EMAN Project

Radiological procedures performed outside the radiological departments (WP 3)

Synthesis document on the impacts on patient and staff exposure and the state of the art of optimisation, including equipment standards and performances

Final version

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SUMMARY

Radiation protection of patients and staff for practices performed outside radiological departments are of particular interest due to:

- the limited information on type and frequency of procedures performed mainly with mobile radiography and fluoroscopy equipment;
- the increased frequency of procedures, some of them complex, in surgical theatres,
- the limited information on patient and staff exposure involved;
- the fact that procedures are performed by non-radiologists and nurses with poor or without training on radiation protection and procedure optimisation.

In the synthesis document, the Chapter 1 provides an overview on the impact on population exposure of radiology, nuclear medicine and dental practices, as derived by the Dose Datamed survey in 2004-2007. It is mentioned that for practices performed outside radiological departments there are limited information on frequency and patient and staff doses.
The Chapter 2 provides a summary of the most frequent radiological procedures as derived from the NCRP Report 133. This report is providing information on potential exposure of staff from the different procedures, both from radiography and from image guided fluoroscopy.
Chapter 3 defines the criteria for the selection of the radiological procedures of interest. The criteria includes: the potential of high patient and/or staff exposure and high frequency.
The selected procedures are performed in Gastroenterology, Orthopaedics, Urology, Vascular surgery, Neurosurgery and Anaesthesiology departments. Radiography performed with mobile units on adult and neonatal patients are also included.
The chapter, for each specialistic group, provides a collection of data on:

- patient doses in term of air kerma-area product (KAP), entrance air kerma (Ke) and effective dose;
- staff dose, mainly for the first and most exposed operator, in term of effective dose and/or equivalent dose to specific organ and tissue, like thyroid, eye lens and hands;
- frequency of procedures.

Data have been derived from literature and from some of the hospital of the WG3 members.
Only for few procedures and for patient doses, e.g. ERCP, most of the orthopaedics and urology procedures, literature data are relative numerous enough and are providing data using homogeneous dose quantities. The data on these few practices are demonstrating the existence of large variation of patient doses, as a demonstration of differences in protocols adopted and of the low optimisation level. The amount of data available will allow the group to derive and propose Reference Levels.
With reference to staff dose data, these are always limited and reported in very different quantities, as annual effective dose or dose per procedure or per minute of fluoroscopy or per unit of KAP, and with very different dose quantities, as effective dose or equivalent dose to some part of the body or equivalent dose over or under the protective apron. The available data don't allow easy comparisons and makes difficult to identify optimised practices. This situation will require the development of recommendations for a more appropriate staff dose monitoring and data communication.
Frequency of examinations are not available in the collected literature. Some figures have been derived from information collected in some hospitals by the WG members.

Chapter 4 provides a short description of the mobile radiography and fluoroscopy equipment used in these practices and a description of the main international standards applicable, like the CE mark of medical devices, IEC and CENELEC.
The quality assurance programme, required by the MED EU Directive, includes the quality control programme of the radiological equipment. For this purpose most of the Medical Physics Societies have provided detailed protocols; the document is mentioning those of AAPM (US) and IPEM (UK). The routine Quality Control of the X/Ray units used outside the X-ray department are adequately covered by the above and other international and national documents and this topic will not further discussed.
Chapter 5 describes the staff protection devices and discusses the effectiveness of the shielding. Because there is a non harmonised adoption of protective devices, the development of a guideline specific for the different specialties it will be necessary.

Chapter 6 on staff exposure monitoring includes:

- a description of the dose quantities and dosimeters to be used;
- the dose limits proposed by ICRP Recommendations and implemented in the EU Directive;
- the methods for the evaluation of personal dosimetry, including investigation of high dose levels;
- a description of the dosimetry practice for 7 European countries as an example of the differences in the national monitoring practices.

A review of the EC RP Report 160 on technical recommendation of staff monitoring is provided.
The content of this chapter will be the base for the development of guidelines specific for the different specialties.

Chapter 7 introduces direct, indirect and calculation methods for patient dosimetry. As an example of the differences in the patient dosimetry practice, a detailed description of the approached adopted in 5 European countries is reported.

Chapter 8 on education and training of health professionals involved in the radiological practices outside radiology departments provides a summary of the EC MED Directive and EC Guideline 116.
In order to assess the present status of education and training in this area of radiology, an extensive survey has been conducted in 23 European countries. The data, summarised in a table, are demonstrating a non harmonised approach and level of education and training that will require further recommendations and actions. In particular it is underlined the need of:

- a more effective harmonisation and implementation of the national regulations;
- the introduction of a credentialing system for RP;
- the reinforcement of the importance of the Continuous Professional Development system.

Chapter 9 describes the EC Guideline for clinical audit. A European survey has been conducted on the clinical audit activities. Information from 6 countries has been reported.
At present, only Finland has performed a clinical audit on the radiological practices outside radiology. The survey revealed that the health care units comply fairly well with the national Degree and good practices. However, a significant number of recommendations to improve practices were given by the auditors, on the average 7 per health care unit. The auditors also gave a number of recommendations about fluoroscopy outside radiological departments, mainly about training and education of the staff, the use of shielding devices, and examination guidelines. According to the auditing organization the auditors shall address more of these activities in the next audit round.
Chapter 10 reports the main outcomes from the inspection on these practices in Norway performed by the national radiation protection authority. Interviews revealed serious lack of skills in radiation protection. Typical examples were:

- unable to identify the X-ray tube from the image intensifier of the C-arm,
- inadequate knowledge of the operating consol,
- unknown with the three cardinal principles for staff protection (time, distance and shielding),
- no deliberate use of collimation and/or pulsed fluoroscopy
- and, total lack of knowledge about patient doses and risks.

Chapter 11 provides a list of lessons learned and examples of bad practices. The WG thinks this material can be conveniently used in training courses.
Chapter 12 is providing a comprehensive list of literature references on all the topics included in the document.
In conclusion, the synthesis document is providing an overview of the present knowledge on the radiation protection level on the radiological practices performed outside the radiology department. The identified lack of optimisation in patient and staff exposure, in data availability and in the education and training will allow the Working Group:

- to search and promote relationships with scientific societies of health professions involved in these radiological practices with the purpose to develop the ALARA Network, to develop recommendations and guidelines;
- and, to address recommendations to European Commission for the improvement of the radiation protection practice in this area of radiology.

1. INTRODUCTION

Medical procedures using ionising radiation constitute by far the largest contribution to people by man-made sources. Although the benefit for the 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 doses 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.

That means that it is essential to foster the implementation of the basic principles in radiation protection, justification and optimisation, and for occupational exposures also dose limitation. It is however recognised that radiation protection in the medical sector is complex, involving a diversity of stakeholders all having an important role in radiological protection. Among the stakeholders concerned about radiological protection in the medical sector the following can be identified:

- those that are exposed as patients, comforters and volunteers,
- those that are occupationally exposed in radiology, nuclear medicine and radiotherapy,
- and other medical professions using radiological equipment, medical doctors of other specialities, medical physicists, manufacturers and service technicians.

Situations in terms of safety culture appear to be quite different between the different European countries and within a country between the different stakeholders. A lot of local approaches to improving the situation are available but they are not communicated to others. In order to strengthen radiological protection in the medical field the different stakeholders have to be addressed and approached differently.

Patient exposures

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 an EU-funded project called DOSE DATAMED (2004 – 2007). In order to find out whether these differences are real or can be explained by differences in the methodologies used for medical exposure surveys or by the associated uncertainties, recent national surveys in ten European countries have been reviewed.

The differences were found to be primarily due to the different healthcare systems operating in each country, which resulted in considerable variations in the amount of equipment and manpower devoted to medical radiology and in the financial incentives for carrying it out. The differences between the various hospitals are even larger. This indicates a lack of optimisation, because optimised procedures for a certain diagnostic task should result in similar patient doses. The implementation of the ALARA principle, doses as low as reasonably achievable, for medical examinations with the addendum “without jeopardising the diagnostic outcome” has thus to be reinforced into daily clinical practice.

In spite of the large differences observed in medical exposures, the relative distribution with respect to imaging modalities and types of examination in European countries was found to be similar:

- The contribution from nuclear medicine is relatively low (4 to 14 %).
- Dental has not a significant impact on the collective doses from all X-ray examinations

- CT, angiography and interventional procedures give the largest contribution to the total collective dose from all X-ray 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% to 26%. These practices include also the procedure performed outside radiological department by non-radiologists.

Occupational exposures

Workers exposed in medicine constitute a significant percentage of the European workforce that is occupationally exposed to radiation. The average annual individual dose, for all workers that are monitored and receive a measurable dose varies from country to country by a factor of up to 10. Only limited data is available on where occupational doses are most significant (both in radiology, interventional radiology and nuclear medicine).

Major areas of concern are in areas involving new methodologies such as in interventional radiology and cardiology, resulting in high extremity doses to the hands, the legs and to the eye lens of interventional radiologists and cardiologists. Similar findings are to be expected for mobile X-ray equipment outside X-ray departments used in complex procedures.

Appropriate training of staff, at all levels, is a fundamental building block in the attainment of good radiological protection culture. But only radiologists, medical physicists and radiographers include radiological protection training in their professional training curriculum.

Practices performed outside radiological departments

EMAN has identified among the practices performed outside radiological departments those that require particular attention due to:

- the limited information on type and frequency of procedures performed manly with mobile radiography and fluoroscopy equipment,
- the increased frequency of procedures, some of them complex, in surgical theatres,
- the limited information on patient and staff exposure involved,
- the fact that procedures are performed by non-radiologists and nurses with poor or without training on radiation protection and procedure optimisation.

This synthesis document provides a collection of existing information on patient and staff dosimetry and exposure and the state of the art of optimisation, including equipment standards and performances, on these radiological practices.

2. RADIOLOGICAL PRACTICES OUTSIDE RADIOLOGICAL DEPARTMENTS

This section introduces and describes the radiological activities performed outside the radiological departments. The type of radiological equipment used, fixed or mobile, and the area where radiological procedures are performed are reported in Table 2-1. Procedures performed in Cardiac catheterisation labs are outside the scope of this report and part of the EMAN WP 2 on interventional radiology.

Table 2-1. Areas where radiological procedures outside radiological departments are performed

Mobile radiography equipment	**Mobile C-arm fluoroscopy equipment**
Trauma suites	Trauma suites
Orthopaedics rooms	Orthopaedics rooms
	Cystoscopy unit
Emergency room	Emergency room
Intensive care units	
Coronary care units	
Reconstructive oral surgery	Coronary care units
Radiography at bed side	Gastrointestinal fluoroscopy
Neonatal units	
Special fixed equipment	
Lithotripsy unit	
Endocrinology bone mineral densitometry	
Cardiac catheterisation laboratory	

The nature of the procedure, the number of images taken, the fluoroscopy time and the level of exposure for workers and patients are reported with the data from the NCRP Report no. 133 (Table 2-2 and Table 2-3). Level of exposure low means less than 1 mSv/year of effective dose to the operator, while high indicates effective doses higher than 20 mSv/year the annual dose limit for occupation exposed workers (data for high dose workload have been normalised to the present 20 mSv/y dose limit from the 50 mSv/y in the NCRP report).

Table 2-2. Common radiographic techniques and exposure potential for workers (from NCRP 133).

Equipment	Procedure	Location	No. of average films	Exposure potential	
				No. Procedure/week	
				Low	High
				Not more than	More than
Fixed or mobile	Cystoscopy	OR	3	0	4
Fixed or mobile	Nephrostomy tube placement	OR	2	0	6
Mobile	Hip pinning	OR	4	0	4
Mobile	Reduction of fracture	ER, OR	3	7	74
Fixed or mobile	Cholangiography	OR	**2**	0	6
Fixed or mobile	Chatheter placement	Various	1	20	200
Mobile	Pediatric chest or abdomen	Newborn ICU	1	30	300
Mobile	Abdomen	ER, recovery room	1	1	14
Mobile	Chest	ICU, Recovery room	1	30	200

OR: Operating room, ER: Emergency radiology, ICU: Intensive Care Unit

Table 2-3. Common fluoroscopic techniques and exposure potential for workers (from NCRP 133).

Equipment	Procedure	Location	Fluoro time (min)	Exposure potential	
				No. Procedure/week	
				Low	High
				Not more than	More than
Fixed or mobile	Line placement	CCU, ICU	2	0	8
Fixed or mobile	Cystoscopy	OR	5	0	3
Mobile	Nephrostomy tube placement	OR	15	0	1
Mobile	Hip pinning	OR	5	0	3
Mobile	Reduction of fracture	ER, OR	2	0	8
Fixed or mobile	Cholangiography	OR	**1**	1	16
mobile	Lithotripsy	OR	3	1	5
Mobile	ESWL	OR	30	0	0
Fixed or mobile	ERCP	Endoscopic suite	5-20	0	3
Mobile	Pacemaker lines	ICU	15	0	1

ERCP: endoscopic retrograde cholangiogram pancreatography; ESWL: extracorporeal shock-wave lithotripsy

3. PRACTICE OF INTEREST FOR RADIATION PROTECTION OF STAFF AND PATIENT

3.1 Criteria for inclusion and selection of procedures of interest

For the purposes of this synthesis document, literature information on radiological practices outside radiological departments have been analysed in order to identify radiological procedures of interest for the radiological protection of patients and staff. Criteria for inclusion includes procedures of high frequency and procedures with high or potentially high doses to patient and/or to staff.

The identified specialities and procedures, both diagnostic and therapeutic are:

- Gastroenterology:
  - Endoscopic retrograde cholangiopancreatography (ECRP)
  - Percutaneous Transhepatic Cholangiography (PTC)
  - Oesophageal dilatation
  - Colon stenting
  - Puncture liver biopsy
- Orthopaedics:
  - Hip
  - Femur
  - Tibia
  - Knee
  - Elbow
- Urology:
  - Percutaneous Nephrolithotomy (PCN)
  - Ureteral stent positioning (USP)
  - Extracorporeal shock wave lithotripsy (ESWL)
- Vascular surgery:
  - Endovascular aneurysm repair (EVAR)
  - Abdominal aortic aneurysm repair (AAA)
  - Arteriogram with and without embolization (AGM),
  - Percutaneous transluminal angioplasty with stent (PTA/S)
- Neurosurgery
  - Pedicle Screw Insertion
  - Percutaneous vertebroplasty (PVP)
- Radiography with mobile units
  - Neonatal radiography
  - Adult radiography
- Anaesthesiology
  - Central venous catheter

3.2 Procedure techniques and patient and staff exposure levels

Patient exposure are mainly derived from available information from literature data and, when available, from individual hospitals of this Network.

Patient dose quantities and dose analogues of interest are:

- radiological workload in the selected specialities (number of procedures, mean fluoroscopy time);

- cumulative air kerma area product (KAP) and cumulative dose at IRP (CK) for each procedure; generally these dose quantities are provided by modern mobile C-arm equipment;
- or, when available, from the dosimetry database and information stored at hospital level in the RIS/PACS & MPPS servers.

Staff exposure are currently measured and expressed in different manner.

- Doses from individual records can be:
  - personal dose equivalent Hp(10) measured over the protective apron
  - personal dose equivalent Hp(10) measured under the protective apron
  - effective dose derived from one of the measured quantities using one of the different algorithms available.
- Doses from literature:
  - Annual effective doses
  - effective dose or Hp(10) over the protective apron per single procedure
  - effective dose or Hp(10) over the protective apron per single procedure normalised to one of the patient dose quantities, usually to total KAP

In general, information on staff exposure is difficult to collect and to compare for the different methodologies used to monitor the staff and, for the frequently poor dosimetry practice. In surgical theatres personal dosimeters are frequently not properly and continuously used and for these reasons hospital or national database can underestimate real exposures.

3.3 Exposure levels for the selected procedure

3.3.1 Gastroenterology

Patient exposure

Kerma-area product (KAP) monitoring is an easy and useful tool for estimating patient effective dose (E) and entrance surface air kerma (Ke) in fluoroscopically guided procedures.

Fluoroscopy time (FT), KAP, Ke and effective dose (E) for ERCP and PTC and other less frequent procedures requiring guidance with fluoroscopy images are reported in Table 3-1. In the table Udine (I) (2009), Kuopio (Fi) (2009), Paijat-Hame (Fi) (2009), Seinajoki (Fi) (2009) and Toulouse H (F) (2009) hospitals of the Network data are also included.

Effective dose is calculated from KAP with a conversion coefficient ranging from 0.19 to 0.23 mSv/Gycm^2 from the different authors.

Exposure to the patient shows large variation due to the influence of patient size, tube load and the variation in the assessed screening time according to the conduct of the procedure and the patient's conditions.

Ki remained well below the threshold single fraction dose of 2 Gy for transient erythema. Nevertheless, care should be taken since patients can undergo two or more ERCP procedures consecutively (within 48 h).

Table 3-1. Mean, median (m), 3rd quartile (3rd) and (range) of FT, KAP, Ki and effective dose to patients in ERCP and PTC.

Procedure		Author/hospital	FT (min)	KAP ($Gycm^2$)	Ke (mGy)	E (mSv)
PTC		Mc Parland (1998)	14	80.2	210	12.8
		Olgar (2009)	6.1	97.5	257	20.8
ERCP	Diagnostic	Larkin (2001)	2.3	13.5		3.1
		Tsalafoutas (2003)	3.1	13.7	55	2.9
		Naidu (2005)	3.55			
		Olgar (2009)	1.9	26.2	85	6.6
	Therapeutic	Heyd (1996)	13.6		80	
		Larkin (2001)	10.5	66.8		12.4
		Buls (2002)	6 (3rd 8.3)	49.9 (3rd 60.3)	347 (3rd 420)	9.9 (3rd 12)
		Tsalafoutas (2003)	6	41.8	179	8.7
		Aroua (2004)	20	220		
		Naidu (2005)	5.67			
		Uradomo (2007)	4.7			
		Olgar (2009)	5.1	89.8	236	21.6
		Tsapaki (2010)	2.6 m	3.1 m(0.1-107)		
		NRPB (2000)	4.5 m	14.1 m		
		IAEA	3.3 m	11.1 m		
		Udine H. (I) (2009)	3.5 (1-25)	6.1 (0.1-49)		
		Kuopio H. (Fi) (2009)	2.5 (0.2-8.5)	3.8 (0.2-17.9)		
		Paijat-Hame H. (Fi) (2009)	4.3 (1-16)	7.5		
		Seinajoki H (Fi)	2.5 (0.2-8.5)	3.8 (0.2-17.9)		
		Wiedmark (2001)	5.7	17.9		
Oesofageal dilatation/prosthesis		Paijat-Hame (Fi) (2009)	1.5 (0.3-3.5)	6.7 (0.9-46)		
		Udine H. (I) (2009)	2.1 (0.1-4.4)	6.7 (0.1-13)		
Colon stenting		Paijat-Hame (Fi) (2009)	0.4	3.5 (1.7-6.2)		
Puncture liver biopsy – transjugular way (PBFTJ)		Toulouse H (F) (2009)		52.7 (3rd 89)		

STAFF EXPOSURES

Data on staff exposure are reported in different ways, some time difficult to compare. Here they are reported in the original form and in a synthetic table. Fig. 3-1 indicates the approximate position of staff during a ECRP procedure, the most frequent gastroenterology procedure.

The data of Table 3-2 on exposure per procedure of the medical doctor and the radiographer are derived from direct measurements with thermoluminescent dosimeters on a sample of procedures (ref. 2).

Table 3-3 summarises staff doses per procedure also for some hospitals of the Network.

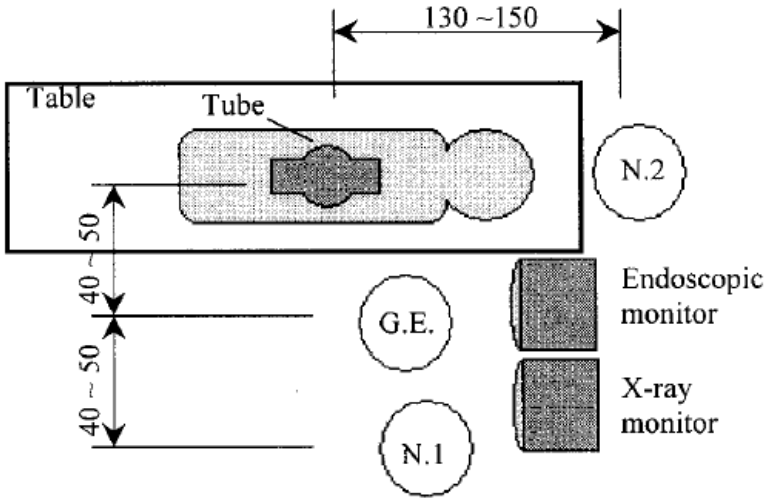


Fig. 3-1. Staff positions relative to the patient and X-ray tube during a typical endoscopic retrograde cholangiopancreatography (ECRP) procedure. G.E., gastroenterologist; N.1., assisting nurse; N.2., second nurse. Distances in cm. (Buls, 2002).

Table 3-2. Mean organ, tissue and effective doses to staff exposure for ERCP and PTC procedures.

Organ/tissue	Medical doctor			Radiographer	Nurse
	ERCP (mGy/proc) (Olgar 2009)	ERCP (mGy/proc) (Buls, 2002)	PTC (mG/proc) (Olgar 2009)	ERCP (mGy/proc) (Olgar 2009)	ERCP (mGy/proc) (Buls 2002)
Thyroid	0.075	0.45	0.363	0.061	0.20
Waist	0.000		0.000	0.000	
Right leg	0.0767		0.456	0.106	
Left leg	0.194		0.627	0.148	
Right finger	0.289		0.536	0.081	
Left finger	0.835	0.64	1.057	0.164	0.27
Eye	0.094	0.55	0.306	0.061	0.26
Effective dose (mSv)	0.001		0.011	0.002	

Table 3-3. Staff doses for ERCP of Toulouse and Udine hospital, F.

Procedure	**Hospital**	**Effective dose (µSv/procedure)**
ERCP	Toulouse (F)	Gastroenterologist: 2.15 Radiographer (behind desk): 0 Anaesthetist: 0.38 Nurse: 0
	Udine (I)	Gastroenterologist: 7.0 Nurse: 6.0 Radiographer: 2.0
	Buls (2002)	
Puncture Liver Biospy (transjugular)	Toulouse (F)	Gastroenterologist: 1.17 Radiographer (behind desk) : 0.36 Nurse: 0.44

Tsapaki (Tsapaki, 2010) is reporting that with proper protective devices (lead apron, collar and two lead-articulated ceiling mounted shields) the monthly endoscopist dose is less than 0.003 mSv.

FREQUENCY

Only few data (Table 3-4) are available on the frequency of grastroenterology procedures; some hospitals of the Network have provided some approximate data taking into account the number of procedures performed in a year and the reference population of the hospital.

Table 3-4. Frequency of grastroenterology procedures

Procedure	Author/hospital	Frequency (proc/million inhab)
PTC		
ECRP	Seinajoki (Fi) (2009) Paijat-Hame (Fi) (2009) Udine (2009)	890 590 845
Oesofageal dilatation/prosthesis	Paijat-Hame (Fi) (2009) Udine (2008)	140 90
Colon stenting	Paijat-Hame (Fi) (2009)	28

3.3.2 Orthopaedics

PATIENT EXPOSURES

During the last few years, the use of mobile C-arm X-ray units in orthopaedic surgery has been expanded, due to the introduction of new technique in which fluoroscopy is used to guide surgeons' manipulations.

The following Table 3-5 includes data of exposure parameters (kV, mAs), fluoroscopy time (FT), air kerma-area product (KAP), entrance surface air kerma (Ke) and effective dose (E) for the most frequent orthopaedic procedures. More detailed data from some hospital of the Network are reported in Table 3-6

STAFF EXPOSURES

In the orthopaedic theatre, staff is working in a non homogeneous scattered radiation field. Fig. 3-2 shows the radiation maps for different angulations of the C-arm and in term of ambient dose per unit of KAP. These figures are produced to inform the medical staff participating in the operation about the positions of lowest exposure that they should ideally occupy. The study (Kirousis, 2009) suggests that orthopaedic surgery do not represent a severe radiation risk for surgeons and the rest of the medical staff within the surgery room. However, attention should be paid given the large variety of procedures, techniques and fluoroscopic equipment used in orthopaedic surgeries worldwide. It is a fact that fluoroscopic units are often operated by physicians with no formal training on the physics of fluoroscopy and on radiation protection issues.

Table 3-5. Mean radiological data and patient doses in some orthopaedics surgical procedures.

PROCEDURE		AUTHOR	kV	mA	FT (min)	KAP ($Gycm^2$)	Ke (mGy)	E (μSv)
Wrist	MUA	Crawley (2000)				0.04		0.1
	ORIF	Crawley (2000)				0.09		0.1
		Udine (2009)			0.2	0.10		
Forearm		Crawley (2000)				0.05		0.6
		Tsalafoutas (2008)	50	1.4	1.8		17	
Elbow		Crawley (2000)				0.27		3.5
		Udine (2009)			0.1	0.10		
Ankle	MUA	Crawley (2000)				0.17		0.8
	ORIF	Crawley (2000)				0.39		1.7
		Udine (2009)			0.5	0.20		
	Injection	Crawley (2000)				0.23		1.0
Tibia/Fibula	MUA	Crawley (2000)				0.17		0.8
	GK nail	Muller (1998)			4.2			
		Crawley (2000)				1.67		14.8
		Madan (2002)			0.6			
		Malek (2007)			2.1		137	
		Tsalafoutas (2008)	67	1.7	5.7			
		Kirousis (2009)			1.2			
Femur	ORIF	Tsalafoutas (2008)	58	1.3	0.2		21	
	GK nail	Crawley (2000)				1.62		14.8
		Udine (2009)			0.7	1.10		
		Tsalafoutas (2008)	89	2.1	2.1		257	
Hip	Screw	Crawley (2000)				2.62		729.5
	Relocation	Crawley (2000)				0.76		120
		Udine (2009)			0.2	0.70		
	Injection	Crawley (2000)				0.64		100

MUA: manipulation under anaesthesia; ORIF: open reduction internal fixation; GK nail, Grosse Kempt nail

Table 3-6. Mean radiological data and patient doses in some orthopaedics surgical procedures in Kuopio hospital and (*) Seinajoki central hospital (Finland) derived form samples of about 15 patients.

Orthopaedics procedures	Fluoroscopy time Mean (range) (min)	KAP Mean (range) (Gycm2)
Tibial intramedullary nailing	1.14 (0.34 – 2.06) (1 – 9)*	3.87 (1.03 – 9.28) (0.16 – 8)*
Ankle (plate, screws)	0.16 (0.03 – 0.44) (0.1 – 0.3)*	2.28 (0.83 – 5.14) (0.02 – 0.03)*
Shoulder (plate, screws, nailing)	0.43 (0.07 – 2.48) (0.2 – 0.3)*	5.88 (1.96 – 9.00) (0.03 – 0.09)*
Distal radius / wrist (plate, external fixation)	0.18 (0.05 – 0.26)	0.96 (0.18 – 2.11)
Antebrachium (radius and ulna; plate, intramedullary nailing, screws)	1.8*	0,409*
Cervical spine (Cloward)	0.14 (0.06 – 0.19)	2.94 (1.04 – 6.07)
Lumbar spine (USS)	0.76 (0.07 – 0.33)	6.69 (3.28 – 11.38)
Knee (osteotomy, screws, plate)	0.34 (0.04 – 1.09)	3.59 (0.71-7.49)
Hip (DHS nailing, intramedullary nailing)	0.8 (0.06 – 2.06) (0.5 - 3)*	2.91 (1.34 – 5.14) (0.47 - 3)*
Femur (diafyseal intramedullary nailing)	1.67 (0.58 - 3.14) (1 – 1.9)*	5.89 (1.74 – 12.22) (0.89 – 2.1)*

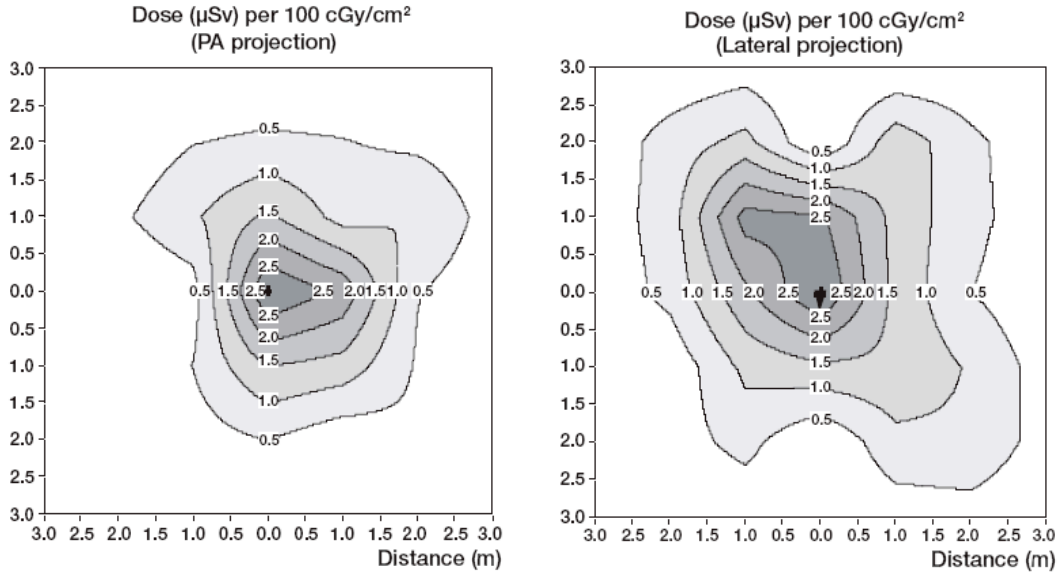


Fig. 3-2. *Ambient dose equivalent dose per unit of KAP for PA and Lateral projection from a fluoroscopy C-arm used in a orthopaedics room (Kirousis, 2009).*

Table 3-7. Staff doses in some orthopaedics procedures, mean and range values are reported.

Procedure	**Author**	**FT (min)**	**E (μSv/procedure)**	**Hands (μSv/procedure)**	**Note**
Foot and Ankle	Singh (2007)	0.6		29	
Hand	Athwak (2005)*	2.3 (0.5-5.5)	0.07 0.80	0.14 1.35	Mini C-arm C-arm
Hip	Theocharopoulos (2003)		5.12		
Spine	Theocharopoulos (2003)		21		
Kyphoplasty	Theocharopoulos (2003)		250		

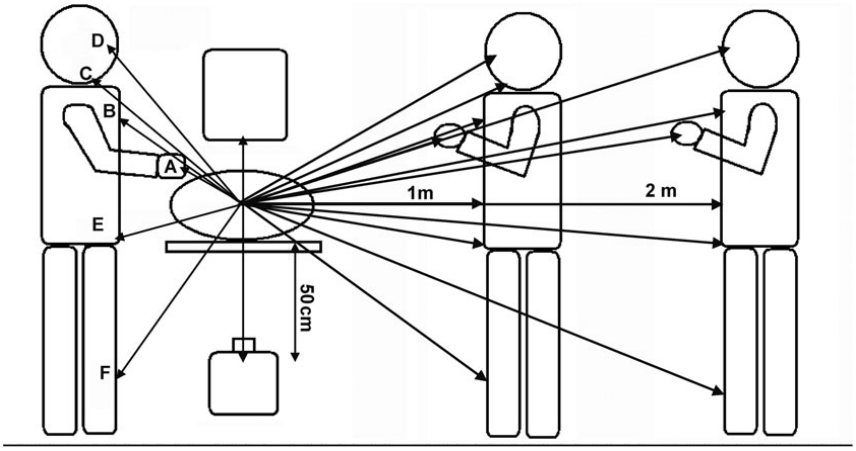
(*) A factor of 8.9 has been applied to doses reported in mR

The data of Table 3-8 are derived from measurements and calculations in image-guided orthopaedic surgery. Patient dose, staff doses in different positions inside the surgical room have been measured and calculated (Tsalafoutas, 2006). Doses to some organ/tissues are reported (Table 3-8) as an average dose per minute of fluoroscopy for a sample of most common procedures.

Fig. 3-3 shows the position of the staff during an orthopaedic procedure.

Table 3-8. Organ/tissue staff doses as an average of common orthopaedics surgical procedures (Tsalafoutas, 2006).

Organ/tissue	First orthopaedist (μGy/min fluoroscopy)	Personnel at 1 m (μGy/min fluoroscopy)
Ds hands	120	4
Ds chest	26	3
Ds thyroid	15	3
DS eyes	13	3
Ds gonads	76	5
Ds legs	50	6



Body part	A: Hands	B: Chest	C: Thyroid	D: Eyes	E: Gonads	F: Legs
Surgeon						
d_r (m)	0.30	0.82	0.75	0.88	0.55	0.90
Scattering angle (θ)	60°	55°	50°	40°	105°	145°
Personnel at 1m						
d_r (m)	0.87	1.05	1.2	1.23	1.02	1.26
Scattering angle (θ)	72°	70°	65°	60°	100°	126°
Personnel at 2m						
d_r (m)	1.84	2.02	2.15	2.13	2.02	2.15
Scattering angle (θ)	81°	80°	77°	72°	95°	112°

Fig. 3-3. Schematic diagram showing the position of the operating surgeon during a procedure with the patient positioned in the posteroanterior position (Tsalafoutas, 2006).

Table 3-9 is reporting staff doses from Touluse hospital.

Table 3-9. Staff doses per procedure from Toulouse Hospital (F).

Procedure	Staff dose (μSv)
Lower limb (any act)	Surgeon: 0.42 Radiographer: 0.04 Anaesthetist: 0.04 Nurse: 0.04
Upper limb (any act)	Surgeon: 0.44 Radiographer: 0.01 Anaesthetist: 0.01 Nurse: 0.01

FREQUENCY

Only few data are available on the frequency of orthopaedics procedures (figure 3-4) (Ref. 3). Some hospitals of the Network have provided some approximate data taking into account the number of procedures performed in a year and the reference population of the hospital (table 3-10).

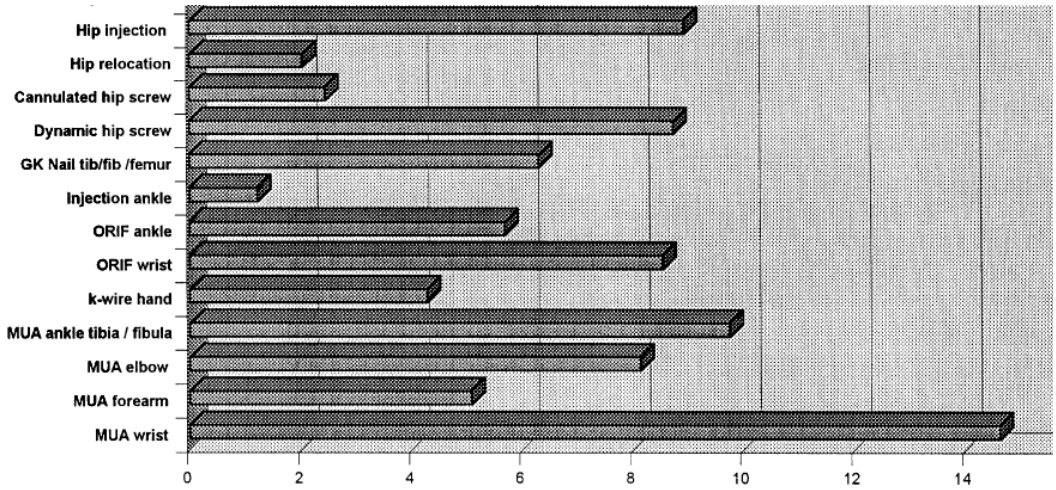


Fig. 3-4. Frequency of most important orthopaedic procedures (Crawley, 2000)

Table 3-10. Frequency of some urology procedures (Seinajoki hospital, Fi)

Orthopaedics procedures	**Frequency (proc/million inhab)**	
	Seinajoki hospital (Fi)	Paijat-Hame hospital (Fi)
Tibia (intramedullary nailing)	130	645
Ankle (plate, screws)	825	410
Shoulder (plate etc)	220	410
Elbow (plate, sdrews)	50	990
Antebrachium (radius and ulna; plate, intramedullary nailing, screws)	230	365
Wrist (fracture reposition)	175	110
Wrist (plate, screws, external fixation)	440	220
Metacarpals / fingers (reposition)	265	480
Spine	575	190
Hip (screws, intramedullary nailing, plate, DHS nailing)	565	
Femur (intramedullary nailing, plate)	55	

3.3.3 Urology

PATIENT EXPOSURE

KAP evaluation and mean fluoroscopy time (FT) for most frequent urology procedures:

- Percutaneous Nephrolithotomy (PCN)
- Ureteral stent positioning (USP)
- Extracorporeal shock wave lithotripsy (ESWL)

are reported in table 3-11. Some hospital data are also included.

Exposure to the patient shows large variation due to the influence of patient size on tube loading and the variation in the assessed fluoroscopy time.

Table 3-11. Mean or median (*) and (range) of FT, KAP, Ki and effective dose to patients in urology procedures.

PROCEDURE	AUTHOR	FT (min)	KAP (Gycm2)	Ki (mGy)	E (mSv)
Ureteral stent positioning (USP)	Seinajoki H (Fi) (2009) Paijat-Hame H. (Fi) (2009) Udine H. (I) (2006)	0.1 1 2.7	(0.17-0.3) 6.3 (2.2-9.5) 4.5		
Extracorporeal shock wave lithotripsy (ESWL)	Seinajoki H (Fi) (2009) Sandilos (2006)	3.1 (0.5-13.2) 3.4	6.3 (0.2-20)	 76 Obl, 44.5 PA	 1.6
Percutaneous nephrolithotomy (PCN)	Kumar (2006) Safak (2009) Hellawell (2005) Yang (2002) Geterud (1988) Udine H. (I) (2006)	6.04 12.0 10.0 12.8 5.3	10.0 19.4	0.56 191 AP, 117 Obl 4.5 250	

STAFF EXPOSURES

The data of tables 3-12 and 3-13 provide some information on the level of staff exposure for different type of procedures in term of effective dose and selected tissue and organ equivalent dose.

Table 3-12. Staff exposure for urology procedures, mean and range values.

PROCEDURE	AUTHOR	E (µSv/procedure)
Percutaneous nephrolithotomy (PCN)	Kumar (2006) Safak (2009)	Urologist 24.9 (7.4-50.2) Nurse 0.3 (0.1-0.7) Urologist 12.7

Table 3-13. Organ/tissue staff doses for PCN procedure.

PROCEDURE	AUTHOR	Urologist (µSv/procedure)		
		Trunk	Eyes	Hands
Percutaneous nephrolithotomy (PCN)	Geterud (1988)	130		630
	Page & walker (1992)	270	320	520
	Bowsher (1992)		120	145
	Kumar (2006)	56		360
	Safak (2009)	48	26	33.5

For PCN it has been observed that radiation dose to the patient's skin and staff have decreased with the advent of new C-arm digital technology.

FREQUENCY

Only few data are available on the frequency of grastroenterology procedures; two hospitals of the Network have provided some approximate data taking into account the number of procedures performed in a year and the reference population of the hospital. These are shown in table 3-14.

Table 3-14. Frequency of some urology procedures

Procedure	Author/hospital	Frequency (proc/million inhab)
Ureteral stent positioning (USP)	Udine (2006) Paijat-Hame (Fi) (2009)	145 45
PCN	Udine (2006)	98
ESWL	Paijat-Hame (Fi) (2009)	300

3.3.4 Vascular surgery

PATIENT EXPOSURE

Dose data for the following procedure are available:

- Endovascular aneurysm repair (EVAR)
- Abdominal aortic aneurysm repair (AAA)
- Arteriogram with and without embolization (AGM),
- Percutaneous transluminal angioplasty with stent (PTA/S)

Fluoroscopy time (FT), KAP, Ke and effective dose (E) are reported in Table 3-15. Exposure to the patient shows large variation due to the influence of patient size on tube loading and the variation in the assessed fluoroscopy time.

Table 3-15. Mean or median (*) and (range) of FT, KAP, Ki and effective dose to patients in some vascular surgery procedures.

PROCEDURE	AUTHOR	FT (min)	KAP (Gycm2)	Ki (mGy)	E (mSv)
Endovascular aneurysm repair (EVAR)	Weerakkody (2008) Pei (2009) Blaszak (2009)	21m (16-31) 13.0 ± 7.5	1.5m(0.9-6.6) 452 thoracic	850m (510-3740) up to 4 Gy	27m(16-117)
Abdominal aortic aneurysm repair (AAA)	Blaszak (2009) Weiss (2008)	20.6 (12.6-34.2)	381 151 (52-245)	up to 4 Gy 750 (270-1250)	
Arteriogram with and without embolization (AGM),	Pei (2009)	6.0 ± 4.6			
Percutaneous transluminal angioplasty with stent (PTA/S)	Pei (2009)	6.3 ± 3.9			

STAFF EXPOSURES

The data of table 3-16 provide some information on the level of staff exposure for different type of procedures in term of effective dose and selected tissue and organ equivalent dose.

Table 3-16. Staff exposure for vascular surgery procedures, mean and range values.

PROCEDURE	AUTHOR	E (µSv/proc)	Eye lens (mSv/proc)	Hand (mSv/proc)
Endovascular aortic repairs (EVAR)	Pei (2009)	0.05	0.10	0.45
Arteriograms with and without embolization (AGM),	Pei (2009)	0.06	0.08	0.33
Percutaneous transluminal angioplasty and stent (PTA/S)	Pei (2009)	0.12	0.11	0.59

Large variation in individual doses are reported that are likely related to individual endovascular techniques and proper use of protective devices, see example in Fig. 3-1 (Pei, 2009).

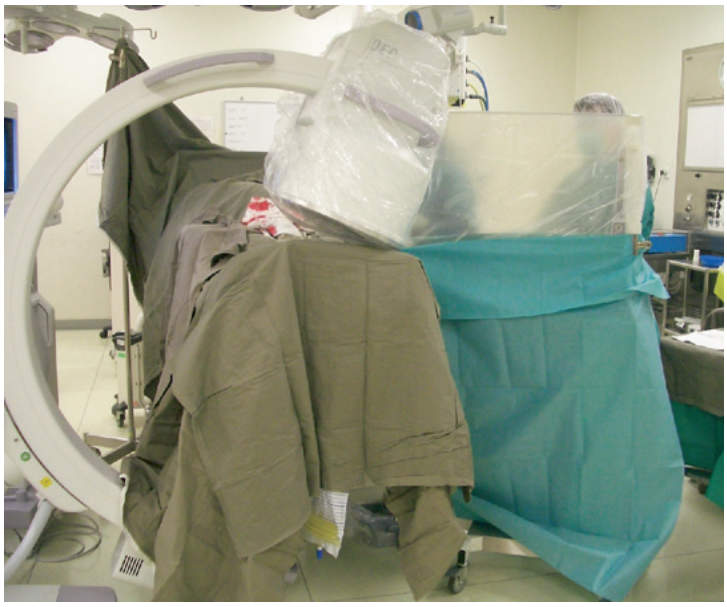


Fig. 3-4. Photograph showing a mobile lead shield being applied to shield operating surgeons from scattered radiation (curtesy Pei, 2009)

3.3.5 Neurosurgery

PATIENT EXPOSURE

Dose data for the following procedure are available:

- Pedicle Screw Insertion
- Percutaneous vertebroplasty (PVP)

Fluoroscopy time (FT), KAP, Ke and effective dose (E) are reported in Table 3-17.

Table 3-17. Mean or median (*) and (range) of FT, KAP, Ki and effective dose to patients in urology procedures.

PROCEDURE	AUTHOR	FT (min)	KAP (Gycm2)	Ki (mGy)	E (mSv)
Pedicle Screw Insertion	Perisinakis (2004) Maahir (2006)	1.2 AP 2.1 Lat 2.8	2.32 5.68		1.52 1.40 1.52
Percutaneous vertebroplasty (PVP)	Fitousi (2006) Von Wrangel (2009) D'Ercole (2010)	27.7 (18.8-43.1)	111.8	688 (446-1034) 184-1834 AP 417-2362 Lat	34.4 12

STAFF EXPOSURES

Staff doses have been located for the Pedicle screw insertion and the percutaneous vertebloplasty (PVP) procedures (Table 3-18).

Table 3-18. Staff doses in some neurosurgical and spinal procedures, mean and range values are reported.

Procedure	Author	FT (min)	E (µSv/proc)	Hands (µSv/proc)	Eyes (µSv/proc)
Pedicle Screw Insertion	Perisinakis (2004)	1.2 AP 2.1 Lat			
Percutaneous vertebroplasty (PVP)	Von Wrangel (2009)		1.2	280 R, 480 L	23
	Fitousi (2006)		11	1661	328

Some patient doses are reported from the Toulouse hospital (France) in table 3-19.

Table 3-19. Patient doses from the Toulouse hospital

Procedure	Patient dose/ KAP (Gycm2)
Osteosynthesis	Mean: 12.1 3Rd quartile: 3.18
Cochlear implant	Mean : 0.21 3rd quartile: 0.30

Some well known methods to reduce staff doses are still only recently applied in the clinical practice. Von Wrangel (2009) reports a dose reduction of a factor 4-5 placing the X-ray tube on the side of the patient opposite to the operator and the use of radiation protection gloves significantly reduces radiation exposure to the operator.

3.3.6 Radiography with mobile units

Adult bedside radiography

PATIENT EXPOSURE

Mobile X-ray units are used for radiography on patients who cannot be moved from their beds. Such examinations are routinely performed in Intensive Care Units (ICU), and less frequently in other wards. The majority of these examinations are AP Chest examinations [Simpson, 1998).

Mobile radiography involves difficulties not encountered in the radiology department Hall-Rollings, 2000):

- Patients usually are unable to cooperate due to their condition, requiring physical strength on the radiographer's part for accurate positioning.
- Room conditions are less than ideal for standard examination protocols as to the source-to-image distance and exposure factors.
- The patient's condition often requires monitoring and access lines and tubes may interfere with the image quality and positioning accuracy.
- Departments cannot assign a dedicated radiographer to mobile radiology, resulting in varying levels of expertise.

This combination of factors makes mobile radiography one of the most challenging assignments in diagnostic radiography.

A more recent study (Charitou, 2010) has confirmed the above points and has shown that out of the 1910 beside examinations performed with mobile X-ray units, the majority of them (65%) were performed at the ICU and 91,2% of these were AP chest examinations. The Ke of the ICU AP Chest examinations varied from 18 to 234 μGy, whereas the mean dose was 60 μGy Although these figures look impressive they should not be taken in isolation, since this study has revealed a number of non-conformities with the hospital protocol (See section 7 on "lessons learned and examples of bad practice" for more details). Their image quality was judged to be from totally unacceptable to satisfactory in comparison with Chest examinations performed at the Radiology Department.

The image quality and Ke for AP Chest examinations taken at the bedside of patients with mobile X-ray units can be improved by using anti-scatter grids and standardised examination parameters [16], two important factors that were not used in the above study.

Some guidelines are available for the correct use and optimisation of the image quality and the reduction of doses to the patient and staff (EUR 16261, 1996; ACR, 2006), but do not cover all the examination types and age groups.

It is also important to note that in some hospitals and especially in ICUs the mobile X-ray units are operated by nurses and or physicians without the necessary background knowledge, training and skills required (Friberg, 2010).

As a conclusion, there is a need:

- For standardisation of the bedside X-ray examination protocols.
- To use high kVp techniques together with the use of anti-scatter grids.
- For further and continuous education and training of all the healthcare professionals involved is such examinations, from the examination prescriber to the radiographer or other professional performing the examination to the radiologists reporting on the examination.

Table 3-20 gives patient doses for chest AP examinations performed at the bed side.

Table 3-20. Mean or median (*) and (range) of KAP, Ki and effective dose to patients in radiography.

Procedure	Author/hospital	KAP (Gycm2)	Ki (mGy)
Chest AP	Charitou (Cy)		0.06 (0.02 – 0.23)
	Udine Hosp (I)		0.6 (0.16-1.00)

FREQUENCY

DATA ON FREQUENCY IS VERY LIMITED AND SHOWN IN TABLE 3-21.

Table 3-21 Frequency of radiography.

Procedure	Author/hospital	Frequency (proc/million inhab)
Chest AP	Charitou (Cy)	65% of total in ICU

Neonatal radiography

PATIENT EXPOSURE

Neonatal radiography is performed at the Neonatal Intensive Care Unit (NICU) on premature babies within incubators with mobile radiography units. A number of studies have reported on the doses received by premature babies that were treated in NICU (Robinson, 1983; Faulkner, 1989; Chapple, 1994; Silson-Costello, 1996; McParland, 1996; Sutton, 1998; Armpilia, 2002; Brindhaban,2004; Donadieu, 2006). The majority were Chest AP projection examinations. All have reported a wide range of Ke and Effective Dose equivalents. They contribute the large range of doses to the large variation of the babies' weight, the area of the baby exposed, as well as to the technique used (kVp, mAs, focal spot, etc.).

The European Guidelines on quality Criteria for Diagnostic Radiographic Images in Paediatrics (EUR 16261) has reported the results from three trials in Europe (from a total of 72 newborns of 1000 grams weight each) for Chest AP projection radiography. The Ke from these trials range from 11 to 386 μGy, with a median value of 45 μGy. These Guidelines proceed to recommend a Diagnostic Reference Level (DRL) of 80 μGy for this examination. They also give guidelines on diagnostic requirements, criteria for radiation dose to the patient and an example of good radiographic technique for Chest AP projection radiography for newborn babies (1000 g) performed at the bedside with a screen/film mobile radiography unit, in an effort to assist in the reduction of doses.

Although the radiation risk of X-ray examinations is found to be low in comparison with the benefit to the infant, radiography of newborns should be performed with full knowledge of the possible harmful effects, considering that infants are particularly susceptible to radiation-induced cancer and that premature babies may require a large number of X-ray examinations during the early weeks of life.

The risk of radiation to the newborn is minimized by making sure that only essential radiographs are taken, that careful collimation confines radiation to the relevant part of the infant, that radiation shields over the lower abdomen are used unless this area is to be included on the radiograph and that adequately trained staff perform the examinations so that the number of repeat radiographs is reduced to the absolute minimum.

Table 3-22. Mean or median (*) and (range) of KAP, Ki and effective dose to patients in neonatal radiography.

Procedure	Author/hospital	KAP (mGycm2)	Ki (mGy)
Chest AP	Kuopio H. (Fi) (2007) Paijat-Hame (Fi) (2009)	2,92 (1,34 - 5.14) 1,98 (0,4 - 2,89)	0,0027 (0,019 - 0,038) 0,023 (0,014 - 0,028)
Abdomen	Paijat-Hame (Fi) (2009)	6,19	0,034

The results show that Ki and kerma-area products (DAP) are low (see table 3-22). On the ground of these results of a chest x-ray examination the risk to children is small. It is important to study how many times one child is being x-rayed during its care at a neonatal intensive care unit. It is also important to find out how doses and choosen image parameters differ between hospitals.

STAFF EXPOSURES

Two studies were identified (Sabau, 1985; Milkovic, 2000), that have investigated the radiation exposure due to scatter from radiographic procedures performed in NICU. These studies concluded that exposure from scatter radiation during neonatal radiographic procedures amount to only a small fraction of the usual background dose.

Film badges worn by technologists performing an average of 20 to 30 examinations per day indicated that their yearly cumulative exposure has not been exceeded (5 mSv). Nurses who have been monitored with film badges during the studies have not registered exposures above background levels. It is important that nurses and other workers in the NICU be reassured about the level of these exposures.

FREQUENCY

Limited data on frequency is given in table 3-23.

Table 3-19. Frequency of neonatal radiography.

Procedure	Author/hospital	Frequency (proc/million inhab)
Chest AP	Paijat-Hame (Fi) (2009)	925
Abdomen	Paijat-Hame (Fi) (2009)	51

3.3.7 Anaesthesiology

PATIENT EXPOSURE

The only available data on central venous catheter placement with fluoroscopy guide is provided in Table 3- from Kuopio hospital. The procedure is a low frequency procedure with a low fluoroscopy time.

Table 3-24. Mean or median (*) and (range) of KAP, FT to patients..

Procedure	Author/hospital	KAP (mGycm2)	FT (min)
Central venous catheter	Kuopio H. (Fi) (2007)	2,04 (0,48 – 7,39)	0,1 (0,01 – 0,33)

4. EQUIPMENT

For radiological procedures performed outside the radiology depts. Mobile radiographic and fluoroscopic C-arm equipment are mainly used.

Mobile radiography equipment

Mobile equipment must be so designed as to be easily accommodated in limited space, i.e. ward side rooms and alongside beds and in the often limited space of an operating theatre. The generator and base unit may be of low design or waist high design.

The range of movements available is one of the most important factors governing ease of use of mobile equipment. An important point in the usefulness of the range of movements is the maximum distance obtainable from the centre of the tube column to the tube head. As this determines how close alongside a bed or operating theatre table the mobile unit can be placed. One of the limitations to the range of movements is dependent on the centre of gravity of the design, if the centre of gravity is low then the distance the tube head can be moved away from the centre of the column is higher than if the centre of gravity is raised. The centre of gravity of a mobile unit is determined by how low the components of major mass can be positioned. Mobile units with battery packs that tend to be heavy and large HT transformers positioned low down tend to be more stable.

Wheels and Drive. In general mobiles have two larger drive wheels at the back and two small steerable castors or wheels at the front There are two types of motive power for mobiles,

- Radiographer power where the motive power is provided by human effort.
- Motor driven or motor assisted, where the rear wheels are driven by an electric motor. As a safety measure the speed / drive control needs continuous human pressure to operate .

Light beam diaphragm and collimator. Most mobiles have a light beam collimator with fully adjustable collimation and a central line light indicator. Capacitor discharge mobiles have an extra lead shutter that closes when the capacitors unused residual charge is being discharged through the tube after use. Many incorporate a retractable tape measure for measuring F.F.D.

Different type *of high voltage generators* are available

- Single phase, full wave rectified, Generator
- Constant Potential Generators.
- Capacitor Discharge Generator

Fluoroscopy equipment

Fluoroscopy is used to visualize the motion of internal fluids, structures, and devices. During a fluoroscopic examination, the operator controls activation of the x-ray tube for real-time imaging of the patient.

Early fluoroscopes produced a dim image on a fluorescent screen that required dark adaptation of the physician's eyes to optimize viewing conditions. Image intensifiers were later developed to replace the fluorescent screen and increase image brightness. Modern fluoroscopy systems include an image intensifier or dynamic flat panel with television image display, digital image storage and post-processing and different types of image recording.

Fluoroscopic equipment is available in many different configurations for use in a wide variety of clinical applications.

Mobile C-arm units provide fluoroscopic imaging for orthopeadic, urology, gastroenterology, and vascular surgical procedures, in addition to placement of devices such as pacemakers or feeding tubes. Some mobile C-arm systems are also configured for angiographic and interventional procedures with high exposure rate output and DSA imaging capabilities.

Mobile C-arm units offer a compact design, imaging chain angulations, and image recording by either film or digital image acquisition.

Mobile fluoroscopy units have also been configured with small image intensifiers, 10–15 cm in diameter. These mini C-arm systems are designed for imaging extremities for which only low exposure levels are needed.

4.1 Standards

4.1.1 CE mark of medical devices

Since 1993, safety aspects of design, manufacturing and placing on the market of medical devices are dealt with by the "Council Directive 93/42/EEC concerning medical devices" (MDD) (Council Directive 93/42/EEC, 1993). Its main goal is to define and list the Essential Requirements, which must be fulfilled by Medical Devices. When such a device is in compliance with the Essential Requirements of the MDD, it can be "CE marked", which opens the full European market to the product.

There are a number of ways with which manufacturers can demonstrate that their products meet the Essential Requirements of the MDD; the one of most interest here involves international standards. Further, demonstration of conformity with the essential requirements must include a clinical evaluation. Any undesirable side-effects must constitute an acceptable risk when weighted against the performance intended. For the types of devices that are the subject of the synthesis document, demonstration of the essential requirements can be achieved by the procedures described in the directive annexes. Conformity of all or part of these requirements can be demonstrated or verified through compliance with harmonised international standards. These are standards that specify essential requirements for the basic safety and essential performance of the device, such as those issued by the International Electrotechnical Commission (IEC) or Comité Européen de Normalisation Electrotechnique (CENELEC).

Although the MDD includes requirements for devices emitting ionising radiation, this does not affect the authorisations required by the directives adopted under the Euratom treaty when the device is brought into use. In this regard, the Euratom Treaty directives have precedence over the MDD. Conformity with the standard will frequently be included as part of the suppliers' specification and will be confirmed during contractual acceptance (acceptance testing) of the equipment by the purchaser.

The MDD was substantially amended by Directive 2007/47/EC (Directive 2007/47/EC, 2007). The amendments include an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. Furthermore, the clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

4.2 Quality control

A comprehensive and consistent suite of approaches to performance and safety assessment of radiological equipment has been proposed by the UK Institute of Physics and Engineering

in Medicine(IPEM, 1997; IPEM, 2005). The American Association of Physics in Medicine (AAPM, 2002; AAPM, 2005; AAPM, 2006) and British Institute of Radiology (BIR, 2001) have also, among other professional organizations, published much useful material. The IPEM system is based on the assumption that deviations from the baseline performance of equipment on installation will provide an adequate means of detecting unsafe or inadequately performing equipment.

The routine Quality Control of the X/Ray units used outside the X-ray department are adequately covered by the above and other international and national documents and will not be discussed further in this synthesis document.

5. STAFF PROTECTION DEVICES

5.1 Description

The greatest source of radiation exposure to the operator and staff is scatter from the patient. Generally, controlling patient dose also reduces scatter and limits operator dose. However, chronic radiation exposure in the work place necessitates the use of protective tools in order to limit occupational radiation dose to an acceptable level. The purpose of radiation protective tools is to improve operator and staff safety without impeding the procedure or jeopardizing the patient's safety.

5.1.1 Shielding

There are three types of shielding: architectural shielding, equipment mounted shields, and personal protective devices. Usually, architectural shielding is built into the walls of fixed and high workload installations. Usually, mobile fluoroscopy units have low or medium workload and for these no architectural shielding is required.

In addition, in surgical theatres, rolling and stationary shields which rest on the floor, constructed of transparent leaded plastic, can be useful for providing shielding for staff not directly involved in the procedure. They are particularly well suited for use by nurses and anaesthesia personnel.

For angiography and high workload installation, equipment-mounted shielding (protective devices suspended from the table and from the ceiling) are recommended. Properly placed shields have been shown to dramatically reduce occupational exposure including operator eyes. The availability of more than one ceiling-suspended shield or other movable form of shields, are indicated when more than one operator has to stay near the patient on different sides of the patient table for long period of time, e.g. in ERCP procedures.

5.1.2 Personal protective devices

Personal protective devices include aprons, thyroid shields, eyewear, and gloves. Protective aprons with thyroid shields are the principal radiation protection tool for workers in interventional practices. They should be employed at all times. The vest/skirt configuration is preferred by many operators in order to reduce the risk of musculoskeletal/back injury when they have to wear them for several hours per day (Klein, 2009). This wrap-around style is typically 0.25 mm lead-equivalent so that, when worn, the double thickness anteriorly provides 0.5-mm lead-equivalence. Aprons should be inspected fluoroscopically on an annual basis to detect deterioration and defects in the protective material (Christodoulou 2003).

Since the current ICRP occupational limit for eye exposure of 150 mSv/year may be too high, leaded eyeglasses are an alternative to ceiling-suspended shields for this purpose. Leaded eye-glasses with protective side shields provide more protection than eyeglasses without these features. The principal disadvantage of leaded eye-glasses is their weight and discomfort.

In general, the operator's hands should be kept out of the primary radiation beam. Leaded gloves may seem useful for radiation protection on those rare occasions when the operator's hands must be in the primary radiation beam, but they do not provide protection in this situation, because of the increased dose when any shielding is placed in the primary beam., The false sense of security that these gloves provide, can result in increased radiation dose to the hand when the gloved hand is in the primary beam (Wagner, 1996). Leaded gloves are

not recommended in this situation. The best way to protect the operator's hands is to keep them out of the radiation field. Leaded gloves may be of benefit if the operator's hands will be near, but not in, the primary radiation beam.

5.1.3 Effectiveness of shielding

The shielding material for protective aprons has evolved from heavy, lead-impregnated vinyl or rubber to lighter, composite (lead plus other high-atomic-numbered elements) or entirely lead-free materials. These lighter materials have largely replaced the all-lead aprons of the past. The lead equivalence of protective aprons can vary, typically in the range 0.25 to 0.5 mm lead equivalence. Transmission of X-rays through a protective apron depends on its lead equivalence, its elemental composition and the energy of the X-rays. For example, transmission of 70 to 100 kVp X-rays through a selection of nominally 0.25 mm lead-equivalent composite or lead-free aprons is approximately in the range 4%-20%, while for nominally 0.5 mm lead-equivalent aprons it was approximately in the range 0.6%-7% [68]. These values can be compared with transmission of 70 to 100 kVp X-rays through 0.25 mm and 0.5 mm of pure lead of 5%-15% and 0.5%-5%, respectively (Christodoulou 2003).

6. STAFF EXPOSURE MONITORING

6.1 Methods and international recommendations

Occupational radiation protection is a necessity whenever radiation is used in the practice of medicine. It is especially important for image-guided fluoroscopy procedures, with their associated high radiation dose rates. The radiation dose received by staff performing fluoroscopy procedure can be highly variable as a function of the complexity of the procedure, skill of operator and radiation protection knowledge. In this chapter a review of published data and data from specific hospitals are reported and discussed.

Workers present in surgical theatres or in rooms where fix or mobile radiography or fluoroscopy devices are used can require appropriate monitoring as well as protective tools according to the radiological workload and to the estimated level of the exposure of an individual. A qualified expert or radiation protection expert (RPE) must prescribe the required monitoring and protection systems.

6.1.1 Quantities and units

International organizations have published recommendations on the quantities and units that should be used in occupational dosimetry (ICRP, 1995; ICRP 2001). National regulations provide specific requirements for personal dosimetry. Dose limits to workers are expressed in terms of equivalent dose in an organ or tissue (H_T) for exposure of part of the body and effective dose (E) for whole-body exposure. The SI unit for both quantities is the sievert (Sv), with sub-multiples in common usage – the millisievert (mSv) and the microsievert (μSv).

Equivalent dose and effective dose cannot be measured directly. They must be calculated from other, simpler operational quantities that can be measured with personal dosimeters. Equivalent dose is the mean absorbed dose in a tissue or organ, T, multiplied by a radiation weighting factor, wR. For diagnostic X-rays, wR = 1, so the absorbed dose and the equivalent dose are numerically equal. Effective dose is the weighted sum of the equivalent doses in all specified tissues and organs of the body. These tissue weighting factors, wT, are highest for red bone marrow, breast, colon, lung, and stomach and lowest for cortical bone, salivary glands, brain, and skin (ICRP 2007).

A typical personal dosimeter, when calibrated appropriately, measures two operational dose quantities, called Hp(0.07) and Hp(10). These represent the dose equivalent in soft tissue at 0.07 and 10 mm below the surface of the body, respectively, at the location of the dosimeter (ICRP, 2007). Hp(10) is used for the assessment of effective dose, and Hp(0.07) for equivalent doses to skin and to hands and feet. A dosimeter worn on the front of the torso between shoulder and waist level, under the protective apron, will provide a good estimate of effective dose, but it does not provide any information about eye dose. Hp(0.07) from a collar dosimeter worn over protective garments (apron, thyroid shield) can provide a reasonable estimate of the dose delivered to the surface of the unshielded skin and to the lens of the eye.

The formula used to estimate E from dosimeter data may be specified by national regulations or by local hospital policy. The choice of an appropriate formula can be complicated in the interventional area because protective clothing is worn and often two dosimeters are used. There are many published algorithms for utilising dosimeter values, from one or more dosimeters, to estimate effective dose (NCRP 122, 1995; Huyskens, 1994; Rosenstein, 1994; Niklason, 1994; Padovani, 2001; von Boetticher, 2008; Clerinx, 2008). In all cases, it is important that the wearing position, the presence or not of protective clothing, the lead

equivalence of any protective clothing, and the reported dosimeter dose quantities are known.

6.1.2 Uncertainties in the assessment of occupational exposure

Uncertainties in assessing occupational exposure arise in three main areas – uncertainties in the dosimetry itself, uncertainties arising from the algorithm used to estimate effective dose, and uncertainties in whether the dosimeter was worn correctly.

Personal dosimeters are exposed to X-rays that irradiate the dosimeter directly and to X-rays that are scattered back from the wearer's body. Accuracy and precision of the dosimeters are affected by factors that influence the relative proportions of radiation reaching the dosimeter from these two pathways compared to those during calibration conditions. A comprehensive report on dosimetric uncertainty has recently been published, giving in-depth technical information (Clerinx, 2008).

All formulas used to estimate E from dosimeter readings are based on certain assumptions about the wearer's radiation protective clothing. For precautionary reasons, most of the commonly used formulas tend to overestimate the individual's actual effective dose. Detailed discussions of algorithms and their associated inaccuracies have been published (Jarvinen, 2008). This emphasizes the need for an appropriately qualified expert to interpret the personal monitoring in a facility.

Inaccurate occupational exposure assessment also arises from dosimeters not being used correctly. For example, a dosimeter may be worn in the wrong location on the body or it may be worn part of the time above the apron and part of the time underneath, or it may be worn back-to-front for some or all of the time. The dosimeter may be left, when not being used, in an area where it is exposed to further radiation. Individuals may also forget to wear their dosimeter or may deliberately not wear their dosimeter some or all of the time. All of these actions would result in a dosimeter value that leads to an incorrect estimate for E, making it impossible to determine the user's true occupational risk.

6.1.3 Dosimeter use

Persons performing or assisting radiological procedures that have been classified by the RPE as occupationally exposed are monitored to determine their level of exposure.

Several international and national organizations have published recommendations on occupational dosimetry that are applicable to workers in performing fluoroscopy guided procedures. The International Commission on Radiological Protection (ICRP) recommends that staff classified as professionally exposed wear two dosimeters, one under the apron and one at collar level above the lead apron (ICRP 85, 2000). Similar advice is given by the IAEA (IAEA, 1999). Hand doses, in particular the left hand, may also be monitored in practices where high doses to the hand are foreseen.

For pregnant workers, fetal dose can be estimated using the dosimeter being worn under the protective apron. Because this dosimeter is usually placed between the shoulders and the waist, sometimes an additional dosimeter is placed on the mother's abdomen, again under her radiation protective clothing. This dosimeter overestimates actual fetal dose because radiation attenuation by the mother's tissues is not considered. The dosimeter should be evaluated monthly.

6.1.4 Dose limits

Dose limits for occupational exposures are expressed in equivalent doses for deterministic effects in specific tissues and as the effective dose for stochastic effects throughout the body.

The current occupational dose limits recommended by the ICRP (ICRP 103, 2007) are the same as had been recommended earlier by the ICRP (ICRP 60, 1990), and as such have been adopted by most countries in the world. The dose limits are summarised in Table 6-1.

Table 6-1. Dose limits for occupational exposure (adapted from ICRP 103).

Dose quantity	**Occupational dose limit**
Effective dose	20 mSv per year averaged over five consecutive years (100 mSv in 5 years), and 50 mSv in any single year
Equivalent dose in:	
Lens of the eye	150 mSv in a year
Skin*	500 mSv in a year
Extremities (hands and feet)	500 mSv in a year

* Averaged over 1 cm2 of the most highly irradiated area of the skin.

Additional restrictions apply to the occupational exposure of pregnant women. For women who are pregnant, the ICRP recommends that the standard of protection for the conceptus should be broadly comparable to that provided for members of the general public [16]. ICRP go on to state that after a worker has declared her pregnancy, her working conditions should ensure that the additional dose to the embryo/fetus does not exceed about 1 mSv during the remainder of the pregnancy.

The current limit for the annual equivalent dose to the lens of the eye is 150 mSv. This limit is under review by an ICRP Task Group, as there is evidence that it is too high (Kleiman, 2007). The annual limit for the hands and feet is 500 mSv. The dose received by specific tissues such as the lens of the eye can be estimated by placing a dosimeter on or near the tissue of interest. The 'collar' dosimeter is commonly used to estimate eye dose in cardiac laboratories. This method is usually acceptable if the X-ray tube is positioned below the patient. However, collar dosimeters do not reflect the effect of protective eyewear, and will overestimate eye dose if protective eyewear are worn.

It is not possible to accurately estimate an operator's hand dose using body dosimeters because of the closer proximity of the hands to the X-ray beam and the source of scatter. A ring or bracelet badge is recommended to estimate hand dose.

6.1.5 Risk estimates

Effective dose (E) is intended to be proportional to the risk of radiation-induced cancer. The ICRP occupational dose limit given in terms of effective dose (see Table 6.1) is intended to limit the risk of stochastic effects to a level that is not considered unacceptable – i.e. the dose limit demarks the value, beyond which doses (and hence risks) would be generally considered unacceptable. Regulatory bodies require that a worker does not receive occupational exposure higher than the dose limits. Regulatory bodies also require the implementation of the principle of optimization of protection and, as a result, would expect occupational doses to be considerably lower than the dose limits.

Operators performing also highly complex fluoroscopy guided procedures who take all appropriate radiation protection precautions are unlikely to have an E exceeding 5 mSv/year and more likely to have an E in the range 1–3 mSv/year.

The risk to specific organs or tissues such as the fingers or the lens of the eye is related to the dose delivered to these tissues. The dose limits for these organs and tissues (see Table 6.1) are set with the purpose of preventing radiation effects, and occupational exposures at levels below the respective dose limits should preclude the occurrence of radiation effects. As noted above, the situation with respect to the lens of the eye is under review.

6.1.6 Evaluation of personal dosimetry data

Personal dose records. The information in a personal dose record will vary depending on the number, type, and location of personal dosimeters used. This record will contain information on the effective dose E, assessed from the readings of one or two dosimeters worn on the chest or abdomen under and/or over the lead apron, and may contain information on the equivalent dose to the lens of the eye from the dosimeter worn at the collar level over the apron or thyroid collar and the equivalent dose to the hand from a ring or bracelet dosimeter.

Dose reports need to be sent to the facility by the dosimetry service provider as soon as possible after each monitoring period. The results must also be made available to all monitored individuals and according to national regulation.

Surveillance of occupational dose. The facility's radiation safety section or medical physics service should review the personal dose records of individual workers regularly. This review ensures that dose limits are not exceeded. It also evaluates whether the dose received is at the level expected for that worker's particular duties. Workers' recorded dose levels should be compared to their own past dose levels and to the average dose levels of others doing similar work at the same facility or at other facilities.

Investigation of high occupational dose. Investigation levels for individual dose should be set for the facility on the basis of expected individual dose levels. The World Health Organization (WHO) recommends investigation when monthly exposure reaches 0.5 mSv for effective dose, 5 mSv for dose to the lens of the eye, or 15 mSv to the hands or extremities (WHO, 2000), these values being pro rata round-figure approximations to the sometimes-used approach of three-tenths of the respective dose limits (IAEA RS-G1.1, 1999). The facility's radiation protection officer or a qualified medical physicist should contact the worker directly to determine the cause of the unusual dose and to make suggestions about how to keep the worker's dose as low as reasonably achievable (ALARA).

Investigation of a high or unusually low personal dose value begins with a check of the validity of the dosimeter reading. Potential sources of invalid dosimeter readings include wearing of designated under- and overprotective apron dosimeters in the wrong location, wearing of a different worker's dosimeter, dosimeter storage in a location where it is exposed to radiation, and (in the case of an unusually low reading) failure to wear the dosimeter. If an invalid reading is suspected, the reading for the individual's next monitoring period should be reviewed to ensure the problem has been corrected.

If the dosimeters have been stored and worn correctly, the worker will be asked if there was a change in work habits that could explain the increase in radiation exposure. Was a new type of procedure initiated during the monitoring period? Were procedure techniques or equipment settings modified? If so, did these new methods require increased patient dose or closer proximity to the patient? Did procedure workload or complexity increase? Sometimes, a temporary cause is found. If this is the case, dose levels should return to usual levels during the next monitoring period, when workload returns to normal, equipment settings are corrected, or there is additional experience with a new procedure or technique. The individual's dose reading for the next monitoring period should be reviewed to confirm that dose levels have returned to the expected range.

If the cause is not thought to be temporary, or if no cause can be identified, the individual's working habits should be observed during a series of representative procedures. The observer could be a qualified medical or health physicist or a physician colleague. In all cases the observer must have good knowledge of radiation protection principles and the operation of the specific imaging equipment being used. The observer should pay close attention to equipment settings (particularly those that affect patient dose and dose-area product), the worker's proximity to the patient, and the use (or not) of equipment mounted shields and personal protective equipment.

6.2 European practice

6.2.1 Finland

In Finland staff engaged in radiation work have been classified into categories A and B.

Those who have or may have more than 6 mSv effective dose / year are classified in group A and they have to have personal/individual dosimeters. Monitoring period is 4 weeks. The others are classified in group B and they can have personal or a group dosimeter. Monitoring period in this group is 12 weeks. The TLD dosimeters are worn on the apron.

Doses are recorded in STUK.

Hospitals /responsible parties should maintain records of the doses of their staff.

Table 6-2. Number of exposed workers and annual doses reported from STUK (Finland) in 2009

Profession	No.	Maximum annual dose (mSv)	No/Total that exceeded 0 dose
Nurses	1134	3,3	116 / 1134
Staff other than nurses	62	0,2	5 / 62
Doctors involved in interventions and fluoroscopy (f.ex. gastroenterologists, neuroradiologist)	19	6,0	6 / 19
Other doctors (urologists, surgeons)	80	20,8	8 / 80
Orthopedics	47	1,2	3 / 47

Since 2009 surgeons have been removed from the STUK register and have been classified in the groups mentioned above but most of the surgeons are still classifying themselves as surgeons (26 / 242 exceeded 0)

There is some variation between hospitals concerning exposure monitoring of the staff. In some hospitals most of the radiologists and radiographers are in group B and have personal dosimeters; only interventional radiologists and some radiographers are in group A. The staff is mostly in group B and use group dosimeters (but the problem is that many of the staff members don´t use any kind of dosimeter!!!)

Medical surveillance

Class A workers have to have an examination by an occupational doctor before they start radiation work. The health examination must be carried out once every three years. A pregnant woman cannot be classified as class A worker.

For class B workers, a general physician can perform the medical examination.

6.2.2 France

General regulation on staff monitoring

Any worker who enters a “controlled area” has to wear both passive and electronic dosimeters.

If the worker only enters a “supervised area”, only a passive dosimeter is mandatory.

Dosimeter over and under the apron

As far as France is concerned, I did not find any detailed recommendations on this topic.

However, in a 2006 article, the French Institute of Radiation Protection and Nuclear Safety stated (A. Rannou, Adéquation de la dosimétrie au poste de travail, Radioprotection, 2006, Vol.41, n°1): “Contrary to others countries (Belgium, Switzerland…), the French regulation does not indicate any peculiar requirement to monitor people wearing lead aprons. Indeed, in these cases, a measurement with a passive dosimeter under the apron underestimates the effective dose as it does not allow taking into account doses delivered to parts of the body,

which are not protected by the apron. A solution can be to wear a second dosimeter at the neck or the shoulder (over the apron) and to combine both measurements in an adequate manner to obtain an effective dose."

In France, the common practice is also to wear the dosimeter under the apron.

6.2.3 Italy

In Italy there are no specific recommendations on the methods to apply staff dosimetry in these practices. National regulation (D.Lgs. 230/1995 and 241/2000) implementing the EU Directives are giving the responsibility of classification, staff and environment monitoring to the Qualified expert. Usually, the staff performing procedures outside radiology dpt. are classified as 'Exposed of category B' or 'Non-exposed'. The practice of personnel monitoring is quite extended: to all Exposed B and, sometimes, to Non exposed. All dose values are registered in personnel files.

From historical reasons, there are several personal Dosimetry services providing dosimeters using both TLDs or radiographic films. National bodies have not yet implemented a national dosimetry database and for this reason is quite impossible to have a national figure of staff exposures in the different areas.

6.2.4 Cyprus

The Medical Physics Department of the Nicosia General Hospital is the only provider of personnel dosimetry in Cyprus. It monitors all the radiation workers on the island. In total, 850 persons are monitored on the basis of six bi-monthly periods per year. The service is based on Thermoluminescence Dosimetry (TLD100). The doses are evaluated for skin ($Hp_{0.07}$) and whole body (Hp_{10}) and are quoted in mSv.

The local regulation foresees that radiation workers should be classified into Class A and Class B workers, depending on the monthly dose they are likely to receive. Workers' psychological factors as well as other union related supported demands hinder the practical application of this classification and all the radiation workers are monitored.

In an effort to collect doses for workers using X-Rays outside the X-Ray Department, the doses of Urologists, Orthopaedists, Gastroenterologists and their supporting staff (nurses) for 2009 were analysed. A conclusion could not be reached for the following reasons:

1. None of the monitored workers submitted their dosimeter regularly for evaluation for all the monitoring periods (6 per year).
2. For some monitoring periods the doses were consistent with the expected range for their respective activities, and in other monitoring periods they were below the reporting level of the personnel monitoring service (< 0.3 mSv).
3. The maximum body dose recorded in a given bi-monthly period in 2009, was for a Gastroenterologist at 1.70 mSv, followed by the dose of an Orthopaedist at 1.56 mSv. The doses of the rest of the workers where well below 0.6 mSv, which is the bi-monthly investigation level. This indicates that most likely the majority of the workers do not use always their dosimeters but only occasionally within a given monitoring period.

Although the local regulation specifies that all radiation workers should be monitored, it does not impose any reprimand; therefore, the workers do not adhere to the dosimetry service instructions of consistently wearing their dosimeters, and further, wearing at the correct position on their body when they are working with ionising radiation.

6.2.5 Greece

In Greece, for the purposes of monitoring, a distinction is made between the following categories of exposed workers: Category A: those exposed workers who are liable to receive

an effective dose greater than 6 mSv per year or an equivalent dose greater than three-tenths of the dose limits for the lens of the eye, skin and extremities and category B: those exposed workers who are not classified as exposed category A workers. Radiation workers carrying out examinations outside radiology department are usually classified as category B workers. For these workers, dose assessment is not systematic. However, monitoring for category B workers shall be sufficient to demonstrate that such workers are correctly classified in category B. Assessment of individual doses is systematic for exposed category A workers. TLD personal dosimeters are worn upon the apron. The Greek Atomic Energy Commission coordinates the work of measuring the doses to the staff exposed to radiation and keeps the official record of these measurements. Dose measurements are carried out by the Commission's staff dose measurement laboratory. The employer keeps the dosimetry results in archives which must be accessible to every employee. In any case in which the effective dose received by the exposed worker exceeds 6 mSv per year, the radiation protection officer investigates the reasons and, where necessary, proposes measures and submits a written report through the official channels to the Greek Atomic Energy Commission.

6.2.6 Norway

Personnel dosimetry in Norway

Medical staff working with radiation is not classified in different categorizes in Norway (i.e. A and B). According to the regulation [1] the health care enterprise shall classify the workplace as a controlled area if employees may be exposed to radiation doses above 6 mSv per year or if the dose to the hands may exceed 150 mSv per year, or classify the workplace as a supervised area if employees may be exposed to radiation doses in excess of 1 mSv per year or if the dose to the hands may exceed 50 mSv per year. Employees who work within a controlled or monitored area shall carry a personal dosimeter or ascertain their personal radiation exposure by other means. The Norwegian Radiation Protection is the only supplier of dosimetry service for medical staff in Norway, and the dosimetry badges are worn over the apron for two months.

In the guidance to the regulation [2], reference dose levels (RDL) are proposed for staff doses in diagnostic radiology (table 1). The RDL should be understood as an action level for investigation of high staff doses. The RDL are differentiated, depending of the type of work performed by the individual.

Table 6-3.Reference dose levels for staff doses in diagnostic radiology (2 month period).

Type of activity	**Action level - Dosimetry badge dose, unshielded over the apron H[10]**
Only X-ray photographing	2 mSv
X-ray photographing and fluoroscopy (i.e. barium studies or fluoroscopy during operations)	4 mSv
Physicians or other staff standing close to the patient during angiography and interventional radiology	10 mSv
Other staff in interventional radiology	3 mSv

There is also a "cooking book" in the guidance for local investigation and follow-up of high staff doses.

Investigation

- Training and education

    - Have the employee sufficient education and competence in radiation protection?
    - Have the employee received education on the actual X-ray equipment?
- Routines and procedures
    - Have the employee changed the procedures or started with new procedures?
    - Is the working technique (no. of images, fluoroscopy time, collimation, exposure settings etc.) different compared to other colleagues?
    - Is it over- or under couch tube?
    - Is it registered any irregular equipment performance?
- Equipment
    - What dose reduction possibilities are there?
    - Is the equipment optimized for the actual procedure in relation to dose and image quality?
    - Is there any equipment failure that can affect the dose?
- Other possibilities
    - Could the dosimeter by a failure been close to the X-ray beam?
    - Have the employee been to an X-ray procedure as a patient without taking off the dosimeter?

Follow-up and actions for reducing the dose to the employee in the future

- Education and training in radiation protection and proper use of X-ray equipment.
- Routines and procedures
    - Is the image quality adjusted to the required diagnostic information?
    - Are the eventually dose reduction possibilities for the actual equipment in use?
    - Can the distance to the X-ray beam be increased?
    - Can the exposure time for the employee be decreased?
    - Are the available shielding devices enough and easy to use?
    - Can the employee be shielded more efficient?
- Personal shielding
    - Are the thickness, length, and covering adjusted to the actual employee and procedure?
    - Use of thyroid collar?
    - Assess the need for lead goggles and lead (or equivalent) gloves.

<u>Staff doses for surgeons and orthopaedics in Norway 2009</u>

There were 52 surgeons and 84 orthopaedics that used personal dosimetry in Norway during 2009. In Norway the dosimeters are worn unshielded over the apron. Doses below 0.1 mSv (H[10]) are not reported back to the hospitals. 86.5% of the surgeons did not have a dosimeter reading during 2009. The same figures for orthopaedics were 73.8%. The average dose for all surgeons and orthopaedics using personal dosimetry were 0.77 and 0.19 mSv respectively. The average dose for surgeons and orthopaedics with a dosimeter reading during 2009 were 5.71 and 0.72 mSv respectively (Table 6-4).

If I would guess which groups that have the highest radiation doses, I believe that may be vascular surgeons and those involved in multi-trauma treatment. My brother is an urologist in Sweden, and he has informed me that they just use little radiation.

Table 6-4. Average dosimeter values (H[10]) for surgeons and orthopaedics in Norway 2009.

	No. monitored	**Dose=0**		**Average dose (mSv)**	**Average dose > 0 (mSv)**	**Maximum annual dose (mSv)**
		No.	%			
Surgeons	52	45	86.5	0.77	5.71	26.6
Orthopaedics	84	62	73.8	0.19	0.72	4.2

Finger doses

In a survey, finger doses to 16 orthopaedic surgeons were measured performing 52 operations, mainly hip operations [3]. The mean annual estimated finger dose was 13.7 mSv and the maximum annual finger dose was estimated to 60.4 mSv. Four vascular surgeons performing 15 stent-grafts had a mean finger dose of 0.35 mSv per treatment, with a maximum finger dose per treatment of 1.2 mSv.

Recognizing the use of radiation in surgical procedures

There is a coding system in Norway for surgical procedures, mainly used for reimbursement purposes. For some of the procedures is it possible to see if there has been radiation involved in the procedure. Common for those procedures are that the use of radiation is an independent part of the operating procedure, i.e. per-operative angiography for controlling a by-pass or per-operative contrast injections in catheters during urology procedures. When the radiation is used only as a device for monitoring (i.e. most of the orthopaedic operations) it is not possible to identify the use of radiation in the surgical coding system.

Stent-grafting of abdominal aortic aneurysms (AAA) and staffing in Europe

Patient doses together with conversion factors for DAP to maximum entrance surface dose (MESD/DAP) and DAP to effective dose (ED/DAP) for eight patients are summarized in Table 6-5 [4]. The effective dose to the patients is quit high, with an average of 50 mSv per procedure. The post-operative controls are performed by CT scanning, typically after 1 day, 1 week, 3 month, 12 month and then every year life-long. In a new project starting up this year, a Ph.D. student (medical doctor) will among other factors evaluate collected dose data for 70 AAA patients. One aim is to compare CT versus ultrasound for the life-long post-operative follow-up, both in relation to clinical outcome and radiation doses.

Table 6-5. Mean values of total DAP, maximum entrance surface dose (MESD) and effective dose (ED) together with DAP to maximum entrance surface dose conversion factor (MESD/DAP) and DAP to effective dose conversion factor (ED/DAP) for the endovascular treatment procedure of AAA. Range is given in brackets.

DAP [$Gycm^2$]	MESD [Gy]	ED [mSv]	MESD/DAP [$Gy/Gycm^2$]	ED/DAP [$mSv/Gycm^2$]
338 ± 32% (167-439)	1,79 ± 26% (1,35-2,27)	50 ± 34% (22-64)	$0{,}61 \cdot 10^{-2}$ ± 33% $(0{,}48\text{-}0{,}85) \cdot 10^{-2}$	0,15 ± 7% (0,13-0,17)

Aortic stent-grafts are performed by different physicians and in different settings around Europe. The practice can also differ within a country. According to a vascular surgeon I talked to, the stent-graft procedures can be performed in the following ways:

1. Performed jointly by radiologists and vascular surgeons in a radiology department or in an operation theatre.
2. Performed independently by radiologists in a radiology department.
3. Performed independently by vascular surgeons in an operation theatre.

C-arms

During ECR2010 I had meetings with a couple of vendors offering mobile C-arms. One of the bigger companies seems to be Ziehm Imaging, which are the only company that have sold C-arms in Norway during 2009. The functionality of the C-arms are often different, depending on the surgical discipline that will use it (orthopaedic, neurologist, vascular etc.). For orthopaedic, neuro and craniomaxillar surgery they are marketing a model that can perform

3D scanning. During the 3D scan the detector and tube will rotate 135° around an isocenter and capture >100 images in a minute. The staff from Ziehm was not able to give any dose values, but compared the dose similar to a CT scan. Other vendors are also developing C-arms with 3D technology. My first thought about the modern advanced C-arm, was whether the orthopaedics are able to utilize all the options on the C-arm? The vendor from Ziehm had the same thoughts also!

References (Norway)

[1] Regulations No. 1362 of 21 November on Radiation Protection and Use of Radiation (Radiation Protection Regulations). Ministry of Health, 2003. http://www.nrpa.no/dav/6cb7606703.pdf
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6.3 Review of the European Commission Radiation Protection Report No. 160

Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation

This report is not directly relevant to the work of Work Package 3. It is mainly relevant to the set up and operation of an individual monitoring service/laboratory. The technical recommendations aim to present good practice for individual monitoring as a comprehensive and consistent text including guidance and recommendations that will contribute to the harmonization of individual monitoring procedures in the European Union Member States.

The report and its recommendations are restricted to routine individual monitoring from external exposures to ionizing radiation.

Important issues such as measurement quantities and units, expression of uncertainty in measurement and in calibration, dosemeters and dosimetry system requirements, the individual monitoring programme, and their link to QA are dealt with. The implementation of a quality system conforming to the EN ISO/IEC17025:2005 standard is a way to demonstrate that the dosimetry service operates a quality system, is technically competent, and capable of generating technically valid results.

The need for individual monitoring depends on the radiation conditions in the area concerned and the type of work. The choice of appropriate monitoring programme and the choice of suitable dosemeter are very important.

It is mentioned that when wearing a lead apron, double dosimetry is recommended. The dosemeter above the apron should be worn at the collar level, and the result from this dosemeter can be used, in addition, to estimate equivalent dose to the eye lens. The dosemeter under the apron may be worn at the waist or chest, preferably the chest, but a different algorithm will be needed for the different positions. In situations where it is well established that doses are low, it is acceptable to wear only one dosemeter. To obtain the best estimate of effective dose this should be worn under the apron, although a more sensitive indication of changes in the working environment can be achieved with a dosemeter worn on the collar with the application of a correction factor. This approach is less likely to lead to an underestimate of effective dose.

The accuracy of a measurement can often be improved by the application of a field-specific correction factor, or normalization factor. This can be determined by carrying out in-field calibrations or by using information of the workplace field characteristics combined with the dosemeter energy and angle characteristics.

The characterization of workplace fields may be done by a combination of measurements and calculations, or by measurements alone. Unless necessary, the measurements need not be too elaborate. As a minimum, knowledge is needed of the location, type and size of sources, the amount of shielding and scattering material and ambient dose equivalent rates. Additional characteristics may also include not only the energy and direction distributions of the radiation field, but also the time dependence, in particular whether it is pulsed or not.

The fields will usually comprise direct and scattered components resulting in broad energy and direction distributions. In some instances, however, simple procedures can be used to identify areas where there is a strong low energy component which may lie below the threshold of an electronic personal dosemeter. Similarly it is possible to search for radiation incident at unexpected angles, by using lead shielding around a Geiger-Müller detector to collimate the response to a few tens of degrees. Radiation fields may be significantly spatially non-uniform, leading to non-uniform exposure of the body. It is then difficult to make appropriate assessments of $H_p(10)$ and $H_p(0.07)$, and of effective dose when this is required.

By implementing these recommendations, the monitoring of individuals occupationally exposed to external radiation will be more accurate, consistent and harmonized throughout the European Union Member States.

7. PATIENT DOSIMETRY

7.1 Methods

When contemplating a patient dose survey it is important to develop a clear measurement strategy. This involves a detailed consideration of the most applicable dose measurement method for the intended survey [1]. There are three measurement methods that are used in practice:

1. Direct measurements.

   Thermoluminescent dosimeters (TLD) are used to measure entrance surface air kerma ESAK. These dosimeters are usually placed in plastic sachets and attached to the patients skin using surgical tape.

   TLD is widely used for patient dosimetry in diagnostic radiology. These dosimeters are very sensitive to radiation which means that the dosimeters can be quite small. TLD dosimetry materials such as lithium fluoride or lithium borate are approximately tissue equivalent and consequently are practically invisible on most radiographs. This means that the use of these dosimeters does not interfere with the clinical diagnosis.

2. Indirect measurements.

   Patient dosimetry for examinations involving fluoroscopy are fraught with difficulties. Direct measurements using TLD are difficult because the area of the patient lying within the primary beam changes during the examination. Calculation is complicated because the technique factors vary for multiple projections under automatic control.

   In fluoroscopy, measurements of dose-area or air-kerma area product (KAP) is the method of choice. A large area ionisation chamber is attached to the X-ray tube housing. The area of the X-ray beam increases with increasing distance from the source of radiation according to the inverse square law. Similarly, the radiation dose decreases with distance from the X-ray tube, also according to the inverse square law. These two effects cancel out and as a result the quantities dose-area and air kerma-area product are independent of distance from the X-ray tube.

   Dose area product instruments must be calibrated on the X-ray equipment with which they are to be used. In particular, an allowance for the attenuation of the patient couch should be made on fluoroscopy equipment with an under-couch X-ray tube and over-couch image intensifier configuration.

3. Calculations

   It is possible to estimate patient doses using the X-ray tube output. The tube output should be measured using a calibrated ionisation chamber at a known distance from the focus and the same technique factors.

   It is possible to extrapolate the output if the technique factors at which the patient was examined do not correspond to those at which the output was measured. Given the tube output, tube potential tube current, exposure time and focus skin distance it is possible to deduce the air kerma at a point corresponding to the position of the patients' skin. Skin entrance dose requires a knowledge of the back scatter factor and hence the X-ray field size and tube filtration.

   Monte Carlo simulations on mathematical or realistic anthropomorphic phantoms are commonly used to asses organ doses and, finally, effective dose.

7.2 European practice

7.2.1 Cyprus

The local regulation for medical exposures states that all patient doses due to diagnostic imaging procedures with ionising radiation should be recorded and kept in a database which should be made available to the competent authority for inspection if and when requested.

The X-ray diagnostic imaging modalities of the Nicosia General Hospital are either Direct Digital Radiology (DDR) or Computed Radiology (CR). All images are archived in a Picture and Archiving Communication System (PACS), which indirectly serves as the hospital's patient dose database.

In an effort to establish Local Derived Reference Levels (LDRLs) for the fixed DDR modalities at the X-Ray department of the hospital, patient doses were calculated by using the x-ray tube output of each modality and the examination procedure exposure parameters extracted from the DICOM header of the images stored in the PACS. It was also possible to extract from the DICOM header the Kerma Area Product of each examination.

The table below gives the average dose to the patient in terms of both Entrance Surface Air Kerma (ESAK) in units of mGy and Kerma Area Product in units of $mGycm^{-2}$, for nine radiographic examinations. The error was estimated as the Standard Error of the Mean value of the collected doses.

Examination	Average Dose	
	KAP ($mGycm^2$)	ESAK (mGy)
Skull AP	795.21±44.51	2.78±0.16
Skull LAT	693.48±34.72	1.71±0,09
Cervical AP	226.31±22.77	1.17±0.12
Cervical LAT	157.27±20.54	1.17±0.15
Chest PA	124.84±4.21	0.39±0.01
Lumbar Spine AP	2228.36±145.60	4.00±0.26
Lumbar Spine LAT	3715.17±119.96	10.49±0.34
Abdomen AP	3126.08±306.52	4.50±0.44
Pelvis AP	2714.73±201.33	3.83±0.28

In a recent study, that investigated the frequency at which the mobile X-ray radiography units are used at the Nicosia General Hospital (500 beds), data was also collected on patient dose from Chest examinations performed at the Intensive Care Unit (ICU). The ESD for this examination ranged from 18 to 234 μGy, with a mean value of 60 μGy.

At a first look these results are impressive since they show values well below those from the fixed DDR modalities. On a closer look at the examination parameters and quality of the images from these procedures revealed that these dose results are not valid since non of the images met the criteria of a good Chest X-ray examination. For more details please refer to case 8 in section 11 of this synthesis document.

7.2.2 Finland

In Finland we have no requirements for monitoring patient doses outside radiological depts but according the legislation it must be possible to assess the patient dose afterwards. After

the intervention such information must be recorded so that the dose assessment is possible. DAP, fluoroscopy time, kV and mA are often recorded in some notebooks or in some hospitals in electronic patient records. STUK has no data / dose records of fluoroscopy outside radiological depts.

7.2.3 France

In France, measurements and records of patient doses are mandatory since the transposition of the EC directive 97/43 (2003): there is an obligation to optimise practices and to inform patients of the received doses.

An order of February 2004 obliges the comparison of doses received by the patients with national references (diagnostic reference levels) and to send data to IRSN (French Institute of Radiation Protection and Nuclear Safety).

Another order of June 2004 obliges hospitals to acquire new equipments and dosimeters that allow display and recording of delivered doses (display of DAP on screens…).

7.2.4 Italy

In Italy the national regulation on medical exposure (D.Lgs. 187/2000) is requiring the responsible person of the radiological installations (a Radiologist in this area) and to the Medical physics expert (a Medical physicist) to make a biennial evaluation of patient doses for each radiological installation where DRL are defined (not fluoroscopy procedures). The practices outside the radiology depts. are not mentioned in the regulation. Some hospitals are considering these practices as interventional radiology procedures and for this, part of the 'Special practices', regulation, is requiring dose monitoring without specifying the periodicity. Frequently the monitoring is performed biennially when DRL for routine practices are checked.

The dose data evaluated by the hospitals are every 5 years and are collected by the regional authorities (21 in Italy) to make a population dose estimation to inform to the Ministry of Health. But, up to now, there are no official data available at the national level on patient and population exposure in the different radiological practices.

7.2.5 Greece

In Greece, national radiation protection regulations require that examinations involving ionizing radiation should be optimized. According to these regulations, 'the optimization process shall include assessment and evaluation of patient doses'. In another paragraph, radiation protection regulations state that 'For each type of radiological examination, the doses to the patient must be measured and evaluated and compared with the corresponding reference level doses. The reference level doses for each radiological examination shall be laid down in circulars published by the Ministry following recommendation and approval by the Greek Atomic Energy Commission'. However, so far reference level doses have been determined only for x-ray mammography and several nuclear medicine examinations. An important provision in the radiation protection regulations related to patient dose measurements is that 'All new radio-diagnostic equipment must have a device informing the physician of the dose or the dose rate during the radiological procedure'.

8. EDUCATION AND TRAINING OF HEALTH PROFESSIONALS INVOLVED IN RADIOLOGICAL PRACTICES OUTSIDE RADIOLOGICAL DEPARTMENTS

Mobile x-ray equipments are often operated by physicians and nurses with limited knowledge of radiation effects and methods of how to avoid or reduce them. This has been recently illustrated by reported examples of bad practices. In particular, it has emerged as a result of a Norwegian survey[1] that there was an inadequate knowledge of the medical staff on:

- C-arms characteristics: for instance, difficulties to identify the X-ray tube from the image intensifier.
- Operation console: new systems are sophisticated and manufacturers have included many technical features to reduce radiation doses. However, a lack of RP knowledge on the detailed operation of these systems can sometimes prevent health professionals from gaining their full advantage (switch on and start fluoroscopy regardless of the default exposure settings).
- The three cardinal principles for staff radiation protection: time, distance and shielding.
- Patient doses and risk.

Consequently, in order to improve current practices of health professionals involved in radiological practices outside radiological departments, there is a need to develop an ALARA culture with the final objective to change their working behaviour. In this perspective, this chapter is structured in three parts:

- A description of the European Commission (EC) directives and guidelines related to radiation protection education and training.
- A first overview of training practices throughout Europe (with the aim to identify good practices).
- The identification of existing training materials that the EMAN network considers as useful and relevant.

It should be noted that a very wide range of staff can be involved in the procedures covered by this report and that they all have their own sensitivity as far as radiation risks are concerned.

8.1 EC DIRECTIVE AND GUIDELINES

The following part is based on the EC Directives 96/29 and 97/43 and associated documents, but it is reminded that the European Commission is currently revising its BSS.

As far as radiation protection training of medical staff is concerned, two different levels can be distinguished:

[1] Friberg et al., Not able to distinguish between x-ray tube and image intensifier: fact or fiction? Skills in radiation protection with focus outside radiological departments

- General RP training of exposed workers, covered by the EC Directive 96/29 “laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation”.
- Training for radiation protection of patients, covered by the EC Medical Exposure Directive 97/23 on “health protection of individuals against the dangers of ionizing radiation in relation to medical exposure”.

8.1.1 General radiation protection training of exposed workers

The Article 22 of the EC Directive 96/29 is dedicated to “Information and Training”. It notably states that: *“Member States shall require the undertaking to arrange for relevant training in the field of RP to be given to exposed workers, apprentices and students.”*

In the case of “practices outside radiological departments”, the problem can be that physicians and nurses operating equipments may not be considered as exposed workers. Consequently, they may not benefit from this training.

8.1.2 Training for radiation protection of patients

Two major articles of the EC Directive 97/43 are devoted to education and training of medical staff for radiation protection of patients: articles 7 and 9. Professions concerned are “practitioners”: a practitioner is defined as a medical doctor, dentist or other health professional, who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements. The Directive covers both initial and continuing training.

According to Article 7 of the Directive, Member States shall also ensure that practitioners have adequate theoretical and practical training for the purposes of radiological practices, as well as relevant competences in radiation protection. In particular, they shall ensure that continuing education and training after qualification is provided and shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools. Moreover, Article 9 requires Member States to ensure that practitioners conducting special practices receive appropriate training. This article applies to professionals working on radiological practices outside radiological departments.

8.1.3 EC guidelines on education and training in radiation protection for medical exposures

In 2000, the European Commission published guidelines to facilitate the practical implementation of the Directive 97/43 and give recommendations for the training of health professionals (Radiation Protection 116, Guidelines on education and training in radiation protection for medical exposures).

This document offers generic recommendations relating to the contents of training of health professionals according to their speciality (physicians or not). It recommends that general practitioners acquire basic knowledge on radiation protection of patients (concepts of justification and optimisation) and that specialists benefit from extra training, including practical work: medical doctors using X-ray systems (especially fluoroscopy systems) such as urologists, vascular surgeons and traumatologists are examples of this second category.

The EC guidelines are structured as follows: a general introduction provides background information and indication of the required level of training in radiation protection. This is followed by a chapter on general recommendations for training programmes in radiation protection. The third chapter gives recommendations for the establishment of credentials in radiation protection. Chapter 4 lays down recommendations for radiation protection of the patient during training programmes in health centres. Chapter 5 provides recommendations for continuing education and training after qualification and when new techniques are

implemented. Chapter 6 includes recommendations for introducing the course on radiation protection in the basic curriculum of medical and dental schools and is followed by seven annexes presenting examples of specific educational objectives to be included in some of the training activities. An annex is dedicated to "outline for specific training in radiation protection for interventional radiology" (see Annex 1).

Table 8-1 describes the recommendations on content and duration[2] of RP training courses according to the concerned profession. It is worth underlying that the EC recommendations include practical exercises and practical sessions in the programmes for training in radiation protection: *"a minimum of 1-2 hours practical session in a clinical installation should be included in the most simple training programmes, while 20-40% of the total time scheduled in more extensive courses should be devoted to practical exercises".*

The columns dedicated to "MD - other medical doctors using X-ray systems" and "NU - nurses" (in grey) are of primary interest for "practices outside radiological departments". It is pointed out that the proposed duration of training is from 10 to 20 hours. In addition, RP 116 recommends that some special consideration may be required in the case of medical doctors (non- radiologists) using fluoroscopy X-ray systems regularly (urologists, vascular surgeons, traumatologists, etc.), but contents are not detailed.

Table 8-1. EC Proposal for training areas and course duration.

Training Area	**DR MD**	**RT MD**	**NM MD**	**CD MD**	**DT**	**MD**	**RD**	**NU**	**ME**
Atomic structure, production and interaction of radiation	M	H	H	L	L	L	M	L	M
Nuclear structure and radioactivity	M	H	H	L	-	-	M	L	M
Radiological quantities and units	M	H	H	M	L	L	M	L	M
Physical characteristics of the x-ray and therapy machines	M	H	L	M	L	M	M	L	H
Fundamentals of radiation detection	L	M	H	L	L	L	M	L	H
Fundamentals of radiobiology. Biological effects of radiation	M	H	H	M	L	M	M	L	L
Radiation protection. General principles	H	H	H	H	M	M	H	L	M
Operational radiological protection	H	H	H	H	M	M	H	M	M
Particular patient RP aspects	H	H	H	H	M	H	H	M	M
Particular staff RP aspects	H	H	H	H	M	H	H	M	M
Quality control and quality assurance	M	H	H	M	L	L	M	L	H
National and European regulations and standards	M	M	M	M	M	M	M	L	H
Suggested number of training hours	**30-50**	**40-60**	**30-50**	**20-30**	**10-15**	**15-20**	**40-100**	**10-15**	**40-60**

Legend:
Health professionals
DR/MD: Diagnostic Radiology Specialists (Medical Doctors)
RT/MD: Radiotherapy Specialists (Medical Doctors)
NM/MD: Nuclear Medicine Specialists (Medical Doctors)
CD/MD: Interventional Cardiology Specialists (Medical Doctors)
DT: Dentists
MD: Other Medical Doctors using X-ray systems
RD: Radiographers
NU: Nurses
ME: Maintenance Engineers

Level of knowledge
L: Low
M: Medium
H: High

Furthermore, RP 116 indicates that the topics listed below should also be considered. These are relevant for the training of professionals using fluoroscopy equipment.

[2] The number of hours indicated in Table 8.1 should be considered as being in addition to the basic training for prescribers and could be included in different training periods such as basic residency programmes and special training courses.

- Radiation effects,
- Definitions of the variety of terms used for dose,
- Relationship of equipment characteristics to dose and image quality,
- Relationship of exposure factors to dose and image quality,
- Concept of risk, comparative risk through age range and period of pregnancy,
- Protocols for over exposure and accidents,
- Clear communication at the appropriate level with patient, staff, comforters and carers and the public,
- Diagnostic reference levels.

Table 8-8. Outline for specific training in radiation protection for interventional radiology from the EC guidelines – RP 116 in the appendix of this chapter provides more details.

8.2 OVERVIEW OF TRAINING PRACTICES THROUGHOUT EUROPE

The following section intends to describe radiation protection training practices of medical staff involved in radiological practices outside Radiology departments in Europe. It is focused on training to radiation protection of patients.

Table 8-2 A, B, C and D briefly describes training practices in European countries as a result of an extended survey in most of the European countries.

Table 8-2. A. RP training practices in European countries

Country	1a. Education for medical students?	1b. Is this assessed by an exam?	2a. Is there a national legislation for compulsatory education and training for staff other than radiographers and radiologists?	2b. What is the duration of the course in hours?	2c If YES on Q2a, who organizes the courses (university, school, hospital etc.)?	2d. Is there an official pass/fail assessment at the end of the course?	3. Are there compulsory refresher courses (CPD), i.e. every 5th year? Please indicate the frequency.
Austria	Yes, 24 hours	Yes	Yes	8 hours/ 5 yrs	University, University of applied sience, society of radiation protection...	Yes	Yes, one/two times per year by society
Belgium	No	-	Yes	50 hours	Universities/schools	Yes	No
Cyprus	No	-	Yes (but no medical university in Cyprus)		-	No	No
Czech Republique	Marginally	No	YES, for other professions working with x-ray (veterinary, interventional cardiologist and dentist). Not for orthopaedics, surgeons etc. because radiographers operate the equipment in operation theatres.		State Office for Nuclear Safety	YES (two stage, or two levels pass).	Lower level is valid for life. Higher level is valid for 10 year
Estonia	Yes	Yes	Yes	1 year – 100 hours, 2 year – 53 hours, 3 year - 27 hours	University, college, hospital and professional society	Yes	Yes, every 5th year
Finland	Yes, 40 hours	Yes	e.g. nurses who are working in operating theatres according the advice of a doctor has to have 40 hours in basic education.	40 hours	University of applied sciences, professional societies, organizations or STUK. Further training locally	Yes	Every 5th year. 40 hrs.: Radiologists, physicans in NM and therapy and other physicians and staff involved in high dose procedures (e.g. cardiology). Also 40 hours for orthopaedist and other physician using radiation a great deal. 20 hrs.: orthopaedics, cardiologists and other physicians using radiation and other involved staff (e.g. operation nurses). 8 hrs.: Referring physicians.

Table 8-3. B. RP training practices in European countries

France	Yes, about 10 hours	No	Yes, during post graduate studies for surgeons, cardiologists, radiologists and dentists	1-3 days	Mainly Universities and hospitals	No	Every 10th year
Germany	No, but a recommendation from National Radiation Protection Commission to implement a radiation protection course(8 hrs) for medical students. Depends on the different Universities.	When the course is implemented it will be assessed by an exam	Yes	Medical doctors: Basic course (24 hours) and additional special courses (between 20 and 28 hours). Other staff: Basic course (between 4 and 90 hours) and additional special courses (between 24 and 28 hours)	University, school, hospital	Yes	Yes, every 5th year (8 hours.)
Greece	Yes (6-+10 hours depending on University)	Yes (certificate)	Yes	18 hours	The Greek Atomic Energy Commission provides education and training courses in radiation protection and organizes seminars and workshops in collaboration with professional and scientific institutions	?	No
Hungary	No	No	26 hours advanced course for the "button-pusher" (e.g. nurse) and 10 hours basic for the rest (scrub nurses, surgeons etc.).	26/10 hours	University, hospital, others, but only accreditated courses are accepted.	Yes	Every 5th year with written assessment.
Iceland	1-2 lectures for 3rd year students	No	1 day for responsible persons	1 day	Icelandic Radiation Safety Authority	No	No

Table 8-4. C. RP training practices in European countries

Ireland	Yes for some Medical Schools and No for others. Some local training in certain hospitals	Yes or No depending on Medical School	Yes	amount of content varies	Medical Schools	Varies	In some centres yes in others No
Italy	Yes (but only a few hours)	Yes	Education for medical doctors and radiographers; training for all (also nurses)		Education: Universities; Training: hospitals and scientific societies	Education: yes. Training: yes but very simple	Yes: every 5th year, but extent of course differs between hospitals.
Latvia	No, only for dentists	Yes	Yes	10 hours	School and hospitals	Yes	Yes, every 5th year
Lithuania	Yes, for some of them from 8 h (dentistry) to 120 h (public health)	Mostly it is assessed by exams and in rare cases it has just an average score (mark)	Required training and CPD in field of RP for everybody who use ionizing radiation.	Depending on risk category of ionizing radiation source from 30 to 270 hours	Higher education is organized by universities and collegies. Training centres are organizing informal training (compulsory training on RP, also refreshing courses). Practical part of trainings is organized in hospitals.	Certificate 36 hours	Yes: every 5th year
Norway	No (some education in one University)	-	Yes	Depending on the different enterprice	Locally	No	No
Portugal	No	No	No	-	No	No	No
Slovakia	Yes	Yes	Yes	16 hours	Institute for Radiation Protection or national public health organizations	Yes (certificate valid for undefinit periode)	Every 5th year (refresher course only for a representative for the department, responsible for RP. Could be MD, radiographer, nurse etc.
Slovenia	No	No	Yes, for all participating in procedures that involve X-ray.	20 hours	Institute of Occupational Safety	Yes	Every 5th year (3 days)

Table 8-5. D. RP training practices in European countries

Spain	Yes (70 hours)	No	Yes	Depending on the different enterprice	University, schools, hospitals	Yes	No
Sweden	No	-	Yes		Locally	No	No
Switserland	Education for medical, veterinary and dental doctors / medical, veterinary an dental assistants, dental hygienists	Yes	Yes		Private Firmas, Research Institutes, Schools for Radiographers	Yes	No
UK	Yes	No	Yes		University/Hospital/other	No	Yes

8.2.1 Cyprus

In Cyprus, there is no compulsory education in radiation protection since none of the Cypriot Universities has a medical faculty. Medical staff studies abroad.

The Cypriot government has transposed the EURATOM directives in July 2002 into a framework law (N. 115(I)/2002) and a number of regulations under this law: Council Directive 96/29/Euratom was transposed into regulation Κ.Δ.Π. 494/2002 and Council Directive 97/42/Euratom into regulation Κ.Δ.Π. 497/2002.

Regulation Κ.Δ.Π. 497/2002 gives the minimum requirements in terms of education and training that the various health professionals using ionising radiation should meet. Table 8-6 corresponds to the first part of this appendix that specifies topics that are relevant to their activities as physicians and operators. Appendix 2 of Κ.Δ.Π. 497/2002 also specifies topics that are relevant to the activities of specialists in radiological practices. These minimum requirements do not make any distinction between the various health professionals. Table 8-7 lists the topics for health professionals using diagnostic radiology equipment only to illustrate the depth of education and training required.

Table 8-6. Minimum requirements about radiation protection for Cypriot health professionals

1. Basic Knowledge on Ionising Radiation Physics

1.1 Properties of Ionising Radiation
- Attenuation of ionising radiation
- Scattering and absorption

1.2 Dangers from Ionising Radiation and Dosimetry
- Biological effects – Elements of Radiobiology
- Risk/Benefits of Ionising Radiation
- Dose Optimisation

1.3 Dosimetry
- Absorbed dose, equivalent dose, active dose and units of measurement

1.4 Special Topics
- Pregnancy and Ionising Radiation
- Children and ionising Radiation
- Population screening programmes

2. Management and Protection of Patients from Ionising Radiation

2.1 Choice of patients
- Justification of Exposure
- Clinical Evaluation of the exposure results
- Alternative Techniques
- Use of Available and Suitable Patient Radiological Information
- Medico-Legal Matters

2.2 Protection from Ionising Radiation
- General Information on Protection from Ionising Radiation
- Use of Devices for the Protection from Ionising Radiation
  1. Patients
  2. Staff
- Procedures for Incidents and Accidents with Over Exposure to Ionising Radiation

3. Legislative Obligations and Advisory or Consultancy Subjects
- Legislation
- Procedures and Rules for each Radiological Installation
- Responsibilities in Relation to Medical Exposures
- Responsibilities in Relation to protection from Ionising Radiation
- Daily Equipment checks and tests
- Defective Equipment Reporting
- Clinical Audit

Table 8-7. Specific requirements for health professionals using diagnostic radiology equipment

1.	**General**
	• Selection and Use of Equipment
	• Factors that influence ionising radiation dose
	• Dosimetry
	• Quality Assurance and Quality Control
2.	**Specialised Techniques**
	• Image Intensifier/Fluoroscopy
	• Digital Fluoroscopy
	• Computed Tomography
	• Interventional Procedures
	• Angiography
3.	**General Image Processing**
	• Effect of Dose on Image Quality
	• Processing of Ordinary Film
	• New Methods of Processing, Printing, Storage and Display of Images
4.	**Contrast Media**
	• Ionic and non-ionic Media
	• Use and Preparation
	• Indications and Contra-Indications
	• Use of Automatic Injectors

From Table 8-6 and Table 8-7, it is evident that the legal requirements for education and training are not sufficient to ensure the radiation protection and safety of the patients and staff from the use of ionising radiation by the various professionals. Indeed, none of the universities of Cyprus has a medical faculty and therefore there are no compulsory education and training study units in radiation protection. It should be mentioned however that some of the universities have nursing schools, whose trainings include a course on biophysics with a number of elementary lectures on ionising radiation and radiation protection.

The Radiation Protection Competent Authority occasionally organises courses on radiation protection but only attendance certificates are given. Usually these courses run for half a day.

In the past, the Cyprus Association of Medical Physics and Biomedical Engineering (CAMPBE) in Collaboration with the Higher Technical Institute have also run courses with duration from 4 to 24 hours after specific requests from interested organisations. A certificate was given after a successful examination.

Finally, the Medical Physics Department of the Nicosia General Hospital which is responsible for all the public healthcare facilities run on a regular basis courses designed for different healthcare professionals. They last 4 hours for the basic course designed for nurses, technologists and other personnel not directly involved with ionising radiation. For healthcare professionals working with ionising radiation, the courses are specifically designed to take into account the peculiarities of each discipline. They usually last 10 to 14 hours. A pre- and post course examination is given to assess the knowledge gained. Certificates are not given but the course attendance is registered in the participant's personal record.

8.2.2 Finland

The structure of the required radiation protection education and training in Finland is found in the Radiation Safety Guide 1.7. It contains requirements for radiation protection training given to physicians referring patients for radiological procedures and examinations and to any person participating in the medical use of radiation, for example fluoroscopy in operational theatre.

According to the safety guide, any medical student receives 40 hours (1 study credit) of basic education in radiation protection in medical schools. Orthopaedists, cardiologists and other physicians using radiation should have 20 extra hours (0,5 study credit) of initial training; then every five years, they receive another 20 hours (0,5 study credit) as continuing training.

The basic education for nurses working in operating theatres varies a lot between universities. Some universities have compulsory studies for them. During basic education, they get 40 hours (1 study credit) of RP training and then every five years, they receive 20 extra hours as continuing training. Topics studied are: fundamentals of radiation physics, fundamentals of radiation biology, radiation protection provisions, radiation safety measures at workplace and medical use of radiation.

In all cases (physicians or nurses), hospitals (or responsible parties) are responsible for organising continuing training according to the safety guide. They should maintain records (both on content and amount of training). Continuing training may be guided training (group work, demonstrations, guided practical exercises) or participation in training events. It shall include at least:

- Revision of essential aspects of radiation protection included in basic training,
- Changes that have occurred in the field of radiation use in question,
- Radiation protection aspects required by the development of new examination and treatment practices and radiological equipment,
- Changes in radiation legislation and recommendations,
- Update on knowledge of radiation exposures arising from examinations and procedures involving exposure to radiation and of radiation safety,
- Latest knowledge on the effects of radiation.

To date, in Finland, it is considered that in spite of the requirements described above, there are still many professionals having too old or not enough education[3]. In practice, the training of the staff involved in fluoroscopy procedures can vary a lot:

- Staff in operational theatres can receive a 2-day education for C-arm (see box below). They receive a general education in radiation safety and protection and should have a “driving license” for C-arms.
- They can only have the opportunity to participate in general RP education.
- They can only have a continuing training on radiation safety every five years.

Good practice: Finnish course on the safe use of C-arm

One example of education and training for staff involved in fluoroscopy outside radiological departments is the course “Safe use of C-arm” held by Oulu University of Applied Sciences.

About 40 sessions have been held in different hospitals in Finland: at least 1600 participants have passed the course (a written examination is organised just after the course). Most of them were nurses, staff from the operational theatres and also some physicians.

The course lasts 16h (lectures) and 2 supplementary hours are dedicated to a demonstration in the operation theatre.

- Fundamentals of radiation biology (1,5 h)
- Structure and operation of C-arm (3h)
- Radiation protection legislation (3 h)
- Radiation protection and safety when using C-arm (patients, staff; 3h)
- Quality assurance, patient doses and measurements
- Demonstrations (2h)

[3] This is illustrated by the fact that during clinical audits a lot of recommendations given to the hospitals concern fluoroscopy and examinations outside radiological departments and are mainly about education and training of the staff.

8.2.3 France

In France, the EC Directive 97/43 was transposed in the Code of Public Health, which regulates the obligation of training in radiation protection of patients for all professionals using ionizing radiation. This article notably stipulates that any professional performing ionizing radiation procedures or participating in their realization have to follow a "theoretical and practical, initial and continuing training, related to radiation protection of patients". It is necessary to note that, under this form, the French regulation does not address prescribers (particularly general practitioners).

A specific order (May 2004) related to the programs of training completes this article and specifies modalities as well as topics of continuing education for health professionals using ionising radiation. No detailed duration is specified.

Initial training

In France, it can be considered that initial training in radiation protection is quite restricted: only a few hours (around 10 hours) are dedicated to radiation protection during the first six years of medical study. Then, only physicians that will work directly in radiology, nuclear medicine and radiotherapy are trained to radiation protection.

Continuous training

As explained above, the training is mandatory since 2004 for any professional performing ionizing procedures or participating in their execution. It has to be organised by the employer and to be renewed every 10 years.

The content of the training is different according to the profession. As far as radiological practices outside radiological departments are concerned, the content of the training sessions is detailed for "physicians using ionising radiation for diagnostic or therapeutic procedures without being specialized in radiology, radiotherapy or nuclear medicine".

Practically, the quality and the duration of these courses can vary very widely. They can last from 1 to 3 days and can be performed by different stakeholders: hospitals, universities, private institutes, etc. To date, there is no "accreditation system" of these courses.

8.2.4 Greece

In Greece, radiation protection regulations have been drawn up with the objective to transpose both EC directives (96/29 and 97/43). According to these regulations:

- Physicians and individuals who participate in the practical aspects of radiological procedures must have received adequate theoretical and practical training in radiological practices and must have relevant knowledge and training in radiation protection. The Greek Atomic Energy Commission (EEAE) issues certificates of competency and training to radiation protection workers or recognizes corresponding diplomas or certificates awarded on the basis of the authorised curricula.
- Only persons with a sufficient knowledge of radiation protection duly accredited by the EEAE may participate in the practical aspects of the radiological procedures.
- The EEAE, in cooperation with those responsible for radiological applications, scientists, and educational and professional bodies, intends to promote continuing education, training and further training in the field of radiation protection.

In practice, EEAE provides education and training courses to radiation workers in the field of radiation protection and organizes seminars and workshops in collaboration with professional and scientific institutions[4].

[4] It is to note that EEAE is the European Regional Training Centre of the International Atomic Energy Agency (IAEA) in the English language on Radiation Protection and Safety of Radiation Sources and provides on-the-

Finally, since 1994, the Inter-University Postgraduate Course in Medical Radiation Physics is organised by the Universities of Crete, Athens, Ioannina, Thessalonica and Thrace, EEAE and the Research Centre "Demokritos". The principal aim of this course is to guarantee the training of an appropriate number of highly qualified Medical Physicists according to the needs of the country.

8.2.5 Italy

In Italy, the EC Directive 97/43 was transposed in the D.Lgs. 187/2000, which regulates the obligation of training in radiation protection of patients for all professionals using ionizing radiation. Article 7 requests that any professional performing procedures with ionising radiation have to follow an initial and continuing training related to radiation protection of patients. Initial training has to be performed at the medical schools, so also prescribers (e.g. general practitioners) have some basic knowledge.

Initial training

Initial training in radiation protection is performed in the medical schools for medical doctor, nurse, radiographer. The regulation does not prescribe a minimum number of hours. We can consider that for medical doctors and nurses only a few hours are dedicated to radiation protection. Only for radiographers it is common practice to have an extensive education on radiation protection, from 20 to 50 hours in the 3 years of the course. At the level of the specialisation course, only physicians that will work directly in radiology, nuclear medicine and radiotherapy are extensively trained on radiation protection.

Continuous training

Any professional performing procedures with ionizing procedures has to follow a training course every 5 years. The courses are organised by the employer or by the accrediatated scientific societies.

The content and the duration of the training is not well defined and there is a certain variability among the different hospitals in the implementation of this regulation requirement. We can assume that the training of specialists performing radiological procedures outside radiological departments is very limited and the level of knowledge generally low.

To date, there is no "accreditation system" of these courses.

8.2.6 Norway

Norway, as a non-member of the European Union, is not obligated to implement the requirements given in the MED. As a consequence, radiation protection is practically absent in the basic curriculum of Norwegian medical schools.

However, a new radiation protection regulation in 2004 stated that all Hospital Trusts (HT) needed an authorization from the Norwegian Radiation Protection Authority (NRPA) in order to use advanced X-ray equipment for medical purposes.

In their application forms, 54% of the HTs reported inadequate skills in radiation protection among personnel involved in radiological examinations at their local hospitals. The lack of skills in radiation protection was mainly associated with physicians and nurses who operated mobile C-arms outside the radiological departments. The authorization to these HTs was issued under the condition that reported non-conformities regarding skills in radiation protection where fully implemented within a given time limit. After some reminders, all of the HTs confirmed compliance with the regulation. Nevertheless, in 2008, a survey performed by NRPA concluded that 91% of the inspected Hospital Trusts had non-conformities with the requirements regarding training in radiation protection.

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job training to scientists proposed by the International Atomic Energy Agency, on issues of radiation protection (regulatory control, dosimetry, calibration of ionizing radiation equipment and environmental radioactivity).

8.3 Examples of training materials

In this section, training materials identified as useful and relevant are presented (this list does not intend to be exhaustive).

As far as mobile image intensifier systems are concerned, it is assumed that their operators are trained, at least, in:

- Handling the hardware correctly,
- Achieving the correct adjustment corresponding to the surgical situation,
- Minimizing the radiation exposure of the patient, surgeon and operating room personnel.

8.3.1 Documents from ICRP

In its project "Radiological protection education and training for medical diagnostic and interventional procedures for healthcare staff and students", ICRP proposes a specific annex (Annex A-4) dealing with the suggested content for training courses for theatre fluoroscopy using mobile equipment.

ICRP suggested Training Course: Theatre fluoroscopy using mobile equipment

Those involved in the use of mobile fluoroscopy equipment should have the knowledge to do the following.

1. X-ray systems.

a. To explain the operation of continuous and pulsed X-ray emission modes.

b. To analyse changes in the dose rate when varying the distance of the X-ray tube from the patient, and the X-ray tube to image receptor distance.

c. To define the DAP, entrance dose and entrance dose rate and their units.

d. To discuss the relationship between DAP and effective dose.

e. To understand the stochastic risks in mobile fluoroscopy.

2. RP of the staff.

a. To analyse the influence of the X-ray C-arm positioning on occupational doses and the implications of using different C-arm orientations.

b. To understand the effects of using personal protection (e.g. leaded aprons, gloves, eyeglasses, thyroid protectors, etc.).

c. To understand the importance of the correct location of personal dosimeters.

3. RP of patients.

a. To analyse the correlation between fluoroscopy time, number of images taken in a procedure and dose received by patients.

b. To analyse the effects of using different fluoroscopy modes on patient doses.

c. To understand the influence of the X-ray tube to skin distance on patient skin dose.

d. To discuss the parameters which should be recorded in the patient history relating to the doses received.

e. To discuss the importance of reference levels related to the patient dose at local levels.

Topics recommended for those who assist in procedures are marked with an asterisk *.

8.3.2 Documents from the EC

The European Commission published a "Multimedia and Audiovisual Radiation Protection Training in Interventional Radiology – MARTIR, RP 119". This material is oriented to interventional radiology and cardiology, but some of the material can be conveniently adopted for the purposes of the training in the field of X-ray usage outside the X-ray Department..

8.3.3 Documents from IAEA

The dedicated IAEA website on radiation protection of patients is considered as very useful. Specific sections are dedicated to:

- Fluoroscopy
- Orthopaedic surgery (http://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/6_OtherClinicalSpecialities/Orthopedic/index.htm)
- Gastroenterology (http://rpop.iaea.org/RPOP/RPoP/Content/News/network-gastroenterologists.htm)

http://rpop.iaea.org - Frequently asked questions on fluoroscopy

1. Does the kV value that I select for fluoroscopy have an effect on the absorbed dose to tissues in the patient?
2. What is the most significant thing I can do to reduce X ray exposure to my patients during fluoroscopy?
3. Does using the automatic brightness control (ABC) ensure that I am delivering the lowest exposure to my patients?
4. Does changing the field of view, or magnification mode, have an effect on the exposure to the patient?
5. Does moving the X ray beam to different areas of the patient's body during a procedure have an effect on the exposure to the patient?
6. Can the exposure to a patient be reduced by factors other than time?
7. Can I estimate the exposure of a patient for a fluoroscopic procedure?
8. What is the appropriate action that a medical facility can take to eliminate unnecessary patient exposure during fluoroscopy?

Moreover, the IAEA issued several documents that can be used:

- Patient dose optimisation in fluoroscopically guided interventional procedures, IAEA, RECDOC-1641, 2010.
- Establishing guidance levels in x-ray guided medical interventional procedures – a pilot study, IAEA Safety Report Series No 59, 2009.
- Other documents may be of interest, notably technical documents (for example: "Dosimetry in diagnostic radiology: an international code of practice", TRS 457).

It is to note that the IAEA has recently launched an initiative called ISEMIR "Information System on Occupational Exposure in Medicine, Industry and Research". To date, ISEMIR focus its works on interventional cardiology.

8.4 Some conclusions

From Table 8-2 and the previous paragraphs, it can be seen that national regulations and practices are quite different throughout Europe. To improve the radiation protection culture of professionals involved in radiological practices outside radiological departments, several steps certainly need to be taken:

- A more effective harmonisation and implementation of the national regulations,
- The introduction of a credentialing system for RP (if a professional is not credentialed then he/she will not be allowed to use radiological equipment): we can remind here the example of the “driving licenses” implemented for the operation of C-arms in Finland.
- The reinforcement of the importance of the Continuous Professional Development (CPD): CPD should be a strong element for personnel assessment (for example, if a health professional does not have undertaken the required CPD in RP, he/she will be denied their annual pay increment).

Table 8-8. Outline for specific training in radiation protection for interventional radiology from the EC guidelines – RP 116

(2) X-ray systems for interventional radiology.
2.1 To explain the effect of a high additional filtration (e.g. copper filters) on conventional X-ray beams.
2.2 To explain the operation of continuous and pulsed X-ray emission modes.
2.3 To explain the benefits of the grid controlled X-ray tube when using pulsed beams.
2.4 To explain road mapping.
2.5 To explain temporal integration and its benefits in terms of image quality.
2.6 To analyse the changes on the dose rate when varying the distance from image intensifier to patient.
(3) Dosimetric quantities specific for interventional radiology.
3.1 To define the dose-area product (DAP) and its units.
3.2 To define entrance dose and entrance dose rate in fluoroscopy.
3.3 To discuss the correlation between surface dose and DAP.
3.4 To discuss the relationship between DAP and effective dose.
3.5 To correlate the dose upon entry into the patient with the dose at the exit surface and the dose at the intensifier input surface.
(4) Radiological risks in interventional radiology.
4.1 To describe deterministic effects which may be observed in IR.
4.2 To analyse the risks of deterministic effect induction as a function of the surface doses received by the patients.
4.3 To analyse the relationship between received doses and deterministic effects in the lens of the eye.
4.4 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.
4.5 To analyse the stochastic risks in interventional procedures and their age dependence.
(5) Radiological protection of the staff in interventional radiology.
5.1 To comment on the most important factors which influence staff doses in IR laboratories.
5.2 To analyse the influence of the X-ray C-arm positioning on occupational doses.
5.3 To analyse the effects of using different fluoroscopy modes on occupational doses.
5.4 To analyse the effects of using personal protection (e.g. leaded aprons, gloves, eyeglasses, thyroid protectors, etc.).
5.5 To analyse the benefits and drawbacks of using articulated screens suspended from the ceiling.
5.6 To understand the importance of the suitable location of personal dosimeters.
(6) Radiological protection of patients in interventional radiology.
6.1 To analyse the correlation between fluoroscopy time and number of images taken in a procedure and dose received by patients.
6.2 To discuss the effects of the focus to skin distance and patient image intensifier input distance.
6.3 To analyse the dose reductions attainable by modifying the image rate in cine or in digital acquisition.
6.4 To give typical examples of patient entrance dose value per image in different procedures.
6.5 To analyse the effect of using different magnifications in the patient dose.
6.6 To discuss the parameters which should be recorded in the patient history regarding (or with reference to data on) the doses received.
(7) Quality assurance (QA) in interventional radiology.
7.1 To discuss the difference between parameters that usually do not downgrade with time and those which could require periodical control.
7.2 To discuss the importance of establishing simple criteria to compare doses at the patient or intensifier entrance in different situations.
7.3 To note the importance in QA programs of the periodical control of patient dose and its comparison with reference dose levels.
(8) Local and international rules for interventional radiology.
8.1 To discuss the different national regulations which apply in IR installations.
8.2 To describe the international recommendations for IR (WHO, IAEA, ICRP, EC, etc.).
8.3 To provide information on the international recommendations concerning the limitation of high-dose modes.
(9) Procedure optimisation in interventional radiology.
9.1 To note the importance of optimisation in IR radiation procedures.
9.2 To discuss the importance of reference levels related to the patient dose at local, national and international levels.
9.3 To analyse the importance of periodical patient dose control in each room.
9.4 To discuss the possibility of using different C-arm orientations during long procedures in which the threshold for deterministic effects may be attained.
9.5 To analyse the importance of recording the dose imparted to every patient.

9. EU GUIDELINES FOR CLINICAL AUDIT

The concept of clinical audit was introduced for medical radiological procedures through the Council Directive 97 / 43 / EURATOM (The MED directive, Article 6.4) (EC MED, 1997) and in the IAEA Guideline (IAEA, 2009). The MED defines clinical audit as a systematic, independent and structured examination or review of medical radiological prodecures which seeks to improve the quality and the outcome of patient care. Radiological practices and results should be examined against agreed standards for good medical radiological procedures. Clinical audit can thus be seen as a review of the success in implementing the principles of justification and optimization.

According to the MED, clinical audits shall be carried out in accordance with national procedures. The Member States can thus adapt the requirements of the Directive to fit the local circumstances. The audit should however cover all the steps of a complete radiological procedure.

The basic requirements of the MED for clinical audit (article 6.4) have generally been implemented in national legislations. In spite of legislation, there is a wide variaton between the Member States in the ways clinical audit have been implemented [2]. In a few Member States clinical audits have been carried out systematically with regular external and internal clinical audits. In most of the other countries external and internal audits are only occasional. In order to improve the implementation, the European Commission published the "Guidelines on Clinical Audit for Medical Radiological Practice" EU Guidelines n. 159, 2009). This document provides practical guidance and information on procedures and criteria for clinical audit.

9.1 Experiences of clinical audit in diagnostic radiology

9.1.1 Bulgaria

In Bulgaria, the MED was implemented in 2005 with the Ordinance No 30/2005 of the Ministry of Health. According to the Ordinance, all medical practices has to be accreditated by external and internal audits based on medical standards. External audits has to be performed in every two years by an auditing group including a university professor in medical imaging and a medical physicist. All diagnostic imaging departments have been audited during the years 2006-2008. Most of the new quality criteria for radiological equipment and quality control were insufficiently implemented. Moreover, the audits did not include patient exposure and image quality assessments [4].

9.1.2 Czech Republic

In the Czech Republic, basic requirements of clinical audit are specified in the Degree No 307/2002 Coll. on Radiation Protection. National standards in diagnostic radiology, radiotherapy and nuclear medicine were developed by professional societies in 2004 and implementation of clinical audit into the health law was meant to be ready in 2008. The Ministry of Health and professional societies carried out "test clinical audits" in selected medical facilities in 2004 - 2006 to develop the methodology of auditing [5].

9.1.3 Finland

In Finland, clinical audits are carried out regularly. Clinical audit was implemented with Degree 423 / 2000 issued by the Ministry of Social Affairs and Health [6]. The Finnish legislation requires that radiological units have to implement both internal and external

clinical audits of their practices. External audits should be carried out every five years and internal audits (or self-assessments) continually. According to the Degree, clinical audits shall be carried out by competent and experienced auditors who are independent of the organization to be audited. The team of auditors includes a phycisian (radiologist, oncologist, or nuclear medicine physician), a radiographer and in most cases also a medical physicist.

The Degree specifies ten points of interest that should at least be covered in clinical audits. These are:

- lines of authorities and responsibilities,
- referrals and recommendations for the referral practices,
- justification practices and information flow observed in assessing justifications,
- examination and treatment practices and guidelines,
- equipment for examinations and treatment,
- radiation doses arising from procedures and the examination and treatment results achieved,
- quality, recording, and flow of information on procedures,
- staff education and training,
- definition and application of quality assurance activities, and
- self-assessments of activities, assessment results and the use of results.

A working group with representatives from different stakeholders was set up to establish the audit program, build the auditing organization and organize education of the auditors in Finland. The audit program was completed at the end of 2001. An independent company, Qualisan, was founded to do the audits.

National coordination of clinical audits is established by a national steering group, the Advisory Committee for Clinical Audit, which was set up by the Ministry of Social Affairs and Health Care (Soimakallio, 2010). The Advisory Committee is a multi-disciplinary group of clinical experts who are independent of auditing organizations. Its main objectives are to coordinate, develop and follow-up clinical audits and to promote good quality and consistency of criteria for good practices in clinical audits in Finland.

The Advisory Committee has issued several recommendations or guidelines on clinical audits. One of the recommendations deals with the competence, experience and independence of the auditors. The auditors are required to have practical clinical experience in the field to be audited, the lead auditors must have at least one week specific training on the audit techniques and the audit team must generally include a physician, radiographer and in certain cases also a medical physicist. One recommendation sets out the priorities for the second audit round. The topics include, for example:

- in audits, it has to be emphasized that clinical audit and self-assessment are meant to be a tool for the management to improve quality and radiation safety,
- how recommendations given in previous audit reports have been implemented,
- how self-assessments are carried out and if internal audits and self-assessments have resulted in the implementation of changes to improve practices,
- clinical audits should be improved to go deeper into selected examinations and procedures.
- In radiological units, the second round of clinical audit has to cover also:
    - at least paediatric radiological and computed tomography practices,
    - how the change from conventional to digital radiology has been used to optimize the radiation dose, and
    - how the examinations have been optimized with the local facilities and resources.

The recommendation also gives references for criteria of good practices. The other

recommendations clarify how to take into consideration the accreditation of nuclear medicine units, the ten main points of interest given for clinical audits in the Degree 423/2000 and the new European guidelines on clinical audit. One recommendation gives guidance on the reports of clinical audit.

The Advisory Committee also co-operates with the national scientific and professional societies to develop criteria of good practice in Finland. Future working plan includes the development of guidelines for self-assessment of practices.

Practical methods of clinical audits follow common principles of auditing with entrance and exit meetings, review and evaluation of procedures and documentary results, observation of practical work and interviews of the staff and clinicians. In Finland, clinical audits also include an assessment of the image quality. The report of clinical audit is given to the audited unit. Implementation of recommendations given by the auditors are systematically reviewed in the next round of clinical audit and regulatory inspection of the Radiation and Nuclear Safety Authority (Jarvinen, 2008).

In Finland, the first round of clinical audits was carried out in 2002 - 2006 (Soimakallio, 2010). All of the audits were carried out by the same organization, employing a total of 38 auditors. The auditing team consisted of a radiologist and a radiographer, in several cases also a medical physicist. The audits were based on the guidance and checklists developed by the auditing organization.

The Advisory Committee conducted a survey of the results of the first round by a review of the audit reports. Practically all radiological health care units were audited for the first time within the five years´ period. The survey revealed that the health care units comply fairly well with the Degree and good practices. However, a significant number of recommendations to improve practices were given by the auditors, on the average 7 per health care unit. They included a number of topics, e.g. assessing examination or treatment outcome, supplementing the quality system, providing medical physics expertise, improving planning and recording of radiation protection training, establishing self-assessment practices, improving referral practices, improving imaging practices in particular in paediatric radiology. In the first audit round the auditors also gave a number of recommendations about fluoroscopy outside radiological departments, mainly about training and education of the staff, the use of shielding devices, and examination guidelines. According to the auditing organization the auditors shall address more of these activities during the second audit round.

The results of the survey also indicated a need to improve the auditing practice. Standards of good practices have been based partly on the legislation and partly from existing recommendations for good clinical practices (referral guidelines, image quality criteria). However the audits have relied to a great extent also on the professional experience and knowledge of the auditors. In the future they should be supplemented by more clinical criteria to avoid unnecessary overlap with the regulatory inspections of the Radiation and Nuclear Safety Authority.

Financing of clinical audits is by charging the recipients. The costs of clinical audit in a large university hospital is only a few cents per examination for five years (Soimakallio, 2008).

9.1.4 France

In France, clinical audits are performed/organised by the HAS, the French National Authority for Health. There is no specific organisation dedicated to audits of radiological practices (ASN, the French Nuclear Safety Authority is in charge of inspections and controls).

The Haute Autorité de santé (HAS) - or French National Authority for Health - was set up by the French government in August 2004 in order to bring together under a single roof a number of activities designed to improve the quality of patient care and to guarantee equity within the healthcare system. HAS activities range from assessment of drugs, medical

devices, and procedures to publication of guidelines to accreditation of healthcare organisations and certification of doctors. HAS is not a government body. It is an independent public body with financial autonomy. It is mandated by law to carry out specific missions and reports to the Government and Parliament.

In France, clinical audits are one of the methods used to perform " Professional Practice Assessment (PPA)".

Example 1

Professional practice assessment. Pertinence of positron emission tomography clinical indications in oncology (Le Stanc E.; Tainturier C.; Swaenepoel J)

Abstract

Introduction

As part of the health care quality and safety policy in France, Professional Practice Assessment (PPA) are mandatory in the health services "certification" process. We present our study regarding the pertinence of Positron Emission Tomography (PET) indications in oncology.

Materials and methods

A multidisciplinary task group used the Quick Audit method with two rounds of 100 request forms each. The assessment list of criteria comprised four items of decreasing relevance grading the PET scans clinical indications, which were derived from three French published guidelines and five additional items: clinical information, patient's body weight, previous treatments dates, diabetes, claustrophobia.

Results

The first round showed that 68% of the requested scans corresponded to the two most relevant groups of indications (SOR Standards and Options). The request forms were correctly filled in regarding the clinical information, but this was not the case for the other items we tested. Several actions were conducted: dedicated PET request form, availability of the SOR on the hospital intranet, boost of the referring physicians awareness during the multidisciplinary oncology meetings (Réunions de Concertation Pluridisciplinaires RCP). The second round showed a better pertinence of the PET scans indications (75% versus 68%); the patient's body weight was more frequently mentioned on the request form.

Discussion

This study is an example of PPA in our discipline. It led to an improvement of the oncologic PET scans clinical indications in our hospital. This work is pursued in everyday discussion with the referring clinicians, especially during the RCP.

Example 2

Procédure d'audit des comptes-rendus radiologiques d'un service hospitalier. Audits of reports on radiological procedures in a hospital. V Barrau, P Rufat, L Charrada, Y Menu, Journal de Radiologie, Vol 83, N° 6-C1 - juin 2002, pp. 717-721

Purpose. Presentation of a clinical audit of the radiology reports in our institution.

Material and methods: This audit has been performed in several steps: launching the project, elaboration of the reference book, elaboration of the protocol, analysis of the results, improvements made.

Results: Several dysfunctions were detected: typing errors, the lack of sentences explaining the procedure of examination, the lack of negative pertinent elements, the lack of synthesis. Several interventions were made: checking the computer screen the report before signing it, purchase of personal voice recorders, restructuring the interpretation room. Other interventions are considered: structured data entry, P.A.C.S. systems

Conclusion: This audit has allowed the modification of the process for attainment of the radiology reports and the stimulation of the medical team, thus improving the quality of our work.

9.1.5 United Kingdom

The Royal College of Radiologists (RCR) has actively promoted Medical Audits in UK for over 15 years (Barter, 2008). It has a special sub-committee for clinical audits (CRASC). At least one national audit is carried out per year. Data is collected via electronic submission and anonymised results are presented at an annual forum. Individual departmental results are analyzed using a specific methodology which enables CRASC to inform departments if they are underperforming against the national mean and if so they recommend corrections. The Committee has also developed a web-based tool for local audits, “AuditLive”. The RCR has also a sub-committee for standards of best practice. It produces a number of standards each year against which radiologists can monitor their practice.

Past national audits include, for example, audits of outcomes of nephrostomy, effective communication and diagnosis of lung cancer on chest radiography but not topics on procedures outside radiological departments.

9.1.6 Ireland

In Ireland all radiological units have to be audited in accordance with agreed criteria once every 5 years. The first audit was done in 2007. Clinical audits are mainly self audits with an independent monitoring overseen by the Health Information and Quality Authority,

In summary:

Results or information of clinical audits on procedures outside radiological practices are difficult to find out, the only ones are from Finland.

10. INSPECTION

10.1 Lessons learned from inspection activity

10.1.1 Norway

During 2008 and 2009 the Norwegian Radiation Protection Authority (NRPA) carried out inspections at 52% of all Hospital Trusts (HT) [5]. A HT can consist of two to five hospitals. The inspections were a direct follow-up of the authorization given to the HTs, with focus to verify that all necessary requirements in the radiation protection regulation were implemented. The inspections were quality system audits, based on document reviews, interviews, on-site inspections and verifications. Documents to be reviewed were collected both in advance and during the inspections. All HTs were asked to submit their procedure(s) for education and training in radiation protection, if available. Interviews covered staff included personnel management and physicians and nurses who were involved in the predefined groups of X-ray guided procedures, both experienced and new employees. The interviewed persons were mainly picked by the HT itself, but some ad-hoc interviews of C-arm users were carried out at the same time as the on-site visual inspection of the C-arms. Spot checks to verify if all involved persons had received training in radiation protection were done for the orthopaedic procedures, by asking for their documentation of training (i.e. signed lists of attending persons). All non-conformities revealed during the inspections were presented in a closing meeting at the end of the inspection. All non-conformities had to be accepted on-site by the responsible persons representing the HTs. Misunderstandings, if any, could in this way immediately be taken into account and corrected for.

All HTs had in the authorization process confirmed that they had an operating system to ensure that all personnel involved in radiological examinations have sufficient qualifications and skills in radiation protection. Despite of this, procedures for education and training in radiation protection were received from only 64% of the HTs. All of the procedures were written by either the radiation protection officer (RPO) or a senior radiographer from the radiological department. Only those procedures with traceability to a quality assurance system (71%) hold an acceptable quality and only two of the received procedures had ever been revised.

To verify if the HTs procedure for education and training in radiation protection were followed and implemented locally at the different hospitals and departments using X-rays, interviews of the staff were carried out. Staff involved in orthopaedic, ERCP and cardiac procedures were interviewed at respectively 100%, 64% and 27% of the HTs. According to the procedures, the responsibility for ensuring that all staff involved in X-ray guided procedures were placed on the head of the department. Despite of this, many of them were unaware of their responsibility for radiation protection and also unfamiliar with the presence of the procedure in general. A clear distinction between the levels of awareness of radiation protection was observed between nurses and physicians within all the included groups of procedures, nurses having the highest level of awareness. Only one HT had a systematic system for education and training in radiation protection. In the other HTs, courses in radiation protection were occasionally held by the RPO without any systematically approach. The level of attendance on these courses varied between the different professionals (physicians and nurses), departments and hospitals within each HT. Existing systems for

[5] Friberg EG, Widmark A, Solberg M, Wøhni T og Saxebøl G. Not able to distinguish between X-ray tube and image intensifier. Fact or fiction? Proceedings from 4th International Conference on Education and Training in Radiological Protection. Lisboa, Portugal 8-12 November 2009. ETRAP 2009.

documentation of performed education and training, if any, were highly insufficient at all HTs. The spot check verification of documentation for staff involved in orthopaedic procedures revealed that 45% and 91% of the HTs had some documentation of performed education and training of physicians and nurses respectively. None of the documentation presented was according to requirements in their own procedures.

Interviews also revealed serious lack of skills in radiation protection. Typical examples were:

- unable to identify the X-ray tube from the image intensifier of the C-arm,
- inadequate knowledge of the operating consol,
- unknown with the three cardinal principles for staff protection (time, distance and shielding),
- no deliberate use of collimation and/or pulsed fluoroscopy
- and, total lack of knowledge about patient doses and risks.

In many HTs nurses assisted the physicians by operating the C-arm console. For those cases it was not uncommon to just switch on the X-ray unit and start to fluoroscopy regardless of the default exposure settings on the consol. The inspections performed by NRPA concluded that 91% of the inspected HTs had non-conformities with the requirements regarding skills and training in radiation protection.

The lack of skills in radiation protection among personnel outside radiological departments is clearly not a fiction. Some of the reasons were that the HT's had an insufficient system for systematic and frequent education and training in radiation protection, responsible persons were unaware of their responsibilities and there were a general lack of involvement and focus on radiation protection outside radiological departments. These findings may be a consequence of the way the Norwegian public health care system is organized. Large organizations like Norwegian HTs, which consist of many hospitals often spread over a large geographical area, make communication and the promise for establishing common procedures in radiation protection a challenge. The lack of knowledge about doses and risks among leaders often tends to unconsciously undermine the importance of radiation protection. As a consequence, radiation protection is often ignored or not prioritized, even though the responsibility is clearly defined.

The fact that as much as 91% of the inspected HTs had non-conformities regarding skills and training in radiation protection rise other questions: Can the HTs self declared compliance with the regulation be trustworthy? Have the HTs purposely misinformed the NRPA or is the self declaration made in the best well meaning? Lack of basic knowledge in radiation protection may itself result in different interpretations of what is sufficient enough to fulfil the requirements in the regulation.

With modern C-arms becoming more and more complex with the possibility to give high patient doses if operated by unskilled persons, the conditions revealed at the Norwegian hospitals give rise of concern.

- There is an urgent need for increasing the knowledge of patient doses and risk among physicians and nurses. The most efficient way to overcome this situation is by introducing radiation protection in the basic education in medical schools, as stated in the MED. Sufficient systems for ensuring adequate skills locally at the HTs should also be of high priority. One way to improve the level of skills locally is by introducing "driving licenses" for operators of X-ray units. Such a system makes it also easier for the responsible persons to keep track of each individual employee's performed training courses and their level of skills in radiation protection. Meanwhile, focus should be on recognizing the importance of having a well functioning system for education and training in radiation protection locally at each HT.

- Finally, a big challenge is to overcome the bad attitudes towards radiation protection of some speciality physicians. All HTs reported a low level of attendance by physicians at courses that had been organised in radiation protection, mainly because of the physicians lack of interest. Working for a change in attitudes can hopefully improve the general skills and awareness of radiation protection among physicians, significantly.

11. LESSONS LEARNED AND EXAMPLES OF BAD PRACTICE

The purpose of this chapter is to provide examples of specific actions taken in some countries (FDA in US and Norway) and example of bad practice in the use of radiological equipment. Examples can be conveniently used for training purposes.

11.1 Lessons learned

FDA Recommendations

In 1994, Food and Drug Administration (FDA) published an alert regarding "serious x-ray-induced injuries to patients during fluoroscopically-guided procedures" (FDA Public Health Advisory: Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures)

The FDA Center for Devices and Radiological Health (CDRH) had received reports of occasional, but at times severe, radiation-induced skin injuries to patients resulting from prolonged, fluoroscopically-guided, invasive procedures. Procedures typically involving extended fluoroscopic time were:

- percutaneous transluminal angioplasty (coronary and other vessels),
- radiofrequency cardiac catheter ablation,
- vascular embolization,
- stent and filter placement,
- thrombolytic and fibrinolytic procedures,
- percutaneous transhepatic cholangiography,
- endoscopic retrograde cholangiopancreatography,
- transjugular intrahepatic portosystemic shunt,
- percutaneous nephrostomy,
- biliary drainage and
- urinary/biliary stone removal.

At that time, it was stated that:

- Physicians performing these procedures should be aware of the potential for serious, radiation-induced skin injury caused by long periods of fluoroscopy during these procedures. It is important to note that the onset of these injuries is usually delayed, so that the physician cannot discern the damage by observing the patient immediately after the treatment.
- The absorbed dose in the skin required to cause skin injury depends on a number of factors, but typical threshold doses for various effects are about 3 Gy (300 rad) for temporary epilation, about 6 Gy (600 rad) for main erythema, and 15 to 20 Gy (1,500 to 2,000 rad) for moist desquamation, dermal necrosis and secondary ulceration (see Reference).
- The absorbed dose rate in the skin from the direct beam of a fluoroscopic x-ray system is typically between 0.02 Gy/min and 0.05 Gy/min (2 to 5 rad/min), but may be higher, depending on the mode in which the equipment is operated and the size of the patient. Even typical dose rates can result in skin injury after less than one hour of fluoroscopy.

FDA suggested that facilities performing fluoroscopically-guided procedures observe the following principles:

- Establish standard operating procedures and clinical protocols for each specific type of procedure performed. The protocols should address all aspects of the procedure, such as patient selection, normal conduct of the procedure, actions in response to complications and consideration of limits on fluoroscopy exposure time
- Know the radiation dose rates for the specific fluoroscopic system and for each mode of operation used during the clinical protocol. These dose rates should be derived from measurements performed at the facility.
- Assess the impact of each procedure's protocol on the potential for radiation injury to the patient.
- Modify the protocol, as appropriate, to limit the cumulative absorbed dose to any irradiated area of the skin to the minimum necessary for the clinical tasks, and particularly to avoid approaching cumulative doses that would induce unacceptable adverse effects. Use equipment which aids in minimizing absorbed dose.
- Enlist a qualified medical physicist to assist in implementing these principles in such a manner so as not to adversely affect the clinical objectives of the procedure.

Physicians should know that radiation-induced injuries from fluoroscopy are not immediately apparent. Other than the mildest symptoms, such as transient erythema, the effects of the radiation may not appear until weeks following the exposure. Physicians performing these procedures may not be in direct contact with the patients following the procedure and may not observe the symptoms when they occur. Missing the milder symptoms in some patients can lead to surprise at the magnitude of the absorbed doses delivered to the skin of other patients when more serious symptoms appear. For this reason, we recommend that information be recorded in the patient's record which permits estimation of the absorbed dose to the skin. Patients should also be advised to report signs and/or symptoms of radiation induced injury to their attending physician.

Poster (Norway)

Some years ago, the Norwegian Radiation Protection Authority (NRPA) produced a poster about radiation protection outside radiological departments. This poster is a tool to help health professionals working in operating theatres to use mobile C-arms. It underlines the main radiation protection principles to apply. It can be laminated with plastic (which makes it easy to wash and disinfect) and placed in the hospital where mobile C-arms are used.

The poster has been translated and it is available on the EMAN website in English and other European languages (Fig. 11-1).

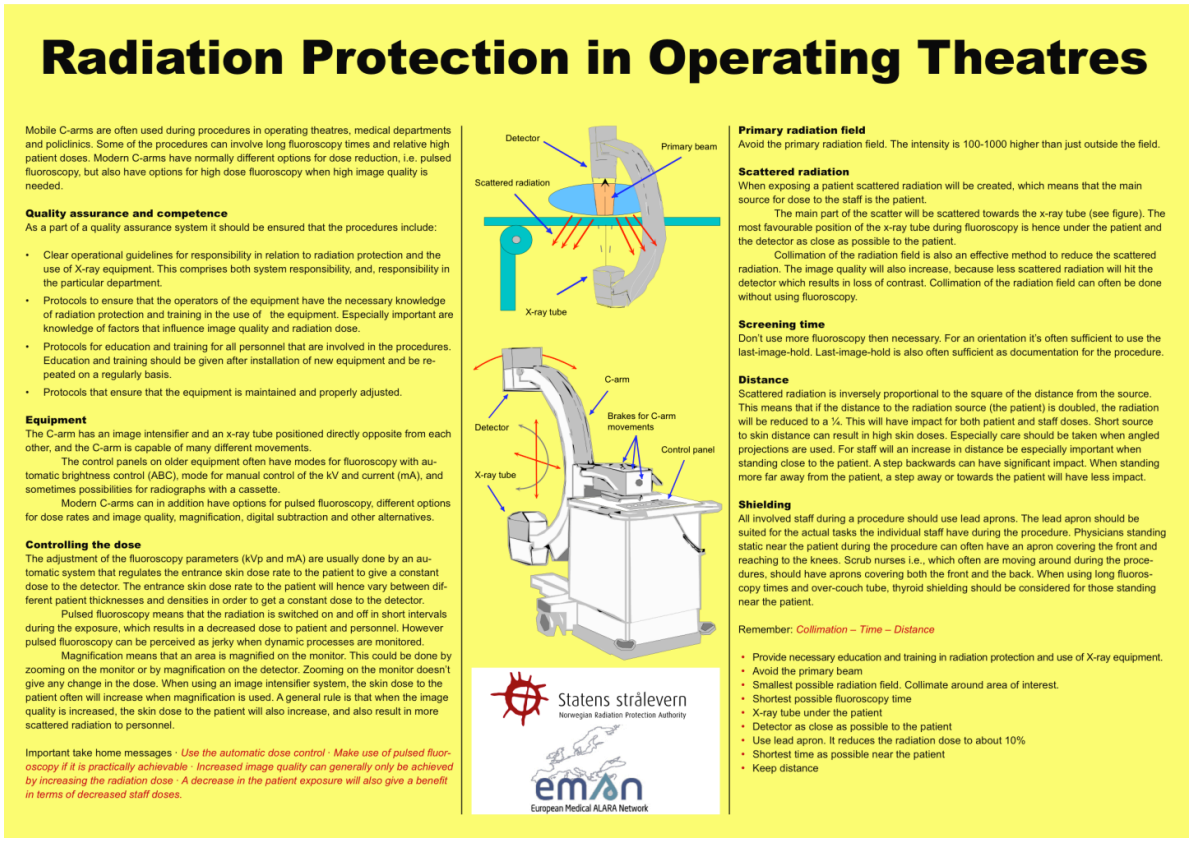

Fig. 11-1. NRPA poster on radiation protection and C-arms (English version).

POSTER TEXT (English translation provided by Anders Widmark)

Mobile C-arms are often used during procedures in operating theatres, medical departments and polyclinics. Some of the procedures can involve long fluoroscopy times and relative high patient doses. Modern C-arms have normally different options for dose reduction, i.e. pulsed fluoroscopy, but also have options for high dose fluoroscopy when high image quality is needed.

Quality assurance and competence

As a part of a quality assurance system it should be ensured that the procedures include:

- Clear operational guidelines for responsibility in relation to radiation protection and the use of X-ray equipment. This comprises both system responsibility, and, responsibility in the particular department.
- Protocols to ensure that the operators of the equipment have the necessary knowledge of radiation protection and training in the use of the equipment. Especially important are knowledge of factors that influence image quality and radiation dose.
- Protocols for education and training for all personnel that are involved in the procedures. Education and training should be given after installation of new equipment and be repeated on a regular basis.
- Protocols that ensure that the equipment is maintained and properly adjusted.

Equipment

The C-arm has an image intensifier and an x-ray tube positioned directly opposite from each other, and the C-arm is capable of many different movements.

The control panels on older equipment often have modes for fluoroscopy with automatic brightness control (ABC), mode for manual control of the kV and current (mA), and sometimes possibilities for radiographs with a cassette. Modern C-arms can in addition have options for pulsed fluoroscopy, different options for dose rates and image quality, magnification, digital subtraction and other alternatives.

Controlling the dose

The adjustment of the fluoroscopy parameters (kVp and mA) are usually done by an automatic system that regulates the entrance skin dose rate to the patient to give a constant dose to the detector. The entrance skin dose rate to the patient will hence vary between different patient thicknesses and densities in order to get a constant dose to the detector. Pulsed fluoroscopy means that the radiation is switched on and off in short

intervals during the exposure, which results in a decreased dose to patient and personnel. However pulsed fluoroscopy can be perceived as jerky when dynamic processes are monitored.

Magnification means that an area is magnified on the monitor. This could be done by zooming on the monitor or by magnification on the detector. Zooming on the monitor does not affect the dose. When using an image intensifier system, the skin dose to the patient often will increase when magnification is used. A general rule is that when the image quality is increased, the skin dose to the patient will also increase, and also result in more scattered radiation to personnel.

Important take home messages

- Use the automatic dose control.
- Make use of pulsed fluoroscopy if it is practically achievable.
- Increased image quality can generally only be achieved by increasing the radiation dose.
- A decrease in the patient exposure will also give a benefit in terms of decreased staff doses.

Primary radiation field

Avoid the primary radiation field. The intensity is 100-1000 times higher than just outside the field.

Scattered radiation

When exposing a patient scattered radiation will be created, which means that the main source for dose to the staff is the patient. The main part of the scatter will be scattered towards the x-ray tube (see figure). The most favourable position of the x-ray tube during fluoroscopy is hence under the patient and the detector as close as possible to the patient.

Collimation of the radiation field is also an effective method to reduce the scattered radiation. The image quality will also increase, because less scattered radiation will hit the detector which results in loss of contrast. Semi transparent collimation is sometimes an option which will reduce the patient dose. Collimation of the radiation field can often be done without using fluoroscopy.

Screening time

Don't use more fluoroscopy than necessary. For an orientation it's often sufficient to use the last-image-hold. Last-image-hold is also often sufficient as documentation for the procedure.

Distance

Scattered radiation is inversely proportional to the square of the distance from the source. This means that if the distance to the radiation source (the patient) is doubled, the radiation will be reduced to a ¼. This will have impact for both patient and staff doses. Short source to skin distance can result in high skin doses. Especially care should be taken when angled projections are used. For staff an increase in distance is especially important when standing close to the patient. A step backwards can have significant impact. When standing further away from the patient, a step away or towards the patient will have less impact.

Shielding

All involved staff during a procedure should use lead aprons. The lead apron should be suited for the actual tasks the individual staff have during the procedure. Physicians standing static near the patient during the procedure can often have an apron covering the front and reaching to the knees. Scrub nurses i.e., which often are moving around during the procedures, should have aprons covering both the front and the back. When using long fluoroscopy times and over-couch tube, thyroid shielding should be considered for those standing near the patient.

Remember

Collimation – Time – Distance

- Provide necessary education and training in radiation protection and use of X-ray equipment.
- Avoid the primary beam
- Smallest possible radiation field. Collimate around area of interest.
- Shortest possible fluoroscopy time
- X-ray tube under the patient
- Detector as close as possible to the patient
- Use lead apron. It reduces the radiation dose to about 10%
- Shortest time as possible near the patient
- Keep distance
- Stay away if you are pregnant

11.2 Examples of bad practices

Case 1 – High patient doses during bi-ventricular pacemaker implants

The particular radiation protection authority was contacted by a Cardiology department with a request for assistance. The department performed bi-ventricular pacemaker (BVP) implants, which is a technically complicated treatment for patients with severe heart insufficiency. The department had recognized a suspicious radiation burn on a patient, three weeks after a BVP procedure. The particular patient had undergone two BVP implants and the lesion was the size of a palm. The lesion was situated on the back of the patient and was recognized as radiation dermatitis.

Sets of thermoluminescent detectors (TLD), each containing 10 TLD's were prepared. The TLD's in each set was arranged in a star pattern for covering a large area of the patients back and dose measurements were performed on eight subsequent patients. After the eight initial dose measurements, a site audit was performed at the Cardiology department. Characteristics for the equipment were registered and the working technique and general skills in radiation protection during a BVP procedure were observed. A short meeting was held with the participating staff after the procedure, where the working technique was discussed. After this, new sets of TLD's were distributed and dose measurements were performed on six new patients.

The average maximum entrance surface dose (MESD) for the first eight patients was 5.3 Gy, ranging from 2.03 to 13.14 Gy and the fluoroscopy time varied from 18.1 to 101 minutes, with an average of 47.8 minutes (Table 11-1).

Table 11-1. Maximum entrance surface dose and fluoroscopy time for the first eight patients.

Patient	Fluoroscopy time [min.]	MESD [Gy]
1	27,0	3,64
2	77,3	4,42
3	18,1	3,03
4	60,4	2,03
5	24,2	3,03
6	22,4	9,12
7	101,0	13,14
8	52,2	4,23
Average	47,8	5,33

The X-ray equipment was a Siemens Multiscope (1989) with an image intensifier with a 40 cm diameter. The equipment was intended for abdominal angiography and not suited for coronary procedures, due to the large image intensifier (II). During the procedures the magnification technique with 28 cm diameter II entrance field was mainly used. The equipment did not have options for pulsed fluoroscopy or last-image hold. However there was a possibility for extra filtering of the X-ray beam, but this option was not used. There was no dose measuring device connected to the equipment. The dose rate was not adjusted by the cardiologists to the actual image quality needs during the different steps of the procedure and the audit gave an impression that it was an over-use of fluoroscopy. During

the image acquisitions, the acquisitions were started at the same time as the contrast injector started. This results in unnecessary radiation, because it takes a few seconds before the contrast medium reaches the heart.

During the meeting after the audit procedure the following “Do’s” and “Don’ts” were given:

- Don’t over-use the fluoroscopy.
- Do adjust the image quality to the actual needs during the different steps in the procedure.
- Don’t start the image acquisition before the contrast medium has reached the heart.

The TLD measurements the following week showed a significant skin dose reduction with an average MESD of 0.44 Gy, ranging from 0.24 to 0.75, which is less than 10 % of the previous average (Table 11-2). The average fluoroscopy time was also reduced from 47.8 to 23.7 minutes.

Table 11-2. Maximum entrance surface dose and fluoroscopy time for six patients after site the audit and the educational meeting after the procedure.

Patient	Fluoroscopy time [min.]	MESD [Gy]
9	32,0	0,28
10	19,5	0,68
11	18,9	0,35
12	47,0	0,75
13	13,7	0,24
14	11,0	0,36
Average	23,7	0,44

The initial eight measured patient doses were all above the threshold for deterministic effects. The threshold for an early transient erythema is about 2 Gy and the patient with the highest dose, which was 13.1 Gy, was above the threshold for severe effects like dermal atrophy and telangiectasis. After the audit and the educational meeting, where the three “Do’s” and “Don’ts” were given, all the six additional monitored patients were far below the threshold for deterministic effects. The 50 % reduction in fluoroscopy time gave a significant contribution to the decrease in skin dose. Additional significant factors to the decrease in skin dose were to start the image acquisition when the contrast media reaches the heart and to adjust the image quality to the actual needs during the different steps in the BVP procedure. In some of the moments in the procedure there are low requirements for good image quality, but when the 0.3 mm pacemaker wire is implanted, there is a need for very good image quality. This case shows that simple basic advice can give significant results in dose reduction, especially if the user has no competence in radiation protection. The measured initial high doses probably motivated a change of attitudes towards radiation protection of the patients. To fully optimize the procedure, with respect to patient doses, much more effort has to be put in the education of the operator.

Main reasons for high doses

- Lack of basic knowledge in radiation protection
- Poor equipment knowledge
- Not optimized equipment

Case 2 - Using image acquisition instead of fluoroscopy

A Cardiology department borrowed an angiography suite during a night. A 90 year old woman had heart insufficiency and was in need for a temporary pacemaker. In an angiography suite there are two foot pedals for initiating radiation. One of them is used for fluoroscopy and the other pedal for image acquisition, where the dose is much higher. The cardiologist wasn't aware of this, and started image acquisition instead of fluoroscopy. The procedure went on until the hard disk was full after 8-900 images, and the image acquisition was blocked. It was not possible to proceed with the procedure, and the woman died on the table.

Main reason

- No education and training on the actual equipment

Case 3 – Using image acquisition instead of fluoroscopy on pregnant patient

A similar incident was reported from a Radiology department. A pregnant patient (38 week) was referred to a nephrostomy catheter implant. During the procedure the physician used the wrong foot pedal, resulting in image acquisition, without any collimation, instead of fluoroscopy. The patient had an estimated effective dose of 17 mSv and the foetus an estimated effective dose between 40 and 50 mSv.

Main reason

- No education and training on the actual equipment

Case 4 – CT scanning without table increment

A smaller hospital had bought a new CT scanner. The radiology department did not have any education and training on the new equipment by an application specialist from the vendor, but was eager to start scanning patients. One of the first patients was a woman referred to CT of the hypophysis. When the radiographer ordered the scan, she didn't order any table increment, resulting in 30 slices without increment. The dose to the hypophysis was about 2 Gy.

Main reason

- No education and training on the actual equipment

Case 5 – Patient shielding on wrong side

Several authority audits in operation theatres, have revealed lack of competence. One discrepancy that has been found in several operation theatres is lead shielding of female patients on the wrong side of the X-ray tube. The motive and intention is good, but it may lead to more harm than benefit if the user do not know on which side the X-ray tube is. Caution should also be given, so that the lead shielding does not block the primary beam and effect the automatic exposure device. This may then significantly increase the kVp and mA, resulting in an increase in patient and staff doses.

- No basic knowledge of equipment

Case 6 – Finger doses to radiologists during CT fluoroscopy guided biopsies

The use of CT fluoroscopy is sometimes an advantage when performing biopsies, especially in the thorax region. The procedure can be performed by two different main protocols. Either setting the needle outside the gantry, and afterwards control the position and further adjust

the needle outside the gantry again. The other way is to insert the biopsy needle during the CT fluoroscopy. This method has the capability to give high finger doses to the operator, since the exposure settings are typically 120 kVp and 20-50 mA. Another reason is also that the needle is long, resulting in a very short finger-focus distance.

During a sight audit, finger doses of the operator were measured during five biopsies, which was a normal work-load for a week (Table 11-3).

Table 11-3. Patient and finger doses to the operator for five subsequent patients during CT fluoroscopically guided biopsies.

Total mAs	Patient ESD [mGy]	Finger doses to operator [mGy]
8343	623	38
?	121	141
8618	65	350
5790	60	20
19163	71	181

The measurements showed that it's possible to reach the proposed annual dose limit by ICRP in a few CT biopsy procedures.

Measurements performed on another hospital, with the correct technique, showed finger doses in the order of 20 to 50 mGy.

Main reason

- Lack of basic knowledge

Case 7 – Doses to surgeon during ERCP

Over a period of 2 months a dose of 69.9 mSv (H[10] over the apron) was recorded on the personal dosimeter of a surgeon. The surgeon had only performed four ECRP procedures during the 2-month period. An investigation, started to assess this high dose. The glow-curve for the TLD was controlled and found normal, indicating that the dose to the dosimeter was correct. One of the four patients, treated with papillotomy, had a weight of +150 kg. Due to weight limitations at the common X-ray laboratory, another laboratory with over-couch geometry and photostimulable plates were used. No dose record was available, but 11 radiographs and an unknown amount of fluoroscopic exposures, were taken during the procedure. During the assessment of the dose, common values for doses and scattered radiation modified to the actual situation were used.

The assessment was done in the two following steps.

1. Estimation of the entrance surface dose (ESD) to the patient
2. Estimation of the scattered fraction from the patient to the dosimeter

Estimation of the ESD to the patient

A typically set-up for a radiographic procedure for an adult patient, weighting 70-80 kg, is a 90 cm source-object distance (SOD), assuming a source-image distance (SID) of 110 cm. The radiographic voltage is typically 75 kVp, resulting in an ESD of approximately 10 mGy to the patient.

"Normal patient" ESD = 10 mGy/exposure

Due to the increased patient volume in this case, the Automatic Exposure Control (AEC) will increase the exposure, to get a sufficient signal to the detector. kVp values > 100 and high mAs values, which probably will increase the ESD by 6-8 times, are assumed.

Patient volume correction $7\ x\ 10\ mGy = 70\ mGy/\exp osure$

The increased patient volume will decrease the SOD. The ESD is hence corrected to a SOD of 70 cm by the inverse square law.

Distance (SOD) correction $ESD_{70cmSOD} = \frac{90^2}{70^2}\ x\ 70\ mGy = 115.7\ mGy/\exp osure$

Finally the ESD per image must be multiplied with the total number of images which were eleven. The total estimated ESD is rounded up to 1300 mGy, by adding a small symbolic fraction from the unknown fluoroscopic exposure

Total no. of images 11 x 116 mGy = 1276 mGy ~ 1300 mGy

The scattered fraction from the patient

For diagnostic X-ray beams the scattered radiation is dependent on field size, beam energy, tissue volume and the type of tissue irradiated. For an entrance field of 400 cm^2 and a beam energy of 80 kVp, this value may be estimated to be approximately 1 ‰ of the incident radiation of the patient, at 1 m and 90 degrees to the incident radiation beam,

A high kVp of 100-110 is assumed which will give a larger fraction of scatter compared to 80 kVp, thus increasing the scattered radiation.

A higher proportion of fatty tissue will also contribute to a larger amount of scatter to the surgeon.

Finally, a large entrance field is assumed because of likely difficulties of centring the area of interest, due to limited image contrast, poor anatomical overview and a small light field for centring the projections.

High kVp, large proportions of fatty tissue and a large entrance field, will probably give a scattered fraction of approximately 5 ‰ at 1 m, 90 degrees to the incident radiation beam.

Total scatter corrected for kVp, tissue and entrance field is taken to be 5 ‰

With a standard over-couch X-ray geometry there will be about 2.5 times more scattered radiation at shoulder level compared with the same distance at 90 degrees to the incident radiation beam. Since the personnel dosimeter is attached at shoulder level this will increase the dosimeter reading.

Scattered fraction at shoulder level is $2.5\ x\ 5‰ = 12.5‰$

During the exposures, the surgeon has to remain near the patient. With the described patient size and the limited length of the scope, it is probably not possible to use distance as an efficient radiation protection tool. The previously suggested large entrance field will further decrease the distance to the surgeon.

Entrance field to dosimeter distance is estimated to be 40-60 cm. A correction to 50 cm, by the inverse square law, will give:

Dosimeter-entrance field distance correction $Dose_{50cm} = \frac{100^2}{50^2}\ x\ 12.5‰ = 50‰ = 5\%$

Dose to the surgeon

From the estimated ESD to the patient of 1300 mGy, and the scatter fraction of 5 % to the surgeon, it is possible to estimate the dose to the dosimeter.

Calculated scatter from the ESD to the dosimeter 5 % x 1300 mGy = 65 mGy

Discussion and conclusions

The high radiation dose to the surgeon can be explained by the obese patient, associated exposure settings and the working technique, in addition to the over-couch tube geometry. This case shows the necessity to pay special attention to staff doses, during situations like the one described. ERCP is not recommended to be performed with over-couch geometry.

The effective dose to the surgeon is difficult to assess exactly. Many factors like e.g. half-value layer, exposed area of the surgeon, design of the lead apron and additional thyroid shielding can reduced the effective dose. With the correct radiation protection, the effective dose will be somewhere between 10 and 40 % of the dosimeter reading. This will give an effective dose to the surgeon between 7 and 28 mSv, which should be compared with the annual dose limit of 20 mSv for occupational exposures, proposed by the International Commission on Radiological Protection (ICRP).

Case 8 – Mobile X-ray radiography

In 2009 a study was carried out to investigate the frequency at which the mobile X-ray radiography units are used at the Nicosia General Hospital (500 beds) in relation to the justification and type of the examinations performed at each ward, the procedure parameters and patient dose. The study aimed at assessing the overall practice in terms of quality of service and radiation protection.

Five mobile x-ray radiography units (BMI/SMAM Mobiledrive AR30) are at present in use at the hospital to perform bedside X-ray examinations. Computed Radiography Cassettes (Agfa MD 4.0 General Code 34) are used and these are read by Computed Radiography Digitizers (Agfa CR 75.0 Digitizer).

Data forms completed by the radiographers before performing each examination have been inspected for data collection.

The Entrance Surface Dose (ESD) as a function of mAs and kVp, was derived from the characteristic curve of each unit.

For comparison purposes, the image quality and dose for each type of examination have been compared with similar examinations performed at the X-ray Department of the Hospital using Direct Digital Radiography (DDR) units (EIDOS MEDCAL 3000).

Data collected from 1910 examinations were analysed. The majority of them (65%) were performed at the Intensive Care Unit and 91.2% of these were chest examinations.

For this particular examination the ESD ranged from 18 to 234 μGy, whereas the mean dose was 60 μGy. There was also a large variation of doses for this examination for the same patient. The table below summarises the results from these patients.

Patient	Days in ICU	No. of CXR	Dose range (μGy)	Average Dose (μGy)	kVp range (kV)	Average kVp (kV)
WJ	37	25	30.28 – 138.66	69.45±23.61	44 - 65	56.8±3.6
AS	67	37	38.77 – 138.66	66.99±18.32	54 - 65	57.2±1.9
AD	47	30	33.78 – 88.26	58.16±19.47	54 - 59	56.9±1.3
KS	19	26	34.72 – 88.26	61.35±13.90	50 - 60	56.4±2.2
CT	66	23	33.47 – 133.24	70.26±21.26	54 - 64	57.2±2.2
CG	37	24	32.18 – 88.26	60.69±12.68	50 - 60	56.4±2.2
CC	34	20	32.18 – 83.68	57.49±15.59	54 - 66	57.3±2.6
CD	13	21	35.42 – 107.41	73.10±20.73	55 - 59	57.3±1.1

It is evident from the above table that the exposure technique used was not the one established for chest X-ray examinations. From further investigation it was revealed that the radiographers were not using anti-scatter grids and this allowed them to use low kVp and

any Focus to skin distance. They had the impression that the scatter radiation would be less and thus protecting themselves during such examinations since there was not adequate shielding in the wards.

On reviewing the image quality from the above examinations it was also revealed that the image quality was unacceptable. None of the images met any of the image quality criteria for a good Chest X-ray examination [1]. From further investigation it was revealed that these examinations were presented to the referring ICU physicians without any reporting from the Radiologists. This is a form of malpractice since the quality of the images was never assessed. It was also revealed that the requests for these examinations were made by telephone calls rather than via written prescriptions.

The conclusions from this study are:

1) Further investigation is needed regarding the frequency of use of mobile x-ray radiography units in relation to patient flow, in order to identify excessive and unjustified use (benchmarking).
2) There is a need for standardisation of the bedside X-ray examination protocols.
3) There is a need to use high kVp techniques together with anti-scatter grids.
4) There is a need to review the ICU protocols with the aim to reduce the number of Chest X-Ray examination referrals.
5) There is a need to establish a quality index as regards the number and quality of bedside examinations.
6) There is a need for further education and training of all involved healthcare professionals.

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