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"Medical Overexposures"

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Working Party on Research Implications on Health and Safety Standards of the Article 31 Group of experts

Directorate-General for Energy and Transport
Directorate H — Nuclear Energy
Unit H.4 — Radiation Protection
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FOREWORD

Luxembourg, December 2008

Under the terms of the Treaty establishing the European Atomic Energy Community, the Community, amongst other things, establishes uniform safety standards to protect the health of workers and of the general public against the dangers arising from ionizing radiation. The standards are approved by the Council, on a proposal from the Commission, established taking into account the opinion of the Group of Experts referred to in Article 31 of the Treaty. The most recent version of such standards is contained in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

The European Commission organises every year, in cooperation with the Group of Experts referred to in Article 31 of the Euratom Treaty, a Scientific Seminar on emerging issues in Radiation Protection – generally addressing new research findings with potential policy and/or regulatory implications. Leading scientists are invited to present the status of scientific knowledge in the selected topic. Based on the outcome of the Scientific Seminar, the Group of Experts referred to in Article 31 of the Euratom Treaty may recommend research, regulatory or legislative initiatives. The European Commission takes into account the conclusions of the Experts when setting up its radiation protection programme. The Experts' conclusions are valuable input to the process of reviewing and potentially revising European radiation protection legislation.

In 2003, the Scientific Seminar discussed "Medical Overexposures". Two scientists working in the medical exposure area reported on occupational overexposure in the medical field and on potential added risks from new technology in medicine.

The Group of Experts discussed this information and drew conclusions that are relevant for consideration by the European Commission and other international bodies.

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CONTENTS

1 INTRODUCTION

Under the terms of the EURATOM Treaty, the European Union has established uniform safety standards to protect the health of workers and of the public against the dangers arising from ionising radiation. Standards are approved by the Council, on a proposal from the Commission after it has obtained the opinion of the Group of experts referred to in Article 31 of the Treaty. Community radiation protection action in the medical field is based on two Council Directives:

- Directive 96/29/Euratom, of 13 May 1996, laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (European Basic Safety Standards); and
- Directive 97/43/Euratom of 30 June 1997, on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (Medical Exposures Directive).

Medical uses of ionising radiation have been identified as one of the key sectors where significant radiation-related challenges will need to be dealt with in a short and long-term perspective. No exposure to X-rays can be considered completely free of risk, so that the use of radiation for medical diagnosis and treatment implies a responsibility to ensure the appropriate protection.

The European Commission organises every year in co-operation with the Group of experts referred to in Article 31 of the Euratom Treaty a scientific seminar to discuss a particular topic of radiation protection suggested by the Group.

The aim of the present Seminar on Medical Overexposures was two-fold:

- to overview occupational and patient overexposures in the medical field, focusing on procedures more frequently or likely involved, and giving indications for preventive and research actions;
- and to review the potential added risks from new technology in medicine and its possible implications for radiation protection.

The presentations in the seminar described how important new applications of ionising radiation and radioactive materials for medical diagnosis and treatment have been evolving, and how the health benefits have greatly exceeded the risks. New techniques using non-ionising radiation for diagnosis and treatment have been developed and have eliminated some of the previous uses of ionising radiation in health care.

There is a variety of disciplines and stakeholders involved in radiation protection for medical exposures. According to the complexity of the procedure, multidisciplinary teamwork may be necessary to justify practices and individual exposures, to optimise protection, to minimise risks, and to prevent the occurrence of potential incidents and accidents.

Programmes on education and training in radiation protection for medical exposures have the potential not only to improve occupational safety for the personnel but also to reduce the inappropriate use of radiological practices.

The Commission has a role to play in the harmonisation of education and training requirements in the field of radiation protection for medical exposures in order to guarantee a high level of health protection for patients, public and workers.

The correct implementation of regulatory requirements with the help of recommendations and guidance is necessary to face the challenges ahead. Safety issues and radiation protection aspects need to be considered as an essential component of any medical radiological practice.

2 OCCUPATIONAL OVEREXPOSURES IN MEDICAL FIELD

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Abstract

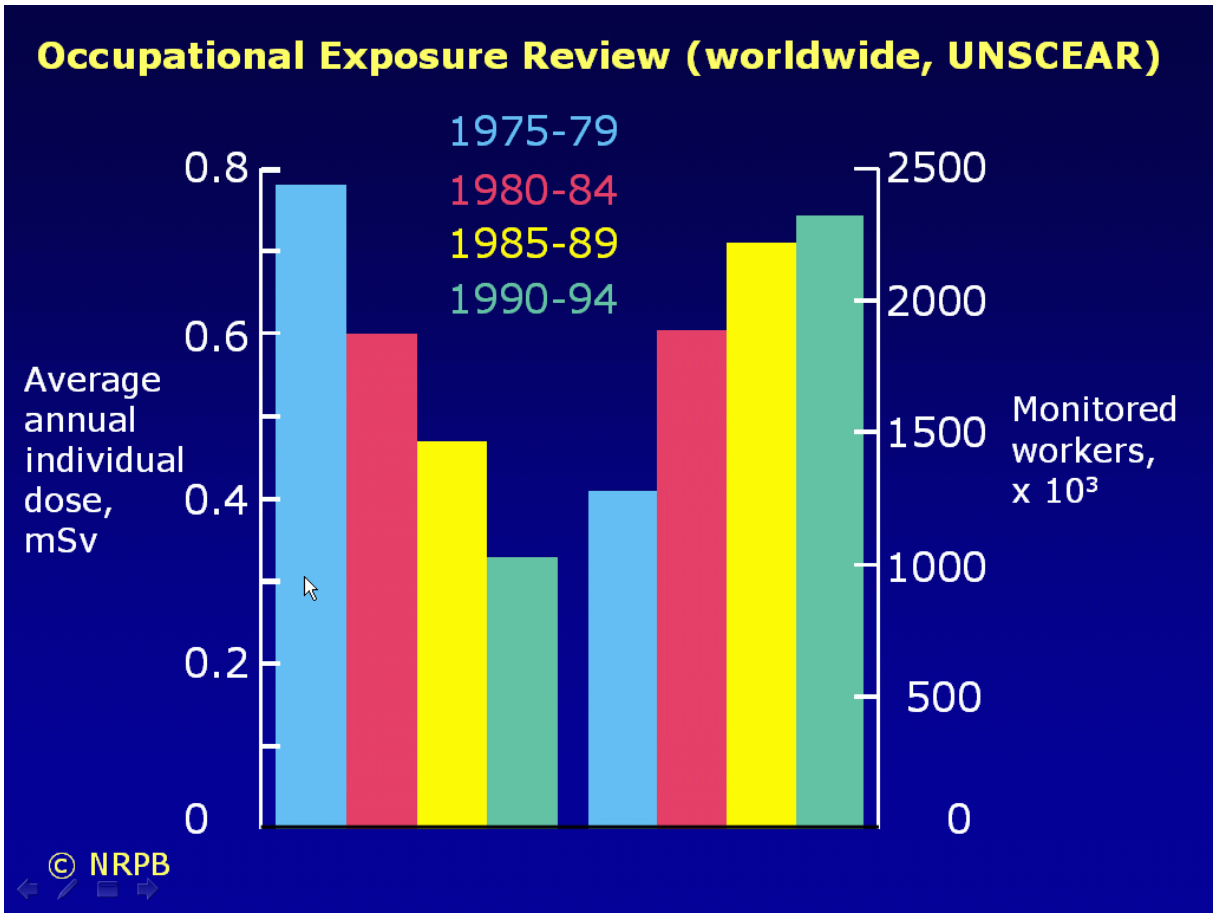
Only a few years after W.C. Roentgen's fundamental discovery of the X-rays, physicists and physicians/radiologists were already aware of the potential deterministic risks of this powerful medical tool. Overexposures and injuries have been described for patients as well as for occupational exposed persons.
Today IAEA reports worldwide 2,500 million diagnostic radiology examinations, 32 million nuclear medicine examinations or therapy procedures and 5.5 million radiotherapy procedures per year are performed on a high level of safety for patients and medical staff.
Despite all precautions, avoidable incidents and accidents occur worldwide every year with low frequency.
Whereas diagnostic radiology is generally safe for patients and staff, interventional procedures (e.g. coronary dilatations) involve the risk of occupational overexposure and skin injuries of patients.
In nuclear medicine, radiation protection is focused for example on the introduction of new procedures with ß-emitters. These isotopes, like Y-90, Re-186 or Er-169, are the sources of reported high ß-doserates of the forearms and fingers of medical specialists during administration. In addition, ß-dosimetry of these procedures is difficult and appropriate dosimeters are not available or expensive. The increasing frequency of examinations with positron emitters (PET) with photons of 511 keV requires a special focus on shielding measures.
In radiotherapy, occupational overexposures are rare. Non optimised treatments due to over- or underexposures often arise from systematic or technical errors and hence in many cases they are harmful to a group of patients. Important accidents with over irradiation of patients have been reported in the scientific literature. The conclusion from most of the analysed incidents and accidents is, that they could have been avoided by simulation and training of critical events.

2.1 Introduction

A short time after the introduction of X-rays into medicine, first deterministic effects with skin injuries have been reported [Groedel 1925]. In the succeeding years erythemas, skin-ulcers, cancers and even fatal outcomes (death) were observed [Koenig 2001]. Today, the use of ionising radiation in medicine can be considered as safe for patients as well as for occupational exposed workers. A worldwide review of UNSCEAR on occupational exposure for all applications of ionising radiation between 1975 and 1994 shows an increase of monitored workers of nearly 100% but a decrease of the effective annual dose from 0.8 mSv to 0.3 mSv (Fig. 1).

A survey of the current situation was given at the 6th European ALARA Network Workshop in Madrid 2002 [Lefaure 2003]. The relative level of occupational exposure in medicine depends on the degree of medical care and shows a wide variation between different countries in Europe and worldwide.

Figure 1 UNSCEAR review of monitored workers worldwide between 1975 and 1994 annual individual dose



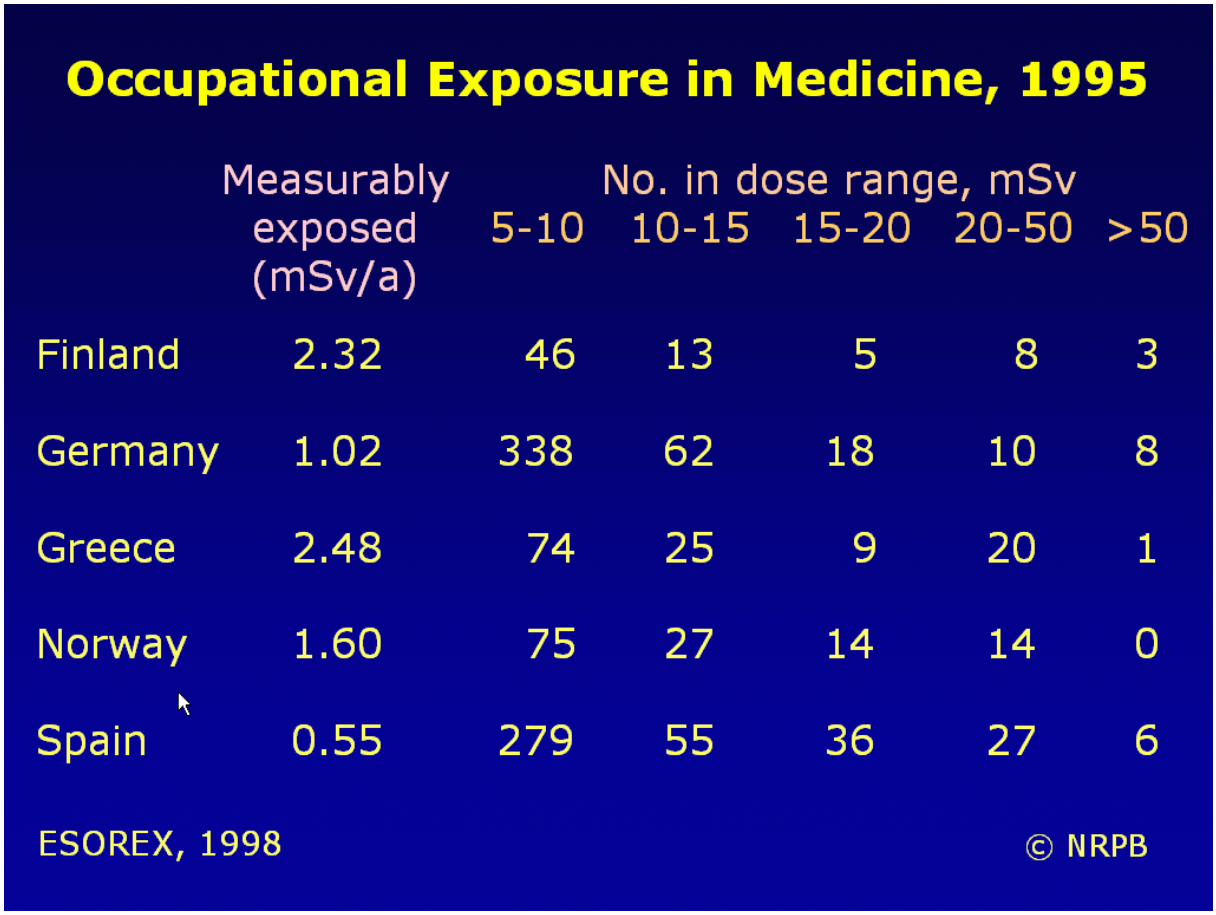
The dose limits of occupational exposure according to the Basic Safety Standards [EC 1996], laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation) are:

- 20 mSv/y averaged over 5 years
- 50 mSv in a single year
- 150 mSv/y to the lens of the eye
- 500 mSv/y to extremities (hand, feet) or skin

Today the risk of an occupational exposed individual to exceed these dose limits is very low. The BfS (Bundesamt für Strahlenschutz) in Germany monitored 313,062 occupationally radiation exposed workers in 2002. 99.41% of these workers had annual individual doses < 5 mSv, 0.48% >= 5 mSv, 0.005% between 20 and 50 mSv and only 0.001% > 50 mSv [Frasch 2004]. Similar data have been compiled by NRPB (Fig. 2) [Lefaure 2003].

An analysis in France [OPRI 1999] demonstrates that by far the highest number of monitored workers (without nuclear industry) comes from radiology (53%) followed by dental radiology (15%), radiotherapy (5%), nuclear medicine (2%) and others (25%). 96% of these monitored workers received annual occupational exposures below 1 mSv. Nevertheless, in other countries / continents these doses are sometimes much higher. UNSCEAR reports [UNSCEAR 2000] annual occupational exposures of > 3 mSv in Latin America and > 4 mSv in non classified “other” countries (Fig. 3).

Figure 2: Occupational exposure in Medicine in Europe 1995



This paper will address three main topics:

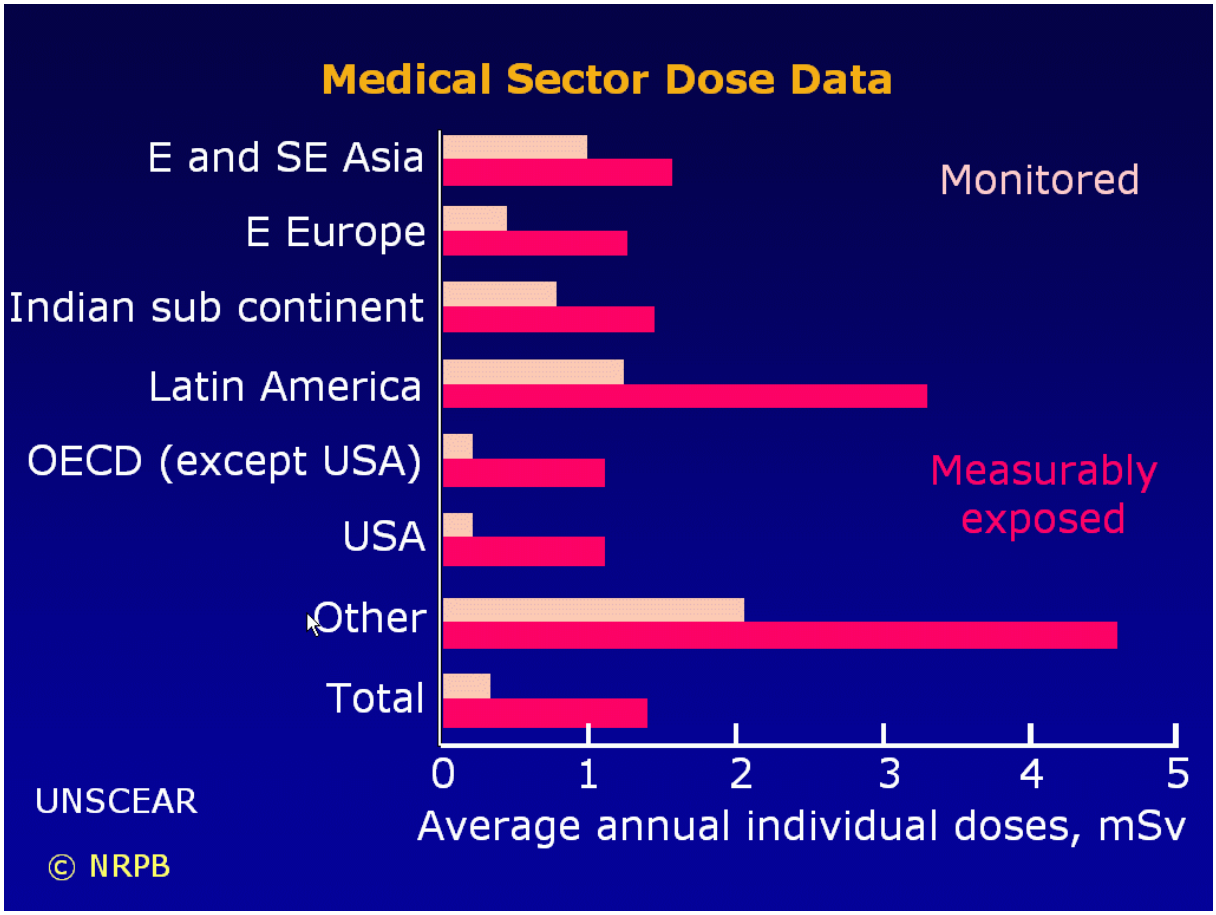
a) give few typical examples of cases with occupational overexposure in interventional radiology, nuclear medicine and radiotherapy;
b) give a survey of applications of ionising radiation in medicine where an increased risk of occupational overexposure is known;
c) focus on possible actions to minimize these risks.

2.2 Three examples of occupational overexposures in medicine

a) In interventional radiology endovascular procedures in radiology and cardiology are performed with high frequencies. At the 6th European ALARA workshop Widmark et.al. [Widmark 2003] presented measurements of occupational doses during endovascular treatment of abdominal aortic aneurysms. The average finger dose of 6 surgeons and 8 radiologists was determined with TLD's. One conclusion of the study was: "Poor working technique, however, can have the potential to cause finger doses exceeding the yearly dose limit on 500 mSv to extremities". This observation is generally valid for all fluoroscopic interventions where the entrance of the catheter into the patients body is close to the radiation field. Other cases reported by Vaño et al. [Vaño 1998-1] show ophthalmologically confirmed lens injuries, occurred in X-ray rooms devoted to vascular and visceral interventional radiology procedures. Laboratories were equipped with overcouch X-ray systems not designed for interventional radiology and without specific tools for radiation protection of the eyes.

Estimates for the dose to eye lens ranged from 450 to 900 mSv per year, over several years.

Figure 3: Occupational exposure in medicine for different countries / continents



b) In nuclear medicine [Tosi 2003] reported an accident in a department where radioimmunotherapy with monoclonal antibodies and/or peptides was performed. 90Y (maximum ß-energy 2.27 MeV) was used with a concentration up to 150 GBq/ml. The operator held the vial not with the special pliers, but directly with his hand, protected only with a very thin glove in lead rubber (0.1 mm Pb equivalent) covered by a disposable glove. After a few days finger erythemas were observed. Film badges, TLD finger ring dosimeter and urine activity were normal. The estimated dose to parts of the fingers (based on the energy of the ß-particles, the attenuation produced by the glass of the vial and the gloves and the referred total time of manipulation) was 12 Gy.

c) In radiotherapy Vuolo et.al. [Vuolo 2003] reported about three accidents that occurred in a cobalt therapy centre in Italy. In all three cases the cobalt source went not into the correct storage position. In one case the personal dosimeter measured 54 mSv, the maximum dose was estimated to be less than 0.1 Gy. The conclusion of these accidents was: “The relatively low frequency of these accidents is such that the personnel does not know how to properly respond and to come to a conclusion with the reported accidents we want to highlight the importance of having specific training for operators together with simulation of emergency procedures”.

2.3 Occupational overexposures in medicine

The risk and frequency of occupational radiation overexposures (incidents and accidents) in medicine depends on the different applications of ionising radiation. Main applications are:

- Diagnostic Radiology
- Interventional Radiology
- Diagnostic nuclear medicine
- Therapy in nuclear medicine
- Radiotherapy with external sources (Co-60 or accelerators)
- Radiotherapy with internal sources (brachytherapy)

2.3.1 Diagnostic Radiology

In diagnostic radiology occupational doses and the risk of an overexposures in general is very low. Most radiographic images with film/screen or digital systems are performed with the staff being outside the x-ray room. Only a low frequency of examinations at the bedside, in operating rooms and with assistance in the x-ray room may cause low detectable annual doses.

Diagnostic Computer Tomography (CT) and nearly all CT-interventions do not require an assistance in the scanner room. Only few CT examinations with general anaesthesia of the patient or a minor number of interventions with CT-fluoroscopy require physicians to be directly at the CT-scanner. CT-fluoroscopy interventions may cause significant doses of fingers, hand or forearm if catheters, biopsy needles or other tools are held by hand inside of the CT-gantry.

Diagnostic fluoroscopic examinations with image intensifiers or new dynamic digital flat panel detectors are either performed with remote controlled systems (most of these x-ray systems have over table x-ray tubes) or with direct patient control by the radiologist at the x-ray system (normally under table x-ray tubes). The first examination technique, which causes no staff exposure, is not applicable for many types of examinations or old immobile patients. If, by any reason, the radiologist has to be inside the x-ray room directly at the patient, due to scattered radiation high doses can be achieved. The second examination technique requires radiation protection measures for radiologist and staff like aprons, lead-glass shielding, thyroid protection collars or lead goggles. Typical applications are fluoroscopic examinations of oesophagus, stomach, small bowel, colon, lung and bony structures. Diagnostic examinations of blood vessels are performed with digital subtraction angiography (DSA). Typical fluoroscopy times of all the above mentioned examinations are between few minutes and less than 30 minutes.

2.3.2 Interventional Radiology

Radiation protection principles in interventional radiology are similar to diagnostic fluoroscopy. The main reason for significant higher occupational doses is the longer fluoroscopy time which, in some cases, may exceed 1 or 2 hours [SSK 1997] [Vaño 1998-2]. Due to the lower dose rate of scattered radiation at eyes, head and neck of the investigator, systems with under table x-ray tube are mandatory. Fig. 4 shows that with under table tube position the dose rate of eyes, head and neck can be reduced significantly.

If horizontal or oblique projections are used, the investigator should stand at the image intensifier side of the C-arm if possible. The dose ratio of stray radiation between tube side and image intensifier side is about 10:1. Fig. 5 shows the dose distribution and isodose curves around a C-arm.

Additional mechanisms to control the occupational and in some aspects the patients exposure are large examination rooms with large lead windows, the proper use of collimation, virtual collimation, additional filters, semitransparent filters, pulsed fluoroscopy,

last image hold (LIH), the use of additional monitors for reference images, the use of contrast injectors, acceptable low frame rates for acquisition of DSA-series and minimized fluoroscopy times.

Figure 4: ***Left: stray radiation with over table tube position, right: with under table tube position (red: without, blue: with lead protection of lower limbs)***

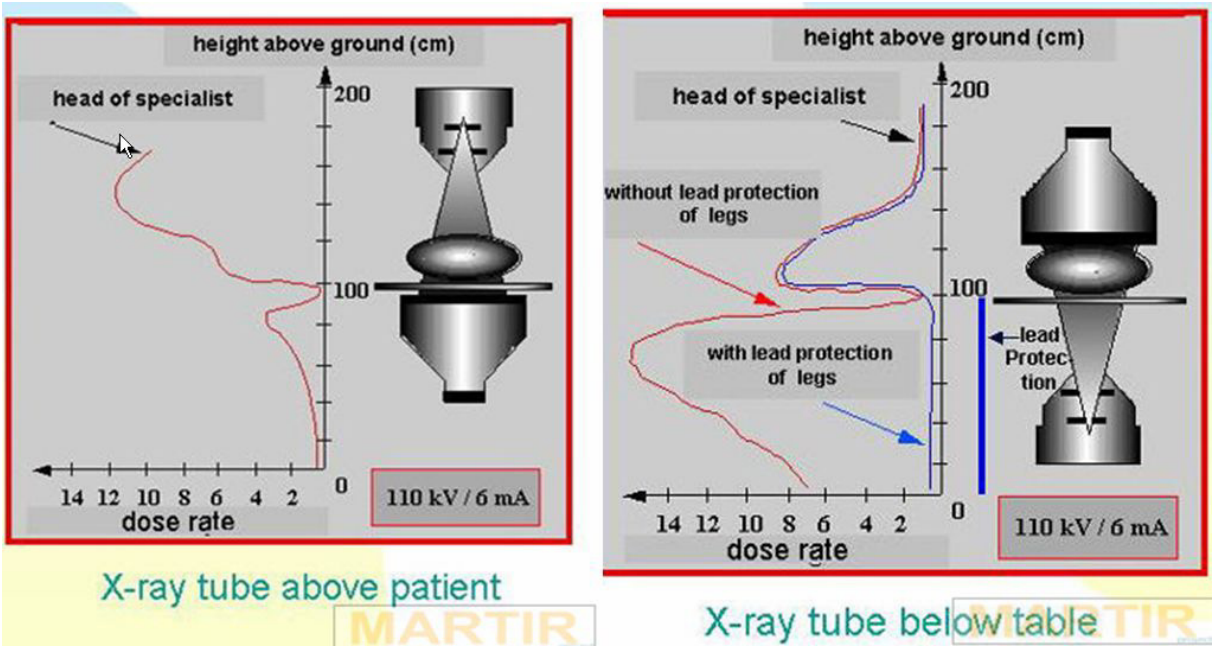
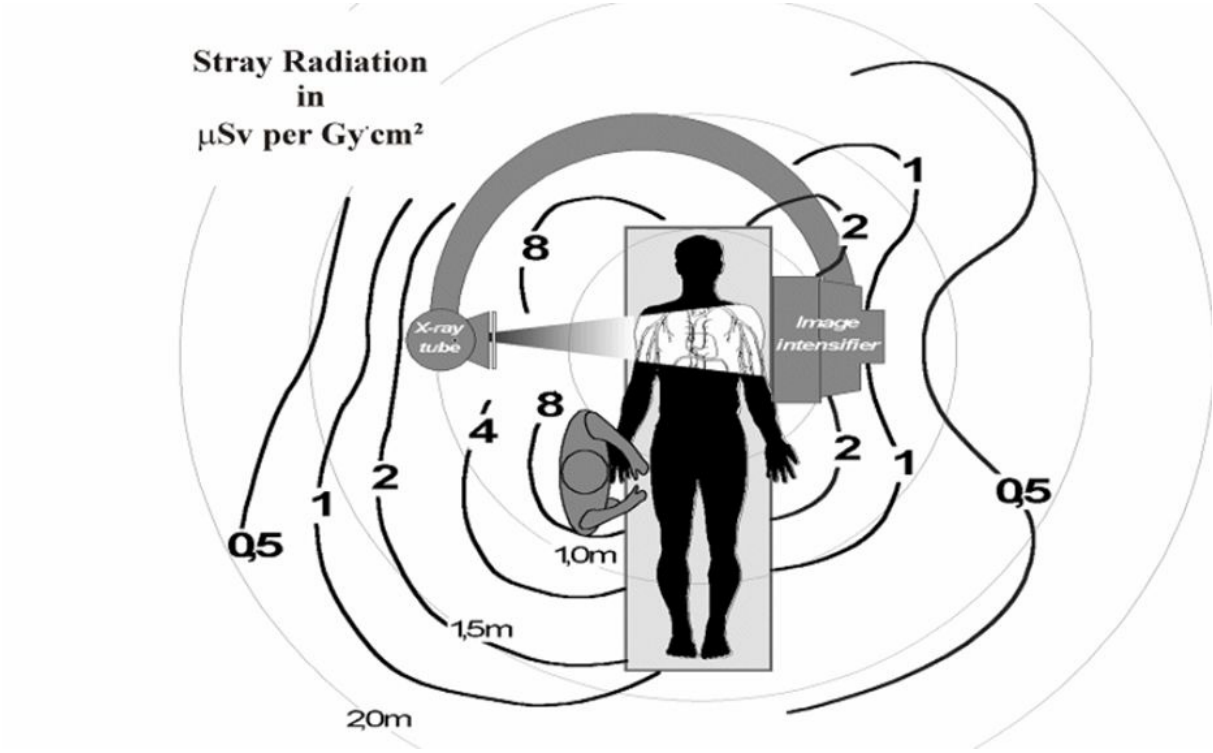


Figure 5: ***Isodose curves around a C-arm for diagnostic or interventional procedures***



If the diagnostic quality of stored images from pulsed fluoroscopy (instead of DSA-series) is sufficient to document the results of an interventional procedure, the patients and hence the

occupational exposure can be reduced by 80% [Loose 2002].

After publication of the directive 97/43-EURATOM [EC 1997] most EU member states introduced diagnostic reference levels (DRL) into radiology. Following these DRL, a physician is able to compare his typical mean values of patient exposures with published data. For interventional fluoroscopic procedures, these values are expressed as dose area product (DAP) and sometimes additionally include fluoroscopy times and number of acquired radiographic images [IAEA 2001].

A survey on all aspects of radiation protection in interventional radiology and cardiology with fluoroscopic systems is given on the MARTIR-CD [MARTIR 2002]. This CD is a multilingual audiovisual teaching system for radiologists, cardiologists, vascular surgeons, medical physicists, radio technicians and other staff members. The CD was sponsored by the European Commission and is available in English, French, German, Italian and Spanish language. The CD includes individual multiple choice questions for all lessons and for all different groups of involved professionals and it is free available from the EC Publication Services.

Figure 6: Correct preparation of radiopharmaceutics

2.3.3 Diagnostic Nuclear Medicine

In diagnostic nuclear medicine high dose rates and hence high occupational exposures are observed during preparation of radio traces in the laboratory and during administration of the radiotracer to the patient. Tab. 1 shows different risk levels of occupational doses in nuclear medicine depending on the type of application. In all cases of preparation or administration it is important not to hold the vial or syringe directly with the hand, without shielding or without shielding pliers. Fig. 6 shows the correct preparation of radiotracers with all measures of shielding, the use of gloves, a forceps and a finger dosimeter. Typical variations in dose rate

at the index finger during preparation and dispensing of kit vials were measured by C.J.Martin et.al. [Martin 2003] with electronic finger dosimeters (Fig. 7). Doses up to 30 mGy/h were observed while dispensing the kit vials.

Figure 7: Variation in dose rate at the index finger during preparation and dispensing of kit vials

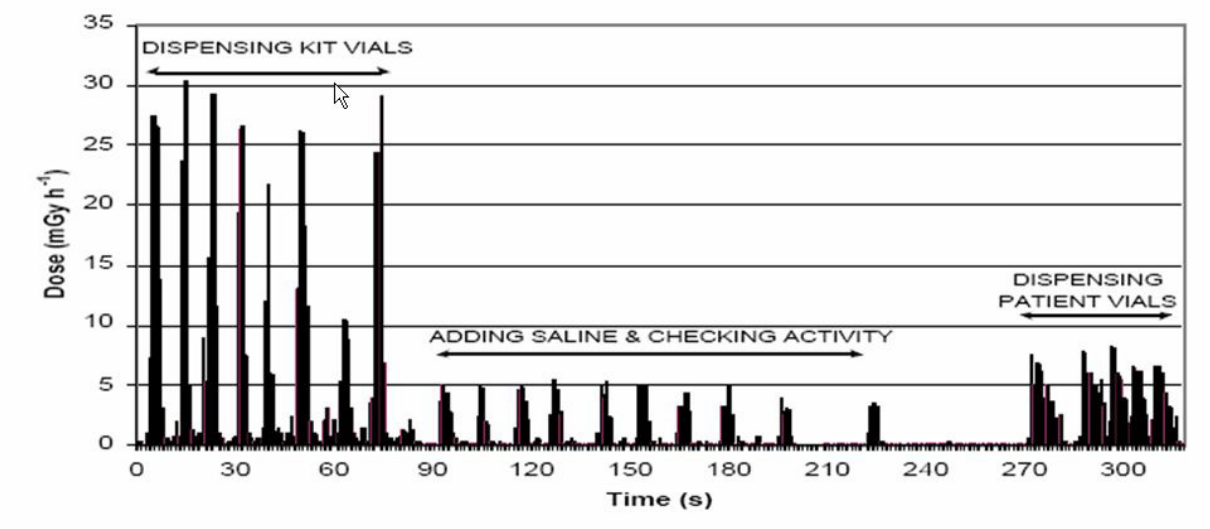


Table 1: Risk of occupational high doses in nuclear medicine
(+ = normal, ++ = moderate, +++ = high)

Diagnostic use of standard isotopes	+(+)
Positron Emission Tomography PET	+
Preparation of beta emitters	+++
Application of beta emitters (e.g. Radiosynoviorthesis)	+++

Due to the high energy of photons emitted from ß+ isotopes in Positron Emission Tomography (PET) elevated occupational dose levels have been reported. Eulisse et.al. [Eulisse 2003] measured effective doses of physicians and technicians with film badges and finger dosimeters and found a twofold increase compared with workers in conventional nuclear medicine.

Gonzalez et al [Gonzales 1999] measured doses to radiopharmacy and medical staff both in normal work and in some handling incidents in a cyclotron PET facility. Doses were monitored by TLD, using extra chips for finger dosimetry and to duplicate individual whole-body dosimetry in order to measure doses in certain single operations. For normal work, average whole-body doses to radiopharmacy staff were between 0.03 and 0.28 mSv/month, wrist doses were between 0.42 and 2.67 mSv/month, and finger doses were between 1.4 and 7.7 mSv/day for the left hand and 0.8 and 2.4 mSv/day for the right hand; such variation reflects the differing expertise of staff and the role played by optimisation. Finger doses between 16 and 131 mSv were measured in handling incidents, and finger doses of 20.2 and 20.7 mSv for the left hand and 22.0 and 22.3 mSv for the right hand were measured during handling of a syringe without shielding, containing 3 GBq. For medical staff, contributions to the whole-body dose of 2.0 and 1.9 microSv/procedure were measured for injection and placing the patient on the examination couch, respectively. Dose measurement on the middle finger of the right hand gives an average of 70 microSv during the injection.

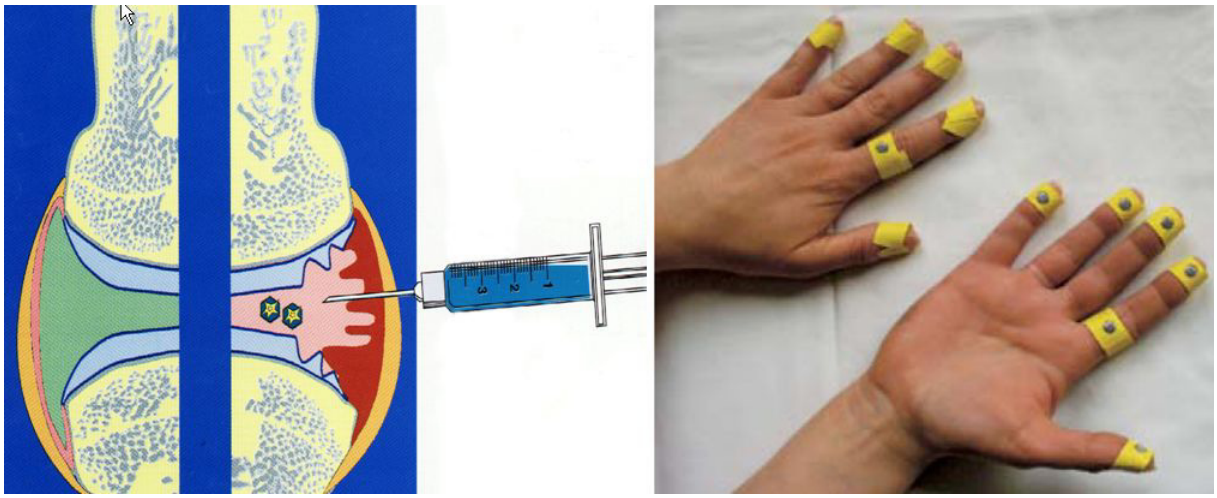
2.3.4 Therapy in Nuclear Medicine:

Therapy with I-131 is the most frequent application in nuclear medicine. As I-131 is already in use for many years in diagnostics as well as in therapy, only few severe incidents or accidents with occupational overexposure have been reported so far. The reasons for these overexposures are generally the same as in diagnostic nuclear medicine.
An underestimated problem in nuclear medical therapy is a high skin dose rate at the fingers when radiosynoviorthesis procedures are performed. Barth and Mielcarek [Barth 2002] analysed different beta workplaces and measured skin doses at the fingers of more than 100 mSv/procedure after treatment of inflammatory joint diseases by (Radiosynoviorthesis, RSO) with maximum beta energies from 0,1 MeV to 3,5 MeV. Typical nuclides for these applications are the ß-emitters Er-169, Re-186 and Y-90. Fig. 8 shows the principles of an radiosynoviorthesis and the dosimetric procedure. The conclusion of the authors is that the following actions are necessary:

- Optimisation of radiation protection
- Introduction of legal beta-particle dosemeter (partial body)
- Training and information of the personnel
- Exchange of experience.

Aubert et.al. [Aubert 2003] demonstrated the dose reduction by optimising the Y-90 injection technique. They found a dose reduction from 14-23 mSv/injection to 1.6-2.8 mSv/injection after optimisation of the procedure.

Figure 8: Principles of radiosynovirorthesis and ß-dosimetry of fingers



2.3.5 Radiotherapy:

Radiotherapy involves mainly two applications:

- Teletherapy with Co-60 sources or accelerators
- Brachytherapy with liquid or solid sealed sources

Whereas radiotherapy with external sources involves a low risk of occupational exposure, more and severe incidents have been reported when using different sources for brachytherapy. Nevertheless by far most of all accidents and incidents with overexposure have been reported for patients. In some cases staff members were overexposed too. Especially occupational overexposure of the fingers can be caused using Beta-sources for therapeutical applications. Therefore education in radiation protection for such procedures should be recommended.

2.3.6 Risks of occupational exposure in radiotherapy

External gamma therapy (Co-60)	(+)
External gamma therapy (LINAC)	(+)
Brachytherapy (Afterloading)	(+)
Brachytherapy (Seeds, e.g. Prostate)	+
Brachytherapy (Endovascular)	++

2.3.7 Radiotherapy with external sources (Co-60 or accelerators)

Whereas Co-60 sources are still in use in developing countries, in industrial countries these sources are more and more replaced by linear accelerators. Occupational overexposures from Co-60 sources may occur if staff members do not leave the radiation room during operation, if the shutter system fails or if the source is not in the right storage position. By reasons of radiation protection nearly all rooms for radiotherapy with external sources have a geometry of the entrance which avoids direct radiation towards the door. Hence, even when radiation is applied to a patient while staff members are in the room and doors are closed, a safe area with low level of stray radiation can quickly be reached. Fig. 9 shows the geometry of a typical radiation room with a protected entrance area behind the door. Fig. 10 shows a new radio frequency controlled protection device which could be used by staff members in the radiation room. This system prevents a start of the radiation while other persons than the patient are in the room.

Figure 9: Typical geometry of a linear accelerator entrance area (Hospital Nuremberg)

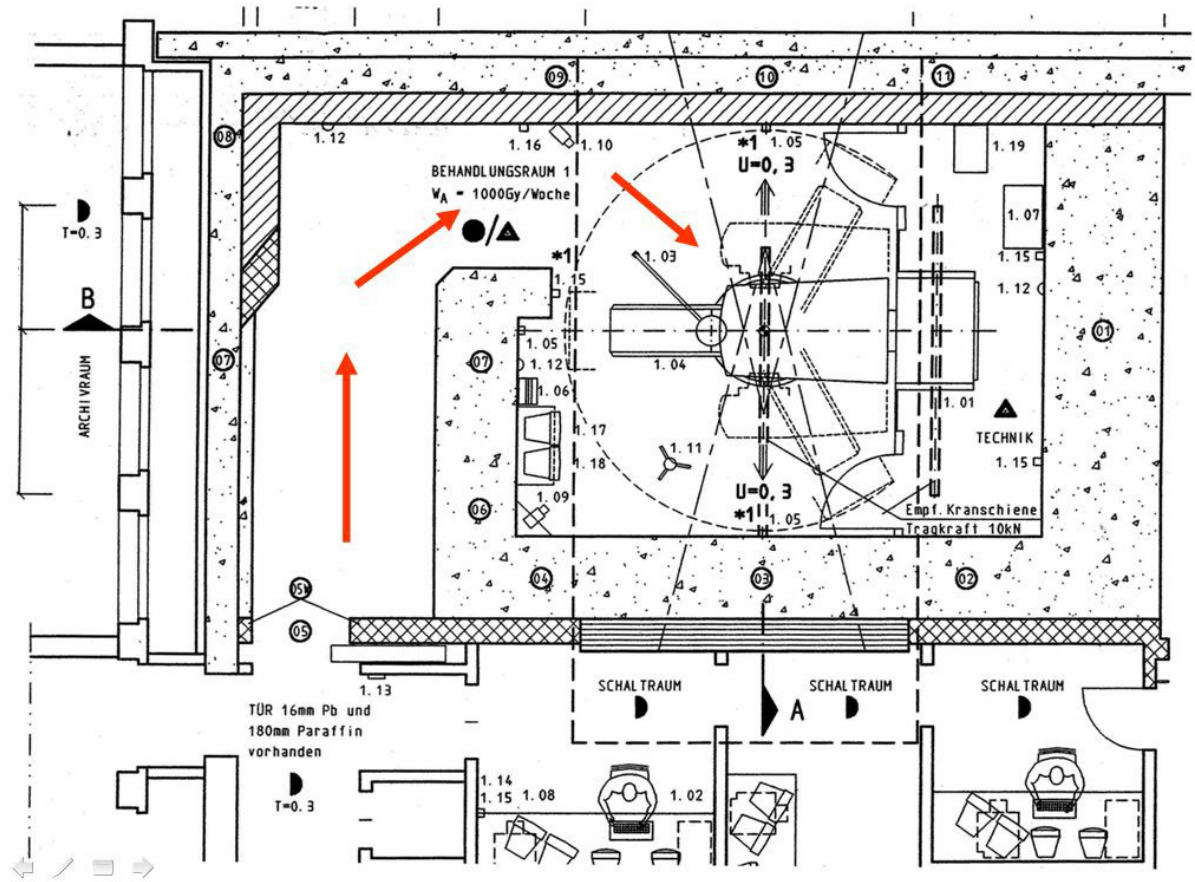


Figure 10: Radio-frequency controlled protection device used by staff members in a radiation room

2.3.8 Radiotherapy with internal sources (brachytherapy)

Therapy where sources are applied internally to the patient is called brachytherapy. As radiation sources Ir-192, Cs-137 and Sr-90 are used with high frequencies for treatment of cancers in gynaecology, gastroenterology and pneumology or treatment of coronary artery stenosis in cardiology. In these last cases beta radiation sources are also used. Fig. 11

shows the housing of a brachytherapy gamma source with two pipes for application. While the insertion of sources in most cases of cancer treatment is performed remote with no staff members in the radiation room, other applications like in cardiology require that the physician controls the insertion and correct position of the source directly at the patient. Fig. 12 shows an application device for intravascular coronary therapy with Sr-90 sources. Tab. 2 shows reported incidents and accidents in Germany from 2001 – 2002 where some of the events are due to folding or bending of application catheters [BMU 2003, DB 2003].

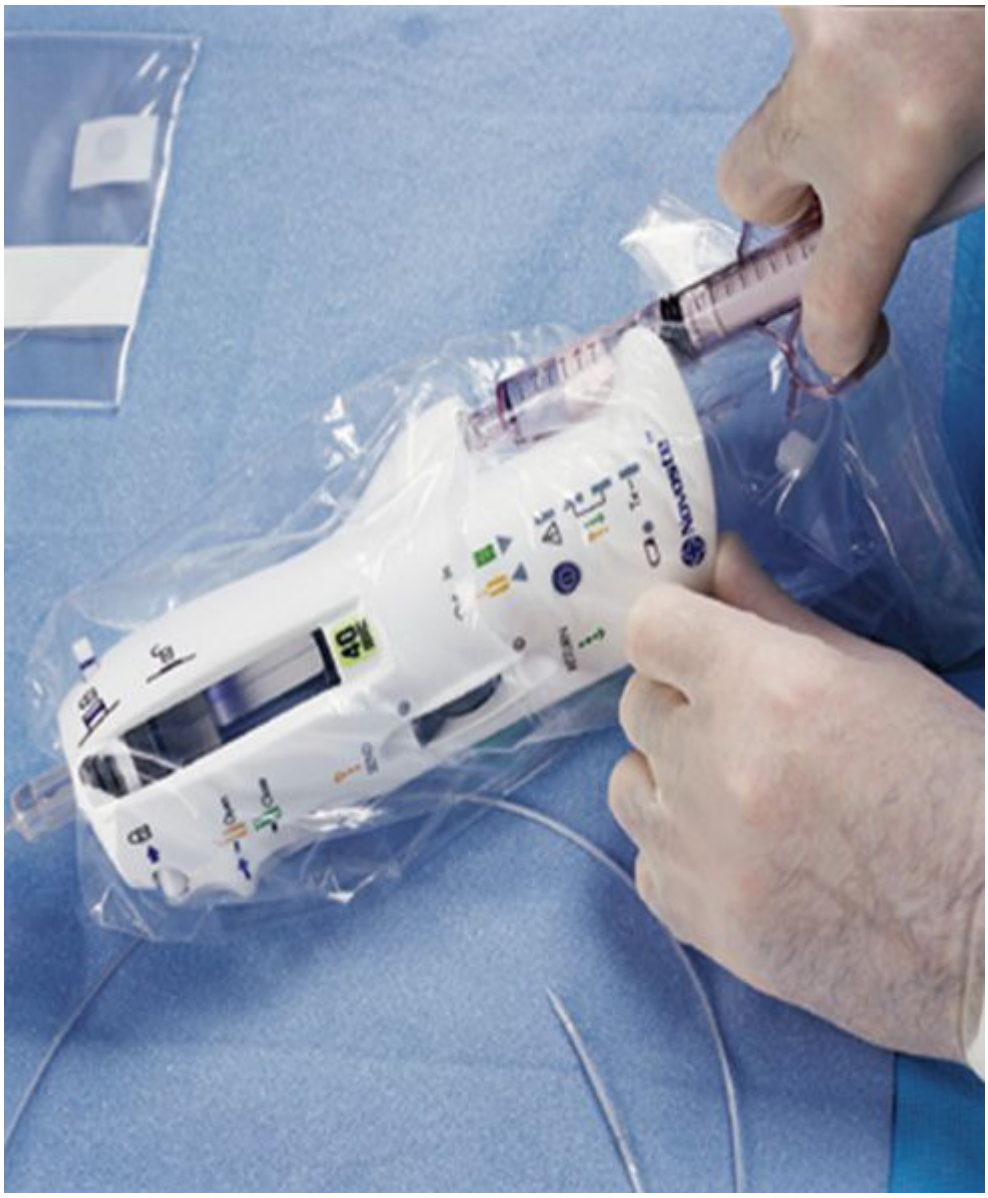
Figure 11: Housing of a brachytherapy system with pipes for source administration

Table 2: Reported incidents and accidents in Germany 2001 – 2002

2001 n=14		
2001		
#5	employee in accelerator room	< 1 mSv
#8	fold / bend of catheter	< 0.1 mSv
#13	cleaning staff in accelerator room	~ 20 mSv
	(misuse of dosimeter) estimated dose	1.3 mSv
#14	employee in afterloading room	0.2 mSv
2002 n=24		
2002		
#5	folded catheter with Sr-90 in groin	~ 1 µSv
#7	employee in accelerator room	“very low”
#8	radiotechnician for 8.6 s in accelerator room	“very low”
#10	CT x-ray tube did not stop after “Scan Stop"	“very low”
	12 incidents in 2001 and 2002 with fold / bend of catheters in brachytherapy	

A special type of brachytherapy is the implantation of I-125 or Pd-103 seeds into the bottom of the pelvis for therapy of prostate cancer. This treatment involves rather low occupational exposures with the additional risk that some of the radioactive seeds may be lost [Fernández 2003].

Figure 12: Application device for intravascular coronary therapy with Sr-90 sources



2.3.9 Conclusions

The risk of occupational overexposures in medicine can be considered in general as very low, but training in radiation protection should be improved specially for medical specialists using x-rays as a complementary armamentarium for their job (e.g. cardiologists, vascular surgeons, etc). The worldwide variation of doses for all monitored workers is between 0.2 and 2.1 mSv [UNSCEAR]. If only measurably exposed workers are analysed, the exposure range is between 1.1 and 4.6 mSv. Between 1975 and 1994 the average annual individual dose of all monitored workers worldwide decreased from 0.78 to 0.33 mSv. In Germany 1998 only 0.09% of monitored workers in medicine exceeded the dose limit of 20 mSv [BfS 1998].

In any case, more data of occupational doses on specific high risk body locations should be obtained (e.g. hands, lens, etc) to help in the optimisation of some procedures, specially for fluoroscopy guided interventional procedures. ICRP recommends (IRCP-85) the use of at least two dosimeters.

Nevertheless, if new techniques like PET, brachytherapy or radiosynoviorthesis are introduced into medicine, new problems of radiation protection or dosimetry may arise. If the introduction of such techniques is not supported by training and exchange of information, occupational overexposures cannot be avoided.

Istvan Turai and Kaalin Veress [Turai 2001] summarized the challenges of new technologies and procedures:

- Do Qualified experts and Radiation Protection Supervisors have a high enough profile within medical establishments both large and small?
- There is often a link between the standard of control of patient exposure and occupational exposure
- Training at al levels is a fundamental building block
- Improve the feedback process so that we learn lessons from accidents and incidents
- Are there concerted actions that could improve the monitoring and control of extremity doses?

As a conclusion, high level training should be mandatory in interventional radiology, brachytherapy and application of ß-sources.

For research projects some of the following questions should be answered:

- Is the typical personal dosimetry with only one dosimeter under the apron sufficient to give an estimate of the occupational dose in interventional radiology?
- Do we have a sufficient ß-dosimetry for medical applications?

Questions for regulatory aspects are:

- Do we need harmonized education and training in radiation protection in medicine (radiologists, cardiologists, medical physics experts, etc)?
- Do we need harmonized regulations for ß-dosimeters?

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3 POTENTIAL ADDED RISKS FROM THE NEW TECHNOLOGY IN MEDICINE

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Abstract

New technologies involving ionising radiation in medicine are a challenge for health professionals, industry, and health care administrators and also for radiological protection. Regulatory, health authority and standardization bodies are involved in the preparation of new guidelines and standards to guarantee a high level of quality and safety. In addition, the most relevant international organizations (ICRP, IAEA, WHO, etc) are very active in this field to promote a high level of radiological protection for patients and staff. The European Commission is supporting research in this field to prepare the European Union for this challenge.

This paper address four main topics: a) High doses techniques (procedures guided by fluoroscopy) sometimes used by non radiologists without (or with scarce) training in radiological protection; b) Computed Tomography (CT) and Positron Emission Tomography (PET), sometimes self referred; c) Digital radiology, that will probably be the most important change in diagnostic imaging during the next years; and d) Other special techniques using ionising radiations and involving several groups of specialists (e.g. nuclear medicine and intravascular brachytherapy).

As conclusions, some possible implications for the European standards are stated in relation to training and accreditation in radiological protection, involvement of industry, promotion of specific research in this field, and production of guidelines and protocols for these new technologies.

3.1 Introduction

The use of new technologies with ionizing radiations in medicine is a very broad field. In this paper, we will concentrate on some of the topics with special potential relevance to the European regulations on radiation protection. Conventional radiotherapy topics are not addressed.

Four main topics are analysed:

1. High doses techniques (procedures guided by fluoroscopy) sometimes used by non-radiologists without (or with scarce) training in radiological protection.
2. Computed Tomography (CT) and Positron Emission Tomography (PET) examinations sometimes self referred by the public.
3. Digital radiology that will probably be the most important change in medical imaging during the next years.
4. Other special techniques using ionising radiations and involving several groups of specialists (e.g. nuclear medicine and intravascular brachytherapy).

3.2 High Doses Techniques

Invasive procedures (using catheters or other similar tools) guided by fluoroscopy imaging, are increasing during the last few years. They can be diagnostic (e.g. to visualize the blood vessels using contrast media) or therapeutic (e.g. to open stenosis in the arteries, or to embolize other vessels to avoid the effects of arterio-venous malformations). The International Commission on Radiological Protection (ICRP) defines interventional radiology as "procedures comprising guided therapeutic and diagnostic interventions, by percutaneous or other access, usually performed under local anaesthesia and/or sedation, with fluoroscopic imaging used to localise the lesion/treatment site, monitor the procedure, and control and document the therapy" (ICRP 2000).

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reported in 2000 (UNSCEAR 2000) that the advances in technology of imaging and ancillary equipment have facilitated the development of increasingly complex radiological procedures for angiography and interventional radiology, and that specific methods are required for assessing and monitoring the resultant patient doses. For the intensive imaging procedures used in interventional radiology, knowledge of the localized dose to skin is also important with respect to the potential for deterministic effects of irradiation. Typical data from Germany for 1990 reported by UNSCEAR, indicated that nearly 60% of such procedures fall within the broad category of angioplasty (dilatation), with significant applications also in biopsy/drainage (11%), pain therapy (11%), embolization (7%), and genitourinary (7%) and biliary (5%) interventions.

The increase of interventional and invasive fluoroscopy guided procedures in cardiology has been substantial during the last years. Data published by the Section of Hemodynamic and Interventional Cardiology of the Spanish Society of Cardiology available on its web (http://www.hemodinamica.com/), indicate that between 1999 and 2001, the increments have been: 22% in the number of interventional rooms, 18% in doctors practising such procedures, 19% in nursing and radiographers involved in the interventional work, 15% in diagnostic procedures and 33% in therapeutic procedures (meaning 2386 diagnostic and 782 therapeutic procedures per million inhabitants respectively, in 2001).

In addition, the increase in other non-cardiac procedures has been very important. Data collected by the Spanish Society of Vascular and Interventional Radiology, indicate that in the year 2001, interventional procedures carried out by the members of the Society have been approximately 308 procedures per million of inhabitants (without taking into account procedures carried out by other medical specialities different from radiology). This figure supposes a mean of 1560 procedures per year and per interventional room. Of this number, 33% are therapeutic procedures (vascular or visceral). This figure represents an increase of 20% between 1999 and 2000 and an increment of 10% from 2000 to 2001.

UNSCEAR reported (UNSCEAR 2000) that CT and angiography are the only radiology procedures increasing in frequency when comparing the data collected for the period 1955-1990 and the ones from 1991-1996 (see figure).

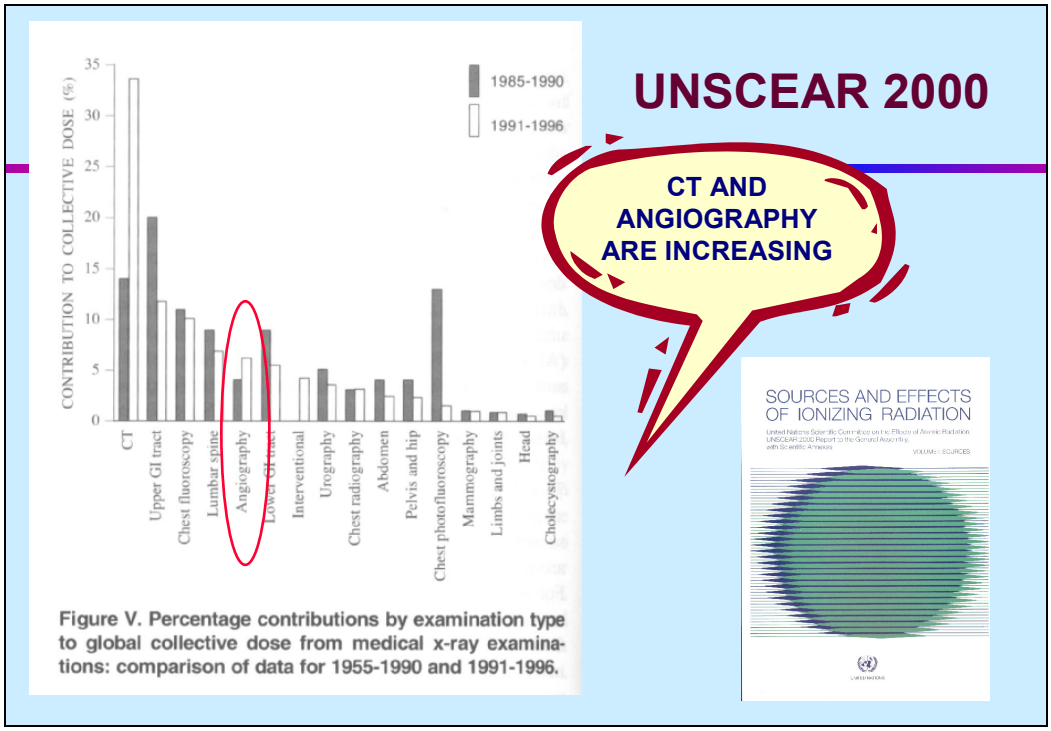
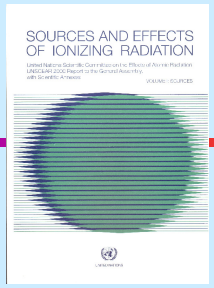


Figure V. Percentage contributions by examination type to global collective dose from medical x-ray examinations: comparison of data for 1955-1990 and 1991-1996.

Both types of procedures, but specially the therapeutic ones, can be especially difficult for certain patients and pathologies requiring extended fluoroscopic times and an important amount of radiographic or cine images. In these cases the risk of deterministic effects in the skin of the patients is relevant and several national (FDA 1994) and international organizations (WHO 2000, ICRP 2000) have published recommendations to avoid these effects. The benefits for the patients, avoiding open surgery, and for the health systems, justify the increase in the number of procedures and the interest of several medical specialities (e.g. radiologists, cardiologists, vascular surgeons, urologists, etc) to use these techniques in routine practice.

European Directive 97/43/Euratom (EC 1997) has considered interventional procedures included in the article of special practices requiring special attention to aspects of quality control and patient dosimetry. Article 9 on Special Practices states that Member States shall ensure that appropriate radiological equipment, practical techniques and ancillary equipment are used for medical exposure involving high doses to the patient, such as interventional radiology. In addition, special attention to the quality assurance programmes, including quality control measures and patient dose for these practices is required. For complex interventional procedures with the risk of deterministic effects, some organisations and Member States of the European Union recommend that individual patient doses be measured and archived. Repeated procedures in the same patients require clinical follow up. The radiological industry should facilitate these tasks (dose measurements and electronic archive) especially for new X ray systems.

Stochastic effects are sometimes in a second level of importance because the mean age of the patients requiring these interventional procedures is quite high. However, in some cases, due to the importance of organ doses imparted during these procedures (10-100 mSv), and the percentage of young patients involved, stochastic effects should also be taken into account. UNSCEAR reported some data about the age distribution for some interventional procedures (UNSCEAR 2000) and there are quite a significant percentage of patients between 16 and 40 years (see figure).



Age distribution for interventional procedures in UNSCEAR 2000 (Sweden)

PROCEDURES	Angiography Cerebral	Angiography Cardiac	Angiography Other	PTCA
Age distribution (%)	16-40 years 27% > 40 years 71%	16-40 years 7% > 40 years 91%	16-40 years 10% > 40 years 88%	16-40 years 15% > 40 years 85%

Some of the main problems concerning the radiological protection (RP) of patients and staff are the sometimes-scarce training in RP for some groups of medical specialists adopting these techniques as part of their therapeutic armamentarium and the use of X ray systems not fully appropriate to carry out these techniques (IEC 2000).

The training offered for starting with these techniques is not always the ideal and the international recommendations should be followed (EC 2000; WHO 2000).

GJ Becker during the 2000 RSNA annual oration in diagnostic radiology (BECKER 2001) addressed some of the problems of the interventional radiology practice. Interventional radiology's major identity problem will require multiple corrective measures, including a name change. Inter specialty turf battles will continue, especially with cardiologists and vascular surgeons. To advance the discipline, interventional radiologists must remain involved in cutting-edge therapies such as endograft repair of aortic aneurysms and carotid stent placement. As the population ages, interventionalists will experience a shift toward a greater emphasis on cancer treatment. The public outcry for accountability will result in changes aimed at reducing errors, and process changes in the way physicians are trained, certified, and monitored.

A recent Editorial (ROGERS 2001) published by the Editor in Chief of the American Journal of Roentgenology under the title “Serious Business: Radiation Safety and Radiation Protection” states “other disciplines that may use fluoroscopy are left to their own devices. It is wrong to be allowed to obtain credentials at weekend courses where they hand out filigreed, gilded certificates simply for attendance. Such impressive documents may then be handed with a wink to friendly chairpersons of medical staff credentials committees in order to secure privileges to perform fluoroscopy. Paying lip service to the requirements for knowledge of radiation is to be deplored. Radiation safety is not a given. If you use radiation, you must respect it. You must be informed and believe that radiation safety is serious business”.

This scarce training in RP could also be the cause of failure to detect abnormal working of the X ray systems (or associated devices) and the use of inappropriate radiographic techniques or

operation modes (e.g. extended time using high dose rate fluoroscopy). This can increase substantially the risk of over irradiation for patients and staff.

To inform health or regulatory authorities about the over exposures and to promote an internet public system to communicate the incidents and the lessons learned is an effective way to improve the safety in such procedures. These actions were discussed in the Art. 31 group of experts of the EURATOM Treaty during 1999 but until now no formal initiative about it has been decided. The USA experience (see: http://www.fda.gov/opacom/enforce.html or http://www.nrc.gov/reading-rm/doc-collections/event-status/prelim-notice/2003/index.html) could be used to start a similar system in Europe.

A recent study of Kashyap et al. (KASHYAP 2002) reported vascular surgery fellows' opinions in USA on various issues related to endovascular surgery (EVS). 116 vascular fellows from the academic years 1998-2000 participated in the study, representing a significant fraction of trainees in North America. The majority of vascular surgery fellows were trained at hospitals performing EVS at the time of the survey. EVS performed in the operating room with portable imaging equipment decreased (67% versus 42%) as access to the radiology and cardiology suites increased. In most communities (63%), radiology specialists performed most of the EVS procedures, but the portion of communities where vascular surgery performed the majority of EVS procedures increased from 20% to 35%. Responders (90%) believed that EVS would become a major component of vascular surgery and comprise 30% of their future practice. The proportion of fellows who believed they were sufficiently trained in endovascular techniques increased from 30% to 50%.

Thus, vascular surgeons are a group of medical specialists requiring special training and accreditation in radiological protection.

The Working Party on Medical Exposures from the Art. 31 Group of Experts of the EURATOM Treaty also addressed this topic. In a meeting held on 8 November 2000 it was decided to promote a discussion platform with some European medical societies to address the topics of RP training and the appropriateness of X ray systems used in interventional procedures (following the IEC 60601-2-43) (IEC 2000). It was felt that some aspects would require specific guidance to fulfil the Medical Exposure Directive 97/43/Euratom (EC 1997).

The European Guidelines RP-116 (EC 2000) recommend a specific level of training in radiation protection for interventional radiology, an initial training of senior practitioners moving to these techniques, and the initial training of new future practitioners together with some continuous training in RP should be planned. Some experiences of this specific RP training have already been started in Europe (VANO 2003a). The European Commission also has funded some projects to produce training material for RP training in interventional radiology (MARTIR 2002).

The Society of Cardiovascular and Interventional Radiological Society of Europe (CIRSE), European Society of Cardiology and European Society of Vascular Surgery were invited to participate in such platform to foster training in RP and standardization of safety measures for theatres and X ray systems to help in the improvement of the RP of patients and staff. However, the invited Societies never formally appointed delegates for the platform and the proposed action in 2000 was cancelled in 2003.

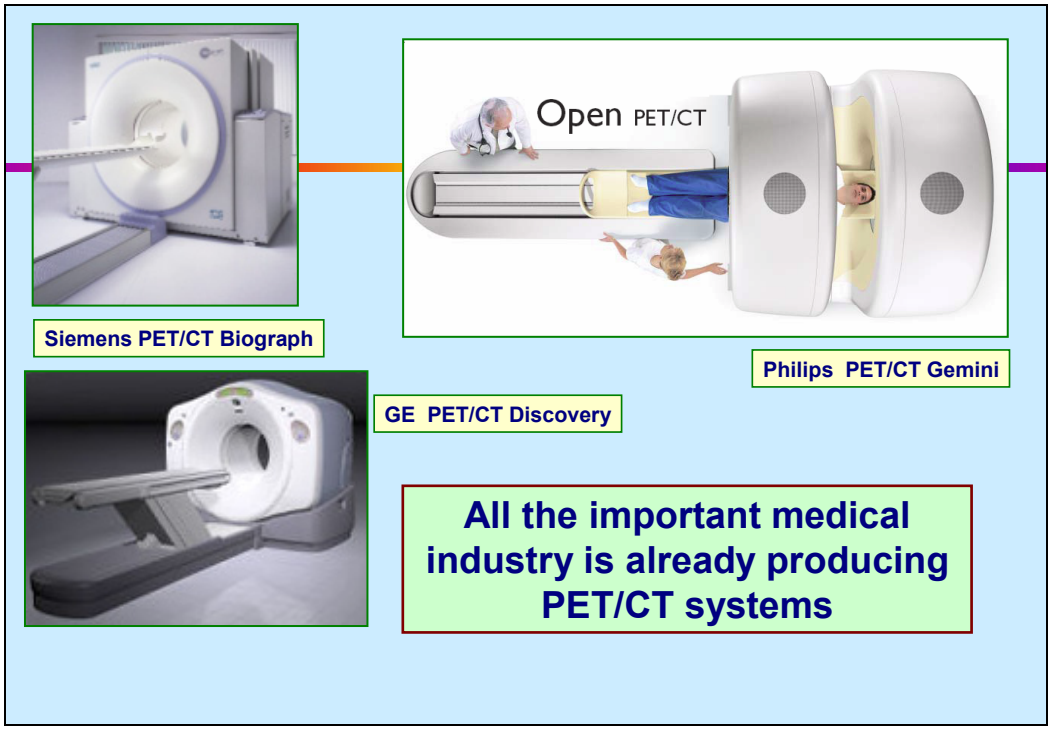
In any case, the safety aspects for patients and health professionals during interventional procedures are still a hot topic (VANO 2003b) and probably the proposals of the Working Party on Medical Exposures of 2000 should be again reconsidered or addressed in the future European regulations.

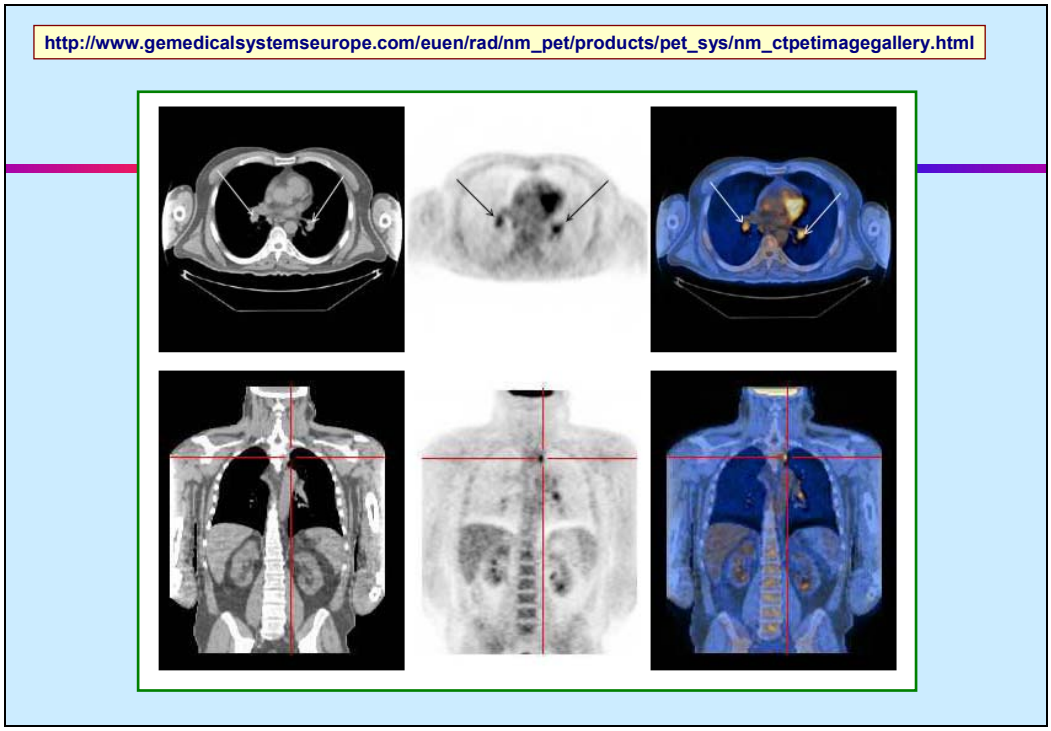
As consequence, the possible implications of these topics on the European Standards could be the following:

- The patient doses for interventional procedures should be measured and archived to allow consistent quality assurance programmes and the clinical follow up of potential deterministic effects.
- To involve industry in these tasks especially for the new x-ray systems.
- Incidents (radiation lesions) should be reported and lessons learned made available to the users.
- Specific training and accreditation in RP for all the health professionals involved in interventional procedures should be required in all Member States.

3.3 Computed Tomography And Positron Emission Tomography

Patient doses are quite high in some of the most frequent diagnostic procedures for certain pathologies. The good spatial resolution of CT is now combined with the functional information offered by PET examinations and image fusion of both modalities. Imaging systems allowing the simultaneous access to both images are already in the market offered by all the main radiology systems producers. Justification of these procedures is a critical issue.





The effective dose for a PET examination is about 5 mSv (BRIX 2002). For typical abdominal CT examinations, this value is about 10 mSv (FDA web site ttp://www.fda.gov/cdrh/ct/). With some especial CT techniques as electron beam computed tomography (EBCT), effective doses for abdomen examinations are up to 26 mSv (BECKER 1998). Doses for CT coronary angiography range from 8 - 11 mSv (TRABOLD 2003). Virtual colonoscopy procedures with CT produce effective doses about 10 mSv (WISE 2003).

Self-referring and non justified screening for some of these procedures is a problem in USA and can be a problem in Europe in the near future. Screening centres attract clients through advertising as well as from referring physicians. Scanning centres offering whole-body imaging, coronary calcium scoring, and virtual colonoscopy to asymptomatic, health-conscious individuals are increasing. Sometimes no referral from a primary care physician is needed.

The radiology community has become divided over how CT should be applied to screening patients for cancer. Some advocate unrestrained availability of CT screening to patients with sufficient interest and economic resources, arguing for patient autonomy in personal health matters. The financial ramifications of screening are huge, and conflict of interest and self-referral are substantial ethical issues in this debate. Informed consent will provide patients with correct information about the benefits, risks, and alternatives for screening, as we currently understand them. It will also positively influence the practice of all who would choose to offer CT screening examinations. Each CT examination of the chest performed with a low-dose technique delivers a radiation dose to the lungs that is equivalent to that of 10 two-view chest radiographs and a dose to the breasts that is equivalent to that of one mammographic film of each breast. A CT examination of the chest performed by using a routine diagnostic technique delivers a radiation dose approximately 10 times higher than that of the low-dose technique (EARNEST 2003).

At this time, the American College of Radiology (ACR), does not believe there is sufficient evidence to justify recommending total body CT screening for patients with no symptoms or a family history suggesting disease. To date, there is no evidence that total body CT screening is cost efficient or effective in prolonging life. In addition, the ACR is concerned that this procedure will lead to the discovery of numerous findings that will not ultimately affect patients'

health but will result in unnecessary follow-up examinations and treatments with significant wasted expense (ACR 2002).

In addition, the FDA has policy discouraging whole-body screening. At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death. Any such presumed benefit of whole-body CT screening is currently uncertain, and such benefit may not be great enough to offset the potential harms such screening could cause (FDA 2002).

Some authors also claim the right of self-screening. It seems silly to consider that some of us readily accept a woman's right to choose an abortion but not her right to choose screening CT (BRANT 2002).

The implications for European Standards in this case could be to promote objective information on the benefits, but also on the risks of these medical exposures, and to reinforce the justification criteria. Ethical issues, patient's rights and informed consent should be considered.

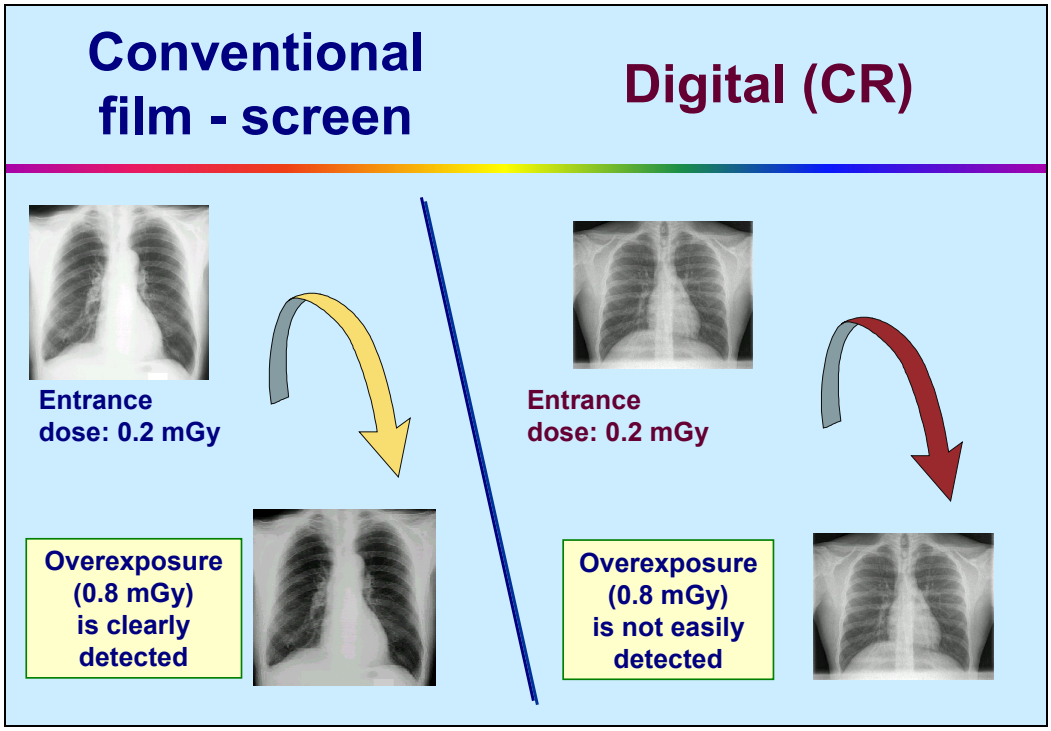
3.4 Digital Radiology

Digital radiology probably represents the greatest technological advance in medical imaging for the last decade. Benefits are enormous. Images can be easily obtained, post processed, archived and in few seconds networked within the hospital and to other health centres. Archiving and retrieving images become much easier and both prescribers and practitioners realize the advantages of computers and networks. The improvement of workflow in radiology departments is a big advantage of digital imaging technology.

The impact in the radiology market is impressive. During the first quarter of 2003, increases of PACS sales have been substantially greater (45%) than other radiology equipment (15%).

In theory, digital detectors should allow good images to be obtained with lower doses than conventional film-screen radiology. Also in theory, and using the advantages of post processing, fewer images per procedure could be used for a correct diagnosis.

In practice, and especially during the transition from conventional to digital radiology, patient doses can be increased without any clinical benefit. Images of the best quality (with the highest doses) can be obtained and more images per procedure than necessary can be obtained. Causes are sometimes lack of training for the operators and practitioners, incomplete quality controls forgetting that computer files (images) are very easy to obtain and to delete but the patient is irradiated in all the cases. There is scarce interest by industry to provide enough user information to appraise easily the radiation doses they are using to obtain the images.



A substantial increase in the use of radiology imaging when digital technology is available has been reported (REINER 2000). Good quality images are available very soon at the computer of the referring physician and this sometimes encourages asking for more examinations not always justified considering irradiation of the patients (and sometimes, unnecessary irradiation of the staff when present in the X-ray room).

Retake analysis is difficult to perform for digital radiology. It is easy to delete image files at the workstations and PACS and RIS producers do not usually offer the capability of retake analysis as part of the standard software.

With digital radiology in a certain range of exposures, there is a clear correlation between dose and image quality. Thus, the required quality for specific clinical tasks should be clearly defined. The same image quality (and the corresponding dose) should not be required for the follow up of a fracture than for the initial diagnosis. Patient dose management is a big challenge for the new technology. Guidelines and continuous education for radiologists will be needed to use the new technology in an appropriate manner.

Patient dose measurements and archiving their values should be a substantial part of the quality assurance in digital radiology. Modern systems have the capability to offer this information to the user very easily and the industry should help on this goal. The ICRP-93 report (ICRP 2004) states the present and the desired situation for data on patient doses in the different digital technologies. The called “desired for the future” should be available as soon as possible to improve the radiological protection of patients.

Managers of the health centres should know the advantages and the risks of the new digital technology before deciding the priorities for budgeting. Initial restrictions in some complementary infrastructure (e.g. a fast network, personal computers with good monitors for clinicians across the hospital, etc), dosimetric tools in the X-ray systems, PACS, etc, could diminish the improvements that digital radiology will introduce in the workflow of the hospitals.

Standardization of effort is also required for digital radiology. Different dose indicators (shown in the monitors or in the printed images) for computed radiology are used at present,

producing confusion to the users. Digital images can contain a lot of useful dosimetric and procedure information in the header (DICOM header) but manufacturers do not always complete this information in a standard way, considering sometimes this as “optional”. Information already existing in the modern digital systems especially that related to patient dose and radiographic techniques allowing audit and optimization should be included in the header of the images in a standardized format.

Diagnostic reference levels are well-recognized tools to manage patient doses and values for non-digital imaging are not necessarily applicable to digital imaging procedures. If the new X ray systems offer the capability of measuring and archiving patient dose values, the re-evaluation and use of reference levels will be a common practice. This will help in the application of optimization programmes when a new digital system or new post-processing software is introduced.

Quality control in digital radiology requires new procedures and protocols. Some of the routine tests are easier to do, sometimes in an automatic way, but acceptance and constancy tests should now include aspects of visualization, transmission and archiving of the images. Initial and continuous training for digital imaging should be offered to radiologists, medical physicists and radiographers before the clinical use of new technology.

Finally, more practical research work (for clinical and physical aspects) should be fostered during the next few years to advance in the benefits of digital radiology. More patient dose in digital, offers better image quality, but clear criteria for the required image quality for different clinical tasks should be established. New quality control procedures for digital equipment should be established. Different post processing algorithms can improve the image quality but could also create artefacts that confuse the interpretation of the images. Clinical trials to test the new post processing algorithms are needed before their routine use. For complex and interventional procedures, the required diagnostic information (related to quality of the images and the number of images per procedure) should be correlated with the clinical task and the complexity of the procedures. In these cases, the great number of images and the extended fluoroscopy time increase the risk of deterministic effects for the patients. Clinicians ask for good images without a long waiting time in the computer and the intricate relation between the level of image compression (loosing sometimes part of image quality) and transmission speed in the networks requires more research.

The International Commission on Radiological Protection has recently approved the publication of a report entitled “Managing Patient Dose in Digital Radiology” (to be published along 2004) with specific recommendations for protection of the patient.

Local diagnostic reference levels should be re-evaluated for digital imaging and patient dose parameters should be displayed at the operator console. Frequent patient dose audits should occur when digital techniques are introduced. Training in managing image quality and patient dose in digital radiology is necessary. Digital radiology will involve new regulations and invoke new challenges for practitioners. As digital radiology, images are easier to obtain and to transmit the justification criteria should be reinforced.

Commissioning of digital systems should involve clinical specialists, medical physicists and radiographers to ensure that imaging capability and radiation dose management are integrated. Quality control requires new procedures and protocols (visualization, transmission and archiving of the images).

The ICRP report also presents the situation desired in the future for the dosimetric parameters available in the DICOM (Digital Imaging and Communications in Medicine) header and their availability in the radiology information system (RIS) and the picture archiving and communication system (PACS). Some experiences in quality control and patient dosimetry on

line have already been carried out in Europe in the framework of the DIMOND research programme (VANO 2002; DIMOND 2002).

Present and desired situation for the different digital technologies for data on patient doses.		
Digital Technology	Available now	Desired in the future
CR	Dose or exposure index	Link with radiographic technique, patient dose estimation and patient data. Archive in the RIS
DR	Radiographic technique, Patient data and patient dose estimation	Automatic extraction of the information from the DICOM header. Archive in the RIS
Fluoroscopy	Radiographic technique, radiation field geometry and dose parameters per series	Fluoroscopy information. On-line skin dose maps and automatic extraction of information from DICOM header. Archive in the RIS

The implications on the European Standards could be the promotion of training for transition to digital techniques, and to foster actions to recommend new diagnostic reference levels for digital techniques. The role of the industry promoting tools to measure and archive exposure parameters and update protocols and guidelines for quality controls should also be considered. More research activities are needed in this area and coordination with other international organisations (e.g. IAEA) is desirable.

3.5 Other Special Techniques Involving Several Groups of Specialists

Some new and special techniques and devices using ionising radiations have been introduced in medicine requiring the cooperation of several professionals. They should work with well-coordinated protocols to guarantee their own safety and the safety of the patients from the radiological protection point of view.

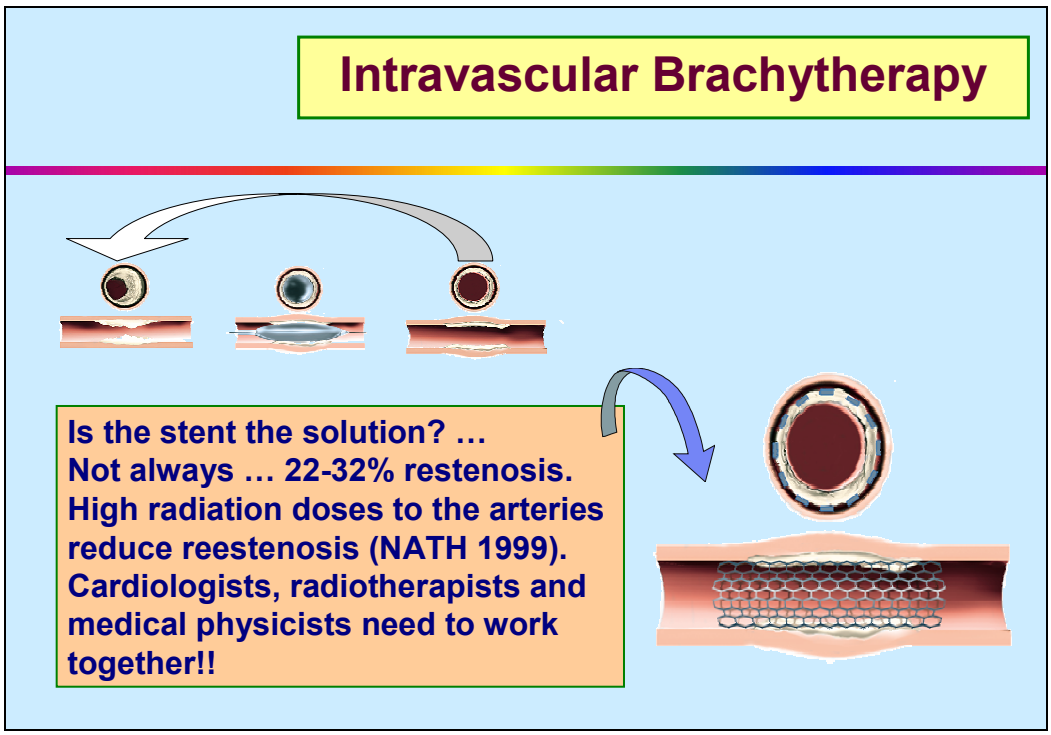
Intravascular brachytherapy, especially in the coronary territory, is a good example. Interventional cardiologists should work together with radiotherapists and medical physicists.

Brachytherapy techniques are a long-established treatment method conventionally used for cancer treatment, placing radioactive sources either temporarily or permanently into or near malignant tumours.

Treatment of atherosclerosis can be done widening the artery using a balloon (percutaneous transluminal angioplasty) or inserting a stent to maintain patency of the lumen of the artery. However, these treatments are limited by the high proportion of restenosis. Endovascular brachytherapy for prevention of neointimal hyperplasia after angioplasty in both coronary and peripheral arteries is a rapidly growing new field of interest. During intravascular brachytherapy radiation is applied directly to the vessel narrowing after balloon angioplasty and has shown good results for reducing the incidence of restenosis (SABATE 2000, WILLIAMS 2002).

The terminology to be used by all individuals involved in such treatments (radiation oncologists, physicists, and interventionalists) is not clearly defined. The European Society for Therapeutic Radiology and Oncology has produced recommendations for a common language

for general use in endovascular brachytherapy and recommendations for dose prescription, recording and reporting. In addition, quality assurance and radiation safety aspects are addressed, together with aspects related to equipment, personnel, and training and education related to endovascular brachytherapy (POTTER 2001).



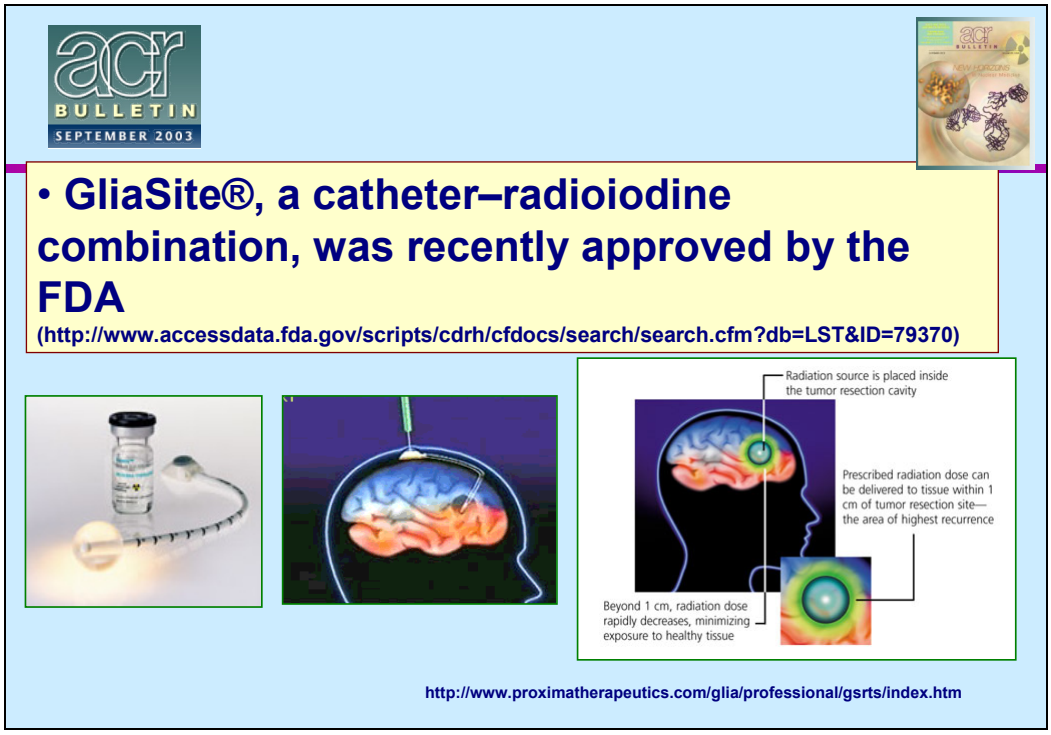
Clinical audit for these procedures should concentrate on the aspects of selection of the patients justification, quality control and safety of the procedure including dose calculations and spatial dose distributions. Clinical follow-up of the patients should include the assessment of skin dose due to the important fluoroscopy time and number of cine frames. All of those should also be a part of the audit (PRIETO 2003a).

Specific training programs for the people involved in these procedures would encourage a positive safety culture in intravascular brachytherapy. They could be used as a starting point by the Regulatory Authority for the authorization of new installations and credentialing of professionals involved in this technique, as well as for the continuous education of the staff (PRIETO 2003b).

Exciting advances have been made in the realm of therapeutic radionuclides, particularly in the oncology setting. The bulletin of the ACR has published a review on “New Horizons in Nuclear Medicine” with some opinions of M. Guiberteau, chair of the ACR Nuclear Medicine Commission and chief of nuclear medicine at St. Joseph Hospital in Houston, Texas (ACR 2003). New forms of radioactive therapy targeting an ever-widening group of cancers are promising. The number of recent breakthroughs in therapeutic radionuclides is very promising; however, they are much more complex than the traditional ones. Many of these techniques require additional training, patient interaction and multidisciplinary approaches to be successfully performed.

Balloon Catheter Brachytherapy (BCB) entails intratumoral radiation administered via a unique catheter and balloon device. A catheter–radioiodine combination (I-125) was recently approved by the FDA.

Intra-arterial Brachytherapy, with radiolabeled microspheres that are chemically bonded to a radioactive pure beta emitter, Y-90 used for hepatocellular carcinoma. There is a debate over who will 'push' the drugs because the process will include a multispecialty team comprising radiology, nuclear medicine, medical oncology and others. All of these will be trained in decision making for these modalities, including patient selection, radiation safety and management of potential side effects (ACR 2003).



Europe is also progressing very well as far as digital imaging for image-guided therapy is concerned. With Food and Drug Administration legal restrictions that are tougher than European CE regulations, many US companies are looking for Europe to gain clinical experience with image-guided therapy systems (LEMKE 2001).

The implications on the European Standards in this area could be the need for specific training in RP and accreditation for all the professionals involved. Strict control of new devices and products and the promotion of guidelines and protocols to facilitate the interdisciplinary work are required.

3.6 Acronyms

ACR = American College of Radiology
CT = Computed Tomography
DIMOND = Measures for Optimising Radiological Information and Dose in Digital Imaging and Interventional Radiology
EBCT = EBT = Electron Beam Tomography
EC = European Commission
FDA = Food and Drug Administration
IAEA = International Atomic Energy Agency
ICRP = International Commission on Radiological Protection
IEC = International Electro-technical Commission
MSCT = Multi-Slice Computed Tomography
NCRP = Nuclear Regulatory Commission

PET = Positron Emission Tomography
RP = Radiation Protection
WHO = World Health Organisation

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4 CONCLUSIONS

4.1 Introduction

This document presents the main conclusions and potential implications of the Scientific Seminar on Medical Overexposures, held in Luxembourg on 16 October 2003
While it is not intended to report, in an exhaustive manner, all the opinions that were expressed by the speakers or by the audience, it takes into account the discussions that found place during the subsequent meeting of the « Article 31 » Group of experts . The content of the document has been discussed within the RIHSS (Research Implications on Health Safety Standards) Working Party*. The final text is the responsibility of the RIHSS Working Party.

4.2 RIHSS seminars: rationale

The RIHSS Working Party of the « Article 31 » Group of experts was set up with the task to help to identify the potential implications of recent research results or new data analysis on the European Basic Safety Standards (BSS), Directives, Guidance and Recommendations.
The adopted approach is the following: on the basis of the input from DG Research and of the information transmitted by the individual experts of the Art. 31 Group, the Working Party proposes yearly to the Art. 31 Group relevant themes that could be discussed during a subsequent seminar. After selection of a theme and approval of a draft program, the WP deals with the practical organisation. The seminars involve invited speakers, who are asked to clearly summarise the state-of-the-art in the field, with special attention to new information. The seminars give the Art. 31 experts the opportunity to discuss the potential implications of consolidated scientific results.

4.3 Ground for theme selection

Medical applications are the main man- made source of exposure to ionising radiation in Europe. The use of ionising radiation in the medical field has allowed for great progress to be made in diagnosis and therapy while continuing to expand and tending towards more complex examinations entailing higher exposures.
The identification and definition of the major issues for the protection of personnel and patients against the dangers of ionising radiation without impairing the medical care is a real challenge. Issues are generally crosscutting in medicine, and multiple factors need to be taken into account for ranking risks and finding the appropriate balance risk-benefit.
Although the use of diagnostic X-rays and ionising radiation in therapy provide great benefits, it can also involve risks of deterministic and stochastic effects.
A number of publications have reported deterministic effects such as radiation lesions of the skin of patients undergoing interventional radiology, especially in cardiological procedures. Stochastic effects become more relevant in young patients exposures.
The Article 31 Group of experts considered it necessary to get an overview of the situation and of the practical radiation protection considerations that can be implemented to avoid or reduce such side effects.

* The members of the Art 31 RIHSS Working Party who took part in the redaction of this document were: P. Smeesters (Art. 31, Chairman of the WP), J. Piechowski (Art. 31), A. Susanna (Art. 31). The following officials of the European Commission assisted them : M. Sarro Vaquero, J. Naegele (Energy and Transport DG).

The aim of the present Seminar on Medical Overexposures was to give an overview of the occupational and patient overexposures in the medical field, focusing on procedures more frequently or likely involved; to review the potential added risks from new technology in medicine; and to identify preventive and research actions.

4.4 Background information

The European Union has established uniform safety standards to ensure the protection of public, staff and patients against the dangers of ionising radiation, and seeks their correct implementation. Community actions on radiation protection in the medical field are mostly based on two Council Directives:

- Directive 96/29/Euratom, of 13 May 1996, laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (Basic Safety Standards Directive, BSS);
- Directive 97/43/Euratom of 30 June 1997, on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (Medical Exposures Directive, MED).

Article 9 of the MED on « Special Practices » requires that Member States ensure that appropriate radiological equipment, practical techniques and ancillary equipment are used for medical exposure involving high doses to patients, such as interventional radiology, computed tomography or radiotherapy; and that special attention is given to quality assurance programmes, including quality control measures and patient dose or administered activity assessment for these practices. In addition, Art 9 (2) requires that Member States ensure that practitioners and operators obtain appropriate training on these radiological practices.
The International Commission on Radiological Protection (ICRP) defined interventional radiology as the “procedures comprising guided therapeutic and diagnostic interventions, by percutaneous or other access, usually performed under local anaesthesia and/or sedation, with fluoroscopic imaging used to localise the lesion/treatment site, monitor the procedure, and control and document the therapy” (ICRP 2000).
The International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy (Malaga, March 2001), recommended the formulation of an Action Plan for future international work relating to the radiological protection of patients on the basis of the Conference’s findings and conclusions.
The objective of the International Action Plan, developed in consultation with the Pan American Health Organisation (PAHO), the World Health Organisation (WHO), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and with the co-operation of relevant International Organisations and the European Commission, is to make progress in patient protection.
It contains actions covering a range of specialities, including conventional and digital radiology, computed tomography, interventional procedures, nuclear medicine and radiotherapy; and a number of activities: education and training, information exchange, guidance and support to IAEA Member States, and research.
This Action Plan was approved by the International Atomic Energy Agency in September 2002.
In conclusion, safety issues and radiation protection aspects are an essential component of any medical radiological practice and their relevance for the health protection of patients and staff is well acknowledged.

4.5 Main points arising from the presentations and subsequent discussion

4.5.1 OCCUPATIONAL AND PATIENT OVEREXPOSURES IN THE MEDICAL FIELD

The paper by Dr R. Loose provided an overview of the risk of occupational and patient exposure in medicine. He summarised the different applications of ionising radiation in medicine, including diagnostic radiology, interventional radiology, diagnostic and therapeutic nuclear medicine, radiotherapy with external irradiation (Co-60 or accelerators) and radiotherapy with internal irradiation (brachytherapy).
His presentation described the occupational risk that can be present when fluoroscopy and/or radioactive substances or sources are used, and the cases of overexposure and types of procedures most frequently or likely to be involved.
He provided indications on preventive measures for physicians, regulators and industry, and on the need for research in particular fields.
He emphasised that radiation protection measures minimise the exposure of both patients and staff on hospital facilities. Nevertheless, the relation between doses to the patient and doses to the medical personnel depends on the technique; there is a strong relation in fluoroscopy but not in CT nor in radiotherapy.
Consideration was also devoted to the use of alternative non-ionising radiation techniques such as Ultrasound (US) and Magnetic Resonance Imaging (MRI) in children and for the follow-up of young patients suffering from particular chronic diseases which require regular radiological examinations.

4.5.2 POTENTIAL ADDED RISKS FROM THE NEW TECHNOLOGY IN MEDICINE

The presentation by Prof. Vaño addressed four main topics**:** a) High dose techniques (procedures guided by fluoroscopy) b) Computed Tomography (CT) and Positron Emission Tomography (PET); c) Digital radiology, and d) Other special techniques using ionising radiation and involving several groups of specialists (e.g. nuclear medicine and intravascular brachytherapy).
He emphasised that new technologies involving ionising radiation in medicine are a challenge both for expertise and for radiological protection, involving specific actions of health professionals, industry, and health care administrators.
He highlighted the relevance of training and accreditation in radiation protection of all the staff performing those practices and the engineering involvement of the radiology industry. He underlined the need to prepare guidelines and protocols, and promote specific research in this field, especially by developing standard operating procedures.

4.5.3 DISCUSSION SALIENT POINTS

The problems shown concerning safety issues and radiation protection matters and the potential implications and proposed solutions arising from the presentations were discussed by the Article 31 Group of Experts. There was a consensus on the need to undertake a wide action in this field of radiation protection in medical applications to tackle the issues considered thereafter.

4.5.3.1 Radiation Protection in Occupational Exposures

The risk of occupational overexposure in medicine has to be considered in some specific fields: in interventional radiology, nuclear medicine therapy and endovascular brachytherapy. This is essentially due to a lack of knowledge about procedures for radiation protection: initiatives have to be undertaken urgently.

Considering the classified radiation workers in the medical sector, the ones that receive the highest radiation doses are those handling unsealed radionuclides and preparing radiopharmaceuticals for diagnostic and therapeutic purposes.
The application of beta emitters like Y90 in Beta workplaces requires the use of appropriate beta shielding of the working place and of rubber fingertip dosimeters on each finger to prevent overexposures.
In the 1980's when radiotherapy sealed sources where implanted manually inside body cavities, radiation oncologists and the nurses assisting them where amongst those receiving the highest radiation doses. Since then, the introduction of the remote afterloading has greatly reduced the radiation exposure of these employees.
Currently, cardiologists, vascular surgeons and chief radiologists performing high dose interventional cardiology and radiological procedures are exposed to higher doses than are nuclear industry workers. This question is actually of paramount concern.
Indications on protective shielding and technical measures and procedures for enhancing radiation protection of physicians and the staff were provided. The use of two dosimeters–one under the apron at waist level and a second one outside and above the apron at the neck – was recommended for the staff performing interventional procedures.
It was emphasised that well managed radiation protection measures minimise radiation exposure of patients, of visitors and of medical staff.

4.5.3.2 Online Database and Reporting System for Incidents/ Accidents in the Medical Field

A series of accidents and incidents were reported in relation to the practice of radiological interventional procedures, brachytherapy, radiotherapy, and the preparation of radiopharmaceuticals.
Some of the reported accidents were due to human factor and could have been prevented if a "safety culture" had been in place.
The need to set up an online European database and system for reporting, collecting and analysing radiological incidents and accidents in the medical sector was pointed out.
The IAEA representative mentioned the Agency's International Reporting system for Unusual Radiation Events (RADEV) providing information about accidental medical exposures in radiotherapy. He also informed that an extended Emergency Response Network (ERNET) on radiological incidents and accidents involving patients is being developed to respond to countries ' needs.
The experts agreed on the need to collect and disseminate information about accidental medical exposures, including, as far as possible, information about events that did not have clinical consequences but from which prevention-relevant lessons can be drawn. They recommended that consideration should be given to mechanisms by which such information could be collected and widely disseminated in co-operation with the Agency's above-mentioned reporting systems.
Reports on incidents and accidents should be available on the Internet and methods should be developed to draw the attention of professionals. Data collected must remain anonymous and confidentiality respected.

4.5.3.3 Information, Education and Training in Radiation Protection

The discussion highlighted the need to set up an effective system for the transfer of appropriate information on the benefits and risks of the new technologies to public and users.
The education of medical and nursing students on radiation protection for medical exposure was pointed out as being highly cost-effective.
Recommendations on referral criteria for imaging and information on typical doses should be widespread to general practitioners prescribing radiological examinations to avoid unnecessary exposures.

The need for appropriate training on RP of all the staff involved in high dose procedures was particularly stressed. The experts agreed on the increasing importance of training aspects in paediatric radiology, digital imaging and interventional procedures.
According to the European guidelines on education and training on radiation protection for medical exposures (RP 116), the specialists performing high dose procedures should follow a second level of training in radiation protection. That is particularly true for cardiologists and surgeons involved in interventional radiology.
The involvement of the professional societies and national bodies in the organisation of the pertinent training is essential.
The suggestion was made to compile the existing training material and guidance on Radiation Protection published by relevant international organisations and professional societies and to set up a devoted website to this end. E-mail distribution lists for sharing this information and for receiving feedback from interested parties was considered useful.
The need to survey the degree of implementation EU-wide of the training requirements laid down in the Medical Exposures Directive was evidenced. The compilation and analysis of data at European level is not available yet. A report on the situation in Europe would be welcomed.

4.5.3.4 Radiation Protection issues concerning currently used High-Dose Techniques

4.5.3.4.1 Interventional Radiology

The advances in technology for imaging and ancillary equipment have facilitated the increasing use of interventional and invasive fluoroscopy guided procedures in cardiology and other non-cardiac procedures for diagnostic or therapeutic purposes.
These procedures require sometimes extended fluoroscopic times and radiographic or cine images, and there is an increased risk of deterministic effects, in particular of patient skin radiation injuries. Radiation lesions have been reported in some patients undergoing interventional procedures. The risk of stochastic effects in the long term is also relevant especially in young patients.
Non-radiology specialists, in particular cardiologists and vascular surgeons, who might have not been adequately trained in radiation protection, sometimes perform interventional radiological procedures. The specific training and accreditation in RP of all the health professionals involved in the interventional procedures is essential.
The industry should incorporate to the new equipment the possibility of automatic registering and on-line display of doses. Fluoroscopic equipment intended for interventional use should be equipped with a cumulative-skin-dose monitor, including alarm, that can be useful to prevent dangerous dose levels.
It was suggested to minimise future risks and unwanted side effects for patients and at the same time improve the occupational safety of the staff, by promoting the use of X-ray systems specially designed for interventional radiology, training cardiologists and vascular surgeons in radiation protection, and performing routine patient dose measurements and registration not only for complex interventional procedures.

4.5.3.4.2 Computed Tomography (CT) and Positron Emission Tomography (PET)

There has been a considerable increase in the number of Computed Tomography (CT) examinations in all its forms (spiral, helicoidal, multislice, whole body scan, and combined with new techniques such as CT/ PET).
Computed Tomography today accounts for about 4% of all radiodiagnostic procedures and results in about 40% of the radiation dose attributed to medical x-rays in developed countries.
The use of Computed Tomography in paediatrics raises particular concerns. Doses received by children undergoing CT examinations, and in particular paediatric patients subject to regular examinations, are a matter of concern.

The correct justification of CT examinations in children is paramount. Specific referral criteria for children should be set out and promoted. ALARA guidelines are particularly important when scanning paediatric patients. Specific standards, dose reference values for paediatric CT, and optimisation protocols for the exposure of children must be developed.
Whole body screening is being promoted through the Internet and offered to the public through misleading publicity. Self-referral and unjustified CT screening examinations are a problem in the USA and could also become a future problem in Europe. The need for a more transparent and adequate information to the public was voiced.
The justification of these practices is critical. Objective information on the benefits and risks and on the alternatives to whole-body screening should be promoted. Ethical issues, patient rights, and the need for informed consent should also be considered.

4.5.3.4.3 Digital Imaging

The introduction of digital radiology has had a great impact in the radiology market.
The use of digital imaging techniques (computed radiography systems with phosphor plates, or direct digital with flat panel detectors) is following a rising trend.
With digital techniques, the collection, archiving, retrieving and transfer of images has become much easier and the possibility to improve the workflow in radiology departments is an advantage.
Digital radiology has the potential in principle to diminish doses. However in practice, particularly during the transition from conventional to digital, there is evidence showing that patient doses can be increased without any additional clinical benefit due to the use of non-optimised techniques and procedures.
In digital radiology, there is a correlation between dose and image quality, so that the required quality for the specific clinical tasks should be clearly defined and agreed with the clinician. Training in the optimisation of image quality and patient dose is necessary, in particular for paediatric patients. On the other hand, the justification criteria need to be reinforced to avoid unnecessary exposures.
Protocols and guidelines to optimise digital techniques should be developed, including appropriate diagnostic reference levels. Frequent patient dose audits should be carried out whenever digital techniques are introduced.
Industry has a role to play to facilitate the measuring, the displaying at the operator console, and the archiving of exposure data. The recording and archiving of patient dose measurements should be part of the quality management.
More research is needed to optimise digital techniques.

4.5.3.4.4 Other Special Techniques Involving Several Groups of Specialists

New techniques and devices using ionising radiation, including percutaneous transluminal angioplasty, unsealed radionuclides for diagnosis and therapy, and endovascular brachytherapy, are rapidly evolving.
These techniques require additional training and accreditation of the staff, and multidisciplinary approaches to be successfully performed.
The strict control of the new devices and products, and the promotion of guidelines and protocols to facilitate the interdisciplinary work are necessary.

4.5.3.5 Non–Ionising Radiation Technologies

The use of non-ionising radiation techniques such ultrasound (US) and Magnetic Resonance Imaging (MRI) were discussed as alternative methods, namely in the case of paediatric patients and young people suffering from diseases requiring regular long-term follow-up. For instance, independently of the dose benefit, MRI gives better imaging than X rays in Crohn disease.

The type of suspected pathology and tissues which are involved, the technique diagnostic value, its availability and costs are relevant issues for the justification of the prescription of one or other method. Specific technical constraints must also be considered, as the requirements for strict immobilisation or non general anaesthesia to perform MRI examination.

4.6 Conclusions and potential policy implications

1. An appropriate anonymous system for reporting about and learning from accidents and incidents with radiation in medical exposures has to be elaborated, possibly in cooperation with the IAEA.
2. In spite of Art. 7 of the 97/43 Euratom directive, physicians using fluoroscopy (especially for interventional techniques) are sometimes not sufficiently trained in Radiation Protection (RP). Systematic training, including new techniques, must be enforced for all physicians and other health professionals involved in the radiological procedures. This training should include theoretical and practical aspects of occupational exposure, and radiation protection of patients. A certification system of training in radiation protection should be implemented in Member States.
3. On-line patient dose reading should be always available in interventional high-dose procedures, with appropriate alarm signals when threshold doses for deterministic effects could be approached. These doses should be archived. Industry should be involved in these efforts at European level.
4. There remain radiation protection problems regarding digital radiology. Research and Guidance at the European level is recommended.
5. Public and patients should be better informed about medical exposures, in particular as regards the whole body CT. European Guidance on how to cope with this topic should be developed.
6. Special attention should be paid to RP and occupational dosimetry in the application of beta emitters in nuclear medicine and intravascular therapy. More generally, the use of additional dosemeters in specific situations should be addressed. EU guidance on these topics should be developed.
7. More emphasis should be placed on medical exposures of children, particularly as regards justification and the development of specific protocols for CT examinations and specific diagnostic reference levels. EU guidance on these topics should be developed.