The duration of this training is variable depending on the speciality, and has been divided in two groups based on their relation with the use of ionising radiation. However in the Autonomous Community of Madrid, the Health Authority decided to include all specialities in the same course with 6 hours of theoretical aspects and 4 hours of practical aspects. This training is regulated and audited by the Spanish Ministry of Health (in collaboration with the Spanish Ministry of Education).

  - **Practitioners.** There are two levels:

    First level. This level is regulated by the Spanish Nuclear Regulatory Authority (Nuclear Safety Council):

    - **Radiology**. To direct installations of X-rays with medical diagnosis purpose is compulsory to be in possession of an accreditation issued by the Spanish Nuclear Regulatory Authority (Nuclear Safety Council). This accreditation is personal and permanent, and can be obtained by two ways:

      For **radiologists**, automatically at the end of the resident physician period, where a training of about 50 hours has been included. Some years ago there was necessary to follow a course of about 40 hours on RP because this training was not included in the formation as resident physician.

      For **non-radiologists**, after following a training course of about 30 hours on RP after or during the resident physician period.

    - **Radiotherapy and Nuclear Medicine**. For this kind of installations is compulsory to be in possession of a license issued by the Spanish Nuclear

Regulatory Authority. This license is personal and renewable for periods of five years, and is obtained after following a training course of about 50 hours on RP during the resident physician period.

Second level. This level is established only for medical specialists that participate in fluoroscopy guided interventional procedures. It is an activity audited and regulated by the Ministry of Health, that issues a personal permanent accreditation. The medical specialist must be in possession of the first level accreditation and follow a training course of about 20 hours specifically devoted to RP in interventional fluoroscopy guided procedures, with at least a 20% of practical sessions. The Ministry of Health has created a national registry of physicians with accreditation, and these accreditations are required in the audits performed to the hospitals with authorisation for the training of medical specialists and also in the yearly audits performed by the Nuclear Safety Council to X-ray installations. Each second level course requires a previous authorisation by the Ministry of Health, after the presentation of a memory that includes the theoretical and practical contents, experience of the teachers in interventional procedures, materials and equipment that will be used for the practical sessions.

For **non-physician** (radiographers, nurses, etc) there is regulation to operate X-ray units for diagnostic radiology purposes. This accreditation, issued by the Nuclear Regulatory Authority is personal and obtained automatically for radiographers, and after a 20 hours training course for nurses, etc. In the case of staff of Radiotherapy and Nuclear Medicine is compulsory to be in possession of a license to operate issued by the Spanish Nuclear Regulatory Authority. This license is personal and renewable for periods of five years, and is obtained after following a training course of about 30 hours on RP. In the case of interventional procedures there is a lack of regulation of specific training on RP for non-physician staff.

The **Medical Physicists** in Spain are trained as the other medical specialities with a post-graduate 3-year residence programme in a hospital. The training on radiation protection is acquired during the 6 months of rotation in this area.

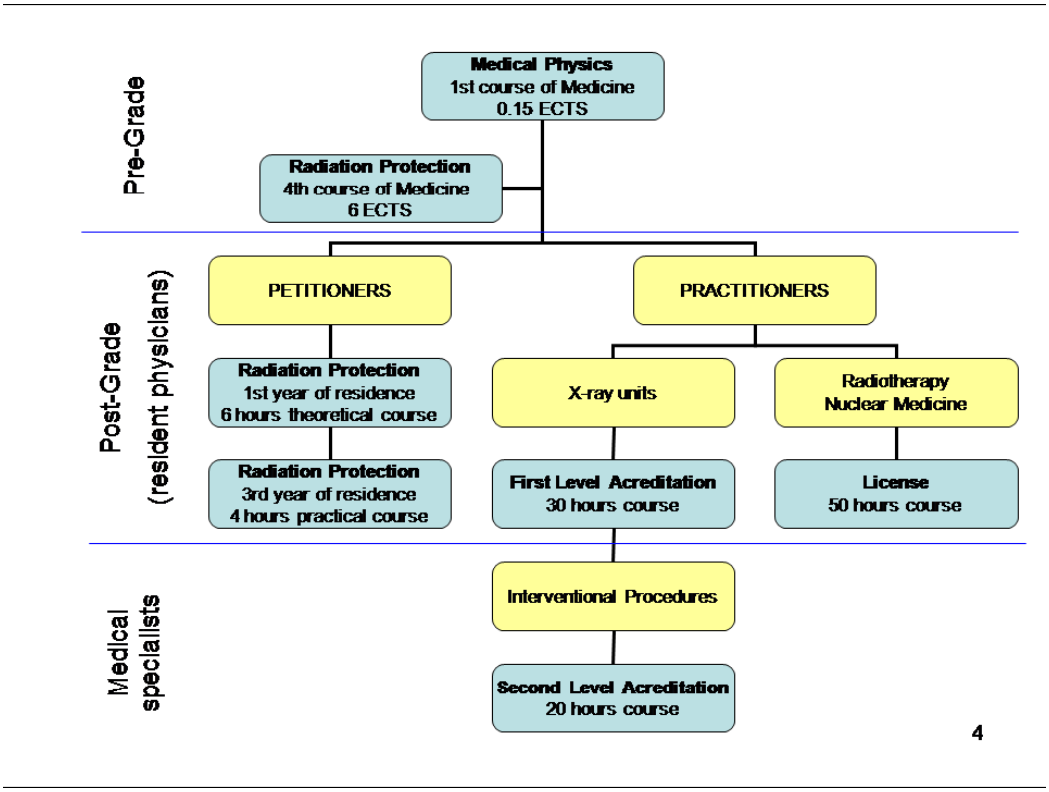

Figure 8. Structure of the training in RP for physicians in Spain in 2011

6.3.4 Austria and Italy

In Austria and in Italy, there is no real mandatory education and training in radiation protection for staff using ionising radiation.

6.4 Clinical audit

According to EC guidelines on Clinical Audit for Medical Radiological Practices (EC, 2009) the aim of clinical audit is to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures. The EC guidelines were published in order to improve implementation of Article 6.4 of Council Directive 97/43/EURATOM (EC, 1997) on Clinical Audit. Clinical audit is based on a systematic examination or review of medical radiological procedures. The EC guidelines provide comprehensive information on procedures and criteria for Clinical audit in radiological practices (diagnostic radiology, nuclear medicine and radiotherapy). The EC document defines what should be a clinical audit. It must be a multi-disciplinary, multiprofessional activity and must follow general accepted rules and standards which are based on international, national or local legal regulations, or on guidelines developed by international, national or local medical and clinical professional societies. It should assess the local practice against the defined good practice, taking into consideration the local facilities and resources when the ultimate good practice cannot be reached by one step. Clinical audit should be a systematic and continuing activity, whereby the recommendations given in audit

reports are implemented and should be carried out by auditors with extensive knowledge and experience of the radiological practices to be audited. It should also combine both internal and external assessments. The objectives of internal audits should be set by the management of the department. The internal clinical audits should be a continuous activity with the aim of having significant parts of the overall audit programme covered once a year. Internal clinical audit is organized in a cycle consists of the following stages: 1/ setting the objectives and identifying the issues to be audited, 2/setting the criteria of good practice, 3/assessing the practice, comparing with criteria 4/ giving recommendations for improvement 5/implementing the improvements 6/ re-audit.

For external audits, the objectives according to the EC guidelines should be agreed between the auditing organization and the health care unit to be audited. The recommended minimum frequencies by EC guidelines are once in five years. Comprehensive external audit organized as a site visit. Limited parts of the process can also be audited through collection of data by mail with central assessment of the data. Site visits include interviews of the staff and observations of practical work, reviews of local documents and data (quality manual, procedural guides and protocols, quality control test data etc), and sometimes also on physical measurements or tests.

External audit should not be confused with regulatory control. Concerning external audit, the auditor gives recommendations to the users; the auditor cannot enforce any actions (actions are decide by the user). Concerning regulatory inspection the non-compliance with specified conditions and requirements leads the regulatory inspector to impose corrective requirements to the user.

Clinical audit is terms of EC directive 97/43/Euratom is implemented according the report in Poland, Finland, Italy, United Kingdom, The Netherlands and Czech Republic.

7. NEW DEVELOPMENTS ASSOCIATED WITH LENS INJURIES

The eye lens is relatively radiosensitive and cataract formation is a major ocular complication associated with exposure to ionizing radiation. Radio-induced cataract used to be considered as a deterministic effect with a dose threshold of a few grays. According to ICRP recommendations, cataract induction is a tissue reaction with a definite threshold between 0.5 and 2 Gy for acute exposures, and 5-6 Gy for prolonged exposures (ICRP, 2007).However, this approach of considering radio-induced cataract as deterministic effect with a dose threshold of a few grays is now being discussed in the literature. This is due to the epidemiological studies on Chernobyl clean-up workers, interventionalists and survivors of the A-bomb (Worgul et al., 2007, Junk et al., 2008, Ainsbury et al. 2009, Chodick et al. 2008, Cirac-Belaj et al., 2010, Vano et al., 2010) which clearly underline the fact that threshold dose for cataract induction is lower than previously considered and may in fact be more accurately described by a linear, no-threshold model. During the 2006 scientific seminar of the European Commission, it was concluded that "*new data […] suggests that lens opacities occur at doses far lower than those generally assumed to be cataractogenic and these observations are consistent with the absence of a dose threshold*" (EC, 2007). However, ICRP has now reviewed the recent epidemiological evidence, and stated that for the lens of the eye, the threshold in absorbed dose is now considered to be 0.5 Gy. Moreover, for occupational exposure in planned exposure situations an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv is recommended (ICRP, 2011).

Eye lens doses reported in the literature for personnel involved in interventional procedures may exceed the threshold for deterministic effects after many years of work (Vano et al., 2008) and according to a more recent and extensive study (Vanhavere et al., 2011) 3/10 of the present annual eye lens limit can be easily exceeded by such personnel. Moreover, some epidemiological studies are currently launched to analyse the occurrence of cataracts within the interventionalist population: for instance, this is the case of the O'CLOC[13] study (Jacob, 2010). Taking also into account the prospective reduction of the dose limit, eye lens monitoring becomes imperative.

Within the ORAMED project an overall procedure for a correct eye lens dose assessment was proposed (Gualdrini et al.2011, Bordi et al.,2011). A sound theoretical and experimental basis to assess eye lens doses was performed. The approach for the definition and calculation of conversion coefficients for Hp(3) was revised. This was done using the Monte Carlo codes MCNPX and PENELOPE. The decision was motivated by two factors: the evidence of a higher incidence of lens opacities and cataracts for a given exposure, compared to what was foreseen in the past and, at the same time, the lack of an up-to-date data and procedures for a sound methodology for eye lens dose assessment, both in the official ICRP and ICRU documents and in the operative guidelines. In addition, a guide for type testing and calibration of eye lens dosemeters was implemented. A new eye lens dosemeter, (EYE-D™,) has been developed (Bilski et al., 2011). This dosemeter is constructed to measure the operational quantity, Hp(3), as the radiation-sensitive part of the lens lies about 3 mm within the eye, and is designed to be placed near the eye (figure ...) Finally, after the characterization of the prototype eye lens dosemeter, a trial campaign in some European Hospitals during IR/IC procedures was performed (Vanhavere et al., 2011).

[13] Occupational Cataracts and Lens Opacities in Interventional Cardiology.

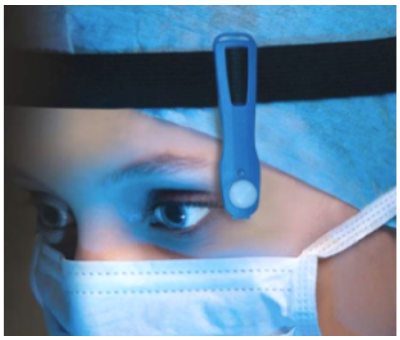

Figure 9. EYE-D™ dosemeter developed by RADCARD to measure the operational quality Hp(3)

8. ISSUES AND RECOMMENDATIONS

8.1 Important issues

Medical procedures using ionising radiation constitute by far the largest contribution to people by man-made sources. Moreover, the increasing use of ionising radiation in the medical sector has also an impact on occupational exposures, and there are a concern that practices such as interventional procedures may cause high individual doses. There are more and more different applications in a wide range of medical specialties using such techniques, which represent huge advantages for patients over invasive surgical procedures (lower risk of infection, shorter recovery time, etc). The following key points summarise the relevant information included in the synthesis document which the working group has delivered on the optimisation level of patient and occupational exposure in interventional radiology and cardiology (IR and IC).

Patient doses

- Angiography and interventional procedures involve relatively high patient doses and the latter have been increasing in frequency in European countries over recent years. Both of these procedures contribute from 10% (Norway, 2002 data) to 26% (The Netherlands, 2002 data) of the total population dose. Moreover, IR and IC procedures are responsible for more than 0.3 mSv per caput effective dose in Germany and Luxembourg, which is for example equivalent to about 80% of the total per caput dose from all X-ray procedures in the UK. A survey of developing countries conducted by the IAEA revealed that about 30% of the 20 participating countries demonstrated a 100% increase in workload in the interventional departments in the 3-year period from 2004 to 2007. Moreover, large differences in the patient dose from all medical exposures have been observed between developed countries.
- The stochastic effects are always present in interventional procedures but there is also a possible risk for patient skin injuries. Though, these injuries are not observed normally in interventional diagnostic examinations, during therapeutic procedures the threshold value of 2 Gy for deterministic effects could be reached (e.g. maximum surface doses of up to 5.4 Gy were observed during cerebral embolizations). In addition, large differences are observed depending on the complexity of the different lesions and interventions but also on the physician and the institution). Despite the fact that the number of these radiation injuries remains relatively small, they have a major impact on the patients who are affected. Moreover, complex cases may be treated in repeated procedures, which increase the risk of skin injury especially when performed within a short period of time.
- Children's sensitivity to cancer induction by radiation is considered to be higher than in adults by a factor of three to five. Follow-up studies in children showed that cancer risks were greater for children irradiated early in life; risks for solid tumours persisted at least until the age of 50 years.
- According to the Council Directive 97/43/Euratom (Article 8), patient radiation doses need to be estimated. The Directive has been implemented in national legislations such as shown for example in France. Other existing regulations recommend dose recording only when entrance surface dose exceeds 1-2 Gy for a procedure. There is a clear need to monitor whether the threshold doses for deterministic effects are being reached or even exceeded for the specific procedure. No patient databases exist in most of the hospitals where interventional procedures are performed. No clear directives for the patient follow up and accident handling exist though in its guideline for patient radiation dose management, the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) and the Society of Interventional Radiology

(SIR) have defined criteria to organize the follow-up of patients after an interventional procedure.

- Concerning optimization of patient and staff doses, CIRSE and SIR recently published joint guidelines respectively on patient radiation dose management and on occupational radiation protection in interventional radiology. In order to optimize medical exposures, the concept of diagnostic reference levels (DRLs) was developed for common diagnostic purposes. The definition and implementation of such diagnostic reference levels for IR and IC procedures are much more controversial, mainly due to the specificities of these procedures, which make difficult to define a standard examination associated with a standard patient. In that context, many national or international studies have been performed in the last years to establish and/or propose DRLs for interventional procedures, but no specific recommendation and/or regulation have been established yet.

Staff doses

- The above-mentioned procedures often imply high radiation doses to occupationally exposed personnel. Workers exposed in ionizing radiation in medical fields constitute a significant percentage of the European workforce that is occupationally exposed to radiation. During IR and IR procedures, staff radiation doses can be high as physicians need to stay close to the patient. Moreover, advanced technologies (e.g biplane systems that are lately used) imply an additional source of staff doses.
- For the estimation of the effective dose for staff involved in IC and IR procedures, double dosimetry is recommended. Double dosimetry is the use of two dosemeters, one located above and one under the protective apron. Many algorithms exist today for the calculation of the effective dose. Many national legislations clearly mention how many, when and where the dosemeters should be worn, and how the effective dose should be estimated. However, no European harmonization exists on the subject of the positioning of the dosemeters and the proper algorithm to use for the estimation of the effective dose.
- Another important issue is the use of active personal dosemeters in IR and IC workplaces. Active personal dosemeters (APD) have traditionally been 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. However, the current technology of APDs does not suit the specificities of the X-ray fields used in IR and IC characterized by low energy photons and pulsed fields.
- Many of the data kept at the national dose databases where the radiation protection regulatory bodies can have access to, do not give reliable data on occupational exposures. The data are often not detailed enough to provide the required information distinction between the various specialties (e.g cardiology and radiology, or cardiologist and anaesthesiologist). A further complicating factor is that recorded doses may underestimate true occupational exposure because compliance of IR and IC personnel can be poor, and because an individual's exposures from different facilities may not be summed.

- Other areas of major concern in the occupationally exposed personnel are the ones involving new methodologies especially IR and IC, resulting in high extremity doses to hands and legs, as well as to the eye lens of the physicians. It should be stressed that there are many parameters that affect the whole body and extremity dose of workers in IR and IC departments. If proper protective equipment is used then the whole body doses can be considerably low. However, the extremity doses can be as high as 1 mSv per procedure for complex procedures. If no proper protective shields

are used then doses can be as much as 3-9 times higher. The doses to the lower limbs of physicians can also be high if no lead protection is used.

- Moreover, interventional radiologists and cardiologists are categories of professionals, who can receive high doses to the eye lens possibly approaching the deterministic threshold for cataracts after some years of regular practices without protection of the eye. Within the ORAMED (Optimization of Radiation Protection of Medical Staff) project, a lot of data on eye-lens doses have been collected and measurements with new types of dosemeters have been performed. The measurements showed that the present dose limit of 150 mSv per year for the personal dose equivalent of $H_p(3)$ is generally not reached, but doses can be sufficiently high. If the dose limit is reduced to 20 mSv, as it is proposed by ICRP in its latest statement due to the reduction of the level of the deterministic threshold for cataracts, many physicians will surpass this limit. Monitoring and the proper use of radiation protection equipment will even be more important.
- The average annual individual dose, for all workers that are monitored and receive a measurable dose, varies from country to country by a factor up to 10. ESOREX (European Study of Occupational Radiation Exposure) project assesses how radiation protection monitoring, recording and reporting is arranged within Europe. However, in these databases/projects there are no references about the storage of extremity and eye lens doses that are very important for the target group that this network is addressed to.
- From the ORAMED project it was seen that the majority of the operators wear protective apron and thyroid collar. However, there is a 2% of the operators in IR who do not use any personal protective equipment. Protective eyeglasses are used in 30% of the cases in the IR and IC procedures. A 2% of the operators use protective gloves in IR procedures. For the room protective equipment, there is a percentage of more than 24% who does not use any room protective equipment.

Equipment

- Concerning the equipment used to perform interventional procedures, IEC defines the essential performance of X-ray equipment to be declared by the manufacturer so that they are suitable for radioscopically guided interventional procedures. The dosimetric indications that will be provided by the equipment are also defined. The WG members agree that it is more and more difficult for the physicians to intervene on the basic parameters of the equipment. In fact before installing the machine the manufactures usually define particular presets depending on the procedures that will be performed with the use of machine. This limits the user to adjust and adopt the protocols required for specific patients.
- Quality assurance of the equipment, acceptance testing and maintenance programmes are mandatory and well defined by international agencies. The role of medical physicist has to be highlighted.
- According to EC guidelines on Clinical Audit for Medical Radiological Practices the aim of clinical audit is to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures. The EC guidelines were published in order to improve implementation of Article 6.4 of Council Directive 97/43/EURATOM on Clinical Audit. Despite all the EC efforts clinical audit is terms of EC directive 97/43/Euratom is only implemented according the synthesis report in Poland, Finland, Italy, United Kingdom, The Netherlands and Czech Republic.

Training

- The Euratom Directive 97/43 on radiation protection related to medical exposure requires an appropriate training in radiation protection of the medical professional using ionising radiation on patients. In 2011, ICRP has published a report on "Education and training in radiological protection for diagnostic and interventional procedures". One of the main findings made in this report is that it is accepted that education and training in radiation protection is deficient in many countries for almost all types of medical professionals requesting or performing diagnostic and interventional procedures. As a consequence, there is a need to provide an adequate education and training to all the medical staff and stakeholders playing a role in the medical procedures using ionising radiation. A process for the revision of the above Directive has been launched by the European Commission following the publication of the last general recommendations of ICRP in 2007. As far as education and training for professionals in the medical sector is concerned, the requirements in the latest Basic Safety Standards are not different from the existing ones.

8.2 Recommendations on what issues to deal with

From the previous list of the identified issues the following recommendation list is presented:

1) Patient radiation dose reports should be produced at the end of the procedures, and archived. A relevant quantity for the patient dosimetry is the absorbed dose in the skin at the site of maximum cumulative skin dose. Various dose indicators can be used for this purpose. The best one is the kerma-area product (KAP), stored at the Digital Imaging and Communications in medicine (DICOM) header entrance. The fluoroscopy time (FT) is an additional useful parameter as a performance index for the quality of the procedure.

   KAP meters should be mandatory, included in all equipment and properly calibrated. An harmonised and unique dose unit should be adopted by the manufacturers.

2) Many national and international studies have been performed in the last years to estimate DRLs for interventional procedures. These data should now be analysed and international recommendations and national regulations should be proposed to implement diagnostic reference levels for interventional procedures. Specific DRLs should also be developed for interventional procedures concerning children.

3) Patient follow-up should be organised to detect skin injuries (deterministic effects). This follow-up should be done at the Department where the procedure was performed, in collaboration of a dermatologist. The doses received by the patient should be communicated to the dermatologist

4) European guidelines should be formulated about the number of the dosemeters that should be worn and their position in IR and IC. A proper algorithm must be used to avoid over- or under-estimation of the effective dose when one or two dosimeters is used. The monitoring and evaluation of doses to the lens should be particularly addressed.

5) When using an APD in IR and IC, the requirements of the IEC 61526 standard and, in particular the points about the energy and angular response should be fulfilled. When

selecting APDs, the characteristic of the pulsed fields met in IR and IC should be taken into account, as some APDs do not have any response to these fields.

6) About the use of protective equipment:
    a. All personnel in the procedure room should wear a wrap-around protective apron of at least 0.25 mm lead-equivalence (so that when worn the double thickness anteriorly provides 0,5 mm lead-equivalence) and a protective collar of at least 0,35 mm lead-equivalence.
    b. The radiation protection glasses of at least 0.5 mm lead-equivalence thickness effectively attenuate radiation transmission. They should have side panels to block scatter radiation. However, they are heavy and uncomfortable (bad acceptance). The glasses are recommended especially in over-couch systems.
    c. Despite the fact that Protective gloves can attenuate the X-rays by 15%-30%, there is an international consensus to not recommend their use because of a series of drawbacks (risk to increase patient dose, uncomfortable for practitioners, cost, etc.). In any case, best practice is to keep hands out of the X-ray beam (Martin, 2009; Miller (CIRSE), 2010; Dumonceau (ESGE), 2012).

7) About the use of room protective equipment:
    a. 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.
    b. 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.
    c. If biplane systems are used, the proper use and positioning of a ceiling shield is very important for the protection of the eyes.
    d. Mobile floor shield should be used for the assisting personnel that need to be in the irradiation room.

8) Quality control of X-ray units is mandatory and acceptance testing needs to be carried out before the first use of the equipment and thereafter on a regular basis.

9) The physicians and the medical physicists should be involved in the specification list of the equipment to be purchased. They should determine in advance the desired performance and radiation protection requirements for patient and staff as well.

10) Manufacturers of interventional procedure equipment should work with the medical physicist, radiographers and health physicians to determine the optimised protocols in terms of dose rates and image quality adapted to the different IR procedures. In choosing an X-ray equipment, the availability of experienced technical personnel in a given centre should also be taken into consideration, so as a prompt service is secured in the event of technical problems. At the time of installation, equipment performance evaluations should be conducted in order to ensure that the purchase specifications meet regulatory requirements. The records of the acceptance testing

should be retained throughout the lifetime of the equipment for comparison with monitoring results in order to assess continued acceptability of performance.

11) The implementation of the requirements described in EC directive 97/43/Euratom concerning the quality audit should be enhanced within all European countries.

12) Appropriate education and training in radiation protection should be required for all healthcare professionals performing interventional procedures. The level of education and training should be adapted to the radiation risk and to the specificities of the procedure. Training of the outside workers involved in the maintenance of the facilities should also be taken into account. These data should be written in the related documents (passbook) and checked by the radiation protection officer of the operator facility.

    The accreditation of radiation protection training programs should be established by regulatory authorities at a national or a regional level, with the help of academic institutions, scientific and/or professional societies.

    Development of training material, distance learning tools, posters, etc, can support this aim.

9. LIST OF ACRONYMS AND ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACR	American College of Radiology
BSS	Basic Safety Standards
CA	Coronary Angiography
CT	Computed Tomography
DRL	Diagnostic Reference Level
EC	European Commission
EFOMP	European Federation of Organizations for Medical Physics
EFRS	European Federation of Radiographer Societies
EMAN	European Medical ALARA Network
EURADOS	European Radiation Dosimetry Group
IAEA	International Atomic Energy Agency
IC	Interventional Cardiology
ICD	Implantable Cardioventar Defibrillator
ICRP	International Commission on Radiological Protection
IEC	International Electrotechnical Commission
IJV	Internal Jugular Vein
IR	Interventional Radiology
KAP	Kerma Area Product
NCRP	National Council on Radiation Protection and Measurements
ORAMED	Optimization of Radiation Protection for Medical Staff
PCI	Percutaneous Coronary Intervention
PPI	Permanent Pacemaker Insertion
PTCA	Percutaneous Transluminal Coronary Angioplasty
QA	Quality Assurance
QC	Quality Control
RL	Reference Level
RP	Radiation Protection
SIR	Society of Interventional Radiology
TIPS	Transjugular Intrahepatic Portosystemic Shunts
UNSCEAR	United Nations Scientific Committee on the Effect of Atomic Radiations
WG	Working Group

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11. ANNEX

ANNEX A. PATIENT DOSE DATA FOR DIFFERENT INTERVENTIONAL RADIOLOGY AND CARDIOLOGY PROCEDURES

Table A1. Patient dose data for different interventional radiology procedures

Procedures	Mean KAP (Gy cm^2)	Number of patients	References
Biopsy			
Biopsy	6	32	Hart (2002)a
Small bowel biopsy	1	15	Hart (2002)a
Biliary and urinary systems			
Bile duct drainage	38	8	Hart (2002)a
Bile duct drainage	43	86	Ruiz-Cruces (1997)
Bile duct drainage	69	10	Vano (1995)
Bile duct drainage	150	18	Ruiz-Cruces (1998)
Bile duct drainage	70.6	123	Miller (2003)
Bile duct drainage	86.7	9	Ruiz-Cruces (1997)
Bile duct drainage	43	14	Ruiz-Cruces (1997)
Biliary drainage/stenting	244	56	Aroua (2007)
Bile duct dilatation/stenting	54	15	Hart (2002)a
Bile duct dilatation/stenting	51	74	Williams (1997)
Bile duct dilatation/stenting	43	30	Mac Parland (1998)
Biliary intervention	54	11.1.1 153	Marshall (2000)
Bile duct stone extraction	27	29	Hart (2002)a
Hepatic chemoembolization	282.3	126	Miller (2003)
Lithotripsy	5	40	Hart (2002)a
Nephrostomy	13	68	Hart (2002)a
Nephrostomy	34.3	143	Miller (2003)
Nephrostomy	22.7	14	Ruiz-Cruces (1997)
Nephrostomy	43	35	Mac Parland (1998)
Nephrostomy	8	21	Vehmas (1991)
Nephrostomy	56	54	Ruiz-Cruces (1998)
Ureteric stenting	18	15	Hart (2002)a
Kidney stent insertion	49	5	Hart (2002)a
Renal/visceral angioplasty, no stent	157.5	53	Miller (2003)
Renal/visceral angioplasty, with stent	190	103	Miller (2003)
Central venous reconstruction, SVC	100.9	12	Miller (2003)
Central venous reconstruction, IVC	195.5	3	Miller (2003)
Aortic fenestration	233.6	2	Miller (2003)
Iliac angioplasty, no stent	163.6	24	Miller (2003)
Iliac angioplasty, with stent	212.8	93	Miller (2003)
Management of varicocele	51	41	Chalmers (2000)
Management of varicocele	106	10	Ruiz-Cruces (1997)
Management of varicocele	131	1	Hart (2002)a
Management of varicocele	75	20	Ruiz-Cruces (1998)
Management of varicocele	50.8	14	Miller (2003)
GI haemorrhage, diagnosis/therapy	347.6	94	Miller (2003)
Neuroembolization	202	1	Hart (2002)a
Neuroembolization	122.2	8	Marshall (1995)
Neuroembolization	116	8	Bergeron (1994)
Neuroembolization	105	5	Mac Parland (1998)

Table A1 (continued). Patient dose data for different interventional radiology procedures

Procedures	Mean KAP (Gy cm^2)	Number of patients	References
Biliary and urinary systems (continued)			
Neuroembolization	320.1	382	Miller (2003)
Neuroembolization	129	21	Johnson (2001)
Neuroembolization	81	35	Johnson (2001)
Neuroembolization	335	58	Aroua (2007)
Neuroembolization, head, AVM	339.8	177	Miller (2003)
Neuroembolization, head, tumour	357.8	56	Miller (2003)
Neuroembolization, head, aneurysm	282.7	149	Miller (2003)
Neuroembolization, spine, AVM	560.4	10	Miller (2003)
Neuroembolization, spine, aneurysm	540.1	1	Miller (2003)
Neuroembolization, spine, tumour	470.6	13	Miller (2003)
Peripheral AVM embolization	119.1	17	Miller (2003)
Bronchial artery embolization	139.4	27	Miller (2003)
Embolization	75	12	Hart (2002)a
Embolization	105	27	Williams (1997)
Embolization	114	128	Marshall (2000)
Other tumor embolization	274.8	91	Miller (2003)
Hepatic embolization	463	70	Aroua (2007)
TIPS	524	4	Mac Parland (1998)
TIPS	335.4	135	Miller (2003)
TIPS	226	13	Zweers (1998)
TIPS	77	10	Zweers (1998)
TIPS	335.4	135	
Valvuloplasty	162	40	Broadhead (1997)
Vascular stenting	40	14	Hart (2002)a
Vascular stenting	42	44	O'Driscoll (1998)
Iliac dilatation/stenting	344	72	Aroua (2007)
Pelvic vein embolization, ovarian vein	413.6	6	Miller (2003)
Pelvic vein embolization, varicocele	50.8	14	Miller (2003)
Pelvic arterial embolization, trauma	316.3	18	Miller (2003)
Pelvic arterial empolization, tumour	302.8	19	Miller (2003)
Pelvic arterial embolization, fibroids	298.2	90	Miller (2003)
Pelvic arterial embolization, AVM	484.3	12	Miller (2003)
Pelvic arterial embolization, aneurysm	223.9	4	Miller (2003)
Uterine fibroid embolization	30.6	18	Andrews (2000)
Uterine fibroid embolization	211.4	16	Andrews (2000)
Stroke therapy	198.2	9	Miller (2003)
Carotid stent	167.9	18	Miller (2003)
Vertebroplasty	78.1	98	Miller (2003)
Vertebroplasty	118,8	Phantom	Fitousi (2006)
Vertebroplasty	41	10	Tappero (2009)
Pulmonary angiogram, no IVC filter	77.3	106	Miller (2003)
Pulmonary angiogram, with IVC filter	108.3	17	Miller (2003)
IVC filter placement only	44.5	279	Miller (2003)
Insertion of caval filters	48	4	Hart (2002)a

Table A2. Patient dose data for coronary angiography examinations

Mean DAP (Gy cm²)	Number of patients	Reference
57.8	2 174	Broadhead (1997)
23.4	126	Broadhead (1997)
66.5	288	Vano (1995)
111.03	6	Vano (2001)b
147.43	3	Vano (2001)b
40.72	4	Vano (2001)b
60.21	13	Vano (2001)b
84.9	27	Delichas (2005)
76.6	45	Delichas (2005)
46	14	Vano (2001)a
60.64	62	Van de Putte (2000)
110.1	15	Van de Putte (2000)
23-79	198	Neofotistou (2003)
55.9	76	Padovani (1998)
27	19 215	Aroua (2000)
55	4	Hart (2002)a
26	187	Hart (2002)a
26.4	231	Hart (2002)b
30.4	8 000	Hart (2002)b
13.97	90	Leung (1996)
63	65	Fransson (2000)
30.4	29	Betsou (1998)
18	167	Paisley (2004)
42		Huyskens (1995)
29	20	Efstathopoulos (2003)
23.6	509	Kuon (2003)a
12.7	473	Kuon (2003)a
12.8	278	Kuon (2003)b

Table A3. Patient dose data for Percutaneous Transluminal Procedures (PTCA) examinations

Mean KAP (Gy cm²)	Number of patients	Reference
77.9	214	Broadhead (1997)
51.6	11	Broadhead (1997)
128	42	Aroua (2007)
82	82	Aroua (2007)
87.5	45	Vano (1995)
113.21	7	Vano (2001)b
125.5	33	Delichas (2005)
59.8	37	Delichas (2005)
82.5	14	Vano (2001)a
115.23	13	Van de Putte (2000)
101.9	54	Padovani (1998)
145	223	Broadhead (1997)
51	89	Paisley (2004)
37.6	12	Fransson (2000)
50.6	6	Fransson (2000)
42		Huyskens (1995)

Table A3 (continued). Patient dose data for Percutaneous Transluminal Procedures (PTCA) examinations

Mean KAP (Gy cm²)	Number of patients	Reference
75	20	Efstathopoulos (2006)
22.2	233	Kuon (2003)a
14.4	269	Kuon (2003)a
68	97	Tsapaki (2005)
63.4	334	Hart (2002)b
94	600	Neofotistou (2003)
40	10	Hunold (2003)
62.6	401	Balter (2006)
50.8	180	Balter (2006)
69.5	183	Balter (2006)
130.5	58	Balter (2006)
50.8	98	Balter (2006)
128.3	121	Balter (2006)
33	9 692	Aroua (2000)
11.8	115	Kuon (2003)b
15	30	Kuon (2003)b

ANNEX B. QUALITY ASSURANCE IN INTERVENTIONAL RADIOLOGY AND CARDIOLOGY DEPARTMENTS - RESULTS OF THE EFRS SURVEY

	Question	Yes	No	Don't know
1	Do you run a quality assurance program in your department?	5	4	
2	Is dose management a part of the overall quality assurance program?			
3	Do you keep records of patient doses?	8	1	
4	Do you record: - fluoroscopy time, - number of fluoroscopic images, - anthropometric patient values (height-weight?).	 7 4 7	 2 5 2	
5	Do you keep records for doses the personnel receive?	9 (100%)		
6	Do you have threshold values for the doses recorded in your department? *(For the purposes of these questionnaire, a threshold is a specific level of an indicator that should prompt a review)*	6	3	
	Does your department have diagnostic reference levels? (*To use DRLs, an institution or individual practitioner collects radiation dose data for cases of a procedure performed in their own practice. The recommended number of cases varies from 10 to more than 50, with the latter number suggested because of the high individual variability of cases of Fluoroscopic Guided Imaging procedures)*	5	4	
7	Does somebody monitor the dose during the procedure?	100%		
	If yes, is this a: - radiographer, - nurse, - physicist, - medical doctor, - other.	 8 3 (and the radiographer)		
8	Has the operator in your suite feedback on doses given to his/her patients?			
9	Is it in the working culture of your department for all staff to recognize unsafe practice and to bring this to the attention of others who can correct the situation?	9	-	
10	Is there a *significant radiation dose* determined? *(a threshold value used to trigger additional dose management actions, including patient follow-up)*	2	7	
11.1	Do you have a follow-up procedure of patients who have received a significant radiation dose?	5	4	
12	Is a patient who received a significant dose given written instructions for follow-up of possible radiation effects in addition to their other discharge instructions?			
13	Does your department have an "Informed consent policy" with special information for the patient about the radiation risks?	1	8	
14	Does your department have detailed protocols for adolescents with adult body size?			
15	Are the peripheral radiation protection equipments (like lead aprons and collars) regularly checked?	9		
	If yes, are records kept of those checks? Are the results presented in QA departmental meetings?	8	1 9	

16	Is your equipment monitored/maintained by qualified staff for its stability-safety and adequate performance?			
	If yes, is this part of your departments QA program? Or is it in the contract with the manufacturer?	**3** **8**	**6** **1**	
17	How often in a year is this maintenance check performed?	**1/9: 4x** **2/9: 2x** **3/9: 1x**		

ANNEX C. EXAMPLE OF SUGGESTED CONTENT FOR TRAINING COURSES - INTERVENTIONAL RADIOLOGY (ICRP, 2010)

Those working in interventional radiology should have the knowledge to do the following.

1. X-ray systems for interventional radiology.
    a. To explain the effect of high additional filtration (e.g. copper filters) on conventional X-ray beams.
    b. To explain the virtual collimation and the importance of wedge filters.
    c. To explain the operation of continuous and pulsed X-ray emission modes.
    d. To explain the benefits of the grid controlled X-ray tube when using pulsed beams.
    e. To explain the concept of road mapping.
    f. To explain temporal integration and its benefits in terms of image quality.
    g. To analyse changes in the dose rate when varying the distance from image intensifier to patient.

2. Dosimetric quantities specific for interventional radiology.
    a. To define the dose area product (DAP) (or kerma-area product) and its units.
    b. To define entrance dose and entrance dose rate in fluoroscopy.
    c. To understand the cumulative air kerma and its relationship to entrance dose.
    d. To discuss the correlation between entrance surface dose and DAP.
    e. To discuss the relationship between DAP and effective dose.
    f. To correlate the dose upon entry into the patient with the dose at the exit surface and the dose at the intensifier input surface.

3. Radiological risks in interventional radiology.
    a. To describe deterministic effects that may be observed in interventional radiology.
    b. To analyse the risks of deterministic effect induction as a function of the surface doses received by the patients.
    c. To be aware of the probability of these effects in interventional practice.
    d. To analyse the relationship between received doses and deterministic effects in the lens of the eye.
    e. To be aware of the likely time intervals between irradiation and occurrence of the different deterministic effects, the required follow-up and control of patients.
    f. To analyse the stochastic risks in interventional procedures and their age dependence.

4. RP of the staff in interventional radiology.
    a. To comment on the most important factors which influence staff doses in interventional radiology laboratories.
    b. To analyse the influence of the X-ray C-arm positioning on occupational doses.
    c. To analyse the effects of using different fluoroscopy modes on occupational doses.
    d. To analyse the effects of using personal protection (e.g. leaded aprons, thyroid collars, lead glasses, gloves, etc.).
    e. To analyse the benefits and drawbacks of using articulated screens suspended from the ceiling.
    f. To understand the benefit of protecting the legs using lead rubber drapes.
    g. To understand the importance of the suitable location of personal dosimeters.

5. RP of patients in interventional radiology.
    a. To analyse the correlation between fluoroscopy time and number of images taken in a procedure and the dose received by patients.
    b. To analyse the effects of using different fluoroscopy modes on patient doses.
    c. To discuss the effects of the focus to skin distance and patient image intensifier input distance.
    d. To analyse the dose reductions attainable by modifying the image rate in digital acquisition or in cine.
    e. To give typical examples of patient entrance dose value per image in different procedures.
    f. To analyse the effect of using different magnifications on patient dose.
    g. To discuss the parameters which should be recorded in the patient history regarding (or with reference to data on) the doses received.

6. Quality assurance (QA) in interventional radiology.
    a. To discuss the difference between equipment performance parameters that usually do not downgrade with time and those that could require periodic control.
    b. To understand how image quality can be assessed.
    c. To discuss the importance of establishing simple criteria to compare doses at the patient or intensifier entrance in different situations.
    d. To note the importance in QA programmes of the periodic control of patient dose and its comparison with “diagnostic reference levels DRLs” (in this case, DRLs are not used in the strict sense of “diagnostic”, but for the patient dose derived from the imaging part of the interventional procedure).
    e. Local and international rules for interventional radiology.
    f. To discuss the different national regulations which apply in interventional radiology installations.
    g. To describe the international recommendations for interventional radiology (WHO, IAEA, ICRP, EC, etc.).
    h. To provide information on the international recommendations concerning the limitation of high-dose modes.

7. Procedure optimization with regard to radiation dose in interventional radiology.
    a. To understand the influence of kVp and mA on image contrast and patient dose when using contrast media.
    b. To understand the different features available on radiology equipment.
    c. To note the importance of optimization of RP in interventional radiology radiation procedures.
    d. To discuss the importance of DRLs related to the patient dose at local, national and international levels.
    e. To analyse the importance of periodic patient dose control in each room.
    f. To discuss the possibility of using different C-arm orientations during long procedures in which the threshold for deterministic effects may be attained.
    g. To analyse the importance of recording the dose imparted to every patient.

ANNEX D. EXAMPLE OF SUGGESTED CONTENT FOR TRAINING COURSES - INTERVENTIONAL CARDIOLOGY (ICRP, 2010)

Those working in interventional cardiology should have the knowledge to do the following.

1. X-ray systems for interventional cardiology.
    a. To explain the effect of high additional filtration (e.g. copper filters) on conventional X-ray beams.
    b. To explain virtual collimation.
    c. To explain the operation of continuous and pulsed X-ray emission modes.
    d. To analyse changes in the dose rate when varying the distance from image intensifier to patient.

2. Dosimetric quantities specific for interventional cardiology.
    a. To define the dose area product (DAP) (or kerma-area product) and its units.
    b. To define entrance dose and entrance dose rate in fluoroscopy.
    c. To understand the cumulative air kerma and its relationship to entrance dose.
    d. To discuss the correlation between entrance surface dose and DAP.
    e. To discuss the relationship between DAP and effective dose.

3. Radiological risks in interventional cardiology.
    a. To describe deterministic effects that may be observed in interventional cardiology.
    b. To analyse the risks of deterministic effect induction as a function of the surface doses received by the patients.
    c. To analyse the relationship between received doses and deterministic effects in the lens of the eye.
    d. To be aware of the likely time intervals between irradiation and occurrence of the different deterministic effects, the required follow-up and control of patients.
    e. To analyse the stochastic risks in interventional procedures and their age dependence.

4. RP of the staff in interventional cardiology.
    a. To comment on the most important factors which influence staff doses in interventional cardiology laboratories.
    b. To analyse the influence of the X-ray C-arm positioning on occupational doses.
    c. To analyse the effects of using different fluoroscopy modes on occupational doses.
    d. To analyse the effects of using personal protection (e.g. leaded aprons, thyroid collars, lead glasses, gloves, etc.).
    e. To analyse the benefits and drawbacks of using articulated screens suspended from the ceiling.
    f. To understand the benefit of protecting the legs using lead rubber drapes.
    g. To understand the importance of the suitable location of personal dosimeters.

5. RP of patients in interventional cardiology.
    a. To analyse the correlation between fluoroscopy time and number of images taken in a procedure and the dose received by patients.
    b. To analyse the effects of using different fluoroscopy modes on patient doses.
    c. To discuss the effects of the focus to skin distance and patient image intensifier input distance.

d. To analyse the dose reductions attainable by modifying the image rate in digital acquisition or in cine.
e. To give typical examples of patient entrance dose value per image in different procedures.
f. To analyse the effect of using different magnifications on patient dose.

6. Quality assurance (QA) in interventional cardiology.
    a. To discuss the difference between equipment performance parameters that usually do not downgrade with time and those that could require periodic control.
    b. To understand how image quality can be assessed.
    c. To note the importance in QA programmes of the periodic control of patient dose and its comparison with “diagnostic reference levels DRLs” (in this case, DRLs are not used in the strict sense of “diagnostic”, but for the patient dose derived from the imaging part of the interventional procedure).
    d. To discuss the different national regulations which apply in interventional cardiology installations.
    e. To provide information on the international recommendations concerning the limitation of high-dose modes.

7. Procedure optimization in interventional cardiology.
    a. To understand the different features available on cardiology equipment and their influence on patient dose and image quality.
    b. To note the importance of optimization of RP in interventional cardiology radiation procedures.
    c. To discuss the importance of DRLs related to the patient dose at local, national and international levels.
    d. To discuss the possibility of using different C-arm orientations during long procedures in which the threshold for deterministic effects may be attained.
    e. To analyse the importance of recording the dose imparted to every patient.

ANNEX E. TRAINING MATERIAL RELATED TO DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY ON THE IAEA RPOP WEBSITE

Lectures/Slides

00. Principles of Radiation Protection and Motivation for the Course
01. Overview of radiation protection in diagnostic radiology
02. Radiation units and dose quantities
03. Biological effects
04. International system of radiation protection
05. Interaction of radiation with matter
06. X-ray production
07. X-ray beam
08. Factors affecting image quality
09. Medical exposure BSS
10. Patient dose assessment
11. Quality assurance
12. Shielding and X-ray facility design
13. Occupational exposure
14. Radiation exposure in pregnancy
15. Optimization of protection in radiography
16. Optimization of protection in fluoroscopy
17. Optimization of protection in interventional radiology
18. Optimization of protection in CT
19. Optimization of protection in mammography
20. Optimization of protection in digital radiology
21. Optimization of protection in paediatrics
22. Optimization of protection in dental radiology
23. Organizing a QA program in diagnostic radiology

Practical

12. Shielding and X-ray facility design
15. Optimization of protection in radiography
16. Optimization of protection in fluoroscopy
18. Optimization of protection in CT
19. Optimization of protection in mammography

ANNEX F. TRAINING MATERIAL RELATED TO CARDIOLOGY ON THE IAEA RPOP WEBSITE

Lectures/Slides

01. Why Talk about Radiation Protection in Cardiology?
02. Talking about Radiation Dose
03. What Radiation Effects are Possible? (besides skin injuries)
04. X ray production and Angiography Equipment
05. Patient Dose Management
06. Standards and Guidance
07. Occupational exposure and protective devices
08. Image Quality in Cardiac Angiography
09. Optimization of Radiation Protection in Cardiology
10. Radiation Protection in Paediatric Interventional Cardiology Download
11. Cardiac CT - radiation doses, dose management and practical issues
12. Examples of Good & Bad Practice (physical factors)

ANNEX G. COMPLETE TABLE OF CONTENT OF THE EC MARTIR TRAINING MATERIAL

General - Introduction to Interventional Radiology

1. Social and economical impact - *basic courses*
2. Importance of radiation protection - *basic course*
3. European and interventional regulations of radiation protection in interventional radiology - *intermediate course*
4. Classification of interventional radiology procedures - *intermediate course*

Fundamentals of Radiation Physics and Introduction to Radiation Protection

Atomic structure. Physics of the X-ray generation - Interaction of radiation with matter

5. Atomic structure. Physics of the X-ray generation - Interaction of radiation with matter - *advanced course*
6. Attenuation - Interaction of photons with matter - *basic course*
7. Photoelectric effect - *advanced course*
8. Compton effect - Scattered radiation - *intermediate course*
9. Coherent scattering - *advanced course*

Radiobiology

10. Biological effects of ionising radiation - *intermediate course*
11. Deterministic effects and review of lesions - *basic course*
12. Genetic susceptibility to cancer - *intermediate course*

Dosimetric quantities and units

13. Dosimetric quantities and units - *basic course*

Fundamentals of detection physics for dosimetry

14. Fundamentals of detection physics for dosimetry - *advanced course*
15. Ionisation chambers - *advanced course*
16. Thermoluminescent dosemeters - *advanced course*
17. Other personnel and area dosemeters - *advanced course*

Basic concept of radiation shielding

18. Primary barriers - *advanced course*
19. Protective devices - *advanced course*

Technology

Introduction to dedicated interventional radiology - X-ray equipment - Generator

20. Continuous emission - *basic course*
21. Pulsed emission - *basic course*
22. X-ray tube - Collimation-Automatic C.-Virtual C. - *advanced course*
23. Filters - High filtration - *advanced course*

24. C-arm movement - *advanced course*

Introduction to dedicated interventional radiology - X-ray equipment - Image intensifier
25. General - *advanced course*
26. Automatic control systems - *advanced course*
27. Magnification - *advanced course*
28. Anti-scatter grid - *advanced course*

Introduction to dedicated interventional radiology - X-ray equipment - Image systems
29. TC cameras and video signal - *advanced course*
30. TV monitors - *advanced course*
31. Digital image systems - *advanced course*
32. Digital imaging and communication in medicine (DICOM) - *advanced course*

Introduction to dedicated interventional radiology - X-ray equipment - Accessories
33. Table - *basic course*
34. Catheters, coils, balloons, stents, etc. - *basic course*
35. Contrast injection systems - *basic course*

Manufacturers' improvements
36. General Electric - *intermediate course*
37. Philips - *intermediate course*
38. Siemens - *intermediate course*
39. Toshiba - *intermediate course*

Radiation Protection in Interventional Radiology
Radiation protection of the staff
40. Dosimetry and dosimetric methods - *advanced course*
41. Literature surveys on staff doses - *advanced course*

Radiation protection of the staff - Influence of personal protection devices
42. Suspended screens and curtains - *basic course*
43. Lead aprons - *intermediate course*
44. Protective gloves - *intermediate course*
45. Eye protection - *basic course*
46. Thyroid protection - *basic course*

Radiation protection of the staff - Influence of X-ray equipment technical parameters
47. Influence of X-ray equipment technical parameters - *intermediate course*

Radiation protection of the staff - Influence of relative position of the staff
48. To the patient and X-ray tube - *basic course*

49. To the TV monitors inside the room - *basic course*
50. Influence of staff training - *basic course*

Radiation protection of the patient
51. General aspects of dosimetry methods - *advanced course*

Radiation protection of the patient - Dosimetric methods
52. Entrance surface dose - *advanced course*
53. Dose area product - *advanced course*
54. Organ doses and effective dose - *advanced course*
55. Slow film method - *advanced course*
56. Other skin dosimetry methods - *advanced course*
57. Diagnostic Reference Levels - *intermediate course*

Radiation protection of the patient - Influence of X-ray equipment technical parameters
58. Image acquisition modes - *intermediate course*
59. Collimation and magnification - *intermediate course*
60. Influence of X-ray equipment technical parameters - *intermediate course*
61. Influence of the patient relative position to X-ray tube - *intermediate course*
62. Influence of the projection - *advanced course*
63. Influence of the patient size - *intermediate course*
64. Influence of removing the grid - *intermediate course*

Quality Assurance in Interventional Radiology
Introduction
65. Introduction - *intermediate course*

Evaluation of image quality by physical…
66. Modulation Transfer Function - *intermediate course*
67. Noise - *advanced course*
68. Contrast - *advanced course*

Evaluation of image quality by anatomical criteria
69. Evaluation of image quality by anatomical criteria - *intermediate course*

Evaluation by phantoms and test objects
70. AAPM approach - *advanced course*
71. Leeds approach - *advanced course*
72. DIN approach - *advanced course*
73. IEC approach - *advanced course*

Basic quality control of generator and X-ray tube

74. Basic quality control of generator and X-ray tube - *advanced course*

Basic quality control of associated equipment

75. Basic quality control of associated equipment - *advanced course*

Project DIMOND III

76. Project DIMOND III - *advanced course*
77. Staff dosimetry in interventional radiology - *advanced course*
78. Patient dosimetry in interventional radiology - *advanced course*
79. Constancy tests for quality control - *advanced course*
80. Verification procedures for ionisation chambers - *advanced course*