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Radiological protection in fluoroscopically guided procedures performed outside the imaging department

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Radiological Protection in Fluoroscopically Guided Procedures Performed outside the Imaging Department

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Abstract – An increasing number of medical specialists are using fluoroscopy outside imaging departments. There has been general neglect of radiation protection coverage of fluoroscopy machines used outside the imaging departments. Lack of radiation protection training of staff working with fluoroscopy outside imaging departments can increase the radiation risk to staff and patients. Procedures such as endovascular aneurysm repair (EVAR), renal angioplasty, iliac angioplasty, ureteric stent placement, therapeutic endoscopic retrograde cholangio-pancreatography (ERCP) and bile duct stenting and drainage have the potential to impart skin doses exceeding 1 Gy. Although deterministic injuries among patients and staff from fluoroscopy procedures have so far been reported only in interventional radiology and cardiology, the level of usage of fluoroscopy outside radiology departments creates potential for such injuries.

A brief account of the radiation effects and protection principles is presented in Section 2. Section 3 deals with general aspects of staff and patient protection that are common to all whereas specific aspects are covered in Section 4 separately for vascular surgery, urology, orthopaedic surgery, obstetrics and gynaecology, gastroenterology and hepato-biliary system, anaesthetics and pain management. Although sentinel lymph node biopsy (SLNB) involves use of radio-isotopic methods rather than fluoroscopy, this procedure being performed in operation theatre is covered in this document as ICRP is unlikely to have another publication on this topic. Information on level of radiation doses to patients and staff and dose management is presented against each speciality. Issues connected with pregnant patient and pregnant staff are covered in Section 5. Although the Commission has recently published a document on training, specific needs for the target groups in terms of orientation of training, competency of those who conduct and assess specialists and guidelines on curriculum are provided in Section 6.

The document emphasizes that patient dose monitoring is essential whenever fluoroscopy is used.

Recommendations for manufacturers to develop systems to indicate patient dose indices with the possibility to produce patient dose reports that can be transferred to the hospital network are provided as also shielding screens that can be effectively

used for protection of staff protection using fluoroscopy machines in operating theatres without hindering the clinical task.

Keywords: Fluoroscopy; Radiological protection; Health care; Medical

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PREFACE

Over the years, the International Commission on Radiological Protection (ICRP), referred to below as 'the Commission', has issued many reports providing advice on radiological protection and safety in medicine. ICRP Publication 105 is a general overview of this area (ICRP, 2007b). These reports summarise the general principles of radiation protection, and provide advice on the application of these principles to the various uses of ionising radiation in medicine and biomedical research.

At the Commission's meeting in Oxford, UK in September 1997, steps were initiated to produce reports on topical issues in medical radiation protection. It was realized that these reports should be written in a style which is understandable to those who are directly concerned in their daily work, and that every effort is taken to ensure wide circulation of such reports.

Several such reports have already appeared in print (ICRP Publications 84, 85, 86, 87, 93, 94, 97, 98, 102, 105, 112, 113 and ICRP Supporting Guidance 2).

After more than a century of the use of x-rays to diagnose and treat disease, the expansion of their use to areas outside imaging departments is much more common today than at any time in the past.

In Publication 85 (2001), the Commission dealt with avoidance of radiation injuries from medical interventional procedures. Another ICRP publication targeted at cardiologists is being published (ICRP 2012). Procedures performed by orthopaedic surgeons, urologists, gastroenterologists, vascular surgeons, anaesthetists and others, either by themselves or jointly with radiologists, were not covered in earlier publications of the Commission, but there is a substantial need for guidance in this area in view of increased usage and lack of training.

The present publication is aimed at filling this need.

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SUMMARY POINTS

An increasing number of medical specialists are using fluoroscopy outside imaging departments and expansion of its use is much greater today than at any time in the past.

There has been general neglect of radiation protection coverage of fluoroscopy machines used outside the imaging departments.

Lack of radiation protection training of staff working with fluoroscopy outside imaging departments can increase the radiation risk to staff and patients.

Although deterministic injuries among patients and staff from fluoroscopy procedures have so far been reported only in interventional radiology and cardiology, the level of usage of fluoroscopy outside radiology departments creates potential for such injuries.

Procedures such as endovascular aneurysm repair (EVAR), renal angioplasty, iliac angioplasty, ureteric stent placement, therapeutic endoscopic retrograde cholangio-pancreatography (ERCP) and bile duct stenting and drainage have the potential to impart skin doses exceeding 1 Gy.

Radiation dose management for patients and staff is a challenge that can only be met through an effective radiation protection programme.

Patient dose monitoring is essential whenever fluoroscopy is used.

Medical radiation applications on pregnant patients should be specially justified and tailored to reduce fetal dose.

Termination of pregnancy at fetal doses of less than 100 mGy is not justified based upon radiation risk.

The restriction of a dose of 1 mSv to the embryo/fetus of pregnant worker after declaration of pregnancy does not mean that it is necessary for pregnant women to avoid work with radiation completely, or that she must be prevented from entering or working in designated radiation areas. It does, however, imply that the employer should carefully review the exposure conditions of pregnant women.

Every action to reduce patient dose will have a corresponding impact on staff dose but the reverse is not true.

Recent reports of opacities in the eyes of staff who use fluoroscopy have drawn attention to the need to strengthen radiation protection measures for the eyes.

The use of radiation shielding screens for protection of staff using x-ray machines in operating theatres, wherever feasible, is recommended.

Pregnant medical radiation workers may work in a radiation environment as long as there is reasonable assurance that the fetal dose can be kept below 1 mSv during the course of pregnancy.

A training programme in radiological protection for healthcare professionals has to be oriented towards the type of practice the target audience is involved in.

A staff member's competency to carry out a particular function should be assessed by those who are themselves suitably competent.

Periodic quality control testing of fluoroscopy equipment can provide confidence of equipment safety.

Manufacturers should develop systems to indicate patient dose indices with the possibility to produce patient dose reports that can be transferred to the hospital network.

Manufacturers should develop shielding screens that can be effectively used for protection of staff protection using fluoroscopy machines in operating theatres without hindering the clinical task.

1. WHAT IS THE MOTIVATION FOR THIS REPORT?

An increasing number of medical specialists are using fluoroscopy outside imaging departments and expansion of its use is much greater today than at any time in the past.

There has been general neglect of radiation protection coverage of fluoroscopy machines used outside the imaging departments.

Lack of radiation protection training of staff working with fluoroscopy outside imaging departments can increase the radiation risk to staff and patients.

Recent reports of opacities in the eyes of staff who use fluoroscopy have drawn attention to the need to strengthen radiation protection measures for the eyes.

1.1. Which procedures are of concern and who is involved?

(1) After more than a century of the use of x-rays to diagnose and treat disease, the expansion of their use to areas outside imaging departments is much more common today than at any time in the past. The most significant use outside radiology has been in interventional procedures, predominantly in cardiology, but there are also a number of other clinical specialties where fluoroscopy is used to guide medical or surgical procedures.

(2) In Publication 85 (2001), the Commission dealt with avoidance of radiation injuries from medical interventional procedures. Another ICRP publication targeted at cardiologists is being published (ICRP 2012). Procedures performed by orthopaedic surgeons, urologists, gastroenterologists, vascular surgeons, anaesthetists and others, either by themselves or jointly with radiologists were not covered in earlier publications of the Commission, but there is a substantial need for guidance in this area in view of increased usage and lack of training. Practices vary widely in the world and so too the role of radiologists. In some countries radiologists play major role in such procedures. These procedures and the medical specialists involved are listed in Table 1.1, although the list is not exhaustive.

(3) These procedures allow medical specialists to treat patients and achieve the desired clinical objective. In many situations, these procedures are less invasive, result in decreased morbidity and mortality, are less costly and result in shorter hospital stays than the surgical procedures that are the alternatives, or these may be the best alternative if the patient cannot have an open surgical procedure. In some situations these procedures may be the only alternative, in particular for very elderly patients.

Table 1.1. Examples of common procedures (not exhaustive) that may be performed in or outside radiology departments, excluding cardiac procedures (adapted from NCRP, 2011).

Organ system or region	**Procedure**
Bones and joints or musculoskeletal *Specialities:* • *Radiology* • *Orthopaedics* • *Neurosurgery* • *Anaesthesiology* • *Neurology*	Fracture/dislocation reduction Implant guidance for anatomic localization, orientation, and fixation Deformity correction Needle localization for injection, aspiration, or biopsy Anatomic localization to guide incision location Adequacy of bony resection Foreign body localization Biopsy Vertebroplasty Kyphoplasty

	Embolization Tumour ablation Nerve blocks
Gastrointestinal tract *Specialities:* • *Radiology* • *Gastroenterology*	Percutaneous gastrostomy Percutaneous jejunostomy Biopsy Stent placement Diagnostic angiography Embolization
Kidney and urinary tract *Specialities:* • *Radiology* • *Urology*	Biopsy Nephrostomy Ureteric stent placement Stone extraction Tumour ablation
Liver and biliary system *Specialities:* • *Radiology* • *Gastroenterology*	Biopsy Percutaneous biliary drainage ERCP[a] Percutaneous cholecystostomy Stone extraction Stent placement TIPSS[b] Chemoembolization Tumour ablation
Reproductive tract *Specialities: Radiology/Obstetrics& Gynaecology*	Hysterosalpingography Embolization
Vascular system *Specialities:* • *Radiology* • *Cardiology* • *Vascular surgery* • *Nephrology*	Diagnostic venography Angioplasty Stent placement Embolization Stent-graft placement Venous access Inferior vena cava filter placement
Central nervous system *Specialities:* • *Radiology* • *Neurosurgery* • *Neurology*	Diagnostic angiography Embolization Thrombolysis
Chest *Specialities:* • *Radiology* • *Vascular surgery* • *Internal medicine*	Biopsy Thoracentesis Chest drain placement Pulmonary angiography Pulmonary embolization Thrombolysis Tumour ablation

[a]ERCP: endoscopic retrograde cholangiopancreatography.
[b]TIPSS: transjugular intrahepatic portosystemic shunt

(4) In addition to fluoroscopy procedures outside the imaging department this document also addresses sentinel lymph node biopsy (SLNB) that utilizes radiopharmaceuticals rather than x-rays as a radiation source. It was deemed appropriate to cover this in this document as it is unlikely this topic will be addressed in another publication in coming years and the topic requires attention from radiation protection angle.

1.2. Who has the potential to receive high radiation doses?

(5) For many years it was a common expectation that people who work in departments where radiation is used regularly on a daily basis as a full time job need to have radiation protection training and monitoring of their radiation doses. These departments include radiotherapy, nuclear medicine and diagnostic radiology. As a result, many national regulatory authorities had the notion that if they looked after these facilities they had fulfilled their responsibilities for radiation protection. In many countries, this is still the situation. However, the use of x-rays for diagnostic or interventional procedures outside these departments has markedly increased in recent years. Fluoroscopic machines are of particular concern because of their potential for causing relatively high exposures of staff or patients. There are examples of countries where national authorities have no idea about how many fluoroscopy machines exist in operating theatres outside the control of radiology departments. Staff working in radiotherapy facilities either work away from the radiation source or work near only heavily shielded sources. As a result, in normal circumstances, staff radiation exposure is typically minimal. Even if radiation is always present in nuclear medicine facilities, overall exposure of staff can still be less than for those who work near an x-ray tube, as the intensity of radiation from x-ray tubes is very high. The situation in imaging (radiography and computed tomography) is similar, in the sense that staff normally work away from the radiation sources, and are based at consoles that are shielded from the x-ray radiation source. On the other hand, working in a fluoroscopy room typically requires that staff stand near the x-ray source (both the x-ray tube itself and the patient who is a source of scattered x-rays). The radiation exposure of staff who work in fluoroscopy rooms can be more than for those working in radiotherapy, nuclear medicine or those in imaging who do not work with fluoroscopic equipment. The actual dose depends upon the time one is in the fluoroscopy room (when the fluoroscope is being used), the shielding garments used (lead apron, thyroid and eye protection wears), mobile ceiling-suspended screen and other hanging lead flaps that are employed, as well as equipment parameters. In general, for the same amount of time spent in radiation work, the radiation exposure of staff working in a fluoroscopy room will be higher than for those who do not work in fluoroscopy rooms. If medical procedures require large amounts of radiation from lengthy fluoroscopy or multiple images, such as in vascular surgery, these staff may receive substantial radiation doses and therefore need a higher degree of radiation protection through the use of appropriate training and protective tools. The usage of fluoroscopy for endovascular repair of straightforward abdominal and thoracic aortic aneurysms by vascular surgeons is increasing and radiation levels are similar to those in interventional radiology and interventional cardiology. Over the next few years, the use of more complex endovascular devices, such as branched and fenestrated stents for the visceral abdominal aorta and the arch and great vessels, is likely to increase. These procedures are long and complex, requiring prolonged fluoroscopic screening. They also often involve extended periods during which the entrance surface of the radiation remains fixed relative to the x-ray tube, increasing the risk of skin injury. Image guided injections by anaesthetists for pain management is also increasing.

1.3. Lack of training, knowledge, awareness and skills in radiation protection

(6) In many countries, non-radiologist professionals work with fluoroscopy without direct support from their colleagues in radiology, using equipment that may range from fixed angiographic facilities, similar to a radiology department, to mobile image intensifier fluoroscopy systems. In most cases, physicians using fluoroscopy outside the radiology department (orthopaedic surgeons, urologists, gastroenterologists, vascular surgeons, gynaecologists, anaesthetists, etc.) have either minimal or no training in radiation protection and may not have regular access to those professionals who do have training and expertise in radiation protection, such as medical physicists. Radiographers working in these facilities outside radiology or cardiology departments may be familiar only with one or two specific fluoroscopy units used in the facility. Thus their skills, knowledge and awareness may be limited. Nurses in these facilities typically have limited skills, knowledge and awareness of radiation protection. The lack of radiation protection culture in these settings adds to patient and staff risk.

1.4. Patient versus staff radiation doses

(7) It has commonly been believed that staff radiation protection is much more important than patient protection. The underlying bases for this belief are that a) staff are likely to work with radiation for their entire career b) patients undergo radiation exposure for their benefit and c) patients are exposed to radiation for medical purposes only a few times in their life. While the first two bases still hold, in recent years the situation with regard to third point has changed drastically. Patients are undergoing examinations and procedures many times. Moreover, the type of examination for patients in modern time, are those that involve higher doses as compared to several decades ago. Radiography was the mainstay of investigation in the past. Currently computed tomography (CT) has become very common. A CT scan imparts radiation dose to the patient that is equivalent to several hundreds of radiographs. The fluoroscopic examinations in the past were largely diagnostic whereas currently a larger number of fluoroscopic procedures are interventional and these impart higher radiation dose to patients. An increase in frequency of use of higher dose procedures per patient has been reported (NCRP, 2009). Many patients receive radiation doses that exceed the typical dose staff members may receive during their entire career.

(8) According to the latest UNSCEAR report, the average annual dose (worldwide) for occupational exposure in medicine is 0.5 mSv/year (UNSCEAR, 2008). For a person working for 45 years, the total dose may be 22.5 mSv over the full working life. The emphasis on occupational radiation protection in the past century has yielded excellent results as evidenced by the above figure and staff doses seem well under control. However, there are examples of very poor adoption of personal monitoring measures in many countries among the group covered in this document.

(9) It is unfortunate that, particularly in clinical areas covered in this document, patient radiation protection has not received much attention. Surveys conducted by the IAEA among non-radiologists and non-cardiologists from over 30 developing countries indicate that there is an almost complete (in over 90% of the situations)

absence of patient dose monitoring (IAEA, 2010). Surveys of the literature indicate a lack of reliable data on staff doses in settings outside radiology departments. This needs to be changed.

1.5. Fear and overconfidence

(10) In the absence of knowledge and awareness, people tend to either overestimate or underestimate risk. Either they have unfounded fears or they have a disregard for appropriate protection. It is a common practice for young medical residents to observe how things are dealt with by their seniors. They start with inquisitive minds about radiation risks, but if they find that their seniors are not greatly concerned about radiation protection, they tend to slowly lose interest and enthusiasm. This is not uncommon among the clinical specialists covered in this document. If residents do not have access to medical physicist experts, which is largely the case, they follow the example of their seniors, leading to fear in some cases and disregard in others. This is an issue of radiation safety culture and propagation of an appropriate safety culture should be considered a responsibility of senior medical staff.

1.6. Training

(11) Historically, in many hospitals, x-ray machines were located only in radiology departments, so non-radiologists who performed procedures using this equipment had radiologists and radiographers available for advice and consultation. In this situation, there was typically some orientation of non-radiologists in radiation protection based on practical guidance. With time, as usage increased and x-ray machines were installed in other departments and areas of the hospital and outside the control of radiology departments, the absence of training has become evident, and needs attention. In surveys conducted by the IAEA in training courses for non-radiologists and non-cardiologists (http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/2_TrainingEvents/Doctorstraining.htm), it is clear that most non-radiologists and non-cardiologists in developing countries have not undergone training in radiation protection and that medical meetings and conferences of these specialists typically have no lectures on or component of radiation protection. This lack of training in radiation protection poses risks to staff and patients. This situation needs to be corrected. The Commission recommends that the level of training in radiation protection should be commensurate with the usage of radiation (ICRP, 2011).

1.7. Why this report?

(12) Radiation usage is increasing outside imaging departments. The fluoroscopy equipment is becoming more sophisticated and can deliver higher radiation doses in short time and thus fluoroscopy time alone is not a good indicator of radiation dose. There is a near absence of patient dose monitoring in settings covered in this document. Over-exposures in digital x-ray equipment may not be detected, machines that are not tested under a quality control (QC) system can give

higher radiation doses and poor image quality, and repeated radiological procedures increase cumulative patient radiation doses. There are a number of image quality factors that, if not taken into account, can deliver poor quality images and higher radiation dose to patients. On the other hand there are simple techniques that use the principles of time, distance, shielding, as described in Section 3 and the individual sections of this publication in Section 4 to help ensure the safety of both patients and staff. Lessons drawn from other situations, not directly those involving fluoroscopy machines outside radiology, demonstrate that both accidental exposures and routine overexposures can occur, resulting in undesirable radiation effects on patients and staff (ICRP, 2001; Ciraj-Bjelac et al., 2010; Vano et al., 2010; http://www.nytimes.com/2010/08/01/health/01radiation.html?_r=3&emc=eta1). There is a lack of radiation shielding screens and flaps in many fluoroscopy machines used in operating theatres and there are specific problems that staff face in radiation protection outside radiology and cardiology departments. Personal dosimeters are not used by some professionals or their use is irregular. As a consequence, occupational doses in several practices are largely unknown.

1.8. References, Chapter 1

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2. RADIATION EFFECTS AND PROTECTION PRINCIPLES

Although deterministic injuries among patients and staff from fluoroscopy procedures have so far been reported only in interventional radiology and cardiology, the level of usage of fluoroscopy outside radiology departments creates potential for such injuries.

Patient dose monitoring is essential whenever fluoroscopy is used.

2.1. Introduction

(13) Most people, health professionals included, do not realize that the intensity of radiation from an x-ray tube is typically hundreds of times higher than the radiation intensity from radioactive substances (radioisotopes and radiopharmaceuticals) used in medicine. This lack of understanding has been partially responsible for the lack of radiation protection among many users of x-rays in medicine. The level of radiation protection practice tends to be better in facilities using radioactive substances. For practical purposes, this document is concerned with radiation effects from x-rays, which are electromagnetic radiation, like visible light, ultra violet, infra-red radiation, radiation from cell phones, radio waves and microwaves. The major difference is that these other types of electromagnetic radiation are non-ionizing and dissipate their energy through thermal interaction (dissipation of energy through heat). This is how microware diathermy and microwave ovens work. On the other hand, x-rays are forms of ionizing radiation—they may interact with atoms and can cause ionization in cells. They may produce free radicals or direct effects that can damage DNA or cause cell death.

2.2. Radiation exposure in context

(14) As a global average, the natural background radiation is 2.4 mSv per year. (UNSCEAR, 2010). In some countries typical background radiation is about 1 mSv per year, and in others it is approximately 3 mSv. There are some areas in the world, (e.g., India, Brazil, Iran, and France) where the population is exposed to background radiation levels of 5 - 15 mSv per year. The Commission has recommended a whole body dose limit for workers of 20 mSv per year (averaged over a defined 5 year period; 100 mSv in 5 years) and other limits as in Table 2.1. (ICRP, 2007; ICRP 2011a).

(15) It must be emphasized that individuals who work with fluoroscopy machines and use the radiation protection tools and methods described in this document, can keep their radiation dose from work with x-rays to less than or around 1 mSv per year and thus there is a role for radiation protection.

Table 2.1. Occupational dose limits (ICRP, 2007; ICRP 2011a).

Type of limit	**Occupational limit**
Effective dose	20 mSv per year, averaged over defined period of 5 years
Annual equivalent dose in:	
Lens of the eye	20 mSv
Skin	500 mSv
Hands and feet	500 mSv

2.3. Radiation effects

(16) Radiation effects are classified into two types: Those that are visible, documented and confirmed within a relatively short time - weeks to a year or so (called tissue reactions: skin erythema, hair loss, cataract, infertility) and others which are only estimated and may take years or decades to manifest (called stochastic effects: cancer and heritable effects).

2.3.1. Deterministic effects

(17) Deterministic effects have thresholds, which are typically quite high (Table 2.2). For staff, these thresholds are not normally reached when good radiation protection practices are used. For example, skin erythema used to occur in the hands of staff a century ago, but this has rarely happened in the last half a century or so in staff using medical x-rays. There are a large number of reports of skin injuries among patients from fluoroscopic procedures in interventional radiology and cardiology (ICRP 2001, Balter et al. 2010) but none so far in other areas of use of fluoroscopy. Hair loss has been reported in the legs of interventional radiologists and cardiologists in the area unprotected by the lead apron or lead table shield (Wiper et al. 2005, Rehani and Ortiz-Lopez 2006), but has not been reported in orthopaedic surgery, urology, gastroenterology or gynaecology because x-rays are used to a lesser extent in these specialties. Although there is lack of information of these injuries in vascular surgeons, these specialists use large amounts of radiation, and their exposure can match that of interventional cardiologists or interventional radiologists. This creates the potential for deterministic effects in both the patients and staff. Infertility at the level of radiation doses encountered in radiation work in fluoroscopy suites or even in interventional labs is unlikely and has not been documented so far.

(18) The lens of the eye is one of the more radiosensitive tissues in the body (ICRP, 2011a; ICRP 2011b). Radiation-induced cataract has been demonstrated among staff involved with interventional procedures using x-rays (ICRP, 2001; Vano et al., 1998). A number of studies suggest there may be a substantial risk of lens opacities in populations exposed to low doses of ionizing radiation. These include patients undergoing CT scans (Klein et al., 1993), astronauts (Cucinotta et al., 2001; Rastegar et al., 2002), radiologic technologists (Chodick et al., 2008) atomic bomb survivors (Nakashima et al., 2006; Neriishi et al., 2007)and those exposed in the Chernobyl accident (Day et al., 1995).

(19) Up until recently, cataract formation was considered a deterministic effect with a threshold for detectable opacities of 5 Sv for protracted exposures and 2 Sv for acute exposures (ICRP, 2001, ICRP 2011). The Commission continues to recommend that optimisation of protection be applied in all exposure situations and for all categories of exposure. With the recent evidence, the Commission further emphasises that protection should be optimised not only for whole body exposures, but also for exposures to specific tissues, particularly the lens of the eye, and to the heart and the cerebrovascular system. The Commission has now reviewed recent epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are or might be lower than previously considered. For the lens of the eye, the threshold in absorbed dose is now considered to be 0.5 Gy. Also, although uncertainty remains, medical practitioners should be made aware that the absorbed dose threshold for circulatory disease may be as low as

0.5 Gy to the heart or brain. For occupational exposure in planned exposure situations the Commission now recommends an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv (ICRP, 2011a).

Table 2.2. Thresholds for deterministic effects (ICRP, 2007)*.

Tissue and effect	**Threshold**	
	Total dose in a single exposure (Gy)	**Annual dose if the case of fractionated exposure (Gy/y)**
Testes		
Temporal sterility	0.15	0.4
Permanent sterility	3.5-6.0	2.0
Ovaries		
Sterility	2.5-6.0	>0.2
Lens		
Detectable opacity	0.5-2.0	>0.2
Cataract	5.0	>0.15
Bone marrow		
Depression of Haematopoiesis	0.5	>0.4

*Note: This Table shall be modified in coming months on finalization of this document in light of new publication on Tissue Reactions.

(20) If doctors and staff remain near the x-ray source and within a high scatter radiation field for several hours a day, and do not use radiation protection tools and methods, the risk may become substantial. Two recent studies conducted by the International Atomic Energy Agency (IAEA) have shown a higher prevalence of lens changes in the eyes of interventional cardiologists and nurses working in cardiac catheterization laboratories (Vano et al., 2010; Ciraj-Bjelac et al., 2010).

2.3.2. Stochastic effects

(21) Stochastic effects include cancer and genetic effects, but the scientific evidence for cancer in humans is stronger than for genetic effects. According to Publication 103 (2007), detriment-adjusted nominal risk coefficient for stochastic effects for whole population after exposure to radiation at low dose rate is 5.5% per Sv for cancer and 0.2% per Sv for genetic effects. This gives a factor of about 27 more likelihood of carcinogenic effects than genetic effects. There has not been a single case of radiation induced genetic effects documented in humans so far, even in survivors of Hiroshima and Nagasaki. All of the literature on genetic effects comes from non-human species, where the effect has been documented in thousands of papers. As a result, and after careful review of many decades of literature, the Commission reduced the tissue weighting factor for the gonads by more than half, from 0.2 to 0.08 (ICRP, 2007). Thus, emphasis is placed on cancer in this report.

(22) Cancer risks are estimated on the basis of probability, and are derived mainly from the survivors of Hiroshima and Nagasaki. These risks are thus estimated risks. With the current state of knowledge, carcinogenic radiation effects are more likely for organ doses in excess of 100 mGy. For example, a chest CT scan that yields about 8 mSv effective dose can deliver about 20 mGy dose to the breast; 5 CT scans will therefore deliver about 100 mGy. There may be controversies about cancer risk at the radiation dose from one or a few CT scans, but the doses encountered from 5 to 15 CT scans approach the exposure levels where risks have been documented. Because radiation doses to patients from fluoroscopic procedures vary greatly, one must

determine the dose to get a rough idea of the cancer risk. It must be mentioned that cancer risk estimates are based on models of a nominal standard human and cannot be considered to be valid for a specific individual person. Since stochastic risks have no threshold, and the Commission considers that the linear no-threshold relationship of dose-effect is valid down to any level of radiation exposure, the risk, however small, is assumed to remain even at very low doses. The best way to achieve protection is to optimize exposures, keeping radiation exposure as low as reasonably achievable, commensurate with clinically useful images.

2.3.3. Individual differences in radiosensitivity

(23) It is well known that different tissues and organs have different radiosensitivities and that overall, females are more radiosensitive than males to cancer induction. The same is true for young patients (increased radiosensitivity) as compared to older patients. For example, the lifetime attributable risk of lung cancer for a woman after an exposure of 0.1 Gy at age 60 is 126% higher than the value for a man exposed to the same dose at the same age (BEIR, 2006). If a man 40 years old is exposed to radiation, his risk of lung cancer is 17% higher than if he was exposed to the same radiation dose at age 60. These general aspects of radiosensitivity should be taken into account in the process of justification and optimization of fluoroscopically guided procedures because in some cases, the level of radiation doses may be relatively high for several organs. There are also individual genetic differences in susceptibility to radiation-induced cancer and they should be considered in specific cases involving relatively higher doses based on family and clinical history (ICRP, 1999).

(24) Pre-existing autoimmune and connective tissue disorders predispose patients to the development of severe skin injuries in an unpredictable fashion. The cause is not known. These disorders include scleroderma, systemic lupus erythematosus, and possibly rheumatoid arthritis, although there is controversy regarding whether systemic lupus erythematosus predisposes patients to these effects. Genetic disorders that affect DNA repair, such as the defect in the ATM gene responsible for ataxia telangiectasia, also predispose individuals to increased radiation sensitivity. Diabetes mellitus, a common medical condition, does not increase sensitivity to radiation, but does impair healing of radiation injuries (Balter et al., 2010).

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3. PATIENT AND STAFF PROTECTION

Manufacturers should develop systems to indicate patient dose indices with the possibility to produce patient dose reports that can be transferred to the hospital network.

Manufacturers should develop shielding screens that can be effectively used for protection of staff protection using fluoroscopy machines in operating theatres without hindering the clinical task.

Every action to reduce patient dose will have a corresponding impact on staff dose but the reverse is not true.

Periodic quality control testing of fluoroscopy equipment can provide confidence of equipment safety.

The use of radiation shielding screens for protection of staff using x-ray machines in operating theatres, wherever feasible, is recommended.

3.1 General principles of radiation protection

(25) Time, distance and shielding (T,D,S) form the key aspects of general protection principles as applicable to the situations within the scope of this document:

(26) Time: minimize the time that radiation is used (it can reduce the radiation dose by a factor of 2 to 20 or more). This is effective whether the object of minimization is fluoroscopy time or the number of frames or images acquired.

(27) Distance: increasing distance from the x-ray source as much as is practical (it can reduce the radiation dose by a factor of 2 to 20 or more). (See Section 3.3.2 and Fig. 3.3.)

(28) Shielding: use shielding effectively. Shielding is most effective as a tool for staff protection (Section 3.4.1). Shielding has a limited role for protecting patients' body parts, such as the breast, female gonads, eyes and thyroid in fluoroscopy (with exception of male gonads).

(29) Justification: The benefits of many procedures that utilize ionizing radiation are well established and well accepted both by the medical profession and society at large. When a procedure involving radiation is medically justifiable, the anticipated benefits are almost always identifiable and are sometimes quantifiable. On the other hand, the risk of adverse consequences is often difficult to estimate and quantify. In the Publication 103, Commission stated as a principle of justification that "Any decision that alters the radiation exposure situation should do more good than harm" (ICRP, 2007a). The Commission has recommended a multi-step approach to justification of the patient exposures in the Publication 105 (ICRP, 2007b). In the case of the individual patient, justification normally involves both the referring medical practitioner (who refers the patient, and may for example be the patient's physician/surgeon) and the radiological medical practitioner (under whose responsibility the examination is conducted).

(30) Optimization: Once examinations are justified, they must be optimized (i.e. can they be done at a lower dose while maintaining efficacy and accuracy). Optimization of the examination should be both generic for the examination type and all the equipment and procedures involved. It should also be specific for the individual, and include review of whether or not it can be effectively done in a way that reduces dose for the particular patient (ICRP, 2007b).

3.2. Requirements for the facility

(31) Each x-ray machine should be registered with appropriate state database under the overall oversight of national regulatory authority. During the process of registration and authorization, the authority will examine the specifications of the machine and the room where it is going to be used in terms of size and shielding. There are safety requirements for x-ray machines that are provided by the international organizations such as International Electrotechnical Commission (IEC) and International Standards Organization (ISO). In many countries, there are national standards for x-ray machine which are applicable. These considerations are aimed at protection of the staff and members of the public who may be exposed. The process will also include availability of qualified staff. There are requirements for periodic quality control (QC) tests for constancy check and performance evaluation. Periodic QC testing of fluoroscopy equipment can provide confidence of equipment safety and its ability to provide images of optimal image quality. If a machine is not working properly it can provide unnecessary radiation dose to the patient and images that are of poor quality.

3.3. Common aspects of patient and staff protection

(32) There are many common factors that affect both patient and staff doses. Every action that reduces patient dose will also reduce staff dose, but the reverse is not true. Staff using lead aprons, leaded glass eyewear or other kinds of shields may reduce their own radiation dose, but these protective devices do not reduce patient dose. In some situations, a sense of feeling safe on the part of the staff may lead to neglect of patient protection. Specific factors of staff protection are covered in Section 3.4.

3.3.1. Patient specific factors

Thickness of the body part in the beam

(33) Most fluoroscopy machines automatically adjust radiation exposure, through a system called automatic exposure control (AEC). This electronic system has a sensor that detects how much signal is being produced at the image receptor and adjusts the x-ray generator to increase or decrease exposure factors (typically kV, mA and pulse time) so that the image is of consistent quality. When a thicker body part is in the beam, or a thicker patient is being imaged (as compared to thinner patient), the machine will automatically increase these exposure factors. The result is a similar quality image, but also an increase in the radiation dose to the patient. Increased patient dose will result in increased scatter and increased radiation dose to staff. Fig. 3.1 below demonstrates the increase in entrance skin dose as body part thickness increases, while Fig. 3.2. presents how much radiation is absorbed in the patient's body.

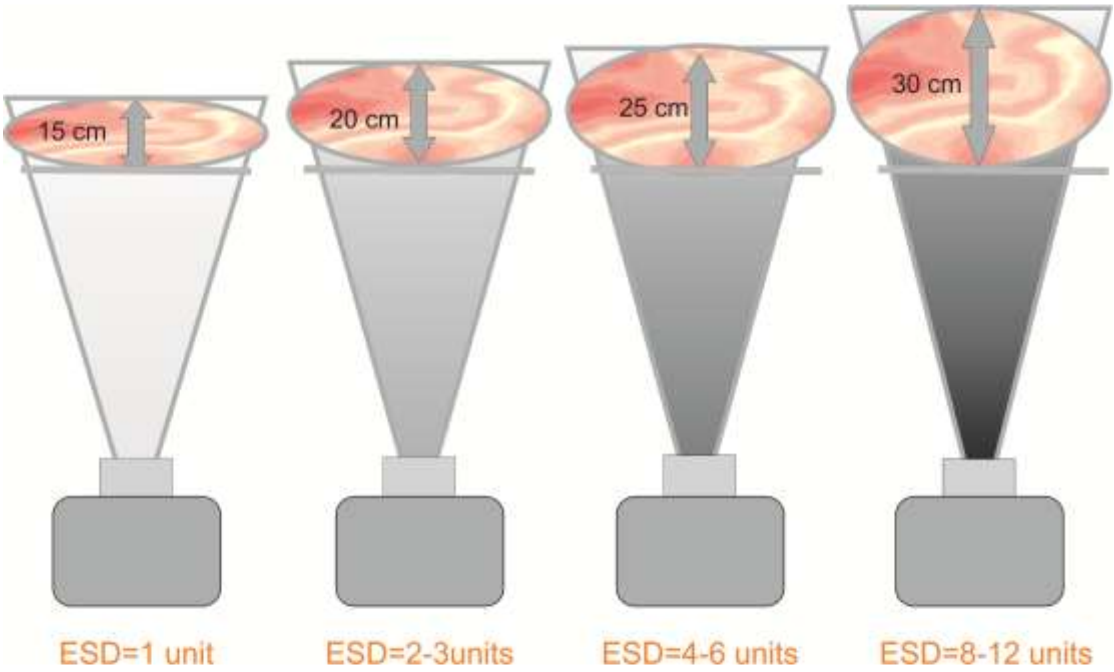

Fig. 3.1 Change in entrance surface dose (ESD) with thickness of body part in the x-ray beam.

Complexity of the procedure

(34) Complexity is mental and physical effort required to perform a procedure. The complexity index is an objective measure. An example would be placement of a guide wire or catheter in an extremely tortuous vessel or across a severe, irregular stenosis. Complexity is due to patient factors (anatomic variation, body habitus) and lesion factors (location, size, severity), but is independent of operator training and experience. More complex procedures tend to require higher radiation doses to complete than less complex procedures (IAEA, 2008).

3.3.2. Technique factors

(35) The magnitude of radiation at the entrance surface of the body is different from the amount of radiation that exits on the exit surface of the body. The body attenuates x-rays in an exponential fashion. As a result radiation intensity decreases exponentially along its path through the body. Typically, only a small percentage of the entrance radiation exits the body. As a result, the major risk of radiation is on the entrance skin. A large number of skin injuries have been reported in patients undergoing interventional procedures of various kinds, but so far these injuries have not been reported as a result of procedures conducted by orthopaedic surgeons, urologists, gastroenterologists and gynaecologists (ICRP, 2001; Rehani & Ortiz-Lopez, 2006; Koening et al. 2001; Balter et al., 2010).

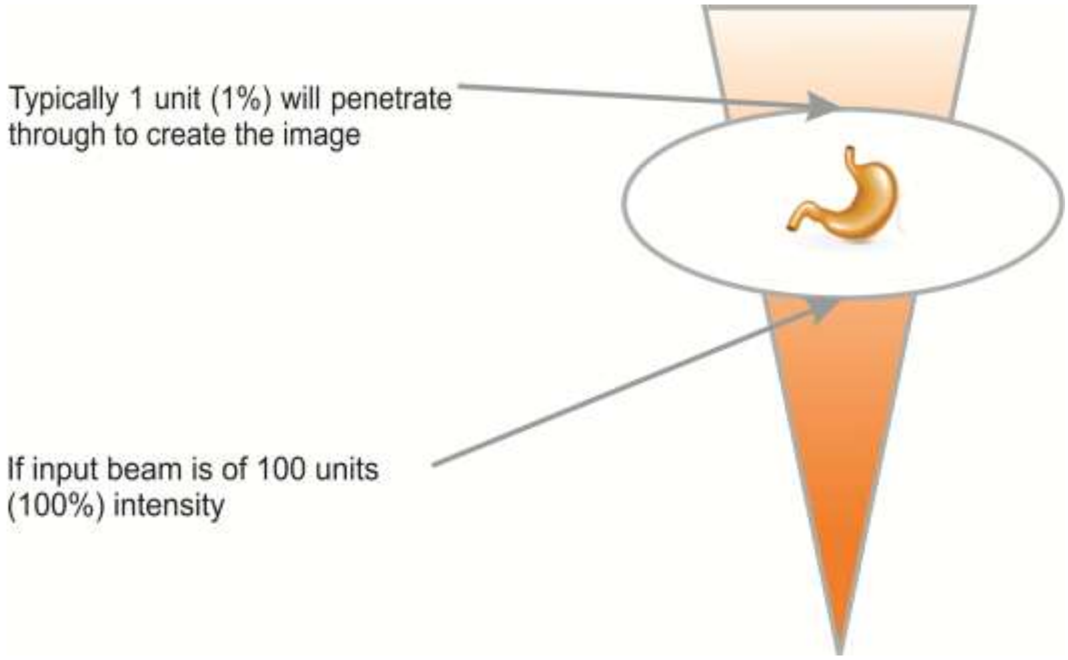

Fig.3.2. Relative intensities of radiation on entrance and exit side of patient.

(36) In addition, it is important that users understand how their equipment functions, as each equipment has some unique features. The standards provided by the National Electrical Manufacturers Association (NEMA; www.nema.org) reduce the variations but there are always features that need understanding. The complexity of modern equipment is such that "know your equipment" should not be compromised with.

Position of the x-ray tube and image receptor

(37) The distance between the x-ray source (the x-ray tube focus) and the patient's skin is called the source-to-skin distance (SSD). As SSD increases, the radiation dose to the patient's skin decreases (Fig. 3.3.), due to the increased distance and the effect of the inverse square law. The patient should be as far away from the x-ray source as practical to maximize the SSD. (This may not be possible if it is necessary to keep a specific organ or structure at the isocenter of the gantry.) Once the patient is positioned to maximize the SSD, the image receptor (image intensifier or flat panel detector) should be placed as close to the patient as practical. All modern fluoroscopes automatically adjust radiation output during both fluoroscopy and fluorography to accommodate changes in source to image receptor distance (SID). Due to the effects of the inverse square law, reducing SID (reducing the distance between the x-ray source and the image receptor) reduces the imaging time. Dose to the image receptor is kept rather constant, and therefore patient entrance dose is reduced (Fig. 3.4.). In simplest terms, to minimize patient entrance dose, maximize SSD and minimize SID. This is an important tool for prevention of deterministic effects.

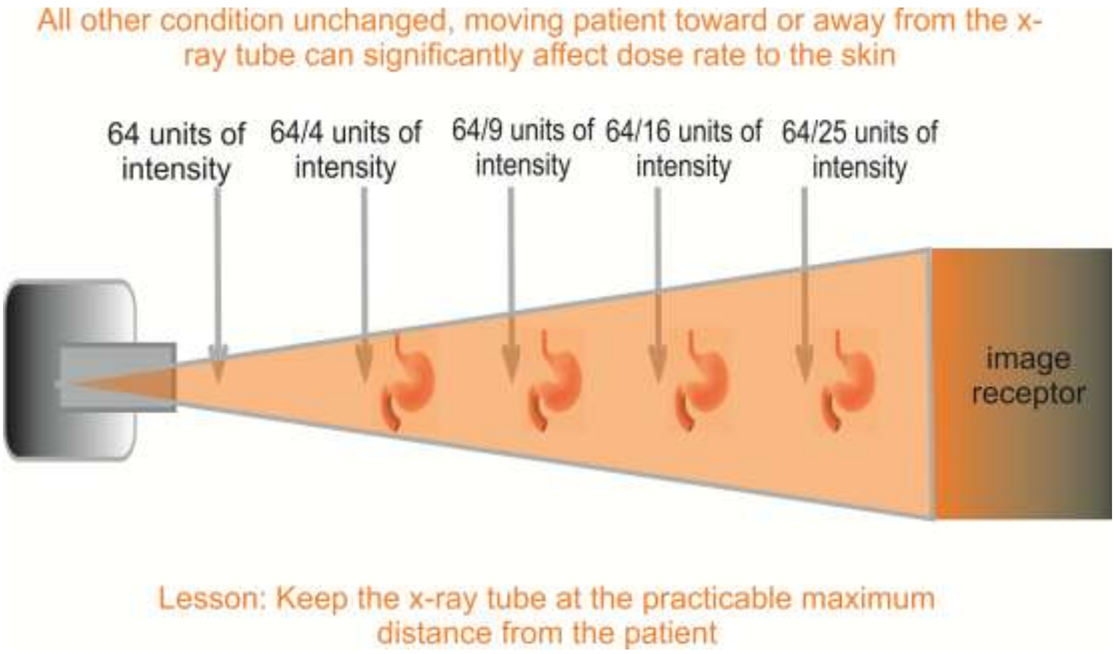

Fig. 3.3. Effect of distance between patient and x- ray tube on radiation dose to patient.

Avoid steep gantry angulations when possible

(38) Steep gantry angulations (steep oblique and lateral positions) increase the length of the radiation path through the body as compared to a posteroanterior (frontal) projection (Fig. 3.5.). A greater thickness of tissue must be penetrated, and this requires higher radiation dose rates. All modern fluoroscopes automatically adjust radiation output during both fluoroscopy and fluorography to accommodate the thickness of the body part being imaged (see Section 3.3.1). As a result, the radiation dose automatically increases when steep oblique or lateral angulations are used. Whenever possible, avoid steep oblique and lateral gantry positions. When these gantry positions are necessary, recognize that the radiation dose is relatively high.

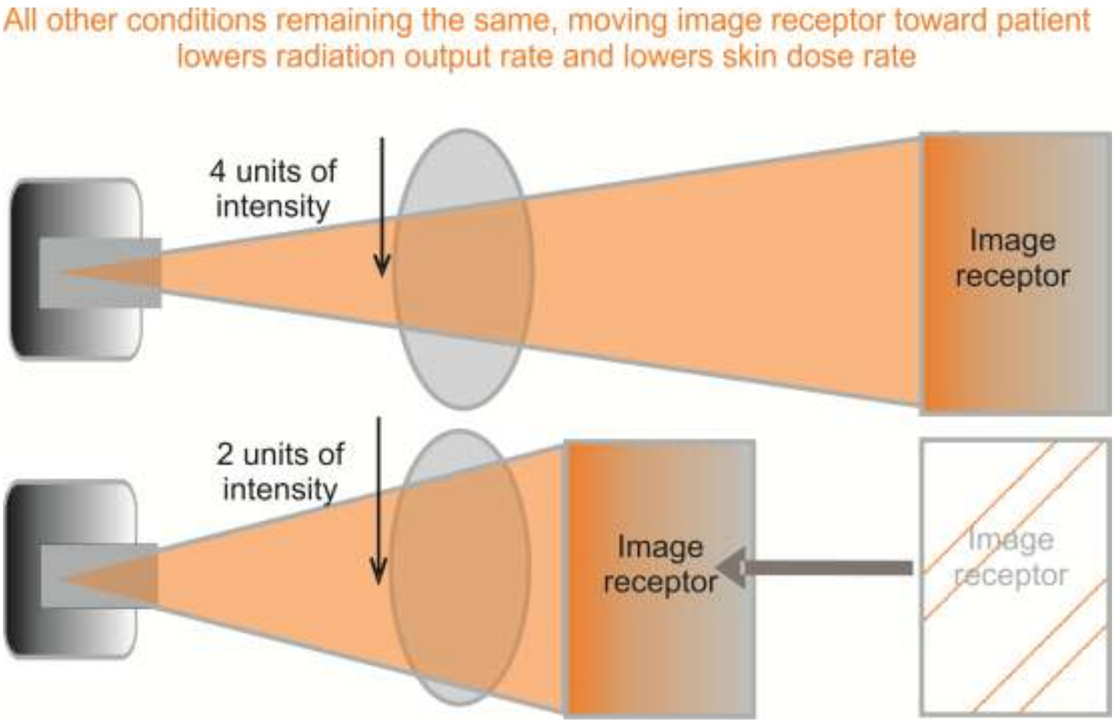

Fig. 3.4. Effect of distance between image intensifier and patient on radiation dose to patient.

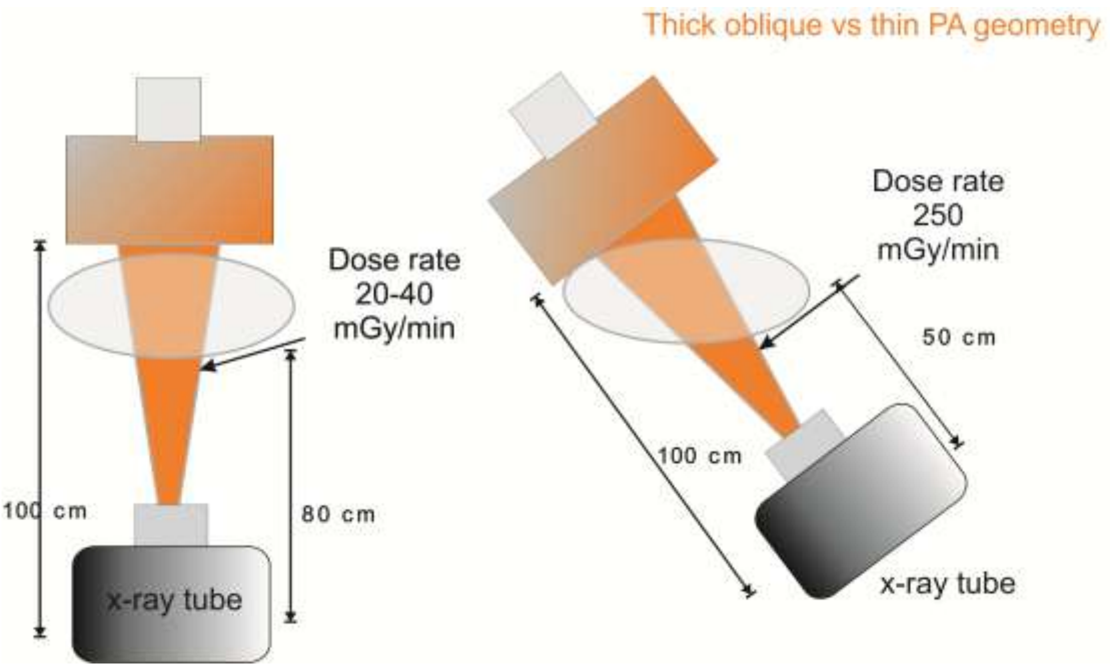

Fig. 3.5. Effect of angulations on patient dose.

Keep unnecessary body parts out of the x-ray beam

(39) It is good practice to limit the radiation field to those parts of the body which must be imaged. When other body parts are included in the field, image artefacts from bones and other tissues can be introduced into the image. Also, if the arms are in the field while the gantry is in a lateral or oblique position, one arm may be very close to the x-ray tube. The dose to this arm may be high enough to cause skin injury (Fig.3.6.). Keep the patient's arms outside the radiation field unless an arm is intentionally imaged as part of the procedure.

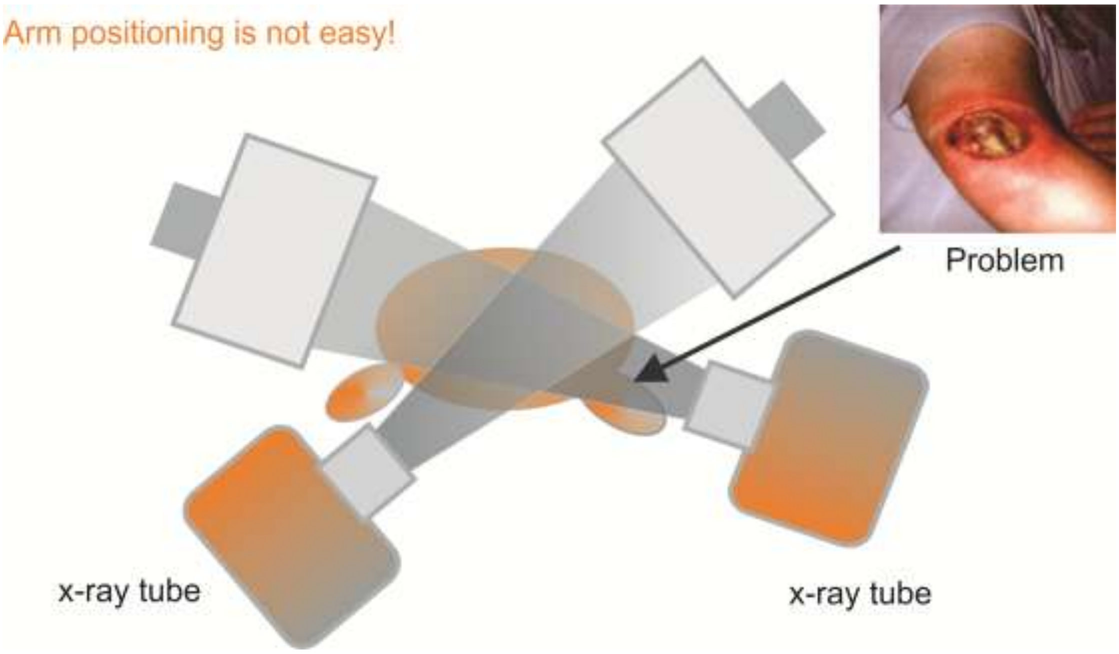

Fig. 3.6. Addition of extra tissue in the path of the radiation beam, such as arm, increases the radiation intensity and can cause high dose to the arm. In lengthy procedure it can lead to skin injury.

Use pulsed fluoroscopy at a low pulse rate

(40) Pulsed fluoroscopy uses individual pulses of x-rays to create the appearance of continuous motion and, at low pulse rates, this can decrease the fluoroscopy dose substantially compared to conventional continuous fluoroscopy, if the dose per pulse is constant. Always use pulsed fluoroscopy if it is available. Use the lowest pulse rate compatible with the procedure. For most non-cardiac procedures, pulse rates of 10 pulses per second or less are adequate.

Use low fluoroscopy dose rate settings

(41) Both the fluoroscopy pulse rate and the fluoroscopy dose rate can be adjusted in many fluoroscopy units. Fluoroscopy dose rate is not the same as fluoroscopy pulse rate. These parameters are independent and can be adjusted

separately. Lower dose rates reduce patient dose at the cost of increased noise in the image. If multiple fluoroscopy dose rate settings are available, use the lowest dose rate setting which provides adequate image quality.

Collimation

(42) Collimate the x-ray beam to limit the size of the radiation field to the area of interest. This reduces the amount of tissue irradiated and also decreases scatter, yielding a better quality image. When beginning a case, position the image receptor over the area of interest, with the collimators almost closed. Open the collimators gradually until the desired field of view is obtained. Virtual collimation (positioning of the collimators without using radiation), available in newer digital fluoroscopy units, is a useful tool to reduce patient doses and if available, should always be used.

Use magnification only when it is essential

(43) Electronic magnification produces relatively high dose rates at the patient's entrance skin. When electronic magnification is required, use the least amount of magnification necessary.

Fluoroscopy versus image acquisition and minimization of the number of images

(44) Image acquisition requires dose rates that are typically at least 10 times greater than those for fluoroscopy for cine modes and 100 times greater than those for fluoroscopy for DSA modes. Image acquisition should not be used as a substitute for fluoroscopy.

(45) Limit the number of images to those necessary for diagnosis or to document findings and device placement. If the last-image-hold fluoroscopy image demonstrates the finding adequately, and it can be stored, there is no need to obtain additional fluorography images.

Minimize fluoroscopy time

(46) Fluoroscopy should be used only to observe objects or structures in motion. Review the last-image-hold image for study, consultation or education instead of continuing fluoroscopy. Use short taps of fluoroscopy instead of continuous operation. Do not step on the fluoroscopy pedal unless you are looking at the monitor screen.

Monitoring of patient dose

(47) Unfortunately, patient dose monitoring has been nearly absent in the fluoroscopy systems that are generally available outside radiology departments. There is a strong need to provide a means for patient dose estimation. Manufacturers should develop systems to indicate patient dose indices with the possibility to produce patient dose reports that can be transferred to the hospital network. Professionals should insist on this when buying new machines.

3.4. Specific aspects of staff protection

(48) Staff can be protected by use of shielding devices in addition to use of principles enumerated in 3.1 and common factors as discussed in 3.3. Further, the staff is typically required to have individual monitoring under the national regulations in most countries.

(49) Fig.3.7 gives a plot of relative radiation intensity near and around the patient table. The primary source of radiation is the x-ray tube, but only the patient should be exposed to the primary x-ray beam. Radiation scattered from the patient, parts of the equipment and the patient table, so called secondary radiation or scatter radiation, is the main source of radiation exposure of the staff. A useful rule of thumb is that radiation dose rates are higher on the side of the patient closest to the x-ray tube.

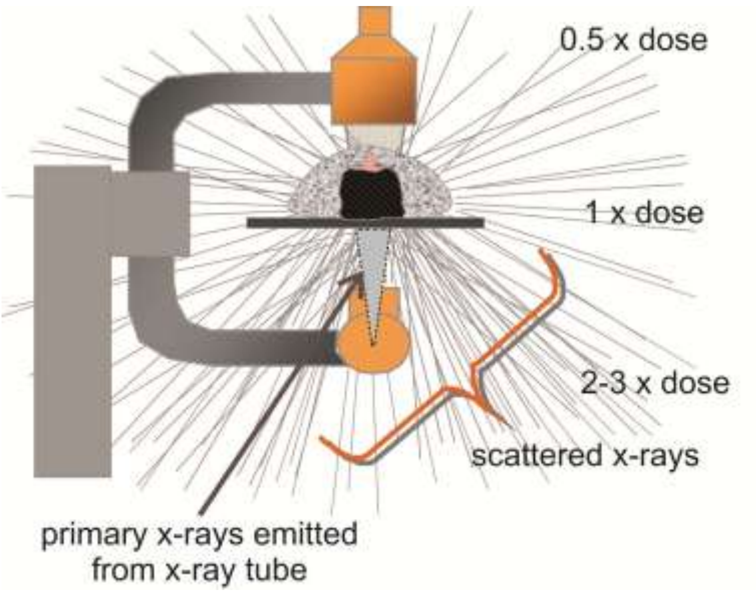

Fig.3.7. Primary and secondary radiation, their distribution and relative intensity.

3.4.1. Shielding

(50) *Lead apron*: The foremost and most essential component of personal shielding in an x-ray room is the lead apron that must be worn by all those present in the fluoroscopy room. It should be noted however that the lead apron is of little value for protection against gamma radiation emitted by radioisotopes, which are mostly more than 100 keV. Since the energy of x-rays is represented by the voltage applied across the x-ray tube (kV) rather than actual energy unit (kilo electron volt, keV), one must not consider them to be equivalent or same. Moreover the energy emitted by x-ray tube is of continuous spectrum varying from x-rays of say 10 keV to some tens of keV. As a general rule, effective keV may be somewhere half to 1/3 the peak kV value. The thicker the part of the patient in x-ray beam, the fluoroscopy machine will set the kV in a higher range typically 70 to 100 kV and the values will be smaller for

thinner body part and children. The higher the kV, the greater the penetration power of the x-ray beam as kV controls the energy of the beam.

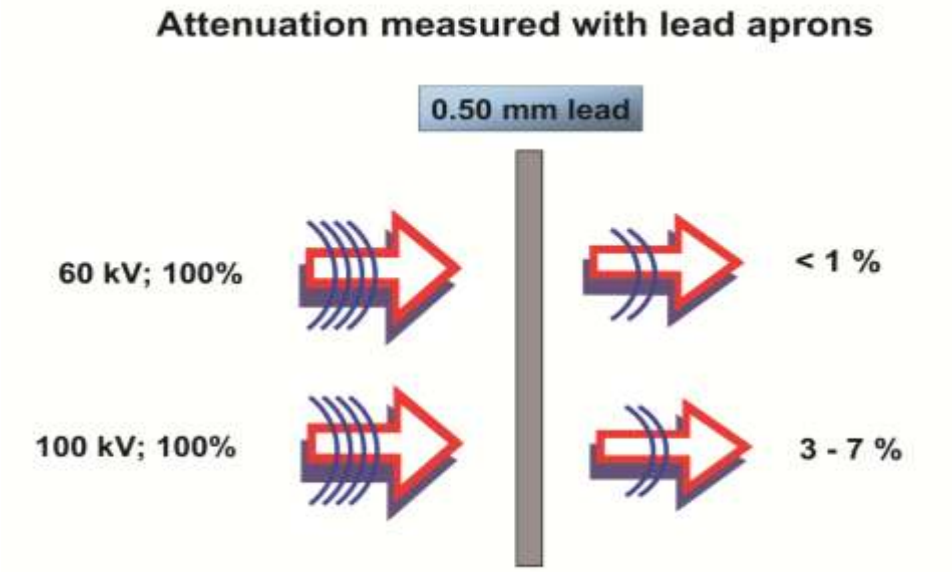

Fig.3.8.a. Percent penetration of x-rays of different kV through lead of 0.5 mm. To note that the result will be different for different x-ray beam filtrations (Figure courtesy of E. Vano).

(51) Clinical staff taking part in diagnostic and interventional procedures using fluoroscopy wear lead protective aprons to shield tissues and organs from scattered x-rays (NCRP, 1995). Transmission will depend on the energies of the x-rays and lead equivalent thickness of the aprons. The attenuation of scattered radiation is assumed to be equal to that of the primary (incident) beam and this provides a margin of safety (NCRP, 2005).

(52) Fig. 3.8a and b provide the relative penetration value as percent of incident beam intensity with lead of 0.5 and 0.25 mm. For procedures performed on thinner patients, in particular many children, a lead apron of 0.25 mm lead equivalence will suffice, but for thicker patients and with heavy workload 0.35 mm lead apron may be more suitable. The wrap-around lead aprons of 0.25 mm lead equivalence are ideal that provide 0.25 mm on back and 0.5 mm on front. Two piece, skirt type help to distribute weight. Heavy weight of aprons can really pose a problem for staff who have to wear these for long spans of time. There are reports of back injuries because of weight of lead aprons with staff who wear these for many years (NCRP, 2011). Some newer aprons are light weight while maintaining lead equivalence. Also they are designed to distribute weight through straps and shoulder flaps.

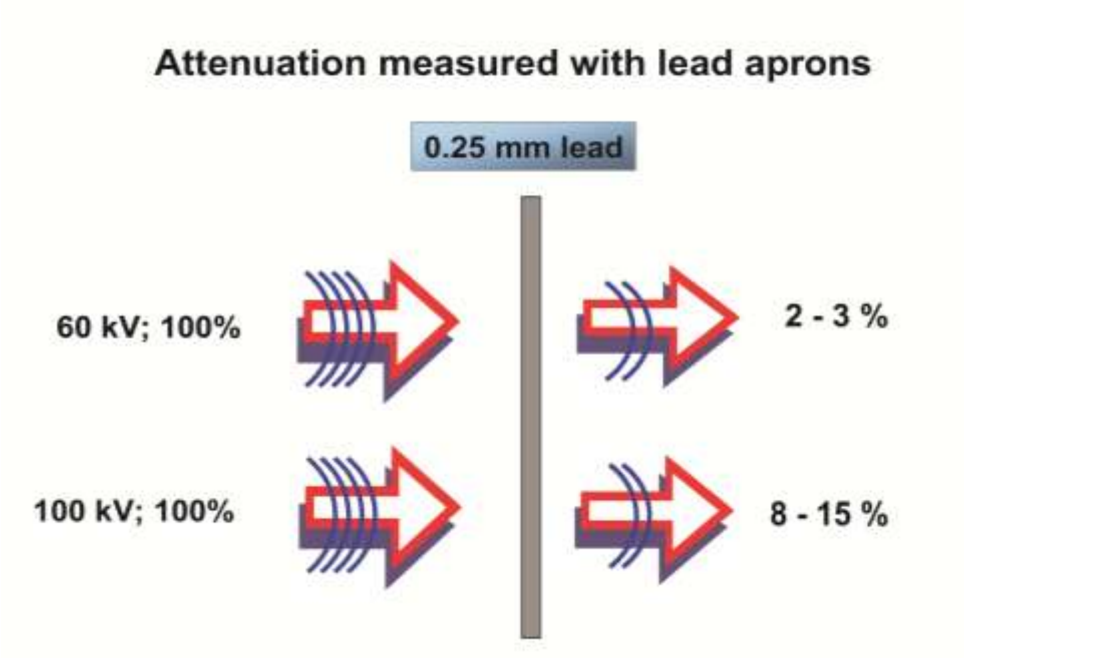

Fig.3.8.b. Percent penetration of x-rays of different kV through lead of 0.25 mm. To note that the result will be different for different x-ray beam filtration (Figure courtesy of E. Vano).

(53) *Ceiling suspended shielding*: Ceiling suspended screens that contain lead impregnated in plastic or glass are very common in interventional radiology and cardiology suits, but are hardly ever seen with fluoroscopy machines that are used in operating theatres. Shielding screens are very effective as they have lead equivalence of 0.5 mm or more and can cut down x-ray intensity by more than 90%. There are practical problems that make use of radiation shielding screens for staff protection more difficult but not impossible in fluoroscopy machines in operating theatres. Manufacturers should develop shielding screens that can be effectively used for staff protection without hindering the clinical task.

(54) *Mounted shielding*: These can be table mounted lead rubber flaps or lead glass screens mounted on pedestal that are mobile. Lead rubber flaps are very common in most interventional radiology and cardiology suites but again they are rarely seen with fluoroscopy systems that are used in operating theatres. Manufacturers are encouraged to develop detachable shielding flaps to suit situations of practice in operating theatres. Lead rubber flaps should be used as they provide effective attenuation being normally impregnated with 0.5 mm lead equivalence.

(55) In addition, leaded glass eye wears of various types are commonly available. These include eyeglasses that can be ordered with corrective lenses for individuals who normally wear eyeglasses. There are also clip-on type eye shields which can be clipped to the spectacles of the staff and full face shields that also function as splash guards. Leaded eyewear should have side shields to reduce the radiation coming from the sides. The use of these protection devices is strongly recommended.

3.4.2. Individual monitoring

(56) The principles of radiation protection of workers from ionising radiation are discussed in Publication 75 (ICRP, 1997) and also reiterated in Paragraph 113 of Publication 105 (ICRP, 2007b). In this section practical points pertaining to who needs to be monitored and what protective actions should to be taken are discussed.

(57) Individual monitoring of persons occupationally exposed to ionizing radiation using film, thermoluminescent dosimeter (TLD), optically stimulated luminescence (OSL) badge or other appropriate devices is used to verify the effectiveness of radiation control practices in the workplace. An individual monitoring programme for external radiation exposure is intended to provide information for the optimization of protection and to demonstrate that the worker's exposure has not exceeded any dose limit or the level anticipated for the given activities (IAEA, 1999a). As an effective component of a program to maintain exposures as low as reasonably achievable, it is also used to detect changes in the workplace and identify working practices that minimize doses (IAEA, 2004; NCRP, 2000). The Commission had recommended in 1990 a dose limit for workers of 20 mSv per year (averaged over defined 5 year period; 100 mSv in 5 years) and other limits as given in Table 1.2 which is continued in the latest recommendations from the Commission in its Publication 103 (2007a). However, all reasonable efforts to reduce doses to lowest possible levels should be utilized. Knowledge of dose levels is essential for utilization of radiation protection actions.

(58) The high occupational exposures in some situations like interventional procedures performed by vascular surgeons require the use of robust and adequate monitoring arrangements for staff. A single dosimeter worn under the lead apron will yield a reasonable estimate of effective dose for most instances. Wearing an additional dosimeter at collar level above the lead apron will provide an indication of head (eye) dose (ICRP, 2001). In view of increasing reports of radiation induced cataracts in eyes of those involved in interventional procedures, monitoring of eye dose is important (Vano et al., 2010; Ciraj-Bjelac et al., 2010). The Commission recommends establishment of methods that provide reliable estimates of eye dose under practical situations. Eye dose monitoring, at current level of usage of fluoroscopy outside radiology departments, is optional for areas other than vascular surgeons and interventional cardiology or equivalent. Finger dose may be monitored using small ring dosimeters when hands are unavoidably placed in the primary x-ray beam. Finger dosimetry is optional in situations of sentinel lymph node biopsy as the level of usage of radioisotopes is small.

(59) Doses in departments should be analysed and high doses and outliers should be investigated (Miler et al., 2010). With the current level of practice of fluoroscopy outside radiology departments in areas covered in this document; a single dosimeter worn under the lead apron may be adequate except in case of vascular surgery. However, the need to use a dosimeter 100% of the time for all staff working in fluoroscopy room is essential.

(60) In spite to the requirement for individual monitoring, the lack (or irregular) use of personal dosimeters is still one of the main problems in many hospitals (Miler et al., 2010). Workers in controlled areas of workplaces are most often monitored for radiation exposures. A controlled area is a defined area in which specific protection measures and safety provisions are, or could be, required for controlling normal exposures during normal working conditions, and preventing or limiting the extent of

potential exposures. The protection service should provide specialist advice and arrange any necessary monitoring provisions (ICRP, 2007a). For any worker who is working in a controlled area, or who occasionally works in a controlled area and may receive significant occupational exposure, individual monitoring should be undertaken. In cases where individual monitoring is inappropriate, inadequate or not feasible, the occupational exposure of the worker should be assessed on the basis of the results of monitoring of the workplace and on information on the locations and durations of exposure of the worker (IAEA, 1996). In addition to the individual monitoring, it is recommended in these installations, to use indirect methods to estimate radiation levels at the workplace using passive or electronic dosimeters (e.g. dosimeters attached to the C-arm) to allow the estimation of occupational doses to the professionals not using regularly their personal dosimeters.

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4. SPECIFIC CONDITIONS IN CLINICAL PRACTICE

Procedures such as endovascular aneurysm repair (EVAR), renal angioplasty, iliac angioplasty, ureteric stent placement, therapeutic endoscopic retrograde cholangio-pancreatography (ERCP) and bile duct stenting and drainage have the potential to impart skin doses exceeding 1 Gy.

Radiation dose management for patients and staff is a challenge that can only be met through an effective radiation protection programme.

(61) There are a number of technicalities that require involvement of or consultation with a medical physicist. These include radiation dose assessment, dose management in day-to-day practice, understanding of different radiation dose quantities, estimating and communicating risks. Effective radiation protection programmes will involve teamwork of clinical professionals with radiation protection experts.

4.1. Vascular surgery

(62) Recent years have witnessed a paradigm shift in vascular intervention, away from open surgery towards endovascular therapy. Endovascular therapy requires image guidance, usually in the form of fluoroscopy. Consequently, radiation exposure has increased among vascular surgical staff and patients. Radiation exposure during endovascular aneurysm repair (EVAR) is greater than during peripheral arterial interventions such as peripheral angioplasty (Ho et al., 2007).

(63) EVAR has gained wide acceptance for the elective treatment of abdominal aortic aneurysms, leading to interest in similar treatment of ruptured abdominal aortic aneurysms. In a recent study covering nationwide inpatient sample data from 2001 to 2006 in USA, an estimated 27,750 hospital discharges for ruptured abdominal aortic aneurysms occurred and 11.5% were treated with EVAR (McPhee et al., 2009). EVAR utilization increased over time (from 5.9% in 2001 to 18.9% in 2006) while overall ruptured abdominal aortic aneurysms rates remained constant. EVAR accounts for about half of elective aneurysm repairs performed annually in the United States (Cowan et al., 2004). As the technology evolves, more patients may be offered complex repairs such as fenestrated and branched grafts.

(64) The practice in different countries varies. In many institutions long-term central venous access lines placement requires fluoroscopy guidance. Renal angioplasty and iliac angioplasty are also done by vascular surgeons at some institutions (Miller et al. 2003a, 2003b).

4.1.1. Levels of radiation dose

Dose to patient

(65) Endovascular therapy procedures require greater screening time, and hence incur greater radiation exposure for patients and staff . The entrance skin dose during EVAR is typically 0.85 Gy, with range of 0.51-3.74 Gy (Weerakkody et al., 2008). Mean dose area product (DAP) in abdominal aortic aneurysm (AAA) repair has been reported to be 1516 Gy.cm^2 (range 520-2453) (Weiss et al., 2008). Routine EVAR for infra-renal aneurysm disease involves mean effective doses to the patient of 8.7- 27

mSv (Weerakkody et al., 2008, Geijer et al., 2005). After EVAR, patients require on-going follow-up to ensure that the aneurysm remains excluded, where multi-slice CT remains the current standard investigation. Thus, these patients require regular and repeated radiation exposure for life, which may have cumulative effects. As an example, the effective dose in the first year of follow-up has been estimated to be 79 mSv (Weerakkody et al., 2008).

(66) In interventional procedures, besides the associated risk of cancer, there is a possibility for skin injuries. Such injuries have been reported following a range of fluoroscopically guided procedures (ICRP, 2001). At present, it is difficult to find specific reports of skin injuries following EVAR. However, as surgeons undertake more complex procedures requiring longer operating and screening time, the risk of radiation injuries will increase (Weerakkody et al. 2008). A recent study indicated that up to one-third of patients may receive entrance skin doses greater than 2 Gy, the approximate threshold for transient erythema (Weerakkody et al., 2008).

(67) During AAA repair, mean total fluoroscopy time has been reported to be typically 21 min (range 12 to 24 min) (Table 4.1.) with an average of 92% spent in standard fluoroscopy and 8% spent in cinefluoroscopy (Weiss et al., 2008). According to the technique used by these authors, approximately 49% of total fluoroscopy time was spent in normal field of view and 51% in magnified view. Peak skin dose was shown to be well correlated with dose-area product and body mass index, but not with fluoroscopy time., For obese patients peak skin dose (PSD) was reported to be twice as compared to no obese patients (1.1 Gy compared to 0.5 Gy) (Weiss et al., 2008)

(68) Radiation doses from venous access procedures are low, with skin doses typically well below 1 Gy. These patients often require multiple repeated procedures, however, often within a relatively short time span (Storm et al., 2006).

(69) Typical patient doses from vascular surgical procedures are presented in Table 4.1.

Table 4.1. Typical patient dose levels (rounded) from vascular surgical procedures

Procedure	**Relative mean radiation dose to patient** 0 mSv 35	**Relative mean radiation dose to patient***	**Reported values**				**Reference**
			Fluoroscopy time (min)	**Entrance skin dose (mGy)**	**Dose-area product ($Gy.cm^2$)**	**Effective dose (mSv)**	
EVAR		F,G	21	330-850	60-150	8.7-27	(a,b)
Venous access procedures		B	1.1-3.5	8-24	2.3-4.8	1.2	(c)
Renal/visceral angioplasty (stent/no stent)		G	20.4	1442	208	54	(d,e)
Iliac angioplasty (stent/no stent)		G	14.9	900	223	58	(d,e)

*A=<1 mSv ; B=1 to<2 mSv ; C=2 to <5 mSv ;D=5 to <10 mSv ;E=10 to<20;F=20 to 35 mSv ;G= >35 mSv, based on effective dose

** mean value

(a) Weerakkody et al., 2009; (b) Geijer et al., 2005; (c) Storm et al., 2006; (d) Miller et al., 2003a ; (e) Miller et al., 2003b ;

Staff dose levels

(70) There has been wide variation in reported staff doses during EVAR. Annual hand doses to the surgeon during EVAR range from 0.2 to 19 mSv (Ho et al., 2007; Lipsitz et al., 2000). The wide variation may be due to the use in some centres of additional free-standing and table mounted lead shielding Annual body doses tend to be lower (about 0.2 mSv) while annual eye doses are about 1mSv in the case of using appropriate protective devices (Ho et al. 2007) for a workload of 150 procedures per year. The respective mean body, eye, and hand doses of the surgeon are 7.7 µSv, 9.7 µSv, and 34.3 µSv per procedure (Ho et al. 2007).

4.1.2. Radiation dose management

(71) With the level of radiation doses as above and the fact that many patients require follow-up examinations and procedures that involve radiation exposure, radiation dose management for patients and staff is a challenge that can only be met through an effective radiation protection programme.

Patient dose management

(72) During standard infra-renal EVAR, the radiation source (x-ray tube) is frequently moved in relation to the patient. The risk of deterministic or stochastic effects to the patient is minimal (see Section 2). Fenestrated or branched stent-graft placement may require cannulation and stenting of multiple visceral branches of the aorta. These manoeuvres may be prolonged, with minimal repositioning of the x-ray beam. Thus, there is a greater risk of deterministic or stochastic effects during these procedures, particularly 4-vessel fenestrated grafts. Patients should be counselled accordingly. The need for repeat procedures for the treatment of endoleaks and the CT scans needed for life-long surveillance for these devices will result in higher exposures.

(73) Fluoroscopically guided venous access procedures are a common part of interventional radiology practice. While the typical radiation dose for a single venous access case is relatively low and are reported to be below the threshold dose for skin effects (deterministic) in all cases studied, these procedures are often repeated in the same patient within a short period of time. There is evidence that venous access procedures performed by experienced operators can result in lower radiation doses. Thus, it is unlikely that any fluoroscopically guided venous access procedure performed by a reasonably well-trained operator will result in a dose high enough to cause concern for skin injury. Nevertheless, operators should remain cognizant of the cumulative effects of radiation, including the potential risk of stochastic effects (Storm et al., 2006).

(74) The dose management actions described in Section 3 are generally applicable in vascular surgical procedures.

Staff dose management

(75) A number of specific technique and operator related factors may reduce overall radiation dose during EVAR (Ho et al., 2007) as:

1. Operators should aim to perform a single cinematography run to confirm stent-graft position immediately prior to deployment. Multiple initial runs to assess anatomy and plan stent-graft positioning are rarely necessary and should be avoided, as they increase both patient and staff doses.
2. The hand must be kept out of the radiation beam. Leaded surgical gloves are not useful for hand protection when hands are placed in the primary x-ray beam. Although other radiation protection tools are effective, they come with drawbacks, including staff physical discomfort and reduced procedure efficiency. Sterile protective surgical gloves providing radiation attenuation levels in the range of 15%-30% are available, but studies have shown they provide minimal protection when hands are placed in the primary x-ray beam for several reasons. Forward and backscattered x-rays within the glove add to hand exposure. In addition, the presence of attenuating material within the fluoroscopy automatic brightness control region results in an increase in x-ray technique factors, exposing the hand to a higher dose rate. These factors, coupled with the false sense of security that may result in increased time spent in the primary beam, more than cancels out any protection the gloves may provide. As a result, further development of new protection devices is encouraged. It is recommended that hands be kept out of the primary x-ray beam unless it is essential for the safety of the patient (Schueler, 2010).
3. The use of a table-side lead shield and portable lead shielding reduces the overall effective dose to staff.

(76) In addition to the above mentioned specific items, all standard equipment factors (e.g. beam collimation, filter usage, regular equipment servicing, minimization of source-image distance, field of view size), described in Section 3 may reduce occupational exposure in vascular surgery.

4.2. Urology

(77) X-rays have been used to diagnose diseases in the kidney and urinary tract for about a century to visualize the urinary tract in order to detect a kidney stone or a tumour that may block the flow of the urine. Procedures without direct enhancement of the urinary tract or with intravenous administration of the iodinated contrast agent are normally performed by radiologists such as intravenous pyelography (IVP) also called intravenous urography (IVU). Whenever there is direct administration of contrast agent into the urinary system, there is more active involvement of urologists. In the past cystogram, retrograde pyelography, voiding cystourethrogram (VCUG) have been common procedures typically performed within the radiology facilities. They involve catheter insertion into the urethra to fill the bladder with the iodinated contrast medium. The fluoroscopy machine then captures images of the contrast medium during the procedure either to study the anatomical details or to study dynamics of the evacuation of urine. Today, IVP is rarely performed in many countries and has been superseded by CT. A number of procedures like percutaneous nephrolithotomy (PCNL), nephrostomy, ureteric stent placement, stone extraction and tumour ablation created the need to have the fluoroscopy unit more easily available to urologists and in some cases even inside the operating theatre.

(78) Further, in the past few decades, lithotripsy (Extracorporeal shock wave lithotripsy, ESWL) has become a common procedure for treating stones in the kidney and ureter. Most devices developed for lithotripsy use either x-rays or ultrasound to help

locate the stone(s). This works by directing ultrasonic or shock waves, created outside body through skin and tissue, until they hit the stones. The stones break down into sand-like particles that can be easily passed through the urine.

(79) Urinary and renal studies present 16% and 1.6% of all fluoroscopically-guided diagnostic and interventional procedures, respectively with mean effective dose of 2 mSv for urinary and 5 mSv for renal procedures with a total contribution of approximately 5% to collective dose (NCRP, 2009).

(80) Most publications dealing with radiation protection in urology have focussed on the radiation risks to the staff and there are relatively fewer that have estimated radiation doses to the patients in urological procedures. Despite the fact that the staff works with radiation for years whereas a patient undergoes radiological procedures only a few times during life time, it must be remembered that the staff faces only scattered radiation that may be typically not more than 1% of the radiation intensity that is falling on the patient. Since the staff is further protected by a lead apron, the radiation exposure of the staff further decreases by almost 90% of the typical 1% figure. On a per procedure basis, this works out to about 0.1% of the radiation dose received by the patient.

4.2.1. Levels of radiation dose

Dose to the patient

(81) Typical dose values from urology procedures are presented in Table 4.2.

(82) Radiological studies performed for an acute kidney stone episode may include a range of radiological procedures on patients including 1 or 2 plain kidney, urinary bladder (KUB) abdominal films, 1 or 2 abdomino-pelvic CT exams, and an IVP during the first year of follow up. The total effective dose from such studies may be in the range of 20 to more than 50 mSv (Ferrandino et al., 2009). With the increasing use of CT, there is evidence that many patients with urolithiasis may be subjected to relatively high doses of ionizing radiation during acute stone episodes and throughout the management of their disease (Mancini et al., 2010). However, the appropriate use of dose management techniques during diagnosis and follow-up may allow for a significant dose reduction.

(83) CT is replacing conventional radiography and IVU for the evaluation of the urinary tracts in many centres of the world in spite of the higher radiation exposure (ICRP, 2007a). Studies comparing CT and conventional urography indicted significantly higher effective dose for CT urography, even when dose reduction strategies in CT are applied (Nawfel et al., 2004; Dahlman et al., 2009). These findings suggest that patient dose estimates should be taken into consideration when imaging protocols are established (ICRP, 2007a; Nawfel et al., 2004; Eikefjord et al., 2007). Several studies have shown that unenhanced CT is more accurate than excretory urography for the examination of patients with renal colic and a preferred technique due to better diagnostic accuracy (Eikefjord et al., 2007; Tack et al. 2003). In the past decade, there is evidence of significant dose reduction through adoption of an appropriate CT kidney-stone protocol. Studies focussing on the evaluation of the low dose kidney-CT protocols have come to the conclusion that its radiation dose is comparable to that associated with excretory urography (Tack et al., 2003; Larsen et al., 2005). Dahlman et al. (2009) reported a decrease of the effective dose to patients undergoing CT urography by 60%, from 29.9

and 22.5 mSv in 1997 to 11.7 and 8.8 mSv in 2008, for female and male patients, respectively. All studies concluded that considerable dose reduction is achievable with an acceptable level of image quality. Following the principle of optimization, it is important to adapt the technical parameters on the basis of clinical indications (ICRP, 2007a). Therefore, both with improvements in technology and optimization at the clinical level, it is expected that the tendency towards dose reduction will continue in the future.

(84) The effective radiation dose to the patient in ESWL through fluoroscopy and radiography is normally < 1 to 2 mSv, with nearly 50-78% through fluoroscopy (UNSCEAR, 2010; Sandilos et al., 2006; Huda et al., 1989; MacNamara et al., 1999). However, it must be remembered that dose from ESWL is always added to the dose from pre- and post-treatment KUB and IVU procedures (Sandilos et al., 2006). For other urological procedures typical effective doses range from less than 1 mSv for abdominal radiography to a mean of about 7 mSv for nephrostomy.

(85) A nephrostomy tube placement is performed by placing a needle into the collecting system of the kidney, to provide percutaneous drainage. It is a fluoroscopy procedure that requires typically about 10 to 15 minutes of fluoroscopy (reported range 1 - 56 minutes)and can result in relatively high doses, in particular when tube angulation is used (NCRP, 2000, Miller et al.2003a). In some patients, repeated examinations may be necessary to provide information on proper nephrostomy tube placement. Typical effective dose from nephrostomy procedures is 7.7 mSv, with an associated range of 3.4-15 mSv (UNSCEAR, 2010; Sandilos et al., 2006).

Staff dose levels

(86) The mean effective dose per procedure for the urologist for PCNL is 12.7 µSv (Safak et al., 2009). With average typical workload of 5 procedures/week, this can imply an effective dose of 3 mSv per year to staff (urologists). With the above workload, the dose to fingers can be 8 to 25 mGy/year (30 to 100 µGy per procedure) and region of the head and neck 5 to 10 mGy/year (20 to 40 µGy per procedure) (Hellawell et al., 2005). Bush et al (1985) reported that for an average fluoroscopy time of 25 min (6 – 75 min), the average radiation dose received by the radiologist at the collar level above the lead apron was 0.10 mSv per procedure (0.02 – 0.32 mSv). The dose to the nurse was 0.04 mSv per procedure (0.01 – 0.11 mSv), to the radiologic technologist assisting with C-arm fluoroscopy it was 0.04 mSv per case (0.01 -0.11 mSv) and to the anaesthetist, the dose was 0.03 mSv (0.01 – 0.1 mSv) (Bush et al., 1985). The dose to the fingers of urologists is typically 0.27 mSv/procedure, with a range of 0.10-2 mSv/procedure (Kumari et al., 2006; Bush at al., 1985).

(87) Depending on the position of the x-ray tube and image detector, the radiation dose to lower extremities can be higher than 126-167 µSv per procedure (Hellawell et al., 2005; Safak et al., 2009). However, for a predicted annual workload of 250 cases, the dose received is about 40 mSv. This may be compared with dose limits of 500 mSv to extremities (ICRP, 2007b).

Table 4.2. Typical patient dose levels (rounded) from urological procedures

Procedure	Relative mean radiation dose to patient 0 mSv 35	Relative mean radiation dose to patient*	Reported values: Fluoroscopy time (min)	Reported values: Entrance skin dose (mGy)	Reported values: Dose-area product (Gy cm^2)	Reported values: Effective dose (mSv)	Reference
IVU/IVP		C,D	na**	3.3-42	2-42	2.1-7.9	(a,b,c,d,e)
Cystometrography		B	na**	/	7	1.3	(b)
Cystography		B	na**	/	10	1.8	(a,b)
Excretion urography/MCU		C	na**	/	0.43-9.9	1-3	(a,b,f)
Urethrography		B	na**	/	6	1.1	(a,b)
PCNL		A	6-12	1-250	4	0.8	(g)
Nephrostomy		D	1.3-20	/	30*** (5-56)	7.7*** (3.4-15)	(a, h, i)
ESWL		B	2.6-3.4	40-80	5	1.3-1.6	(a, j)
Ureteric stent placement		E	/	/	49	13	(a)

*A=<1 mSv; B=1 to<2 mSv ; C=2 to <5 mSv ;D=5 to <10 mSv ;E=10 to<20;F=20 to 35 mSv ;G= >35 mSv, based on effective dose
** not available; *** mean value
(a)UNSCEAR, 2010;(b) NCRP, 2009 ;(c) EC, 2008 ;(d) Fazel et al., 2009 ;(e) Yakoumakis et al., 2001 ;(f) Livingstone et al., 2004;(g) Kumar et al., 2008;
(h) Miller et al. 2003b; (i) McParland, 1998; (j) Sandilos et al., 2006.

(88) Based on reported dose levels in the region of the urologist's head and neck (0.10 mSv/procedure) (Bush et al., 1985), the radiation doses to the eye lens without protection for a typical workload of 250 procedure/year can be 25 mSv and this requires protection of the eyes in view of recent reports of lens opacities observed in interventional cardiology staff (Ciraj-Bjelac et al., 2010; Vano et al., 2010). With the appropriate use of protection, staff doses can be low enough to avoid deterministic effects. Mean radiation dose per procedure are 33 µSv, 26 µSv and 12 µSv for the fingers, eyes and whole body of the urologist, respectively (Safak et al., 2009). For a typical workload of 250 procedures/year, whole body occupational dose to personnel would reach 3 mSv, which is well below the occupational dose limits.

(89) The above radiation protection actions are valid for all urology and renal procedures involving x-rays.

4.2.2. Radiation dose management

Patient dose management

(90) It is necessary for the urologist to weigh the anticipated clinical benefits to the patient from the urological procedure requiring x-ray fluoroscopy against radiation risks involved. This will be in line with the Commission's principle of justification. Once justified, it is the responsibility of the operator to perform the procedure using the Commission's principle of optimization using techniques as described in this publication and other techniques that are contemporarily available. One of the most efficient radiation protection requirements is to avoid unnecessary examinations and procedures.

(91) Certain imaging modalities, most notably those using digital image receptors have shown promising results of radiation dose reduction to patients while maintaining image quality. Significant dose reduction in urethrocystography has been reported by Zoeller et al. (1992) with the use of photostimulable phosphor plates when compared to screen-film radiography. Tube potential of 77 kVp with a phototimer was used for film screen radiography. Exposure parameter settings of 81 kVp and 6.4 mAs were used to achieve sufficient image quality while using photostimulable phosphor plates.

(92) During ESWL, radiation exposure increases with stone burden. A larger stone requires longer treatment, with possibly more associated x-rays. If unilateral radiography of the kidney, ureter and bladder (hemi-KUB) is performed whenever possible and appropriate during diagnosis and follow-up, radiation exposure associated with ESWL can be significantly reduced (Talati et al., 2000). Also, the use of ultrasound for stone localization could significantly reduce patient dose compared to those where x-rays are used for stone localization. Dose reduction could be even 4-5 times, as typical dose levels are 0.25 mSv and 1.2 mSv, for ultrasound and x-ray localization, respectively (MacNamara et al., 1999). A typical ESWL procedure involves approximately 2.6- 3.4 min of fluoroscopy time and 4-26 spot films and results in an average dose of 1.6 mSv per patient (Sandilos et al., 2006; Carter et al., 1987). Dose reduction strategies described in Section 3 apply for all urological and renal procedures. By introducing radiation protection actions such as the reduction of the number of spot films, use of "last image hold" and the training of the operators, significant dose reduction may be obtained. The entrance surface dose from an ESWL procedure performed by experienced operator is

approximately 30% lower dose compared to that performed by inexperienced operators (26.4 mGy vs. 33.8 mGy) (Chen et al., 1991), while the reduction of the number of radiographies results in a dose reduction 20-62%, depending on patient’s body mass (Griffith et al., 1989).

(93) The dose management actions described in Section 3 are generally as well applicable in urological procedures.

Staff dose management

(94) The majority or the most common procedures in urology can be performed with little radiation exposure of staff, much below the limits prescribed by the Commission, as long as radiation protection principles, approaches and techniques as briefly mentioned in this publication are utilized. On the other hand, there are chances of radiation injuries and long term risks when radiation protection is not employed.

(95) In radiography and diagnostic CT imaging, typically the staff is outside the room and room is well shielded. Thus, the staff is exposed to very little radiation dose. But within the operating theatre, a few staff members including the operators are in the same room as the fluoroscopy unit and thus they are exposed to much higher levels of radiation. Radiation exposure of the staff who works in the fluoroscopy room can be significant when suitable radiation protection tools are not utilized. The actual exposure depends upon the time, workload and shielding such as lead apron and additional lead glass protective screens.

(96) For endourologic procedures, dose rate levels to the urologist of up to 11 mSv/h with a dose reduction of 70% to 96% due to the use of fluoroscopic drape have been reported (Giblin et al., 1996; Yang et al., 2002). Therefore, urologists should be cognizant of the radiation risk, and the concepts of time, distance, and shielding (as described in Section 3) are critically important.

(97) At present, in many cases (except in surgical theatres), overcouch x-ray tube systems are still used for urological procedures involving x-rays. The scatter radiation distribution in those systems is such that radiation dose to the lens of the eye may be relevant if eye protection is not utilized. Therefore, the use of undercouch systems is recommended in addition to personal protective devices for staff.

4.3. Orthopaedic surgery

(98) Orthopaedic specialties commonly utilize x-rays as a diagnostic tool and as a technical aid during various procedures. Despite its widespread use among orthopaedic surgeons, x-ray radiation and risks associated with its use are infrequently discussed in the orthopaedic literature.

(99) Although x-rays have been used since the early 20th century to image bones and joints, the use of fluoroscopy for orthopaedic imaging did not gain popularity until much later. In the 1980’s, fluoroscopy gained a prominent foothold in the orthopaedic trauma community where it was championed as a valuable tool during femoral nailing and hip pinning (Giachino et al., 1980; Giannoudis et al., 1998; Levin et al., 1987). Now, nearly every discipline of orthopaedics has adopted the use of fluoroscopy to meet its

various needs. In the orthopaedic literature, C-arm fluoroscopy has been reported for a wide variety of procedures including anatomic localization, bony reduction, implant placement, correction of malalignment, arthrodesis, intra and extramedullary bony fixation, joint injections, aspirations, and myriad other common procedures. As indications for the use of mobile C-arm fluoroscopy have expanded, its relative popularity has grown commensurately. Now, through its relevance to numerous applications and overall convenience, the use of fluoroscopy has become commonplace, and in some cases indispensable, in the daily clinical practice of orthopaedics (Table 4.3).

(100) Currently, the trend among many orthopaedic surgeons is to strive for minimal invasiveness when performing surgery. Through the collective initiative of medicine and industry, new technologic advances have emerged, enabling orthopaedic surgeons to execute procedures with much less soft tissue damage and resultant morbidity for the patient. Unfortunately, operating in this manner creates a heightened dependence on indirect visualization to view pertinent anatomy. Thus, radiation exposure of the patient and surgical team has increased commensurately with this pursuit. Although some ascribe to the philosophy of “as low as reasonably achievable”, others exhibit a much more cavalier attitude towards radiation safety. In many teaching institutions, this nonchalance is often passed along to trainees through the practice of careless habits and ignorance of basic radiation safety principles.

(101) At present in the United States, arthrograms, orthopaedics, and joint imaging procedures represent 8.4% of all fluoroscopy guided procedures, with an average effective dose to patient of 0.2 mSv per procedure and contribution to the total collective dose of 0.2% (NCRP, 2009). Similarly, in The United Kingdom, various imaging procedures in orthopaedics result in a dose of few µSv to a mSv per procedure, with contribution of less than 1% to the total collective dose to the population (Hart et al. 2002).

4.3.1. Levels of radiation dose

Dose to patient

(102) Patients receive radiation by direct exposure to the x-ray beam. This exposure is much more intense than the scattered radiation that reaches the staff. Nonetheless, orthopaedic patients are at low risk for exhibiting deterministic effects, unlike patients undergoing interventional vascular or cardiac procedures. Table 4.4 gives typical fluoroscopy times and radiation dose to the patient during various orthopaedic procedures

(103) For the commonly performed procedures (intramedullary nailing of petrochanteric fractures, open reduction and internal fixation of malleolar fractures and intramedullary nailing of diaphyseal fractures of the femur), the respective mean fluoroscopy times were 3.2, 1.5 and 6.3 min while the estimated mean entrance skin doses were 183, 21 and 331 mGy, respectively (Tsalafoutas et al., 2008).

(104) The typical effective dose to patients with femoral fracture treated surgically is 11.6-21.7 µSv (Perisinakis et al, 2004). Effective dose to patients for nailing osteosynthesis of proximal pertrochanteric fractures has been shown to average 14 mSv, while effective dose to patients for lower extremity fractures averaged 0.1 mSv (Suhm et al, 2001).

(105) Orthopaedic trauma surgeons are often responsible for stabilizing pelvic fractures. C-arm fluoroscopy is indispensible to the trauma surgeon for guiding bony reduction and implant placement adjacent to major neurovascular structures. Given the large cross sectional diameter of the pelvis, fluoroscopic pelvic imaging has the potential to produce increased exposure of the patient and surgeon. Exposure data has been collected during pelvic phantom imaging and has demonstrated considerable dose rate in the primary beam at patient entrance surface (40 mGy/min) (Mehlman et al, 1997). Other studies have found that during femoral or tibial fracture nailing, entrance skin dose to the patient is 183 mGy for 3.2 min mean fluoroscopy time (Tsalafoutas et al., 2008). The same study has examined patient exposure during pedicle screw placement in both the lumbar and cervical spine. Surgical time for these cases averaged from less than a minute to 7.7 minutes, which produced average entrance surface dose of 46 mGy and 173 mGy for the lumbar spine and for the cervical spine, respectively. Associated ranges are 18-118 mGy and 5-407 mGy (Tsalafoutas et al, 2008).

1468 Table 4.3. Indications for the use of mobile C-arm fluoroscopy in various orthopaedic procedures

Orthopaedic Applications	Use of C-arm Fluoroscopy
General	Removal of some metallic items
	Foreign/loose body removal
Trauma	Anatomic localization
	Diagnostic (ipsilateral femoral neck/shaft fracture)
	Fracture reduction (for casting/splinting or surgical fixation)
	Intramedullary nailing
	Kirshner-wire/external fixator pin placement
	Percutaneous hardware placement (i.e., Cannulated/headless screws, minimally invasive plate osteosynthesis (MIPO plating, etc.)
Sports	Guidance of joint entry for arthroscopy
	Orientation and confirmation of acceptable implant placement (i.e., distal biceps repair)
	Ligament reconstruction (i.e., ACL, PCL, MCL, posterolateral corner/LCL reconstruction)
	Assessment of depth and extent of bony resection
Spine	Trauma
	Level confirmation
	Deformity correction
Hand/Upper extremity	Trauma
	Assessment of adequate bony resection
	Deformity correction
	Anatomic localization
Tumour	Percutaneous biopsy
	Cyst aspiration
	Diagnostic (adjacent lesions)
	Fracture reduction and implant placement
	Radiofrequency ablation
Foot/ankle	Trauma
	Deformity correction
	Assess adequacy of bony resection
Joint reconstruction	Assessment of implant orientation/fixation
	Assessment of limb alignment/joint line

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(106) In another study, an average pedicle screw insertion procedure requires 1.2 minutes and 2.1 minutes of fluoroscopic exposure along anteroposterior and lateral projections, respectively, resulting in a dose area product of 2.32 Gy cm^2 and 5.68 Gy cm^2, correspondingly. Gender-specific normalized data for the determination of effective, gonadal, and entrance skin dose to patients undergoing fluoroscopically guided pedicle screw internal fixation procedures were derived. The effective dose from an average procedure was 1.52 mSv and 1.40 mSv and the gonadal dose 0.67 mGy and 0.12 mGy for female and male patients, respectively (Perisinakis et al, 2004).Minimally invasive spine procedures require indirect visualization to facilitate implant placement. Intuitively, this would require longer procedural times, with greater associated direct and scatter radiation exposure. The mean dose to the patient's skin is 60 mGy (range 8.3-252 mGy) in the posteroanterior plane and 79 mGy (range 6.3-270 mGy) in the lateral plane (Bindal et al, 2008).Overall, almost 90% of the collective dose from all orthopaedic screening can be attributed to examination in five categories, namely dynamic hip screw, cannulated hip screw, hip injection, lumbar spine fusion and lumbar spine discectomy. In fact, hips and spines account for 99% of total collective dose from these common orthopaedic procedures and therefore present as the obvious target for dose reduction strategies (Crawley et al, 2000).

Staff dose levels

(107) A host of studies have established that orthopaedic surgeons who use C-arm fluoroscopy are subject to occupational radiation exposure at levels that are typically much lower than the dose limits as recommended by the Commission. Reported doses during various orthopaedic procedures usually fall well below international standards for annual occupational exposure limits (Giordano et al., 2007; Giordano et al., 2009a; Jones et al., 2000; Singer, 2005). However, there is a lack of real and reliable data on radiation doses to staff as many professionals do not use regularly their personal dosimeters. Orthopaedic surgeons sustain the bulk of their exposure in the form of scattered radiation but also sometimes in primary beam. Typical scatter radiation dose levels arising from one of the most frequent orthopaedic procedures (intramedullary nailing of peritrochanteric fracture) for hands, chest, thyroid, eyes, gonads and legs of the operating surgeon are in average to 0.103, 0.023, 0.013, 0.012, 0.066 and 0.045 mGy/min, respectively (Tsalafoutas et al., 2008). For a total number of 204 procedures, corresponding cumulative dose would be 72, 16, 9.4, 8.3, 46 and 31 mGy hands, chest, thyroid, eyes, gonads and legs, respectively. When protective aprons and collars are used the actual effective dose will be only a small fraction (about 10%) of the personal dosimeter reading (Tsalafoutas et al., 2008).

Table 4.4. Typical patient dose levels (rounded) from various orthopaedic procedures

Procedure	Relative mean radiation dose to patient 0 mSv 35	Relative mean radiation dose to patient*	Reported values Fluoroscopy time (min)	Entrance skin dose (mGy)	Dose-area product ($Gy.cm^2$)	Effective dose (mSv)	Reference
Skull		A	na**	na**	na**	0.1	(a)
Cervical Spine		A	0.2-0.8	na**	0.42-1.3	0.1-0.2	(a,b)
Thoracic Spine		B	0.85	na**	3.26	0.3-1.0	(a,b)
Lumbar Spine		B	0.10-1.4	na**	0.54-10	0.07-1.5	(a,b)
Pelvis		A	na**	na**	na**	0.6	(a)
Hip		A	0.020-1.15	na**	0.64-2.6	0.10-0.74	(a,b)
Shoulder		A	na**	na**	na**	0.01	(a)
Knee		A	na**	na**	na**	0.005	(a)
Other extremities		A	na**	na**	na**	0.001	(a)
Hand/wrist		B,C	0.20-0.55	0.08-1.1	0.04-0.22	<0.004	(b, c)
Distal radius plate osteosynthesis	na**	na**	1.8***	17***	na**	na**	(d)
Osteosynthesis of malleolar fracture	na**	na**	1.5***	21***	na**	na**	(d)
Plate osteosynthesis of tibial plateau fracture	na**	na**	1.2***	35***	na**	na**	(d)
Arthroscopy for ACL reconstruction	na**	na**	0.9***	19***	na**	na**	(d)
Tibial intramedullary nailing	na**	na**	5.7***	137***	na**	na**	(d)
Intramedullary nailing of diaphyseal femoral fracture	na**	na**	3.0***	149***	na**	na**	(d)

Intramedullary nailing of peritrochanteric fracture	na**	na**	3.2***	183***	na**	na**	(d)
Bilateral pedicle screw placement in the lumbar spine	na**	na**	0.8***	46***	na**	na**	(d)
Bilateral pedicle screw placement in the cervical spine	na**	na**	4.2***	173***	na**	na**	(d)
Vertebroplasty	na**	na**	5- 16**	70-323***	na**	na**	(d, e)

*A=<1 mSv ; B=1 to<2 mSv ; C=2 to <5 mSv ;D=5 to <10 mSv ;E=10 to<20;F=20 to 35 mSv ;G= >35 mSv, based on effective dose

** not available; *** mean value

(a) Mettler at. al., 2008; (b) Crawley at. al., 2000; (c) Giordano et al., 2007; (d) Tsalafoutas et al. 2008 ; (e) Miller et al. 2003a

(108) The reported radiation doses to the surgeon's and supporting staff eye and thyroid from a mini C-arm unit during fluoroscopically guided orthopaedic ankle surgery range from 0.36 µGy/min to 3.7 µGy/min, depending on the distance from patient (Mesbahi et al., 2008). The tenfold decrease of scattered dose rate corresponds to increased distance from 20 cm to 60 cm from the central beam axis. For a typical 5 min procedure and workload of 250 procedures per year, the unshielded dose to eye lens would be less than 5 mSv, when radiation protection is employed.

(109) The use of intraoperative C-arm fluoroscopy in hand surgery is common (Table 4.3.). Both standard and mini C-arm units are used. Some data indicate that exposure of the surgeon is higher than predicted during elective procedures involving operative treatment of the fingers, hand, and wrist (Singer, 2005). The dose to the hands of surgeons has been found to range from less than 10µSv/case to 320 µSv/case during mini C-arm fluoroscopy (Giordano et al., 2007; Singer, 2005). Exposure of the surgeon is believed to occur mainly as the result of direct exposure from beam contact during extremity positioning, implant placement, and confirmation of acceptable bony alignment. Radiation sustained from scattered exposure, on the other hand, has been shown to be low. During hand surgery, depending on the position of a surgeon, typical dose rate levels at chest level of a surgeon range from 4to 20 µGy/h for mini C arm, while when standard C-arm is used dose rate is typically 230 µGy/h. Corresponding in-beam radiation dose are 37 mGy/h and 65 mGy/h for mini and standard C-arm, respectively (Athwal, et al., 2005).

(110) Cadaveric specimens have been used to procure exposure data to patients and surgeons during simulated foot/ankle procedures using both large and mini C-arm fluoroscopes (Giordano et al., 2009b). Variable levels of dose to the patient and surgeon have been found to depend on the location of the specimen within the arc of the C-arm and surgeon distance from the x-ray source. Surgeon exposure has been shown to be universally low throughout all imaging configurations during foot/ankle procedures (Giordano et al., 2009b; Gangopadhyay et al., 2009). An average rate of 2.4 µG/min has been documented for mini C-arm imaging of a foot/ankle specimen at a distance of 20 cm from the x-ray beam (Badman et al., 2005). When distance is increased, dose rates decrease according to the inverse square law, as described in Section 3. For typical positions with respect to a beam axis of 30 cm for surgeon, 70 cm for first assistant and 90 cm for scrub nurse, corresponding scatter dose rate at eye levels are: 0.1 mSv/min for the surgeon and 0.06 mSv/min for the first assistant, while it is negligible at nurse position. This indicates that individuals working at 90 cm distance or greater from the beam receive an extremely low amount of radiation (Mehlman et al., 1997).

(111) Procedures such as intramedullary nailing of tibial and femoral fractures requires an average procedural time of 1-10 minutes, resulting in an average unprotected surgeon exposure rate of 0.128, 0.015 and 0.028 mSv/min for hands, eye and chest, respectively. These values correspond to doses of 0.44, 0.05 and 0.10 mSv per case (Tsalafoutoas et al., 2008; Sanders et al., 1993; Muller et al., 1998). Average unprotected thyroid dose rate during such procedures is 0.016 mSv/min or 0.06 mSv/case for a fluoroscopy time of 3.2 min per case (Tsalafoutas et al., 2008).

(112) During procedures of intramedullary nailing of femoral and tibial fractures, equivalent dose to the hands of the primary surgeon and the first assistant are 1.27 mSv and 1.19 mSv, respectively and the average fluoroscopy time per procedure is 4.6 min

(Muller et al., 1998). For an average workload of 250 procedures per year, this would lead to the dose of extremities of 300 mSv, which is significantly less than dose limit of 500 mSv for extremities (Section 2).

(113) In a trauma setting, it is sometimes necessary for the surgeon to practice "damage control orthopaedics". In this scenario, the severity of a patient's injuries and overall hemodynamic stability prevents execution of the definitive stabilization procedure. The patient in this case would not tolerate a lengthy surgical time and therefore, external fixation of unstable musculoskeletal injuries is an appropriate temporizing measure to achieve acceptable bony alignment and reduce haemorrhage. Fluoroscopy is used to confirm adequate bony alignment and external fixator pin placement. Exposure during external fixator placement has been measured and it has been found that the cumulative dose to the fingers of a surgeon for a total of 44 procedures ranges from 48 to 2329 µSv. In 80% of procedures the dose of radiation to the surgeon's hand was less than 100 µSv (Goldstone et al, 1993). Nordeen et al. (1993) reported monthly levels of radiation dose to orthopaedic surgeons involved in the care of injured patients: 1.25 mSv total body dose, 3.75 mSv eye dose and 12.5 mSv extremity dose. The dose to hands is slightly higher: 3.95 mSv/month.

(114) Sports medicine specialists and surgeons practicing arthroscopy do not usually find need to use C-arm fluoroscopy as an adjunctive measure during surgery. Most procedures are performed under direct visualization using the arthroscope or through open means. Nonetheless, some surgeons prefer to use C-arm during drilling of bony tunnels for ligament reconstruction and to confirm proper implant positioning (Larson et al., 1995). In general, primary ligament reconstructions require less intraoperative fluoroscopy time, and primary allograft reconstruction seems to require the least amount of radiation if C-arm is used. Surgeon exposure has been measured during such procedures and has been found to be uniformly low 0.7 µSv/min (Larson et al, 1995). For typical fluoroscopy time of 2.38 min, average dose to the surgeon is 16 µSv/ procedure or 4 mSv/year for a workload of 250 procedures performed annually. Further studies using other techniques and implants confirm low scatter radiation to the surgeon (Tsalafoutas et al., 2008; Larson et al., 2008).

(115) Orthopaedic surgeons who practice spine surgery frequently use C-arm fluoroscopy to localize anatomic levels, assess bony alignment during deformity correction, and guide implant placement. Because large body segments are imaged and these areas fill the entire field of view of the image intensifier, potential for amplified radiation exposure of the patient and surgeon is high. Fluoroscopically assisted thoracolumbar pedicle screw placement exposes the spine surgeon to significantly greater radiation levels (10-12 times) than other, nonspinal musculoskeletal procedures that involve the use of a fluoroscope (Rampersaud et al, 2000). Radiation dose rates to the surgeon's neck and dominant hand are 0.08 and 0.58 mGy/min, respectively. The dose rate to the torso was greater when the surgeon was positioned lateral to the beam source (0.53 mGy/min, compared with 0.022 mGy/min on the contralateral side) (Rampersaud et al, 2000). Use of standard C-arm fluoroscopy during pedicle screw fixation has been shown to expose the surgeon to an average of 0.58 mSv/min. This relatively high exposure requires strict adherence to radiation protection measures.

(116) During minimally invasive transforaminal interbody lumbar fusion (TLIF), for an average fluoroscopy time of 1.7 min, mean exposure per case to the surgeon on his dominant hand is 0.76 mSv, at the waist under a lead apron was 0.27 mSv, and at an unprotected thyroid level 0.32 mSv. Kyphoplasty and vertebroplasty, which are minimally invasive spine procedures, require both anteroposterior and lateral real-time visualization, often using biplane fluoroscopy equipment. In fact, 90% of the orthopaedic surgeon's effective dose and risk is attributed to kyphoplasty, while another 8% is attributed to spine procedures (Theocharopoulos et al., 2003). The effective dose to the orthopaedic surgeon working tableside during a typical hip, spine and kyphoplasty procedure was 5.1, 21, and 250 µSv, respectively, when a 0.5-mm lead-equivalent apron alone was used. The additional use of a thyroid shield reduced the effective dose to 2.4, 8.4, and 96 µSv per typical hip, spine, and kyphoplasty procedure, respectively.

(117) Procedures involving the standard C-arm fluoroscopy of the cervical spine have been shown to produce a dose rate to surgeon's hands of 0.25-0.30 mSv/min, which is somewhat lower than 0.53-0.58 mSv/min for procedures involving the lumbar spine (Giordano et al., 2009a; Jones et al., 2000; Rampersaud et al., 2000).

4.3.2. Radiation dose management

Patient dose management

(118) Diagnostic testing in orthopaedics relies heavily on imaging studies. Many of these imaging modalities can be used interchangeably, with variable sensitivity for soft tissue or bony anatomy. Meanwhile, procedures that rely on imaging for localization, indirect visualization, or instrument guidance often depend specifically on ionizing radiation as an imaging tool. For some minimally invasive orthopaedic procedures, C-arm fluoroscopy has supplanted direct visualization, and is requisite to successful completion of that procedure. To help reduce intraoperative radiation exposure, some authors have begun to use alternate imaging modalities such as ultrasound to perform procedures that formerly relied more heavily on fluoroscopy (Hua, et al., 2009; Mei-Dan et al., 2009; Weiss et al., 2005). Although the use of such modalities is relatively untested, they offer promising new alternatives to imaging tools that use ionizing radiation.

(119) Patient exposure, has been shown to be considerably reduced (10 times) by adhering to proper radiation safety practices and imaging the specimen closest to the image intensifier. A significant learning curve is expected when using C-arm fluoroscopy during surgical procedures 20. Beam orientation, surgeon positioning, image optimization, and other logistical challenges require time for the surgeon to make the most efficient use of the C-arm. Screening times can be a useful tool to measure optimum use of the C-arm during such surgical cases.

(120) Recent data suggests that although the mini C-arm is capable of limiting exposure dose to the patient and surgeon, care must nonetheless be taken during its use (Giordano et al., 2007; Giordano et al., 2008; Giordano et al., 2009a; Giordano et al., 2009b). If the mini C-arm is used in an injudicious manner, the surgeon, patient, and surrounding staff may be subjected to considerable scattered radiation exposure. Careless use of the mini C-arm can even exceed doses encountered when using the large C-arm under equivalent imaging conditions. Therefore, strict radiation protection measures,

including the routine use of protective lead garments, should be observed when using both mini and large C-arm fluoroscopes. The mini C-arm device should be utilized whenever feasible in order to eliminate many of the concerns associated with use of the large C-arm device, specifically those related to cumulative radiation hazards, positioning considerations, relative distance from the beam, and the need for protective shielding (Badman et al., 2005).

(121) Depending on the imaging configuration used, patient entrance skin dose rate in the mini C-arm can be about half that of the standard C-arm. The typical reported values are: 0.60 mGy/min (mini C-arm) and 1.1 mGy/min (large C-arm) for a wrist surgery with cadaveric upper extremity (Athwal et al. 2005) and immobilization of wrist fractures. A frequent mistake in using the C-arm is to increase exposure parameters to improve image quality. However, most imaging problems can be solved by adjusting brightness and contrast (Athwal et al. 2005). Distance from the C-arm radiation source to the imaged object also determines the amount of direct radiation exposure. Surgeons should make a conscious effort to image patients as far from the x-ray source as possible. With the mini C-arm this would mean placing the imaged extremity directly onto the image intensifier. With the standard C-arm used in the recommended vertical position, the source should be lowered to the floor to maximize the source to skin distance (Athwal et al. 2005).

(122) As the cross-sectional dimensions of the imaged body area or tissue density of a patient increases, there is a precipitous amplification in exposure of both the patient and surgical team. Thicker body portions remove more x-rays than thinner portions and must be compensated for to provide consistent image information. When the C-arm fluoroscope is set to the “normal” mode, technique factors are adjusted automatically to produce an image of good clarity. Radiation production may therefore increase significantly when imaging a larger body area. For orthopaedic surgeons, this concept is pertinent because the amount of direct and scattered exposure may vary considerably depending on the body area to be imaged. As the size of the imaged extremity or tissue density increases, there is a notable augmentation of both direct exposure of the patient as well as indirect scatter exposure of the surgical team (Giordano et al., 2007; Giordano et al., 2008; Giordano et al., 2009a; Giordano et al., 2009b; Yanch et al., 2009). This idea is particularly relevant to orthopaedic surgeons who practice spine surgery as mentioned previously.

(123) Even for orthopaedic surgeons who do not practice spine surgery, the same principles still apply and are critical to maintaining appropriate safety precautions. During fluoroscopic examination using a large C-arm, radiation dose to the patient has been shown to increase nearly 10 times when imaging a foot/ankle specimen versus a cervical spine. The dose to the surgical team, meanwhile, was found to increase 2-3 times (Giordano et al., 2007; Giordano et al., 2008; Giordano et al., 2009a; Giordano et al., 2009b). If a mini C-arm fluoroscope was used for the same scenario, the dose to the patient increased 3-4 times and the dose to the surgical team increased 2 times.

(124) Finally, all patient dose reduction actions described in Section 3, also apply to orthopaedic surgery.

Staff dose management

(125) X-rays travel in straight line and diverge in different directions as shown in Fig. 3.7. The intensity decreases with distance according to the inverse-square law. In a study in orthopaedic theatre, it was shown that standing at 90 cm from the x-ray source versus 10 cm away decreased surgeon exposure from 0.20 mSv per case to 0.03 mSv per case (Mehlman et al., 1997). Traditionally, surgeons have been taught that as long as they stand at least 1.8 m from the x-ray source, they are at essentially zero risk of being exposed to radiation (Tsalafoutas et al., 2008). This is not correct and has been called into question in studies which have demonstrated higher exposure levels at a distance of 6 m from the x-ray source (Badman et al., 2005).

(126) Over the past several decades, mini C-arm fluoroscopy has emerged as a convenient imaging tool that has the potential to reduce radiation dose. Exposure levels have been studied during various orthopaedic procedures and scenarios (Giordano et al., 2009b; Giordano et al., 2007; Athwal et al., 2005; Love et al., 2008; Larson et al., 2008). Some operators may believe that so long as they are outside the primary beam and they do not see their body part in the image, their exposure is negligible. This is based on the fact that, most studies that give such advice have been conducted under ideal circumstances, in contrast to more realistic applications that are encountered in practice. Exposure of the surgeon and operating team has been shown to vary in relation to the orientation of the x-ray beam. In some cases, it is unavoidable that the surgeon must stand in close proximity to the beam in order to maintain a reduction or to secure implant placement. In those instances, the surgeon may be at risk of exposure either by direct beam contact or through scatter radiation. Some authors have demonstrated a dramatically reduced exposure dose when the surgeon stood on the image intensifier side of the patient (Rampersaud et al., 2000). In effect, placing the x-ray source under the operating table provides an effective beam stop in some cases (Jones at al. 2000). When using the C-arm in a lateral or oblique orientation the surgeon should work on the image intensifier side of the table to reduce exposure from scattered radiation. While this may be true when imaging body areas that completely intercept the beam fully, the same principle may not necessarily apply when imaging a smaller body area where the beam may not be collimated to smaller size. In such a situation, some of the x-ray beam passes by the specimen un-attenuated, resulting in a higher dose on the opposite side. This must be taken into consideration when positioning operating staff safely.

(127) Lead shielding is commonly used to attenuate exposure from scattered radiation. Manufacturers cite variable protection depending on the thickness of the garment. In general, one can expect greater than 90% reduction in scatter exposure from a lead gown of 0.5mm lead thickness. Realistically, the ability of a lead garment to attenuate scattered radiation is dependent upon the quality control (QC) actions taken to ensure that lead garments are well maintained. The protective benefit afforded by lead can be compromised by poor maintenance. In a study of 41 lead aprons, 73% were found to be outside the tolerance limit (Finnerty et al., 2005). Furthermore, a recent report by the American Academy of Orthopaedic Surgeons showed exposures under lead to be only 30-60% less than those over the lead (AAOS, 2010). This underscores the fallibility of this protective measure, as well as the importance of proper maintenance and storage. Lead aprons should not be folded, but rather hung to improve their longevity. Imaging factors such as higher tube voltages and imaging larger body areas can further decrease

effectiveness. These often ignored variables should be clearly understood and corrected to improve protection measures.

(128) Use of a lead thyroid shield can reduce radiation exposure by a factor of almost 90% or more depending upon the kV used and lead equivalence (see Section 3).

(129) The highest levels of exposure to the hands of the surgeon arise from inadvertent exposure to the direct beam. One should be careful to be on the exit side of the x-ray beam rather than on the entrance side. The radiation intensity on the exit side of the x-ray beam is typically around 1% (Section 3). Thus, every care should be taken for staff to be on the exit side. Lack of awareness of this leads to unnecessary exposure of staff. It is recognised that sometimes it may be unavoidable when maintaining a difficult reduction, confirming adequate bony alignment, or securing implant placement. In most cases, however, direct hand exposure is avoidable. When the orthopaedic surgeon's or assistant's hand is visible on a stored fluoroscopic image, it is generally evidence of poor radiation protection practices (Fig. 4.1). In cases where direct hand exposure is unavoidable, consideration may be given to using lead gloves.

Fig.4.1. Fluoroscopic image obtained to demonstrate satisfactory internal fixation of a fracture of the distal humerus. The assistant is holding the forearm, and three of the assistant's fingers are included in the image. This is poor practice (Figure courtesy of B. Giordano).

(130) Some of the first radiation exposure data recorded in the orthopaedic literature was collected during hip pinning and femoral nailing in the traumatized patient (Giachino et al., 1980; Giannoudis et al., 1998). As described in Section 3, increased distance from the patient is an efficient tool for dose reduction. For lateral projection and laterally directed x-ray beam (surgeon stands beside image receptor), the dose rate decreased from 1.9 to 0.2 mGy/h when distance is increased from 2.5 to 45 cm. Similarly,

for a lateral projection and x-ray beam directed towards the midline (surgeon stands beside x-ray tube), the dose rate decrease from 77 to 1.5 mGy/h when distance is increased from 2.5 to 45 cm (Giachino et al, 1980).

4.4. Obstetrics and gynaecology

(131) Most radiological examinations in obstetrics and gynaecology are performed within radiology, but there are situations where they are performed in gynaecology practice and thus are included in this document.

(132) Obstetrics and gynaecological studies in USA present 4.5 % of all fluoroscopically-guided diagnostic and interventional procedures with mean effective dose of 1 mSv and contribution of less than 1% to total collective dose (NCRP, 2009).

(133) Hysterosalpingography (HSG) is a relatively frequent radiological procedure which is used to assess the uterine cavity and the patency of Fallopian tubes. The common indication for HSG is primary and secondary infertility. It should not be forgotten that pregnancy can occur in these patients and pregnancy tests should be performed, unless there is information that precludes a pregnancy.

(134) Pelvimetry is an old procedure that was performed for assessment of maternal pelvic dimensions and may still be in use in some countries. Pelvimetry is usually considered necessary where vaginal delivery is contemplated in a breech presentation or if reduced pelvic dimensions are suspected in a current or previous pregnancy.

(135) Historically, in a number of countries, pelvimetry represented the major single source of ionising radiation to the fetus. While radiographic pelvimetry is sometimes of value, it should be undertaken only on the rare occasions when this is likely to be the case and should not be carried out on a routine basis. X-ray pelvimetry provides only limited additional information to physicians involved in the management of labour and delivery. In the few instances in which the clinician thinks that pelvimetry may contribute to a medical treatment decision, the reasons should be clearly delineated (ICRP, 2000).

(136) Conventional pelvimetry includes radiography but digital fluorography, computed tomography (CT) and magnetic resonance imaging (MRI) and ultrasound are currently used for pelvimetry (Thomas et al., 1998; ICRP, 2000).

4.4.1. Levels of radiation dose

Dose to patient

(137) The radiation dose to mother and fetus in pelvimetry can vary a factor 20 to 40 depending upon the techniques used namely, computed tomography (CT), conventional radiography or digital fluorography (Table 4.5.).

(138) CT pelvimetry with a lateral scanogram generally gives the lowest radiation dose and conventional radiography using an air gap technique with a single lateral view is a relatively low-dose alternative where CT is not available (Thomas et al., 1998). For comparison, reported effective dose from conventional pelvimetry is in the range 0.5-5.1

mSv, that is significantly higher than effective dose of 0.2 mSv from CT pelvimetry (Hart et al., 2002).

(139) Typical effective dose to patient undergoing HSG as a part of their infertility work-up is 1.2 to 3.1 mSv (Table 4.5.) and ovarian dose in the range 2.7-9.0 mGy. However, higher values of effective dose of 8 mSv and ovarian dose of 9-11 mGy have been reported (Fernandez et al., 1996; Nakmura et al., 1996; Gregan et al., 1998).

Staff dose levels

(140) During HSG procedure if examination protocol involves fluoroscopy guidance, it will require staff to be located inside the x-ray room. In the case when the procedure involves only radiography, staff is outside the room at the console. A protective lead apron should be worn by the staff when inside the x-ray room and other protection measures mentioned in Section 3.

(141) There is a lack of publications on this subject. One recent paper cites values as entrance surface dose (ESD) and reports 0.18 mGy per procedure, with a slight increase when an HSG is performed on conventional x-ray film compared to digital (0.21 mGy vs. 0.14 mGy). Staff eye lens, thyroid and hand doses are reported to be 0.22, 0.15 and 0.19 mGy per procedure, respectively. The risk for staff is negligible when a lead apron of 0.35-0.5 mm lead equivalence is worn (Sulieman et al., 2008).

Table 4.5. Typical patient dose levels from gynaecological procedures (rounded) and comparison with CT

Procedure	Relative mean radiation dose to patient 0 mSv 35	Relative mean radiation dose to patient*	Reported values: Fluoroscopy time (min)	Reported values: Entrance skin dose (mGy)	Reported values: Dose-area product ($Gy.cm^2$)	Reported values: Effective dose (mSv)	Reference
Pelvimetry, conventional		A	na**	4.2-5.1	1.4	0.4-0.8	(a, b, c)
Pelvimetry, digital fluorography		A	0.3	3.6	0.10-0.46	0.43	(d)
CT Pelvimetry		A	na**	na**	na**	0.2	(c)
HSG		B,C	0.3-14	9.7-30	4-7	1.2-3.1	(b, c, e, f, g, h, i, j)

*A=<1 mSv; B=1 to<2 mSv ; C=2 to <5 mSv ;D=5 to <10 mSv ;E=10 to<20;F=20 to 35 mSv ;G= >35 mSv, based on effective dose

** not available

(a)Russel et al., 1980; (b) NCRP, 2009; (c) Hart et al., 2002 ; (d) Wright et al., 1995 ; (e) Suileman, et al., 2008 ; (f) Gregan et al., 1998 ; (fg Perisinakis et al., 2003 ; (g) Fife, et al,. 1994 ; (h) Fernandez, et al. 1996 ; (i) Fernandez, et al., 1996 ; (i) Calcchia, et al., 1998; (j) Gregan, et al., 1998.

4.4.2. Radiation dose management

Patient dose management

(142) Section 3 deals with patient dose management in great detail.

(143) In HSG a standard procedure may involve around 0.3 min of fluoroscopy and 3-4 images (Perisinakis et al., 2003). Prolonged fluoroscopy time and a higher number of acquired images will increase patient dose. HSG is typically performed in anterior-posterior and oblique projection. For total effective dose in HSG of 2 mSv, the contributions from AP and oblique projections are typically 1.3 and 0.7 mSv, respectively (Calcchia et al., 1998).

(144) Increasing the tube voltage is an efficient method for dose reduction in HSG, as ovarian dose is decreased by about 50% when tube voltage is increased from 70 kV to 120 kV (Kramer et al., 2006). Choice of posterior-anterior projection and increased filtration are other possible steps to reduce dose to patients. As an example, use of additional filtration could lead to dose reduction of more than 80% without loss of image quality in HSG in computed radiography systems (Nagashima et al., 2001).

(145) There is evidence of almost six times dose reduction as a result of transition from screen-film to digital imaging equipment. In a comparative dosimetric study of HSG performed on conventional screen-film undercouch x-ray units and digital C-arm radiological fluoroscopy unit, reported entrance surface doses were 15 mGy and 2.5 mGy for screen-film and digital unit, respectively (Gregan at. al., 1998). The corresponding ovarian doses were 3.5 mGy and 0.5 mGy (Gregan at. al., 1998). As almost 75% of total dose in HSG is due to radiography and only 25% due to fluoroscopy (Fernandez et al., 1996), significant dose reduction could be achieved by using stored digital images without further patient exposure. Use of C-arm fluoroscopic imaging systems with pulsed fluoroscopy and last-image-hold capability are desirable (Phillips et al., 2010).

(146) The fundamental approach in dose reduction in HSG is to reduce fluoroscopy time and number of images taken.

Staff dose management

(147) It has been demonstrated that mean screening time is highly operator dependant. The observed screening time for procedures performed by gynaecologists or trainee doctors is higher as compared to radiologists (Sulieman et al., 2008). Therefore, HSG should be performed by experienced physicians with training and skill in radiation protection and radiation management. In general, all patient dose reduction methods can also reduce dose to physicians and support personnel involved in the examination. Furthermore, the use of overcouch x-ray unit increases scatter dose to the face, neck and upper parts of the operator’s body.

(148) The staff dose management actions described in Section 3 are also generally as well applicable in gynaecological procedures.

4.5. Gastroenterology and hepato-biliary system

(149) The use of ionizing radiation in gastroenterology and hepato-biliaryproceduresis somewhat in transition. In the past, gastroenterologists performed a variety of interventions involving radiation exposure, including performing gastrointestinal and hepato-biliary x-ray studies, placement of small bowel biopsy tubes, oesophageal dilation, and assistance with colonoscopy, as well as diagnostic and therapeutic procedures on the pancreatico-biliary system during ERCP (endoscopic retrograde cholangiopancreatography). Endoscopic retrograde cholangiopancreatography (ERCP) and other biliary procedures require fluoroscopic guidance and most of the current x-ray exposure is from ERCP, luminal stents and dilation while the other procedures are becoming supplanted by improvements in diagnostic equipment and techniques. Gastroenterologists who are involved in ERCP procedures may work at specialized centres and may perform multiple procedures daily. In many circumstances where fluoroscopic and/or x-ray equipment are used, gastroenterologists have the opportunity to minimize risk to patients, staff and themselves.

(150) ERCP studies present 8.5 % of all fluoroscopically-guided diagnostic and interventional procedures in USA with mean effective dose of 4 mSv and contribute 4-5 % of total collective dose from fluoroscopically guided interventions (NCRP, 2009).

(151) During ERCP, fluoroscopy is used to verify position of the endoscope and its relationship within the duodenum. The placement of catheters and guide wires is also verified fluoroscopically. Once contrast injections are performed, fluoroscopy is used to evaluate the anatomy of the ductal systems of both the biliary tree and pancreas, and to help define potential diseases present. Images are usually taken to record the findings, either by capturing the last fluoroscopic image or spot radiographs. Finally, the use of fluoroscopy to assist therapy, such as sphincterotomy, stone extraction, biopsy or cytology, and stent placement is required. Additional devices that allow direct visualization of ductal anatomy may ultimately reduce the need for fluoroscopy (WGO, 2009).

4.5.1. Levels of radiation dose

Dose to patient

(152) Typical patient dose levels for common gastroenterology and hepato-biliary procedures involving x-rays are presented in Table 4.6. Single and double contrast barium enema are x-ray examinations of the large intestine (colon and rectum). Barium swallow is the x-ray examination of the upper gastrointestinal tract. These traditional x-ray examinations in gastroenterology are associated with doses ranging from 1-3 mSv for barium swallow and barium meal, to 7-8 mSv for small bowel enema and barium enema (UNSCEAR, 2010). Although these studies are performed mostly within a radiology department, it is important that gastroenterologists are aware of typical levels of doses and risks. At present, many barium studies have been replaced by endoscopic procedures that exclude use of ionising radiation.

(153) For the patient, the source of exposure is the direct x-ray beam from the x-ray tube. It is estimated that patients receive about 2–16 min of fluoroscopy during ERCP,

with therapeutic procedures taking significantly longer. Studies have found that DAP values of approximately 13–66 Gy·cm2 are typical for ERCP. Effective doses ranging from 2 to 6 mSv per procedure have been reported (WGO, 2009).

(154) Care of the patient undergoing an endoscopic procedure continues to become more complex as technology advances. Due to higher complexity, doses from therapeutic ERCP procedures are typically higher than from diagnostic procedures. For a diagnostic procedure the average DAP is as 14-26 Gy·cm2 , while it reaches 67-89 Gy·cm2 for therapeutic ERCP. Corresponding entrance skin dose are 90 mGy and 250 mGy for diagnostic and therapeutic ERCP, respectively. The mean effective doses are 3-6 mSv for diagnostic and 12-20 mSv for therapeutic ERCP (Olgar et al., 2009; Larkin et al., 2001). Fluoroscopic exposure represented almost 70 % of the dose for diagnostic ERCP and more than 90% of the dose for therapeutic ERCP, indicating that reduction of fluoroscopy time is an efficient method for dose management (Larkin et al., 2001).

(155) The estimated radiation dose and associated risks for fluoroscopically guided percutaneous transhepatic biliary drainage and stent implantation procedures indicated that radiation-induced risk may be considerable for young patients undergoing these procedures. The average effective dose varied from 2 to 6 mSv depending on procedure approach (left vs. right access) and procedure scheme. However, effective dose could be higher than 30 mSv for prolonged fluoroscopy times (Stratakis et al., 2006; UNCSEAR, 2010). In the available literature, the reported dose-area product values for biliary drainage are in the range of 51-132 Gy cm2, that, based on appropriate conversion factor from DAP to effective dose, corresponds to an effective dose of 13-33 mSv per procedure (Dauer et al., 2009; Miller et al., 2003a; NCRP, 2009).

Table 4.6. Typical patient dose levels (rounded) from gastroenterology and hepato-biliary procedures

Procedure	**Relative mean radiation dose to patient** (0 mSv 35)	**Relative mean radiation dose to patient***	**Reported values**				**Reference**
			Fluoroscopy time (min)	**Entrance skin dose (mGy)**	**Dose-area product (Gy cm^2)**	**Effective dose (mSv)**	
ERCP (diagnostic)		C,D	2-3	55-85	15	3-6	(a,b)
ERCP (therapeutic)		E,F	5-10	179-347	66	20	(a,b)
Biopsy		C	na**	na**	6	1.6	(a,c)
Bile duct stenting		E	na**	499	43-54	11-14	(a,c,d)
PTC#		D	6-14	210-257	31	8.1	(a)
Bile duct drainage		F,G	12-26	660	38-150	10-38	(a,d,e)
TIPS***		F,G	15-93	104-7160	14-1364	19-87	(a,e,f)
Transjugular hepatic biopsy		D	6.8	na**	34	5.5	(f)

*A=<1 mSv; B=1 to<2 mSv ; C=2 to <5 mSv ;D=5 to <10 mSv ;E=10 to<20;F=20 to 35 mSv ;G= >35 mSv, based on effective dose

** not available

*** transjugular intrahepatic portosystemic shunt (TIPSS) creation; # PTC=Percutaneous transhepatic cholangiography

(a) UNSCEAR, 2010 ; (b) Olgar et al., 2009; (c) Hart et al., 2002; (d) Dauer et al., 2009 ; (e) Miller et al. , 2003a ; (f) McParland, 1998

Staff dose

(156) For gastroenterologists and other staff, the major source of x-ray exposure is scattered radiation from the patient, not the primary x-ray beam. Average effective doses of about 2-70 µSv per procedure have been observed for endoscopists wearing a lead apron (Olgar et, al., 2009; WGO, 2009). Although the endoscopist's body is well protected by a lead apron, there can also be substantial doses to unshielded parts. For a single ERCP procedure, typical doses for the head and neck region (eyes and thyroid) of 94-340 µGy and 280-830 µGy to the fingers have been reported (Olgar et al., 2009; Buls et al., 2002). For PTC, reported doses are in the range 300-360 µGy and 530-1000 µGy per procedure for head and neck and fingers, respectively (Olgar et al., 2009). For a workload of 3-4 procedures per week, Naidu et al. (2005) reported extrapolated annual dose to thyroid gland and extremities for operators performing ERCP studies as 40 mSv and 7.92 mSv, respectively. Doses to assisting personnel are usually a few times lower, depending on position and the time spent near the x-ray source, as they usually stand further away from the patient (WGO, 2009).

(157) Jorgensen et al. (2010) reported the typical annual workload for the ERCP providers, stating that 34% of them perform less than 100 ERCP procedures, 38% performs 100-200 procedures and 28% performs more than 200 procedures.

(158) It is not possible to document radiation effects at the level to which gastroenterologists performing ERCP or fluoroscopy are exposed—typically annual effective doses of 0–3 mSv when appropriate radiation protection tools and principles are applied (WGO, 2009). Nevertheless, many gastroenterologists involved in diagnostic and therapeutic procedures using ionising radiation do not routinely wear full protective clothing (protective aprons, thyroid shield, lead glasses). Audit s of radiation exposure of personnel performing ERCP found that staff can be exposed to significant radiation exposure, as only half of respondents reported wearing a thyroid shield regularly (Frenz et al., 2005).

(159) Typical dose for hands, neck, forehead, and gonads during percutaneous procedures under fluoroscopic guidance, such as percutaneous cholangiography and transhepatic biliary drainage are: 13-220 µSv for hands, 0.007 -0.027 µSv for thyroid and eye lens, while dose for gonads was negligible under the lead apron. The assessed annual dose levels fall below regulatory dose limits for occupational exposure (Benea et al., 1988).

(160) Whilst it is well known that an overcouch tube x-ray unit is not adequate for performing interventional procedures, ERCP commonly involved the use of this type of equipment. Olgar et al. (2009) reported typical dose per ERCP procedures of 94 and 75 µGy for eye and neck of a gastroenterologist. With an overcouch unit typical eye and neck doses are 550 and 450 µGy, with maximal doses up to 2.8 and 2.4 mGy per procedure, respectively (Buls et al., 2002). Dose to the lens of the eye will be the critical, as for a moderate workload the annual dose limit for lens of the eye of 20 mSv could be reached. This is clearly owing to the type of x-ray equipment used.

4.5.2. Radiation dose management

Patient dose management

(161) Where possible, ERCP should be reserved for situations where intervention is likely, using alternative modalities for purely diagnostic purposes e.g. MRCP, 'magnetic resonance cholangio-pancreatography' (Williams et al., 2008). Reported staff dose level using overcoach tube units may indicate that ERCP procedures are often performed without attention to equipment and radiation protection. There is evidence that a correctly operated C-

arm unit with the availability of pulsed fluoroscopy will dramatically reduce dose to both patients and staff (Buls et al., 2002). In addition, use of a grid-controlled fluoroscopy unit could achieve significantly lower patient doses without loss in diagnostic accuracy compared to a conventional continuous fluoroscopy unit for a variety of abdominal and pelvic fluoroscopic examinations (Boland et al., 2000).

(162) In any procedure, when fluoroscopy is used for guidance, the least amount of fluoroscopy time possible is recommended. Therefore, both patient and staff doses could be reduced by time-limited fluoroscopy that significantly decreases fluoroscopy time and thus, dose (Uradomo et al., 2007).

(163) Best practice during ERCP includes positioning of the x-ray tube below the table as far away as possible, positioning oneself as far away as possible from the x-ray tube and patient, wearing a protective apron, thyroid shields, and leaded eyewear. Maintaining x-ray equipment in optimum operating condition, using pulsed fluoroscopy, minimizing fluoroscopy time, limiting radiographic images, using shielding barriers, collimation and reduced use of magnification will help to reduce x-ray exposure of the staff as well as of the patient. Anything that increases the amount of radiation exposure e.g. longer fluoroscopy times, more radiograph images generated, proximity to the radiation source, positioning the x-ray source above the patient, and your closeness to the patient will increase the radiation dose and potential risk from ionizing radiation.

(164) The patient dose management actions described in Section 3 are generally also applicable in gastroenterology and hepato-biliary procedures.

Staff dose management

(165) Patient and staff exposure are related. Any action to reduce patient dose will also bring to staff dose reduction.

(166) It is obvious that an ERCP procedure has the potential to cause high staff doses and consequently requires attention regarding radiation protection. The reported dose levels indicate that an ERCP procedure requires the same radiation protection practice as all interventional procedures. The Commission has well covered radiation protection issues in interventional procedures in the Publication 85 (2001).

(167) Specific written policies and procedures for the safe use of radiographic equipment must be available to all gastroenterology personnel. Endoscopy personnel can limit occupational exposure to radiation by using the principles based on distance, time, and shielding, as already described in Section 3 of this document. As an example, well positioned 0.5 mm lead equivalent acrylic shield will reduce staff exposure by a factor of 11 (Chen et al., 1996). Besides basic dose management actions, if using a single sided apron, it is important to always face the unit that is emitting radiation. If this is not possible and duties require staff members to turn away from the radiation source, exposing their backs, a wrap-around apron that provides all around protection to the body must be used (SGNA, 2008).

(168) As outlined in Section 3 of this document, training and experience are powerful dose reduction tools. Fluoroscopy time is shorter when ERCP is performed by endoscopists with more years of performing ERCP and a greater number of ERCPs in the preceding year. Endoscopists who performed less than 100 and 100 to 200 ERCP procedures have 59% and 11% increases in fluoroscopy time, respectively compared with endoscopists who performed more than 200 ERCP procedures annually. Every 10 years of experience was associated with a 20% decrease in fluoroscopy time (Jorgensen et al., 2010).

4.6. Anaesthetics and pain management

(169) Local spinal pain and radiculopathy are very common conditions. Because imaging abnormalities do not correlate with symptoms in most cases, many patients do not receive a specific diagnosis and have continued pain. Percutaneous injection techniques have been used to treat back pain for many years—and have been controversial. Many of these procedures have historically been performed without imaging guidance. Imaging-guided techniques with fluoroscopy or computed tomography (CT) increase the precision of these procedures and help confirm needle placement. Because imaging-guided techniques should lead to better results and reduced complication rates, they are now becoming more popular (Silbergleit, et al., 2001). Epidural injections are commonly used for the treatment of lower back pain in patients for whom conservative disease management has failed and who may wish to avoid surgery (Wagner, 2004).

(170) Reported patient doses during fluoroscopy guided epidural injections are higher when continuous fluoroscopy is used. When pulsed fluoroscopy is used, patient dose per minute of fluoroscopy is significantly lower: 0.08, 0.11 and 0.18 mSv for 3, 7.5 and 15 pulses per second, respectively (Schmid et al., 2005). During CT fluoroscopy guidance, typical patient doses are in the range 1.5-3.5 mSv for standard protocol and 0.22-0.43 mSv for low dose protocol, depending on the number of consecutive scans performed. Therefore, by applying pulsed fluoroscopy effective dose reduction by 80-90% has been reported, while use of low-dose CT protocol in terms of reduced mA and tube rotation time reduces effective dose by more than 85% (Schmid et al., 2005).

(171) Reported radiation dose to the operator during CT fluoroscopy guided lumbar nerve root blocks outside the lead protection are typically 1-8 µSv per procedure (Wagner, 2004).

(172) The factors that greatly influence operator's dose are: equipment technology, use of shielding, operator's experience, use of lower mA, and smaller scan volume. Radiation dose to the patient has also been greatly reduced by these techniques as well as by using pulsed fluoroscopy and reduced mAs values during CT fluoroscopy guidance (Wagner, 2004, Schmid et al., 2005).

4.7. Sentinel lymph node biopsy (SLNB)

(173) The sentinel lymph node (SLN) is the first lymph node to which cancer is likely to spread from the primary tumour. Cancer cells may appear in the sentinel node before spreading to other lymph nodes. SLN biopsy (SLNB) is based on the premise that cancer cells spread (metastasize) in an orderly way from the primary tumour to the sentinel lymph node(s), then to other nearby lymph nodes. A negative SLN biopsy result suggests that cancer has not spread to the lymph nodes. A positive result indicates that cancer is present in the SLN and may be present in other lymph nodes in the same area (regional lymph nodes).

(174) Several reports have demonstrated accurate prediction of nodal metastasis with radiolocalization and selective resection of the radiolocalized SLN in patients with cancer of breast, vulva, penis, head and neck and melanoma. The list is expanding with on-going research. Accurate identification of the SLN is paramount for success of this procedure. SLNB is the evolving standard of care for the management of early breast cancer. In SLNB, only the first node draining a tumour is removed for analysis. Clearance to achieve local control is reserved for those with a positive SLNB.

(175) Various techniques are described for SLN identification, but the injection of the radiotracer into the tumour is more common. Pre-operative lymphoscintigraphy provides a road map for the surgeon and requires a reporting template. 99mTechnetium sulphur colloid has been commonly used for over a decade and it offers the potential for improved staging of breast cancer with decreased morbidity. Intra-operative gamma-ray detection is used to identify and remove the ‘hot’ node(s).

(176) The use of radioactive materials in the operating room generates significant concern about radiation exposure. As reliance on this technique grows, its use by those without experience in radiation safety will increase.

4.7.1. Levels of radiation dose

Dose to patient

(177) ^{99m}Tc-sulfur colloid or nano colloid is a commonly used radiotracer, but in recent years there has been an inclination to find positron emitting radiopharmaceuticals too. 99mTc is a pure gamma emitter. When injected as a colloid, it remains localized and with the activity used for this procedure, the radiation dose to the patient is extremely small. As a result, currently there is a lack of published reports on radiation doses to patients in SLNB procedures and most papers address the issue of staff exposure. One needs to address the concern of radiation dose to the pregnant patient and fetus. Estimated fetal dose is normally much below 0.1 mGy (typically 0.01 mGy or still less) and effective dose to the patient generally lower than 0.5 mSv using 18.5 MBq of 99mTc-colloid. These doses are too small to preclude use of this technique in pregnancy when there is clinical benefit and alternative techniques cannot provide the same information. The fact that due considerations have taken place should be recorded (Pandit-Taskar, N.et al., 2006; Spanheimer et al., 2009).

Staff dose levels

(178) Physicians administering the radiotracer injection in SLNB receive hand doses of between 2.3 and 48 µSv per case, with maximal dose up to 164 µSv. Surgeons receive hand-doses of 2 to 8 µSv per case (Nejc et al., 2006). However, there are studies indicating that dose to hands of operating surgeons can be as high as 22-153 µSv, depending on the technique applied (de Kanter et al., 2003). Notably, other members of the medical team receive similar doses (4.3 to 7.9 µSv per case) (Nejc et al., 2006). Other numerous studies report similar minimal staff radiation doses with SLNB (Klausen et al., 2005; Miner et al., 1999; Waddington et al., 2000). Considering a typical workload in a moderate hospital of about 20 patients per year, the annual dose to the hands using these figures can be a maximum of 3 mSv against the Commission’s dose limit of 500 mSv.

4.7.2. Radiation dose management

Patient dose management

(179) Use of the principle of ‘as low as reasonably achievable’ promotes administration of the lowest amount of radioactivity required to obtain the desired clinical information. Further, use of alternative techniques using non-ionizing radiation is preferred when similar information can be obtained, particularly in pregnancy.

Staff dose and radioactive waste management

(180) There are indications that radiation dose to hands of medical staff are smaller when SLNB is performed as a 2-day procedure. The surgery is performed 24 h after the injection of radiotracer. During 24 h, four physical half-lives of the radiotracer pass (99mTc, t1/2=6.02 h). Moreover, the activity is further diminished due to clearance of the radiotracer from the blood (Nejc et al., 2006, Waddington et al., 2000).

(181) Radioactive waste is created in the operating theatre, and may be generated in the pathology laboratory if specimens are not routinely stored until fully decayed.

(182) A general framework for radiation protection and disposal of radioactive waste was published by the Commission in the Publication 77 (1998). It should be remembered that the primary aim of radiation protection is to provide an appropriate standard of protection for man without unduly limiting the beneficial practices giving rise to radiation exposure. For the control of public exposure from waste disposal, the Commission has maintained in its latest recommendations (Publication 103) the previously recommended value of Publication 77 for the dose constraint for members of the public of no more than about 0.3 mSv in a year (ICRP, 1998; ICRP, 2007). Special considerations for the waste radioactive materials are not required, but it is suggested that such waste materials are sealed and stored for decay before disposal at the designated place in accordance with local rules.

(183) Radioactivity contamination in operating room materials is also minimal and requires normal precautions in handling. Letting radioactivity decay with time by storing the specimens for a few hours is a sufficient precaution for pathologists handling the SLNB specimens. Following the safety guidelines, the specimens arising from SLNB procedure should be stored for decontamination until the dose rate falls to background levels (Stratmann et al., 1999). Depending upon the administered activity, this takes about 60- 70 hours for primary specimens and 30 to 40 hours for nodes following ^{99m}Tc- sulphur colloid injection (Miner et al., 1999; Filippakis et al., 2007). A local risk assessment should be carried out prior to undertaking these procedures. Transport and disposal of decayed radioactive waste should proceed further according to national regulatory requirements.

4.8. References for Chapter 4

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5. PREGNANCY AND CHILDREN

Medical radiation applications on pregnant patients should be specially justified and tailored to reduce fetal dose.

Termination of pregnancy at fetal doses of less than 100 mGy is not justified based upon radiation risk.

The restriction of a dose of 1 mSv to the embryo/fetus of pregnant worker after declaration of pregnancy does not mean that it is necessary for pregnant women to avoid work with radiation completely, or that she must be prevented from entering or working in designated radiation areas. It does, however, imply that the employer should carefully review the exposure conditions of pregnant women.

5.1. Patient exposure and pregnancy

(184) Medical exposure of a pregnant female presents a unique challenge to professionals because of the concern about the radiation risk to the fetus compared with the risk of not carrying out the procedure. Thousands of pregnant patients and radiation workers are exposed to ionising radiation each year. Lack of knowledge is responsible for great anxiety and probably unnecessary termination of pregnancies (ICRP, 2000). This section is focused on situations of known pregnancy as well as exposure in situations of unknown or undeclared pregnancy. The Commission has extensively covered this topic in Publication 84 (2000).

(185) The potential biological effects of in utero radiation exposure of a developing fetus include prenatal death, intrauterine growth restriction, small head size, mental retardation, organ malformation, and childhood cancer. The risk of each effect depends on the gestational age at the time of exposure, fetal cellular repair mechanisms, and the absorbed radiation dose level (ICRP, 2000; McCollough et al., 2007).

(186) It is unlikely that radiation from diagnostic radiological examinations will result in any known deleterious effects on the unborn child, but the possibility of a radiation-induced effect cannot be entirely ruled out. However, for invasive procedures , radiation dose to the fetus will vary and can be from a very small dose of little significance when the fetus is not in the primary beam, to a significant dose when the fetus lies in the primary beam or adjacent to the primary beam boundary. This requires prospective planning. Radiation risks are most significant during organogenesis and the early fetal period, somewhat less in the second trimester, and least in the third trimester (ICRP, 2000).

(187) As the Commission stated in the Publication 84 (2000), analysis of many of the epidemiological studies conducted on prenatal x-ray and childhood cancer are consistent with a relative risk of 1.4 (a 40% increase over the background risk) following a fetal dose of about 10 mGy. This is essentially equivalent to a risk of 1 cancer death per 1,700 children exposed in utero to 10 mGy (ICRP, 2000).

(188) Prenatal doses from most properly performed diagnostic procedures typically present no measurably increased risk of prenatal death, malformation, or impairment of mental development over the background incidence of these entities. Typical fetal doses from selected x-ray procedures are presented in Table 5.1.

(189) When the number of cells in the conceptus is small and their nature is not yet specialized, the effect of damage to these cells is most likely to take the form of failure to implant, or of an undetectable death of the conceptus; malformations are unlikely or very rare. Since organogenesis starts 3 to 5 weeks post-conception, it is felt that radiation exposure very

early in pregnancy couldn't result in malformation. The main risk is that of fetal death. It requires a fetal dose of more than 100 mGy for this to occur.

(190) Occasionally, a patient will not be aware of a pregnancy at the time of an x-ray examination, and will naturally be very concerned when the pregnancy becomes known. In such cases, the radiation dose to the fetus/conceptus should be estimated, but only by a medical physicist experienced in dosimetry. The patient can then be better advised as to the potential risks involved.

(191) When a pregnant patient requires an x-ray procedure, the indications should be evaluated to ensure justification. The procedure should then be optimized by strict adherence to good technique, as described in Section 3.

5.2. Guidelines for patients undergoing radiological examinations/procedures at child bearing age

(192) Prior to radiation exposure, female patients in the childbearing age group should be evaluated and an attempt made to determine who is or could be pregnant.

(193) Particular problems may be experienced in obtaining this information from females under the age of 16 years. There should be agreed procedures in place in all clinical imaging facilities to cover this and also to deal with unconscious patients and those with special needs (HPA, 2009). In addition, it should not be forgotten that pregnancy can occur in adolescent girls, thus precautions for this group should be followed for exposures which may involve a fetus. With this group, care and sensitivity must be exercised with regard to the circumstances in which they are asked the relevant questions both to respect their privacy and to optimize the possibility of being told the truth. With respect to pregnancy tests, many are of little value in excluding early pregnancy and generate a false sense of security.

(194) It is prudent to consider as pregnant any female of reproductive age presenting herself for an x-ray examination at a time when a menstrual period is overdue, or missed, unless there is information that precludes a pregnancy (e.g. hysterectomy or tubal ligation). In addition, every woman of reproductive age should be asked if she is, or could be, pregnant. In order to minimize the frequency of unintentional radiation exposures of the embryo and fetus, advisory notices should be posted at several places at areas where x-ray equipment is used.

Table 5.1. Typical fetal dose from x-ray examinations

Examination	Typical fetal dose (mGy)	Reference
Abdomen AP	2.9	(a)
Abdomen PA	1.3	(a)
Pelvis AP	3.3	(a)
Chest	<0.01	(b)
Lumbar spine (average for various projections)	4.2	(b)
Hip joint	0.9	(b)
IVP (4 images)	6	(c)
IVU	1.7-4.8	(d)
Small bowel study	7	(c)
Double contrast barium enema	7	(c)
Barium meal	1.5	(b)
Cholecystography	3.9	(b)
Abdominal CT, routine	4	(c)
Abdomen/pelvis CT, routine	25	(c)
Abdomen/pelvis CT, stone protocol	10	(c)
ERCP	3.5-56	(e)

Pelvimetry	0.1-1.0	(f)
Fluoroscopically assisted surgical treatment of hip	0.425	(g)
Sentinel lymph node biopsy	<0.1	(h)
Fluoroscopically assisted surgical treatments of spinal disorders	4 (conceptus outside the primary beam) 105 (conceptus in primary beam)	(i)
Transjugular intrahepatic portosystemic shunt	5.5	(j)

2463 (a)UNSCEAR, 2010; (b)Osei et al., 1999; (c)McCollough, et al., 2007; (d) ICRP, 2000; (e)Samara et al.,
2464 2009; (f)RPII, 2010; (g)Damilakis et al., 2003; (h)Pandit-Taskar et al., 2006; (i)Theocharopoulos et al.,
2465 2006; (j)Savage et al., 2007

(195) Since fetal doses are usually well below 50 mGy in x-ray procedures, pregnancy tests are not usually done. In cases where a high-dose fluoroscopy procedure of the abdomen or pelvis (e.g. embolization) is contemplated, depending on the patient reliability and history, the physician may want to order a pregnancy test (ICRP, 2000).

(196) If there is no possibility of pregnancy, the examination can be performed. If patient is definitely or probably pregnant, the justification for the proposed examination must be reviewed, and decision on whether to defer the investigation until after delivery must be made, bearing in mind that a procedure of clinical benefit to the mother may also be of indirect benefit to her unborn child and that delaying an essential procedure until later in pregnancy may present a greater risk to the fetus (HPA, 2009).

(197) When a patient has been determined to be pregnant or possibly pregnant, a number of steps are usually taken prior to performing the procedure, as described in Section 5.3.

5.3. Guidelines for patients known to be pregnant

(198) Medical exposure of pregnant women poses a different benefit/risk situation than most other medical exposures. In most medical exposures the benefit and risk are to the same individual. In the situation of in utero medical exposure there are two different entities (the mother and the fetus) that must be considered (ICRP, 2000).

(199) Medical radiation applications should be optimized to achieve the clinical purposes with no more radiation than is necessary, given the available resources and technology. If possible, for pregnant patients, the medical procedures should be tailored to reduce fetal dose. Prior to and after medical procedures involving high doses of radiation have been performed on pregnant patients, fetal dose and potential fetal risk should be estimated (ICRP, 2000).

(200) Termination of pregnancy at fetal doses of less than 100 mGy is not justified based upon radiation risk. At higher fetal doses, informed decisions should be made based upon individual circumstances (ICRP, 2000).

5.4. Occupational exposure and pregnancy

(201) It is the Commission's policy that methods of protection at work for women who are pregnant should provide a level of protection for the embryo/fetus broadly similar to that provided for members of the public. The Commission recommends that the working conditions of a pregnant worker, after declaration of pregnancy, should be such as to ensure that the additional dose to the embryo/fetus would not exceed about 1 mSv during the remainder of the pregnancy. The restriction of a dose of 1 mSv to the embryo/fetus of pregnant worker after declaration of pregnancy does not mean that it is necessary for pregnant women to avoid work with radiation completely, or that she must be prevented from entering or working in designated radiation areas. It does, however, imply that the employer should carefully review the exposure conditions of pregnant women. (ICRP, 2007a; ICRP 103).

(202) There are many situations in which the worker wishes to continue doing the same job, or the employer may depend on her to continue in the same job in order to maintain the level of patient care that the work unit is customarily able to provide. From a radiation protection point of view, this is perfectly acceptable providing the fetal dose can be reasonably accurately estimated and falls within the recommended limit of 1 mGy fetal dose after the pregnancy is declared. It would be reasonable to evaluate the work environment in order to provide assurance that high-dose accidents are unlikely (ICRP, 2000).

(203) The recommended dose limit applies to the fetal dose and it is not directly comparable to the dose measured on a personal dosimeter. A personal dosimeter worn by diagnostic radiology workers may overestimate fetal dose by about a factor of 10 or more. If the dosimeter has been worn outside a lead apron, the measured dose is likely to be about 100 times higher than the fetal dose. (ICRP, 2000).

(204) Finally, factors other than radiation exposure should be considered in evaluating pregnant workers' activities. In a medical setting there are often requirements for lifting patients and for stooping or bending below knee level. There are a number of national groups that have established non-radiation related guidelines for such activities at various stages of pregnancy (ICRP, 2000).

(205) The position of the Commission is that discrimination should be avoided based on radiation risks during pregnancy and if the pregnant woman prefers to continue her work in fluoroscopy guided procedures laboratories, this should be allowed with the following conditions: a) she should do it on a voluntary basis and confirm having understood the information on radiation risks provided, b) a specific dosimeter should be used at the level of the abdomen to monitor the dose to the fetus monthly and the worker should be informed of the dose values, c) a radiation protection programme should exist in the hospital or clinic and supervised by a medical physicist or equivalent competent expert, d) the worker should know the practical methods to reduce her occupational doses including the use of the existing radiation protection tools, e) the worker should try to control the workload in fluoroscopy guided procedures during her pregnancy and f) the worker should know the risk of potential exposures and how to reduce their probability. It should be noted that points d), e) and f) actually should be part of a radiation protection programme and point d) is applicable irrespective of pregnancy.

5.5. Procedures in children

(206) X-ray procedures in children involve a different spectrum of disease conditions specific to the very young child and some conditions common in the adult population. The data derived from UNSCEAR estimates suggest that in the region of 250 million paediatric radiological examinations (including dental) per annum were performed worldwide in the 1997 to 2007 period (UNSCEAR, 2010). Children undergoing these examinations require special attention both because of the diseases specific to childhood and the additional risks to them. In addition they also need special care, both in the form provided by parents and carers as well as that the additional care which should be provided by specially trained personnel.

(207) In the last decade and a half the special issues that arise in protecting children undergoing radiological examinations have come to the consciousness of a gradually widening group of concerned professionals and public (Sidhu et al, 2009, Strauss et al, 2010). There are many reasons for this, not least the natural instinct to protect children from unnecessary harm. There is also their known additional sensitivity to radiation damage, and potentially longer lifetime in which disease due to radiation damage may become manifest. Their sensitivity to cancer induction is considered to be a factor 3-5 higher than in adults (ICRP, 2007a).

(208) Children, particularly those with life-threatening disease in very early life, are at the greatest risk as a consequence of the substantial radiation doses they incur doing investigations. These children may subsequently develop leukaemia within a few years as a result of the irradiation of bone marrow, and breast cancer or thyroid cancer as a result of chest or neck irradiation (ICRP, 2000).

(209) Therefore, the justification and optimization principles are even more important when children are exposed to ionizing radiation (ICRP, 2007a). The Commission has recommended a multi-step approach to justification of the patient exposures in the Publication 105 (ICRP, 2007a; 2007b).Optimization of the examination in children should be both generic for the examination type and all the equipment and procedures involved. It should also be specific for the individual, to reduce doses for the particular paediatric patient.

(210) It is important that the equipment used for paediatric imaging is well designed and suited for the purpose for which it is applied. This is best ensured by having an appropriate procurement policy that includes rigorous specification of what is required and verification that this is what the supplier delivers. In addition it requires a good QC programme to ensure the equipment continues to be both functional and safe throughout its life.

5.5.1. Levels of radiation dose

(211) At present in the USA, the estimated proportion of fluoroscopy procedures performed on paediatric patients is about 15%, and it falls to less than 1 % in interventional procedures (NCRP, 2009). There is a lack of published information on patient dose levels for children undergoing x-ray procedures outside the radiology department. Therefore, in addition to examinations performed outside the radiology department, typical dose levels for patients of different ages undergoing radiological examinations are presented in Table 5.2 for the purpose of comparison. However, the introduction of new imaging technologies has in some instances resulted in increased use of paediatric imaging, influencing the age profile for the examinations performed (UNSCEAR, 2010).

(212) Data on paediatric doses are very difficult to analyse, because the height and weight of children is very dependent on age. In addition, it is inappropriate to use effective dose to quantify patient dose levels for paediatric and neonatal imaging. In order to compare centres, an agreement was reached within the European Union to collect data for five standard ages, i.e. for newborn, 1-year-old, 5-year-old, 10-year-old and 15-year-old children (UNSCEAR, 2010).

(213) The main issue following childhood exposure at typical diagnostic levels (a few to a few tens of mGy) is cancer induction. It should be emphasised that interventional procedures lead to higher doses to patients than conventional diagnostic investigations. The Commission has extensively covered this topic in the Publication 85 (2001).

(214) As a general principle, parents or family members should support the child during any radiological examination. The reported dose level for parents present in the room during x-ray examination of a child are typically 4-7 µSv (Mantovani et al., 2004).

Table 5.2. Patient dose level for various radiological examinations in children (UNSCEAR, 2010; Righi et al., 2008; Molina Lopez et al., 2008; Calama Santiago et al., 2008; Martinez et al., 2007).

Examination	**Age (years)**	**ESD (mGy)**	**DAP (mGy cm^2)**	**Effective dose (mSv)**
Abdomen PA	0	0.11	na	
	1	0.34	na	
	5	0.59	na	0.10-1.3
	10	0.86	na	
	15	2.0	na	
Chest AP/PA	0	0.06	na	
	1	0.080	na	
	5	0.11	na	0.005
	10	0.070	na	
	15	0.11	na	
Pelvis AP	0	0.17	na	
	1	0.35	na	
	5	0.51	na	na*
	10	0.65	na	
	15	1.30	na	
Skull AP	1	0.60	na	na*
	5	1.2	na	
Skull LAT	1	0.34	na	na*
	5	0.58	na	
MCU	0	na	430	
	1	na	810	
	5	na	940	0.8-4.6
	10	na	1640	
	15	na	3410	
Barium meal	0	na	760	
	1	na	1610	
	5	na	1620	na*
	10	na	3190	
	15	na	5670	
Cardiac interventions (various)	<1	46	19	2.1-12
Percutaneous treatment of varicocele	na	na	na	18
Biliary drainage with bilioplasty	1-3	35-50	1500-2300	0.9-1.5
Pieloureteral surgery	5	20	na	0.36 (per min fluoroscopy)
Varicocele embolization	14	250	60000	8.8

*not available

5.5.2. Radiation dose management

(215) All dose management actions described in Section 3, also apply for x-ray examinations of children. Examination parameters must be tailored to the child's body size. For children, dose reduction is achieved by using technical factors specific for

children and not using routine adult factors (Sidhu et al, 2009). Techniques to reduce patient dose are very much the same as for adult examinations and include: (a) no grids (b) collimation to the irradiation volume of interest only; (c) extra beam filtration (extra Al or Cu filters); (d) low pulsed fluoroscopy; (e) reducing magnification (f) large distance x-ray tube-patient and short distance patient-detector; (g) DSA and road-mapping techniques in fluoroscopy which can save contrast medium and patient dose. In x-ray procedures in children care should be taken to minimize the radiation beam to affect only the area of interest. Thus, collimation is even more important for children (Section 3.3.2). Always reduce the irradiation beam to the organ/organs of interest and nothing else to reduce the dose. With automatic brightness control used in the equipment this could result in a slightly higher dose within the field, but a lower effective dose and a better image quality.

(216) In the exposure of comforters and carers (parents holding a child during examination), dose constraints are applicable to limit inequity and because there is no further protection in the form of a dose limit (ICRP, 2007b). Parents must be provided with suitable radiation protection tools and be informed about the need of their protection prior to supporting their child during the examination.

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6. TRAINING

A training programme in radiological protection for healthcare professionals has to be oriented towards the type of practice the target audience is involved in.

A staff member's competency to carry out a particular function should be assessed by those who are themselves suitably competent.

(217) The main purpose of training is to make a qualitative change in practice that helps operators use radiation protection principles, tools and techniques to reduce one's own exposure without cutting down on work and to reduce patient's exposure without compromising on image quality or intended clinical purpose. The focus has to remain on achievement of skills. Unfortunately, in many situations it takes the form of complying with requirements of number of hours. While number of hours is an important way to provide a yardstick, actual demonstration of skills to reduce staff and patient exposure is an essential part. A staff member's competency to carry out a particular function should be assessed by those who are themselves suitably competent. Further, in large part of the world, clinical professionals engaged in fluoroscopy outside the radiology department have either no or inadequate training. The Commission has recommended that the levels of education and training should be commensurate with the level of usage of radiation (ICRP, 2011).

(218) The issue of delivery of training has been dealt with in a recent publication (ICRP, 2011) and the text has been drawn from this publication.

6.1. Curriculum

(219) Conventional training programmes utilize a structure that is curriculum based. There is a fundamental difference between training methodologies employed in non-medical subjects and in medical or rather clinical ones. While much of the training in sciences such as physics or biology is based on knowledge transmission, there is much greater emphasis in clinical training on imparting skills to solve day-to-day problems. A training programme in radiological protection for healthcare professionals has to be oriented towards the type of practice in which the target audience is involved. Lectures should deal with essential background knowledge and advice on practical situations, and the presentations should be tailored to clinical situations to impart skills in the appropriate context. Practical training should be in a similar environment to the one in which the participants will be practising and provide the knowledge and skills required for performing clinical procedures. It should deal with the full range of issues that the trainees are likely to encounter (ICRP, 2011). For further details please refer to ICRP Publication 113 (ICRP, 2011).

6.2. Who should be the trainer?

(220) The primary trainer in radiation protection should normally be a person who is an expert in radiation protection in the practice with which he or she is dealing

(normally a medical physicist). That means a person having knowledge about the clinical practice in the use of radiation, the nature of radiation, the way it is measured, how it interacts with the tissues, what kind of effects it can lead to, principles and philosophies of radiation protection, and international and national guidelines. Since radiation protection is covered by legislation in almost all countries of the world, awareness about national legislations and the responsibilities of individuals and organizations is essential (ICRP, 2011).

(221) The radiation protection trainer, in many situations, may lack the knowledge of practicalities and thus talk from an unrealistic standpoint relating to idealised or irrelevant situations. The foremost point in any successful training is that the trainer should have a clear perception about the practicalities in the work that the training has to cover. It should deal with what people can practice in their day to day work. Many trainers in radiation protection cannot resist the temptation of dealing with basic topics such as radiation units, interaction of radiation with matter, and even structure of the atom and atomic radiations in more depth than is appropriate. Such basic topics while being essential in educational programmes should be dealt with only to a level such that they make sense. A successful trainer will not be ego-centric about definitions which are purely for academic purposes but will be guided by the utility of the information to the audience. The same applies to regulatory requirements. The trainer should speak the language of users to convey the necessary information without compromising on the science and regulatory requirements. Health professionals who use radiation in day-to-day work in hospitals and impart the radiation dose to patients have knowledge about practical problems in dealing with patients who may be very sick. They understand problems with the radiation equipment they deal with, the constraints of time they have in dealing with large numbers of patients and the lack of radiation measuring and radiation protection tools. Inclusion of lectures from practising clinicians in courses to dwell on good and bad practice of radiation protection is strongly recommended. It may be useful for the radiation protection trainer to be on hand during such lectures to comment and discuss any issues raised (ICRP, 2011).

6.3. How much training?

(222) Most people and organizations follow the relatively easy route of prescribing the number of hours. The Commission gives some recommendations on the number of hours of education and training which should act as a simple guideline rather than be applied rigidly (ICRP, 2011). This has advantages in terms of implementation of training and monitoring the training activity, but is only a guide.

(223) The issue of how much training is given should be linked with the evaluation methodology. One has to be mindful about the educational objectives of the training, i.e. acquiring knowledge and skills. Many programmes are confined to providing training without assessing the achievement of the objectives. Although some programmes have pre and post training evaluations to assess the knowledge gained, fewer training programmes assess the acquisition of practical skills. Using modern methodologies of online examination, results can be determined instantaneously. It may be appropriate to encourage development of questionnaire and examination systems that assess the

knowledge and skills, rather than prescribing the number of hours of training. Because of the magnitude of the requirement for radiation protection training, it may be worthwhile for organizations to develop online evaluation systems. The Commission is aware that such online methods are currently available mainly from organizations that deal with large scale examinations. The development of self-assessment examination systems is encouraged to allow trainees to use them in the comfort of the home, on a home PC or anywhere where the internet is available. The Commission recommends that evaluation should have an important place (ICRP, 2011).

(224) The amount of training depends upon the level of radiation employed in the work and the probability of occurrence of over-exposures either to the patient or to staff. For example radiotherapy employs delivery of several gray (Gy) of radiation per patient and a few tens of gray each day to groups of patients. Interventional procedures could also deliver skin doses in the range of a few gray to specific patients. The level of radiation employed in radiography practice is much lower than the above two examples and also the probability of significant over-exposure is lower, unless a wrong patient or wrong body part is irradiated. The radiation doses to patients from CT examinations are also relatively high and thus the need for radiation protection is correspondingly greater. Another factor that should be taken into account is the number of times a procedure such as CT may be repeated on the same patient.

(225) The training given to other medical specialists such as vascular surgeons, urologists, endoscopists and orthopaedic surgeons before they direct fluoroscopically guided invasive techniques is significantly less or rather absent in many countries. Radiation protection training is recommended for physicians involved in the delivery of a narrow range of nuclear medicine tests relating to their specialty.

6.4. Recommendations

(226) Training for healthcare professionals in radiation protection should be related to their specific jobs and roles.

(227) The physicians and other health professionals involved in procedures that irradiate patients should always be trained in the principles of radiation protection, including the basic principles of physics and biology (ICRP, 2007a).

(228) The final responsibility for radiation exposure lies with the physician providing the justification for the exposure being carried out, who should therefore be aware of the risks and benefits of the procedures involved (ICRP, 2007b).

(229) Education and training, appropriate to the role of each category of physician, should be given at medical schools, during residency and in focused specific courses. There should be an evaluation of the training, and appropriate recognition that the individual has successfully completed the training. In addition, there should be corresponding radiation protection training requirements for other clinical personnel that participate in the conduct of procedures utilizing ionizing radiation or in the care of patients undergoing diagnosis or treatment with ionizing radiation (ICRP, 2007b).

(230) Scientific and professional societies should contribute to the development of the syllabuses, and to the promotion and support of the education and training. Scientific congresses should include refresher courses on radiation protection, attendance at which could be a requirement for continuing professional development for professionals using ionizing radiation.

(231) Professionals involved more directly in the use of ionizing radiation should receive education and training in radiation protection at the start of their career, and the education process should continue throughout their professional life as the collective knowledge of the subject develops. It should include specific training on related radiation protection aspects as new equipment or techniques are introduced into a centre.

6.5. References, Chapter 6

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7. RECOMMENDATIONS

(232) There is a need to rectify the neglect of radiation protection coverage to facilities outside the control of radiology departments

(233) There is high radiation risk to staff and patients in fluoroscopy facilities outside the imaging departments primarily owing to the lack of training of staff in radiation protection in many countries,

(234) There are a number of procedures, such as endovascular aneurysm repair (EVAR), renal angioplasty, iliac angioplasty, ureteric stent placement, therapeutic endoscopic retrograde cholangio-pancreatography (ERCP) and bile duct stenting and drainage, that involve radiation levels exceeding the threshold for skin injuries. If due attention is not given, radiation injuries to patients are likely occur in the future.

(235) Many patients require regular and repeated radiation exposure for many years and quite a few even for life. In some cases the effective dose for each year of follow up has been estimated to be a few tens of mSv. This unfortunately has largely not received the attention it needs. The Commission recommends that urgent attention be given to application of justification and optimization to achieve lowest exposure consistent with desired clinical outcomes.

(236) Staff should be familiar with the radiation dose quantities used in fluoroscopy equipment to represent patient dose.

(237) Modern sophisticated equipment requires understanding of features that have implications for patient dose and how patient dose can be managed.

(238) For fluoroscopy machines in operating theatres, there are specific problems that make the use of radiation shielding screens for staff protection more difficult but not impossible and such staff protection measures should be used.

(239) Manufacturers should develop shielding screens that can be effectively used for protection of staff using fluoroscopy machines in operating theatres without hindering the clinical task.

(240) Manufacturers should develop systems to indicate patient dose indices with the possibility to produce patient dose reports that can be transferred to the hospital network.

(241) Manufacturers are encouraged to develop devices that provide representative staff doses without the need for extensive cooperation of staff.

(242) Health professionals involved in procedures that irradiate patients should always be trained in radiation protection. The Commission recommends a level of training in radiological protection commensurate with radiation usage.

(243) Medical professionals should be aware about their responsibilities as set out in regulations.

(244) Scientific and professional societies should contribute to the development of training syllabuses, and to the promotion and support of education and training. Scientific congresses should include refresher courses on radiation protection, attendance at which could be a requirement for continuing professional development for professionals using ionizing radiation.

ANNEX A. DOSE QUANTITIES AND UNITS

(A 1) Dosimetric quantities are needed to assess radiation exposures to humans in a quantitative way. This is necessary in order to describe dose–response relationships for radiation effects which provide the basis for setting protection standards as well as for quantification of exposure levels.

(A 2) Absorbed dose in tissue is the energy absorbed per unit mass in a body tissue. The unit of absorbed dose is joule per kilogram (Jkg-1) whose special name is gray (Gy). Although gray is not an SI unit, it is used as a unit in practice: 1 Jkg-1 = 1Gy. It is assumed that the mean value of absorbed dose in an organ or tissue is correlated with radiation detriment from stochastic effects in the low dose range. The averaging of absorbed doses in tissues and organs of the human body and their weighted derivatives are the basis for the definition of protection quantities.

(A 3) The protection quantities are used for risk assessment and risk management to ensure that the occurrence of stochastic health effects is kept below unacceptable levels and tissue reactions (deterministic effects) are avoided. The average absorbed dose to an organ or tissue is called organ absorbed dose or simply organ dose.

(A 4) The equivalent dose to an organ or tissue is the organ dose modified by a radiation weighting factor that takes account of the relative biological effectiveness of the radiation relevant to the exposure. This radiation weighting factor is numerically 1 for x-rays. The equivalent dose has the same SI unit as that of absorbed dose, but it is called Sievert (Sv) to distinguish between them.

(A 5) For medical exposures, the assessment of stochastic risk is complex as more than one organ is irradiated. The Commission has introduced the quantity effective dose, as a weighted sum of equivalent doses to all relevant tissues and organs, intended to indicate the combination of different doses to several different tissues in a way that is likely to correlate well with the total of the stochastic effects. This is therefore applicable even if the absorbed dose distribution over the human body is not homogeneous. The effective dose has the same unit and special name as those of equivalent dose; i.e. Jkg-1 and Sv.

(A 6) While absorbed dose in a specified tissue is a physical quantity, the equivalent dose and effective dose include weighting factors which are based on radiobiological and epidemiological findings. The main and primary use of effective dose is to provide a means of demonstrating compliance with dose limits in occupational and public exposures. In this sense effective dose is used for regulatory purposes worldwide. Effective dose is used to limit the occurrence of stochastic effects (cancer and heritable effects) and is not applicable to the assessment of the possibility of tissue reactions (deterministic effects).

(A 7) The use of effective dose for assessing the exposure of patients has severe limitations that must be taken into account by medical professionals. Effective dose can be of value for comparing doses from different diagnostic procedures, in a few special cases from therapeutic procedures and for comparing the use of similar technologies and procedures in different hospitals and countries as well as using different technologies for the same medical examination. For planning the exposure of patients and risk-benefit assessments, however, the equivalent dose or preferably the absorbed dose to irradiated tissues is the more relevant quantity. This is especially the case when risk estimates are intended (ICRP, 2007).

(A 8) Collective dose is a measure of the total amount of effective dose multiplied by the size of the exposed population. Collective dose is usually expressed in terms of person-Sieverts.

A.1. Quantities for assessment of patient doses

(A 9) Air kerma (kinetic energy released in a mass) is the sum of the initial kinetic energies of all electrons released by the x-ray photons per unit mass of air. For the photon energies utilized in x-ray procedures, the air kerma is numerically equal to the absorbed dose free in air. The unit of air kerma is joules per kilogram (J kg–1), which is also called gray (Gy) (ICRU, 2005; IAEA, 2007).

(A 10) A number of earlier publications have expressed measurements in terms of the absorbed dose to air. Recent publications point out the experimental difficulty in determining the absorbed dose to air, especially in the vicinity of an interface; in reality, what the dosimetry equipment registers is not the energy absorbed from the radiation by the air, but the energy transferred by the radiation to the charged particles resulting from the ionization. For these reasons, ICRU (2005) recommend the use of air kerma rather than absorbed dose to air, that applies to quantities determined in air, such as the entrance surface air kerma (rather than entrance surface air dose) and the kerma area product (rather than dose–area product).

(A 11) In diagnostic radiology, the incident air kerma (Ka,i) is frequently used. It is the air kerma from the incident beam on the central x-ray beam axis at focal spot-to-skin distance, i.e. at skin entrance plane. Incident air kerma can be calculated from the x-ray tube output, where output is measured using a calibrated ionizing chamber (ICRU, 2005).

(A 12) Entrance surface air kerma (Ka,e) is the air kerma on the central x-ray beam axis at the point where x-ray beam enters the patient. The contribution of backscatter radiation is included trough backscatter factor (B), thus: $K_{i,e} = K_{i,a} \cdot B$. The backscatter factor depends on the x-ray spectrum, the x-ray field size, and the thickness and composition of the patient or phantom. Typical values of backscatter factor in diagnostic and interventional radiology are in the range 1.2-1.6 (ICRU, 2005). The unit for entrance surface air kerma is the gray (Gy). Entrance surface air kerma can be calculated from incident air kerma using suitable backscatter factor or directly determined using small dosimeters (thermoluminescent or semiconductor) positioned at the representative point on the skin of the patients.

(A 13) Incident air kerma and entrance surface air kerma are recommended quantities for establishment of Diagnostic Reference Levels (DRL) in projection radiography or to assess maximal skin dose in interventional procedures (ICRU, 2005).

(A 14) The incident and entrance surface air kerma do not provide information on extend of the x-ray beam. However, the air kerma–area product (PKA), as product of the air kerma and area A of the x-ray beam in a plane perpendicular to the beam axis, provides such information.

(A 15) The common unit for air kerma–area product is Gy·cm2. The PKA has the useful property of being approximately invariant with distance from the x-ray tube focal spot. It can be measured in any plane between x-ray source and the patient using specially designed transparent ionizing chambers mounted at the collimator system or, in digital systems, calculated using data of the generator and the digitally recorded jaw position (ICRP, 2001). Air kerma-area product is recommended quantity for establishment of DRL in conventional radiography and complex procedures including fluoroscopy. It is helpful in dose control for stochastic effects to patients and operators (ICRP, 2001).

(A 16) In radiology it is common practice to measure a radiation dose quantity that is then converted into organ doses and effective dose by means of conversion coefficients. These coefficients are defined as the ratio of the dose to a specified tissue or effective dose divided by the normalization quantity. Incident air kerma, entrance surface air kerma and kerma-area product can be used as normalization quantities. Conversion coefficients to convert air kerma-area product to effective dose for selected procedures are given in Table A.1.

Table A.1. Conversion coefficients to convert air kerma-area product to effective dose for adults in selected x-ray procedures (NCRP, 2009; EU, 2008; HPA, 2010)

Group	Examination	Conversion coefficient [mSv (Gy cm^2)$^{-1}$] (NCRP, 2009)	Conversion coefficient [mSv (Gy cm^2)$^{-1}$] (EU, 2008)	Conversion coefficient [mSv (Gy cm^2)$^{-1}$] (HPA, 2010)	Conversion coefficient [mSv mGy $^{-1}$] (HPA, 2010)
Urinary and renal studies	Cystography	0.18			
	Excretion urography, micturating cysto-urethrogram	0.18			
	Antegrade pyelography	0.18			
	Nephrostogram	0.18			
	Retrograde pyelogram	0.18			
	IVU		0.18		
Endoscopic retrograde cholangiopancreatography		0.26			
Orthopaedics and joints		0.01			
	Femur AP			0.036	0.023
	Femur LAT			0.0034	0.002
	Knee AP			0.0034	0.001
	Knee LAT			0.003	0.001
	Foot (dorsi-plantar)			0.0032	0.001
	Foot (oblique)			0.0032	0.001
Obstetrics and gynaecology	Pelvimetry	0.29			
	Hysterosalpingogram	0.29			
Renal	Retrograde pyelogram	0.18			
	Nephrostogram	0.18			
Barium meal			0.2		
Barium enema			0.28		
Barium follow			0.22		
Cardiac angiography			0.2		
Percutaneous transluminal angioplasty (PTA)		0.26			

Stents	Renal/visceral PTA (all) with stent; Iliac PTA (all) with stent; Bile duct, dilation and stenting	0.26			
Radiography	Chest (PA+LAT) low kVp		0.10		
	Chest (PA+LAT) high kVp		0.18	0.158/0.125	0.131/0.090
	Thoracic spine		0.19	0.244/0.093	0.094/0.031
	Lumbar spine		0.21	0.224/0.092	0.116/0.027
	Abdomen		0.26	0.180	0.132
	Pelvis		0.29	0.139	0.099
	Hip		0.29	0.13	0.064
Skeletal survey	Average of arms, legs, skull LAT, lumbar spine LAT, chest AP, abdomen/pelvis AP			0.09	
Whole spine/scoliosis	Average of thoracic and lumbar spine AP			0.22	
	Average of cervical, thoracic and lumbar spine (AP+lateral)			0.16	

A.2.Quantities for staff dose assessment

(A 17) Dose limits for occupational exposures are expressed in equivalent doses for tissue reactions (deterministic effects) in specific tissues, and expressed as effective dose for stochastic effects throughout the body. When used for tissue reactions (deterministic effects), equivalent dose is an indicator of weather threshold for the tissue reaction (deterministic effect) is being approached.

(A 18) Occupational dose limits are recommended by the Commission (ICRP, 1991; ICRP, 2007) for stochastic effects (dose limits for effective dose) and tissue reactions (dose limits for equivalent dose to the relevant tissue). As presented in Table 2.1., dose limits are given in mSv (millisievert). For x-ray energies in diagnostic and interventional procedures, the numerical value of the absorbed dose in mGy is essentially equal to the numerical value of the equivalent dose in mSv.

(A 19) The main radiation source for the staff is the patient's body, which scatters radiation in all directions during fluoroscopy and radiography. The personal dosimeter should be worn and determined dose will be used as a substitute for the effective dose. To monitor doses to the skin, hands and feet, and the lens of the eyes, special dosimeters (e.g. ring dosimeter) should be used (ICRP, 2001). The instruments used for dose measurement are commonly calibrated in terms of operational quantities, defined for practical measurement and assessment of effective and equivalent dose (ICRU, 1993).

A.3. References, Annex

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