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Patient and Staff Radiological Protection in Cardiology

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Abstract- Cardiac nuclear medicine, cardiac CT, percutaneous coronary interventions and electrophysiology procedures are increasing in number and account for an important share of patient radiation exposure in medicine. Complex percutaneous coronary interventions and cardiac electrophysiology procedures are associated with high radiation doses. These procedures can result in patient skin doses high enough to cause radiation injury and, in children, an increased risk of cancer. Treatment of congenital heart disease in children is of particular concern. Additionally, staff in cardiac catheterization laboratories may receive high radiation doses if radiological protection tools are not used properly.

The Commission has provided recommendations for radiological protection during fluoroscopically guided interventions in *ICRP Publication 85*, for radiological protection in CT in *ICRP Publications 87 and 102*, and for training in radiological protection in *ICRP Publication 113* (ICRP 2000a,b, 2007, 2009). This report is focused specifically on cardiology, and brings together information relevant to cardiology from the Commission's published documents. There is emphasis on those imaging procedures and interventions specific to cardiology. The material and recommendations in the current document have been updated to reflect the most recent recommendations of the Commission.

This report provides guidance to assist the cardiologist with justification and optimization of cardiac CT studies, cardiac nuclear medicine studies and fluoroscopically guided cardiac interventions. It includes discussions of the biological effects of radiation, principles of radiological protection, protection of staff during fluoroscopically guided interventions, radiological protection training and establishment of a quality assurance programme for cardiac imaging and intervention.

Because tissue injury, principally skin injury, is a risk for fluoroscopically guided interventions, particular attention is devoted to clinical examples of radiation-related skin injuries from cardiac interventions, methods to reduce patient radiation dose, training recommendations, and quality assurance programs for interventional fluoroscopy.

Keywords: Cardiology, Computed Tomography, Nuclear Medicine, Cardiac Catheterization, Radiological Protection

PREFACE

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

Some previous reports have dealt in part with issues relevant to cardiology and have appeared in print as *Publications 85, 87, 102 and 113* (ICRP, 2000a,b, 2007b, 2009) and *Supporting Guidance 2* (ICRP, 2001). The present report continues this series of concise and focused documents.

In cardiology, patient radiation exposure is due to nuclear medicine, CT, percutaneous coronary interventions and electrophysiology procedures. This rapidly expanding field of medicine, both in numbers and complexity, requires guidance for practitioners.

At their meeting in Beijing in 2004, the Commission decided that there would be value in developing guidance on radiological protection for cardiologists. Due to a variety of other priorities, work on the document was interrupted for a time and resumed in earnest in 2010.

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References

ICRP, 2000a. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann. ICRP 30 (2).

ICRP, 2000b. Managing patient dose in computed tomography. ICRP Publication 87. Ann. ICRP 30 (4).
ICRP, 2007a. Managing patient dose in multi-detector computed tomography. ICRP Publication 102. Ann. ICRP 37 (1).
ICRP, 2007b. Radiological protection in medicine. ICRP Publication 105. Ann. ICRP 37 (6).
ICRP, 2009. Recommendations of the International Commission on Radiological Protection. ICRP Publication 113, Ann. ICRP 39 (5).
ICRP, 2001. Radiation and your patient – a guide for medical practitioners. ICRP Supporting Guidance 2. Ann. ICRP 31 (4).

EXECUTIVE SUMMARY

In cardiology, patient radiation exposure is due to nuclear medicine, CT, percutaneous coronary interventions and electrophysiology procedures. Cardiac nuclear medicine, cardiac CT, percutaneous coronary interventions and electrophysiology procedures are increasing in number and account for an important share of patient radiation exposure in medicine. Complex percutaneous coronary interventions and cardiac electrophysiology procedures are associated with high radiation doses. These procedures can result in patient skin doses high enough to cause radiation injury and, in children, an increased risk of cancer. Treatment of congenital heart disease in children is of particular concern. Additionally, staff in cardiac catheterization laboratories may receive high radiation doses if radiological protection tools are not used properly.

1. The Biological Effects of Radiation

Stochastic effects are malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose without threshold. The likelihood of inducing a stochastic effect increases with dose, but the exact relationship between dose and effect is not known. Children are approximately 2-3 times more sensitive to the stochastic effects of radiation than adults. They also have a longer potential lifespan than do adults, so they have more time to develop possible radiation related sequelae.

Deterministic effects (e.g., skin injury) are due to injury in populations of cells, characterised by a threshold dose and an increase in the incidence and severity of the reaction as the dose is increased further. Deterministic effects are also termed tissue reactions. Radiation-induced skin injuries may not become fully manifest until months after the radiation dose was administered. The diagnosis of a radiation-induced skin injury is often delayed. Deterministic injuries may extend into deeper tissues and can cause symptoms that persist for years. Deterministic injuries may be accompanied by an increase in stochastic risk.

The mechanisms of heart radiation damage include inflammatory processes, in particular after low doses, and after higher doses there is a progressive reduction in the number of patent capillaries eventually leading to ischemia, myocardial cell death and fibrosis, accelerated atherosclerosis in major blood vessels, decreased cardiac function, and fatal congestive heart failure. Cardiovascular radiation effects have been reported to occur at doses > 0.5 Gy. Organ doses may reach this level in some complex fluoroscopically guided cardiac procedures.

The lens of the eye is a radiosensitive tissue. Ionizing radiation typically causes posterior subcapsular cataract formation in the lens of the eye. Surveys of cardiologists and support staff working in catheterization laboratories have found a high percentage of lens opacities attributable to occupational radiation exposure when radiological protection tools have not been used properly.

2. Principles of Radiological Protection for Patients and Staff

The Commission recommends three principles of radiological protection: justification, optimization of protection, and application of dose limits (ICRP, 2007). The first two are source related and apply to all radiation exposure situations. The

third applies to staff, but does not apply to medical exposures of patients or to carers and comforters.

Justification means that a medical procedure should only be performed when it is appropriate for a particular patient— the anticipated clinical benefits should exceed all anticipated procedural risks, including radiation risk. For CT and nuclear medicine studies, justification is a responsibility shared between the referring clinician and the cardiac imager. For fluoroscopically guided interventions, the responsibility rests with the interventionalist.

Optimization means that the radiation dose to the patient is suitable for the medical purpose, and radiation that is clinically unnecessary or unproductive is avoided. Patient radiation dose is optimized when imaging is performed with the least amount of radiation required to provide adequate image quality, diagnostic information, and for fluoroscopy, adequate imaging guidance.

3. Managing patient dose in fluoroscopically guided interventions

The informed consent process should include information on radiation risk if the risk of radiation injury is thought to be significant. Important aspects of the patient's medical history that should be considered when estimating radiation risk are genetic factors, co-existing diseases, medication use, radiation history, and pregnancy.

Some of the factors that affect the patient's radiation dose depend on the x-ray system, but many others depend on how the operator uses the x-ray system. During the procedure, the cardiologist should be kept aware of the fluoroscopy time, the number of cine series and cine frames, and the total patient dose. As patient radiation dose increases, the operator should consider the radiation dose already delivered to the patient and the additional radiation necessary to complete the procedure.

Patient radiation dose reports should be produced at the end of the procedure, and archived. Radiation dose data should be recorded in the patient's medical record after the procedure. When the patient's radiation dose from the procedure is high, clinical follow-up is essential for early detection and management of skin injuries. Patients who have received a substantial radiation dose should have follow-up at 10-14 days and at one month after the procedure for potential radiation injuries.

4. Protection of staff during interventional fluoroscopy

The basic tools of occupational radiological protection are time, distance and shielding. The use of personal protective shielding is necessary in the cardiac catheterization laboratory. Occupational doses can be reduced to very low levels if ceiling suspended lead screens and protective lead curtains suspended from the side of the procedure table are used properly. In general, reducing patient dose will also reduce operator dose. With proper use of radiological protection tools and techniques, the effective dose (E) for an interventionalist is typically 2–4 mSv/year, and is well below the 20 mSv/year limit recommended by the Commission.

Radiation exposure to the operator is neither uniform nor symmetric. Radiological protection for the eyes is necessary for interventionalists. Proper use of

personal monitoring badges is necessary in cardiac catheterization laboratories in order to monitor and audit occupational radiation dose.

5. Radiological protection for nuclear cardiology

Appropriate use criteria and guidelines that help to set standards for justification of nuclear cardiology procedures have been developed through consensus efforts of professional societies. Justification needs to be performed on an individualized, patient-by-patient basis. Optimization of nuclear cardiology procedures involves the judicious selection of radiopharmaceuticals and administered activities to ensure diagnostic image quality while minimizing patient dose. Administered activities should be within pre-specified ranges, as provided in international and national guidelines, and should reflect patient habitus. If stress imaging is normal, rest imaging can be omitted to minimize total dose. For SPECT protocols, Tc-99m-based agents yield lower effective doses than Tl-201, and are preferred on dosimetric grounds. Practitioners need good quality dosimetry data to perform proper benefit-risk analyses for their patients.

6. Radiological protection for cardiac CT

Appropriate use criteria and guidelines for justification of cardiac CT have been developed through consensus efforts of professional societies. Justification needs to be performed on an individualized, patient-by-patient basis, weighing the benefits and risks of each imaging test under consideration as well as of doing no test. Assessment of radiation risk is one part of this process.

Dose from cardiac CT is strongly dependent on scanner mode, tube current, and tube voltage. For patients with a heart rate less than 65-70 bpm and a regular rhythm, diagnostic image quality can generally be maintained while using dose-reduction methods such as ECG-controlled tube current modulation and axial imaging. The maximum tube current should be appropriate for the patient's habitus. Further research is needed to develop and validate methods, such as newer scan modes and low-voltage scanning, to minimize radiation dose to patients and practitioners.

7. Radiological protection training for interventional fluoroscopy

Legislation in most countries requires that individuals who take responsibility for medical exposures must be properly trained in radiological protection (RP). Interventional cardiologists worldwide typically have little or no training in RP. The Commission recommends that, in addition to the training recommended for other physicians who use X-rays, interventionalists, including interventional cardiologists, should receive a second, higher level of RP training.

Training programmes should include both initial training for all incoming staff and regular updating and retraining. Scientific congresses should include refresher courses on RP, attendance at which could be a requirement for continuing professional development.

Training activities in RP should be followed by an evaluation of the knowledge acquired from the training programme (a formal examination system). Physicians who have completed training should be able to demonstrate that they

possess the knowledge specified by the curriculum by passing an appropriate certifying examination.

The Commission recommends that nurses and other healthcare professionals who assist during fluoroscopic procedures should be familiar with radiation risks and radiological protection principles, in order to minimise their own exposure and that of others.

8. Quality assurance programmes

Two basic objectives of the radiological protection quality assurance programme (QAP) are to evaluate patient radiation dose on a periodic basis and to monitor occupational radiation dose for workers in cardiology facilities where radiation is used. A cardiologist should be in charge of the QAP aspects of RP for cardiology procedures, and should be assisted by a medical physicist. A senior interventionalist and a medical physicist should be included in the planning for a new interventional fluoroscopy laboratory, installation of a new x-ray or nuclear medicine system and the upgrade of existing equipment.

Periodic evaluation of image quality and procedure protocols should be included in the QAP. The QAP should establish a trigger level for individual clinical follow-up when there is a risk of radiation-induced skin injuries. The QAP should ensure the regular use of personal dosimeters and include a review of all abnormal dose values.

Patient dose reports should be produced at the end of procedures, archived and recorded in the patient's medical record. If dose reports are not available, dose values should be recorded in the patient's medical record together with procedure and patient identification. Patient dose audits (including comparison with Diagnostic Reference Levels) and reporting are important components of the QAP.

9. Reference

ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103. Ann. ICRP 37, 1-332.

Recommendations

- **Individuals who request, perform or interpret cardiology imaging procedures should be aware of the radiation risks of the procedure.**
- **Appropriate use criteria and guidelines for justification have been developed and should be used in clinical practice.**
- **Nuclear cardiology examinations and cardiac CT examinations should be optimized and dose reduction techniques used whenever applicable.**
- **The informed consent process should include information on radiation risk if a risk of radiation injury is thought to exist.**
- **Radiation dose data should be recorded in the patient's medical record after the procedure; patient dose reports should be archived for quality assurance purposes.**
- **When the patient's radiation dose from an interventional procedure exceeds the institution's trigger level, clinical follow-up should be performed for early detection and management of skin injuries.**
- **Suggested values for the trigger level are a skin dose of 3 Gy, a kerma-area product of 500 Gy·cm^2, or an air kerma at the patient entrance reference point of 5 Gy.**
- **Individuals who perform cardiology procedures where there is a risk of deterministic injury to patients should be able to recognize these skin injuries.**
- **Individuals who perform interventional cardiology procedures should be familiar with methods to reduce radiation dose to patients and staff.**
- **Nurses and other healthcare professionals who assist during fluoroscopic procedures should be familiar with radiation risks and radiological protection principles, in order to minimise their own exposure and that of others.**
- **Whenever there is a possibility of occupational radiation exposure, staff should use personal protective shielding.**
- **Training programmes in radiological protection should include both initial training for all incoming staff and regular updating and retraining.**
- **In addition to the training recommended for other physicians who use X-rays, interventionalists, including interventional cardiologists, should receive a second, higher level of radiological protection training.**
- **A cardiologist should be in charge of the quality assurance programme aspects of radiological protection for cardiology procedures, and should be assisted by a medical physicist.**
- **Quality assurance programmes in cardiology should include patient dose audits.**
- **Quality assurance programmes should ensure the regular use of personal dosimeters and should include a review of all abnormal dose values.**

GLOSSARY

1. Definitions

Absorbed dose, *D*

The fundamental dose quantity given by

$$D = \frac{d\bar{\varepsilon}}{dm}$$

Where $d\bar{\varepsilon}$ is the mean energy imparted to matter of mass d*m* by ionising radiation. The SI unit for absorbed dose is joule per kilogram (J kg^{-1}). Its special name is gray (Gy) (ICRP, 2007). In layman's terms, absorbed dose is the measure of energy absorbed by tissue from ionizing radiation.

Acceptance test

A test carried out after new equipment has been installed or major modifications have been made to existing equipment, in order to verify compliance with the manufacturer's specifications, contractual specifications and applicable local regulations.

ALARA

An acronym for As Low As Reasonably Achievable. *See* Optimisation of protection.

Becquerel (Bq)

The special name for the SI unit of activity. 1 Bq = 1 s^{-1} (≈2.7 10^{-11} Ci).

Brachytherapy

Radiation treatment of a patient using sealed or unsealed sources of radiation placed within the patient's body.

Bradycardia

An abnormally slow heart rhythm. Depending on the heart rate and the underlying abnormality, bradycardias may or may not require treatment.

Cardiomyopathy

Any condition that results in weakening of the pumping strength of the cardiac ventricles, or that causes areas of scar tissue to develop in the ventricles.

Cardiovertor-defibrillator

Devices, usually implanted in the same way as pacemakers, that continuously monitor the heart rhythm, automatically function as pacemakers

for bradycardia, and deliver life-saving shocks if a dangerous tachycardia is detected.

Carers and comforters

Individuals, other than staff, who care for and comfort patients. These individuals include parents and others, normally family or close friends, who hold children during diagnostic procedures or may come close to patients following the administration of radiopharmaceuticals or during brachytherapy (ICRP, 2007).

Commissioning

Testing carried out after new equipment has been installed, in order to verify that the equipment is properly configured for its clinical application at the centre (NCRP, 2010).

Constancy test

Each of a series of tests, carried out to ensure that the functional performance of equipment meets established criteria, or to enable the early recognition of changes in the properties of components of the equipment (IEC, 1993).

Deterministic effect

Injury in populations of cells, characterised by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Deterministic effects are also termed tissue reactions. In some cases, deterministic effects are modifiable by post-irradiation procedures including biological response modifiers (ICRP, 2007).

Diagnostic reference level

Used in medical imaging with ionizing radiation to indicate whether, in routine conditions, the patient dose or administered activity (amount of radioactive material) from a specified procedure is unusually high or low for that procedure (ICRP, 2007).

Diastasis

The midportion of diastole, when the blood enters the ventricle slowly or ceases to enter. Diastasis duration is in inverse proportion to heart rate and is absent at very high heart rates.

Dose coefficient

Used as a synonym for dose per unit intake of a radioactive substance, but sometimes also used to describe other coefficients linking quantities or concentrations of activity to doses or dose rates, such as the external dose rate at a specified distance above a surface with a deposit of a specified activity per unit area of a specified radionuclide (ICRP, 2007).

Dose limit

The value of the effective dose or the equivalent dose to individuals from planned exposure situations that shall not be exceeded (ICRP, 2007).

Dysrhythmia

A disorder of heart rhythm, also called arrhythmia. Dysrhythmias may be due to electrical, circulatory or structural diseases or disorders. Some dysrhythmias are harmless, and some are life-threatening.

Effective dose, E

The tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body, given by the expression:

$$E = \sum_{\mathbf{T}} w_{\mathbf{T}} \sum_{\mathbf{R}} w_{\mathbf{R}} D_{\mathbf{T,R}} \quad \textbf{or} \quad E = \sum_{\mathbf{T}} w_{\mathbf{T}} H_{\mathbf{T}}$$

where H_T or $w_R D_{T,R}$ is the equivalent dose in a tissue or organ, T, and w_T is the tissue weighting factor. The unit for the effective dose is the same as for absorbed dose, J kg^{-1}. Its special name is sievert (Sv) (ICRP, 2007). Effective dose was developed as a practical quantity for use in the general system of radiation protection, particularly with regard to applying the principles of optimization of radiation protection and dose limitation for stochastic effects.

Electrophysiology

Cardiac electrophysiology is directed at evaluation and treating abnormalities of the electrical conduction system of the heart. Cardiac electrophysiology procedures involve the recording of intracardiac electrical signals and programmed electrical stimulation of the heart. The procedure may be performed for diagnostic purposes only or may be part of a combined diagnostic and therapeutic (e.g., ablation) procedure. Catheters for pacing and recording are advanced through blood vessels into multiple cardiac chambers. The designs of the catheters and the sites appropriate for their placement are determined according to the nature of the arrhythmia under investigation.

Employer

An organisation, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity, or other persons designated in accordance with national legislation, with recognized responsibility, commitment, and duties towards a worker in her or his employment by virtue of a mutually agreed relationship. A self-employed person is regarded as being both an employer and a worker (ICRP, 2007).

Equivalent dose, H_T

The dose in a tissue or organ T given by:

$$H_{\mathbf{T}} = \sum_{\mathbf{R}} w_{\mathbf{R}} D_{\mathbf{T,R}}$$

where $D_{T,R}$ is the mean absorbed dose from radiation R in a tissue or organ T, and w_R is the radiation weighting factor. Since w_R is dimensionless, the

unit for the equivalent dose is the same as for absorbed dose, J kg^{-1}. This unit's special name is sievert (Sv) (ICRP, 2007). For x-rays used in fluoroscopy, $w_R = 1$, so the equivalent dose is numerically equal to the mean absorbed dose in mGy.

Fluoroscopically guided interventions

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).

Gray (Gy)

The special name for the SI unit of absorbed dose: 1 Gy = 1 J kg^{-1}.

Justification

The process of determining whether either (1) a planned activity involving radiation is, overall, beneficial, i.e. whether the benefits to individuals and to society from introducing or continuing the activity outweigh the harm (including radiation detriment) resulting from the activity; or (2) a proposed remedial action in an emergency or existing exposure situation is likely, overall, to be beneficial, i.e., whether the benefits to individuals and to society (including the reduction in radiation detriment) from introducing or continuing the remedial action outweigh its cost and any harm or damage it causes (ICRP, 2007).

Interventional Reference Point, *see* Patient Entrance Reference Point

KAP, *see* Kerma-area product

Kerma, K

The quotient of the sum of the kinetic energies, dE_{tr}, of all charged particles liberated by uncharged particles in a mass dm of material, and the mass dm of that material.

$$K = \frac{dE_{tr}}{dm}$$

Kerma is defined as a non-stochastic quantity and dE_{tr} is the expectation value of the sum of the kinetic energies. The unit for kerma is joule per kilogram (J kg^{-1}). This unit's special name is gray (Gy) (ICRP, 2007). "Kerma" is an acronym for Kinetic Energy Released in a Mass.

Kerma-area product, KAP

The integral of air kerma across the entire x-ray beam emitted from the x-ray tube. Kerma-area product is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. Kerma-area product is measured in units of Gy·cm^2. This quantity was previously called dose-area

product. Earlier publications used the abbreviation 'DAP' for this quantity (Stecker et al, 2009).

Mean absorbed dose in a tissue or organ (T), D_T

The absorbed dose D_T, averaged over the tissue or organ T, which is given by

$$D_T = \frac{\varepsilon_T}{m_T}$$

where ε_T is the mean total energy imparted in a tissue or organ T, and m_T is the mass of that tissue or organ (ICRP, 2007).

Medical exposure

Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly, while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure (ICRP, 2007).

Myocardial perfusion

Blood flow to the heart muscle.

Occupational exposure

This refers to all exposure incurred by workers in the course of their work, with the exception of 1) excluded exposures and exposures from exempt activities involving radiation or exempt sources; 2) any medical exposure; and 3) the normal local natural background radiation (ICRP, 2007).

Optimisation of protection (and safety)

The process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable, economic and societal factors being taken into account (ICRP, 2007).

Patient Entrance Reference Point

For isocentric fluoroscopic systems such as C-arm fluoroscopes, the Patient Entrance Reference Point is located along the central x-ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot (IEC, 2010). The earlier version of this standard refers to this point as the Interventional Reference Point. (IEC, 2000). The Patient Entrance Reference Point is close to the patient's entrance skin surface when the heart is at the isocenter of the gantry.

Peak Skin Dose, PSD

The maximum absorbed dose to the most heavily irradiated localized region of skin (i.e., the localized region of skin that lies within the primary x-ray beam for the longest period of time during an FGI procedure). Peak skin dose is measured in units of Gy (NCRP, 168).

Percutaneous coronary intervention (PCI)

PCI encompasses a variety of procedures used to treat patients with diseased coronary arteries. A catheter is advanced into the diseased artery, and a balloon is inflated within the stenotic portion of the artery, often accompanied by placement of a stent (a wire mesh tube) to act as a permanent scaffold. The procedure is commonly known as coronary angioplasty.

Principles of protection

A set of principles that apply equally to all controllable exposure situations: the principle of justification, the principle of optimisation of protection, and the principle of application of limits on maximum doses in planned situations (ICRP, 2007).

PSD, *see* Peak Skin Dose

Radiation weighting factor, w_R

A dimensionless factor by which the organ or tissue absorbed dose is multiplied to reflect the higher biological effectiveness of high-LET radiations compared with low-LET radiations. It is used to derive the equivalent dose from the absorbed dose averaged over a tissue or organ (ICRP, 2007).

Radiofrequency ablation

In cardiology, a procedure where one or more catheters are guided via fluoroscopy into the blood vessels and directed to the heart muscle. A burst of radiofrequency energy destroys very small areas of tissue that give rise to abnormal electrical signals.

Reference Air Kerma (RAK)

Air kerma of the primary X-ray beam measured under specific conditions and expressed as the equivalent value at the Patient Entrance Reference Point (IEC, 2004, IEC, 2010). It is the air kerma accumulated at a specific point in space relative to the fluoroscopic gantry (see Patient Entrance Reference Point, above) during a procedure. Reference air kerma does not include backscatter and is measured in units of Gy. Reference air kerma is sometimes referred to as reference dose or cumulative air kerma. Earlier publications used the term ‘cumulative dose’ and the abbreviation ‘CD’ for this quantity (Stecker, 2009).

Sievert (Sv)

The special name for the SI unit of equivalent dose, effective dose, and operational dose quantities. The unit is joule per kilogram (J kg^{-1}).

SRDL, *see* Substantial Radiation Dose Level

Stochastic effects of radiation

Malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose without threshold (ICRP, 2007).

Stenosis

Narrowing of a hollow structure. With respect to percutaneous coronary interventions, narrowing of the inner diameter of a coronary artery.

Stress test

A standardized procedure for assessing the effect of stress on heart function and myocardial perfusion. Stress may be induced by exercise or simulated by administration of drugs. A normal stress test implies that blood flow through the coronary arteries is normal.

Substantial Radiation Dose Level (SRDL)

An appropriately selected reference value used to trigger additional dose management actions during a procedure and medical follow-up for a radiation level that might produce a clinically relevant injury in an average patient. There is no implication that radiation levels above the SRDL will always cause an injury or that radiation levels below the SRDL will never cause an injury (NCRP 168, 2010).

Tachycardia

An abnormally fast heart rhythm. Depending on the heart rate and the underlying abnormality, tachycardias may or may not require treatment.

Threshold dose for tissue reactions

Dose estimated to result in only 1% incidence of tissue reactions (ICRP, 2007).

Tissue reaction

See 'Deterministic effect'.

Tissue weighting factor, w_T

The factor by which the equivalent dose in a tissue or organ T is weighted to represent the relative contribution of that tissue or organ to the total health detriment resulting from uniform irradiation of the body (ICRP 1991). It is weighted such that:

$$\sum_{T} w_T = 1$$

(ICRP, 2007).

Valvular heart disease

Heart disease due to one or more abnormal heart valves. Abnormally narrowed or leaky heart valves can interfere with the heart's ability to push blood forward from chamber to chamber, and then out to the lungs and body.

Worker

Any person who is employed, whether full time, part time or temporarily, by an employer, and who has recognised rights and duties in relation to occupational radiological protection (ICRP, 2007).

2. References

IEC, 1993. Medical electrical equipment - Part 1-61223: Evaluation and routine testing in medical imaging departments. 1st ed. Geneva, Switzerland: International Electrotechnical Commission.

IEC, 2000. Medical electrical equipment. Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures. IEC 60601-2-43. Geneva, Switzerland: International Electrotechnical Commission.

IEC, 2004. Medical electrical equipment - Technical Report 60788: Glossary of defined terms. IEC TR 60788. 2nd edition. Geneva, Switzerland: International Electrotechnical Commission.

IEC, 2010. Medical electrical equipment. Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures. IEC 60601-2-43. 2nd edition. Geneva, Switzerland: International Electrotechnical Commission.

ICRP, 1991. The 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann ICRP 21(1-3):1-201.

ICRP, 2000. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann ICRP 30:7-67.

ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann ICRP 37(2-4):1-332.

NCRP, 2010. Radiation dose management for fluoroscopically guided interventional medical procedures. NCRP Report No. 168. Bethesda, MD: National Council on Radiation Protection and Measurements.

Stecker MS, Balter S, Towbin RB, Miller DL, Vañó E, Bartal G, Angle JF, Chao CP, Cohen AM, Dixon RG, Gross K, Hartnell GG, Schueler B, Statler JD, de Baère T, and Cardella JF. Guidelines for patient radiation dose management. J Vasc Interv Radiol 2009; 20: S263-S273.

1. INTRODUCTION

Main Points

- **In cardiology, patient radiation exposure is due to nuclear medicine, CT, percutaneous coronary interventions, electrophysiology procedures, procedures for the correction of congenital heart disease or acquired valvular disease, and other vascular interventional procedures.**
- **Cardiac nuclear medicine, CT, percutaneous coronary interventions and electrophysiology procedures are increasing in number and account for a disproportionate share of patient radiation exposure.**
- **Interventional cardiology procedures can result in patient skin doses high enough to cause radiation injury and an increased risk of cancer in children.**
- **Complex percutaneous coronary interventions and cardiac electrophysiology procedures are associated with higher radiation doses**
- **Treatment of congenital heart disease in children is of particular concern, due to their greater sensitivity to radiation.**
- **Staff in cardiac catheterization laboratories may receive high radiation doses if radiological protection tools are not used properly.**

1.0 Introduction

(1) In cardiology, patients are exposed to ionizing radiation from three different modalities: fluoroscopy (including cineangiography), computed tomography (CT) and nuclear medicine. These three modalities differ considerably in the frequency with which they are performed, in patient radiation doses, in the way radiation is administered to the patient, and in radiation dose to operators and staff.

1.1 Fluoroscopically guided procedures

(2) Cardiologists perform a variety of fluoroscopically guided procedures. These include procedures to diagnose and treat abnormal coronary arteries, procedures to diagnose and treat cardiac dysrhythmias, procedures to diagnose and treat congenital and valvular heart disease and other vascular interventions. These procedures may be performed on patients of all ages, from newborns to the elderly. The Commission has addressed avoidance of radiation injury from fluoroscopically guided procedures in the past (ICRP 2000), but advances in technology and in our understanding of radiation effects have occurred in the past decade.

1.1.1 Percutaneous coronary interventions (PCI)

(3) Despite the continuing development of non-invasive cardiac imaging techniques over the past decade, including echocardiography, cardiac CT scanning and cardiac MRI, an increasing number of patients undergo fluoroscopically guided

invasive cardiac diagnostic and therapeutic procedures. In Europe there was a 3-fold increase in coronary angiography (CA) and a 5-fold increase in percutaneous coronary interventions (PCI) between 1992 and 2001, primarily due to the introduction of coronary stents (Togni, et al, 2004, fig. 1.1) Between 1990 and 2003, the average annual rate of increase in coronary angioplasty procedures in Europe ranged from 3.78% in the Netherlands to 11.82% in Finland, with a mean of 6.73% (Faulkner and Werduch, 2008a). An estimated 3,043,000 coronary arteriograms and 910,000 percutaneous coronary interventions, with 690,000 coronary stent placements, were performed in Europe in 2007 (Faulkner and Werduch, 2008b).

(4) Similar growth rates were observed in North America (Laskey et al, 2000, Anderson et al, 2002) for the time period 1990-2000. Between 2006 and 2008, however, the number of invasive coronary procedures in the U.S. declined by approximately 2% (NCRP Report 168, 2010), and appears to be declining in some European countries as well (Meier, 2010). This is presumed due to the increase in cardiac CT.

(5) In the United States, interventional fluoroscopy procedures were the third largest source of medical exposure of patients in 2006, accounting for 14% of medical exposure (NCRP report 160, 2009). Cardiac procedures were 28% of the total interventional fluoroscopy procedures, but accounted for 53% of the interventional fluoroscopy exposure.

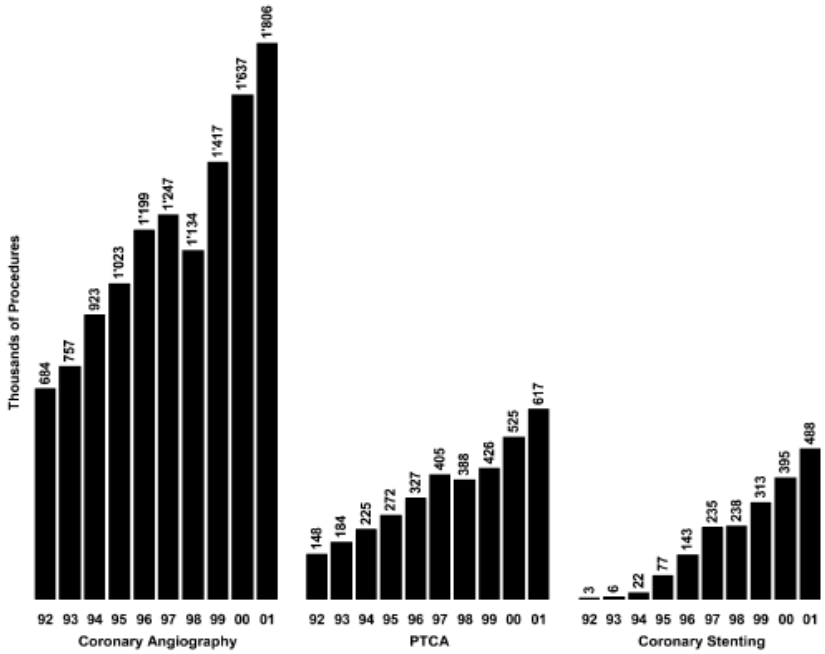


Figure 1.1: Coronary angiograms, coronary angioplasty (PTCA) and coronary stenting in Europe from 1992—2001, in thousands of procedures (from Togni, EHJ reproduced with permission [to be requested from Elsevier Ltd.])

(6) This growth has involved mainly the Western world, but a similar trend is seen in other countries: in China the annual increment rate for PCI is around 40% (Cheng et al, 2004). This number is relatively small and may reflect the lower prevalence of coronary artery disease in the Chinese population (3-7%, about one quarter of that of Western Caucasians), but is expected to grow as a consequence of changing dietary habits, life-style and cigarette smoking (Cheng et al, 2004, Moran 2010).

(7) A survey of developing countries conducted by the IAEA revealed that about 30% of the 20 participating countries demonstrated a 100% increase in workload in the 3-year period from 2004 to 2007 (Tsapaki, 2009). The same study indicated that the numbers of paediatric interventional procedures can reach the levels of adult interventional procedures, even in developing countries.

1.1.2 Skin injuries

(8) Both PCI and interventional electrophysiology procedures can result in patient skin doses high enough to cause deterministic skin injuries (see Chapters 2 and 3) (Miller 2008). At one centre, the frequency of skin injuries was estimated at 3×10^{-4} (Padovani 2005). Although the number of radiation injuries due to cardiac procedures remains small, these injuries have a major impact on the patients who are affected. Therefore, it is important to inform and continue to remind practicing clinicians of the potential risks involved with these procedures.

(9) The number of patients undergoing multiple procedures continues to increase (Laskey et al, 2001). Complex cases may be treated in more than one session (staged procedures). Restenosis and disease progression may also prompt repeated interventions. In a recent series of 3332 patients (Padovani et al, 2005) almost one third underwent at least two procedures. Vano et al. (Vano 2001) observed a much greater rate of skin effects in patients who had undergone multiple fluoroscopically guided coronary procedures. Repeated procedures, especially when performed within a short period of time, increase the risk of skin injury (Balter, 2010). Multiple cardiac fluoroscopic procedures should be a cause of concern with regard to radiological protection. The risk of skin injuries should not be underestimated.

(10) Patient radiation dose is related to procedure complexity (Bernardi et al, 2000, Peterzol et al, 2002, Balter et al, 2009, IAEA 2009). Multi-vessel PCI is considered a complexity factor, but this may not be always the case (Bernardi et al, 2000). Other factors that appear to affect complexity for PCI include the type of lesion, the chronicity of the occlusion, the degree of vessel tortuosity and the involvement of vessel bifurcations (Balter et al, 2009, IAEA 2009).

1.1.3 Cardiac electrophysiology procedures

(11) A second field where there has been an increase in both the number and complexity of procedures is interventional electrophysiology. Permanent pacemaker implantation for bradycardia is carried out in large numbers of patients. From 1997 to 2001, the number of new pacemaker implants increased about 50% worldwide (Mond et al, 2004). More recently, bi-ventricular pacemakers (cardiac resynchronisation therapy) have been introduced for the treatment of patients with cardiac failure and cardiomyopathies (Salukhe et al, 2004). The use of cardioverter-defibrillators has also increased, as a result of studies (Moss et al, 2002, Salukhe et

al, 2004) that demonstrated their life-saving role in patients at risk of sudden cardiac death. An estimated 554,000 pacemaker implantations were performed in Europe in 2007 (Faulkner and Werduch, 2008b) and an estimated 189,000 electrophysiology procedures and 361,000 cardiac device implantations were performed in the U.S. in 2008 (NCRP Report No. 168, 2010).

(12) Cardiac electrophysiology procedures also include treatment of patients with re-entrant tachycardias. These patients are often much younger than patients with coronary heart disease, and require both diagnostic procedures and treatment by radiofrequency ablation. Due to the long fluoroscopy times required for these procedures, these patients can be exposed to very high radiation doses and a substantial risk of deterministic effects if technique is not optimized (Rosenthal, 1998, McFadden, 2002).

1.1.4 Congenital and valvular heart disease

(13) Two other groups of cardiac disease where catheter techniques are used and are likely to expand in the near future are congenital and valvular heart disease. These groups represent a small percentage of patients undergoing percutaneous interventions, but these diseases are seen in both children and adults. Children are at greater risk for the development of stochastic radiation effects, principally cancer, due to their longer expected life span and their increased sensitivity to radiation as compared to adults (Hall, 2009). It has been estimated that approximately 7% of all cardiac angiography procedures are carried out in children aged 0 to 15 years (UNSCEAR 2000). The most widely performed procedures are balloon valvuloplasty, device closure of atrial septal defect, patent foramen ovale or ductus arteriosus, stenting of pulmonary artery stenosis or coarctation of the aorta and electrophysiology studies. These procedures may involve long fluoroscopy times. In addition to these well-established procedures, new procedures have been introduced, including percutaneous pulmonary and aortic valve replacement, ventricular septal defect closure, implantation of banding devices to limit pulmonary blood flow, and radiofrequency perforation to create continuity between cardiac chambers and vessels (Levi et al, 2003). (Percutaneous aortic valve replacement is performed primarily in elderly patients unfit for surgery). A percutaneous or combined percutaneous/surgical approach has been proposed to treat complex diseases such as hypoplastic left heart syndrome. Fetal interventions are also possible.

(14) These techniques to treat congenital and valvular heart disease are largely justified as they may replace very high-risk surgical procedures. Although transesophageal and intracardiac ultrasound may partially replace fluoroscopy (Rice et al, 2002, Zanchetta et al, 2004), radiation risk still remains a problem and is often underestimated. Fluoroscopy times as high as 129 minutes may be required to implant a pulmonary valve (Bonhoeffer et al, 2002). There is little literature concerning the safety issues of these new devices to be used in infants and children (Levi et al, 2003).

1.1.5 Paediatric patients

(15) A survey of patient doses in 137 children, aged from < 1 year to 16 years, undergoing cardiac procedures performed using a biplane flat panel detector X-ray system, demonstrated mean values of 1.9 to 8.6 $Gy \cdot cm^2$ for diagnostic procedures. Mean dose values for therapeutic procedures, in both extremes of the paediatric age

group, ranged from 2.4 to 17.8 Gy·cm^2 (Martinez et al, 2007). In a series of 205 children (mean age 4.1 y) who underwent diagnostic cardiac catheterization, the mean dose was 17 Gy·cm^2 (Chida et al, 2010). In comparison to proposed diagnostic reference levels for fluoroscopically guided cardiac interventions in adults of 50 Gy·cm^2 for diagnostic procedures and 125 Gy·cm^2 for therapeutic procedures (Balter et al, 2008), paediatric patients have typically received less than 20% of the dose received by adult patients. Nonetheless, radiation doses from paediatric cardiac catheterization procedures are of concern (Andreassi, 2006, Andreassi, 2009).

1.2 Cardiac CT

(16) Cardiac CT technology has evolved rapidly in recent years, and these advancements have enabled a variety of types of cardiac CT studies to be performed that go well beyond detection of the coronary arteries. Today, cardiac CT encompasses several distinct procedures, including coronary artery calcium (CAC) scoring, CT coronary angiography (CTCA), pulmonary vein CT angiography, and CT attenuation correction of nuclear cardiology image data. Recent technological advances have been associated with an increase in the number of procedures performed, although reliable statistics on worldwide numbers are not presently available. In the United States, CT was the largest source of medical exposures to patients in 2006, accounting for 49% of the medical exposure of patients (NCRP report 160, 2009). Cardiac CT (including CTCA and CAC) accounted for 4.7% of CT examinations, but 12.1% of patient exposure from CT.

1.3 Nuclear cardiology

(17) An estimated 32.7 million diagnostic nuclear medicine procedures are performed annually worldwide (UNSCEAR 2008). Of these, approximately 14 million are nuclear cardiology procedures, and this number has increased rapidly (Davis, 2006). More than 90% of nuclear cardiology studies are myocardial perfusion scintigraphy studies for the assessment of myocardial perfusion and/or viability. The vast majority of nuclear cardiology procedures performed employ single photon emission computed tomography (SPECT), although a small but growing number of laboratories perform positron emission tomography (PET) studies.

(18) In the U.S., nuclear medicine procedures accounted for 26% of the medical exposure of patients in 2006, and cardiac studies accounted for 85% of the nuclear medicine exposure (NCRP report 160, 2009). Nuclear medicine procedures were the second largest source of medical exposures, after CT.

(19) More nuclear cardiology procedures are performed in the United States than in the rest of the world combined. Reasons suggested for this disparity include better access to testing, a more litigious medicolegal climate, and profit motives for testing. However, multiple U.S. series have demonstrated that for those procedures where sufficient data are available to permit a determination of appropriateness, only ~15% are performed for inappropriate indications (Gibbons, 2008; Hendel, 2010). Nonetheless, cardiologists should consider using alternative methodologies that do not require ionizing radiation, such as stress echocardiography, whenever possible.

1.4 Occupational radiation risk

(20) Radiation risk is not limited to patients. Operators and staff receive radiation exposure during fluoroscopically guided procedures. The increased complexity of interventional cardiology procedures appears to have offset dose reductions due to improvements in technology (Kim, 2008). There is considerable variation in operator doses observed for the same type of procedure, indicating that radiological protection practices can be improved (Kim, 2009). Recent studies have shown that there is an increased incidence of radiation-related cataracts in interventional cardiologists when radiological protection tools are not used properly (Vano, 2010, Ciraj-Bjelac, 2010) Unfortunately, there is lack of proper monitoring of radiation doses to staff and lack of reliable data on occupational doses (Padovani, 2011).

1.5 Summary

(21) In summary, fluoroscopically guided cardiology procedures are increasing in number and complexity. The benefits for patients are clear, but radiation doses for both patients and staff are important and must be managed appropriately. For young patients, the increased risk of cancer should be considered in the optimisation of these procedures. For older patients cancer risk is not as important, but avoidance of deterministic effects (skin injuries) should be taken into account. Interventional cardiologists are among the radiation workers with the highest occupational radiation risk, and should know how to protect both patients and themselves. This ICRP report is intended to help achieve this goal.

1.6 References

Anderson HV, Shaw RE, Brindis RG, Hewitt K, Krone RJ, Block PC, McKay CR, Weintraub WS. A contemporary overview of percutaneous coronary interventions. The American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR). J Am Coll Cardiol 2002; 39:1096-103.

Andreassi MG, Ait-Ali L, Botto N, Manfredi S, Mottola G, Picano E. Cardiac catheterization and long-term chromosomal damage in children with congenital heart disease. Eur Heart J 2006; 27:2703–2708.

Andreassi MG. Radiation risk from pediatric cardiac catheterization: friendly fire on children with congenital heart disease. Circulation 2009;120(19):1847-1849.

Balter S, Miller DL, Vano E, Ortiz Lopez P, Bernardi G, Cotelo E, Faulkner K, Nowotny R, Padovani R, Ramirez A. A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures. Med Phys 2008;35:673-80.

Balter S, Hopewell JW, Miller DL, Wagner LK, Zelefsky MJ. Fluoroscopically guided interventional procedures: A review of radiation effects on patients' skin and hair. Radiology 2010;254:326-341.

Bernardi G, Padovani R, Morocutti G, Vano E, Malisan MR, Rinuncini M, Spedicato L, Fioretti PM. Clinical and technical determinants of the complexity of PTCA procedures. Analysis in relation to radiation exposure parameters. Cathet Cardiovasc Interv 2000;51:1-9.

Bonhoeffer P, Boudjemline Y, Qureshi SA, Le Bidois J, Iserin L, Acar P, Merckx J, Kachaner J, Sidi D. Percutaneous insertion of the pulmonary valve. J Am Coll Cardiol 2002;39:1664-9.

Ciraj-Bjelac O, Rehani MM, Sim KH, Liew HB, Vano E, Kleiman NJ. Risk for radiation induced cataract for staff in interventional cardiology: Is there reason for concern? Catheter Cardiovasc Interv 2010;76(6):826-834.

Cheng TO. The current state of cardiology in China. Int J Cardiol. 2004 Sep;96(3):425-39.

Chida K, Ohno T, Kakizaki S, Takegawa M, Yuuki H, Nakada M, Takahashi S, Zuguchi M. Radiation dose to the pediatric cardiac catheterization and intervention patient. AJR American Journal of Roentgenology 2010; 195(5):1175-1179.

Davis W. Mapping improvements in molecular imaging. Medical Imaging. 2006;May 2006. Available at: http://www.imagingeconomics.com/issues/articles/MI_2006-05_01.asp Accessed December 31, 2010.

Fajadet J, Morice MC, Bode C, Barragan P, Serruys PW, Wijns W, Constantini CR, Guermonprez JL, Eltchaninoff H, Blanchard D, Bartorelli A, Laarman GJ, Perin M, Sousa JE, Schuler G, Molnar F, Guagliumi G, Colombo A, Ban Hayashi E, Wulfert E. Maintenance of long-term clinical benefit with sirolimus-eluting coronary stents: three-year results of the RAVEL trial. Circulation 2005;111:1040-4.

Faulkner K, Werduch A. An estimate of the collective dose to the European population from cardiac x-ray procedures. Br J Radiol 2008a; 81:955-962.

Faulkner K, Werduch A. Analysis of the frequency of interventional cardiology in various European countries. Rad Prot Dosim 2008b; 129(1-3):74-76.

Hall EJ. Radiation biology for pediatric radiologists. Pediatr Radiol 2009;39 Suppl 1:S57-64.

Gibbons RJ, Miller TD, Hodge D, et al. Application of appropriateness criteria to stress single-photon emission computed tomography sestamibi studies and stress echocardiograms in an academic medical center. J Am Coll Cardiol. 2008;51(13):1283-1289.International Atomic Energy Agency. Establishing guidance levels in x ray guided medical interventional procedures: A pilot study. Safety Reports Series No. 59. Vienna: International Atomic Energy Agency; 2009.

Hendel RC, Cerqueira M, Douglas PS, et al. A multicenter assessment of the use of single-photon emission computed tomography myocardial perfusion imaging with appropriateness criteria. J Am Coll Cardiol. 2010;55(2):156-162.

International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann ICRP 2000;30:7-67.

Kim KP, Miller DL, Balter S, Kleinerman RA, Linet MS, Kwon D, Simon SL. Occupational radiation doses to operators performing cardiac catheterization procedures. Health Phys 2008;94:211-227.

Kim KP, Miller DL. Minimising radiation exposure to physicians performing fluoroscopically guided cardiac catheterisation procedures: a review. Radiat Prot Dosimetry 2009;133:227-33.

Laskey WK, Kimmel S, MD, Krone RJ. Contemporary Trends in Coronary Intervention: A Report From the Registry of the Society for Cardiac Angiography and Interventions Cathet. Cardiovasc. Intervent. 49:19–22, 2000.

Laskey WK, Williams DO, Vlachos HA, MS, H, Holmes DR, King SB, Kelsey SF, Slater J, Faxon D, Al-Bassam M, Block E, Detre KM for the Dynamic Registry Investigators. Changes in the Practice of Percutaneous Coronary Intervention: A Comparison of Enrollment Waves in the National Heart, Lung, and Blood Institute (NHLBI) Dynamic Registry. Am J Cardiol 2001;87:964–969.

Lemos PA, Serruys PW, van Domburg RT, Saia F, Arampatzis CA, Hoye A, Degertekin M, Tanabe K, Daemen J, Liu TK, McFadden E, Sianos G, Hofma SH, Smits PC, van der Giessen WJ, de Feyter PJ. Unrestricted utilization of sirolimus-eluting stents compared with conventional bare stent implantation in the "real world": the Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital (RESEARCH) registry. Circulation 2004;109:190-5.

Levi DS, Alejos JC, Moore JW. Future of interventional cardiology in pediatrics. Curr Opin Cardiol. 2003;18:79-90.

Martinez LC, Vano E, Gutierrez F, Rodriguez C, Gilarranz R, Manzanas MJ. Patient doses from fluoroscopically guided cardiac procedures in pediatrics. Phys Med Biol. 2007;52(16):4749-59.

McFadden SL, Mooney RB, Shepherd PH. X-ray dose and associated risks from radiofrequency catheter ablation procedures. Br J Radiol 2002;75:253-65.

Meier, B. Cardiac catheterization interventions: European statistics 2007/2008. Presented at Euro PCR, May, 2010. Available at: http://www.escardio.org/communities/EAPCI/Documents/Cardiac-catheterization-Interventions-stats07-08-EAPCI-Assembly-may2010.pdf Accessed February 22, 2011.

Miller DL. Overview of contemporary interventional fluoroscopy procedures. Health Phys 2008;95:638-44.

Mond HG, Irwin M, Morillo C, Ector H. The world survey of cardiac pacing and cardioverter defibrillators: calendar year 2001. Pacing Clin Electrophysiol 2004;27:955-64

Moran A, Gu D, Zhao D, Coxson P, Wang YC, Chen CS, Liu J, Cheng J, Bibbins-Domingo K, Shen YM, He J, Goldman L. Future cardiovascular disease in china: markov model and risk factor scenario projections from the coronary heart disease policy model-china. Circ Cardiovasc Qual Outcomes. 2010;3(3):243-52.

Morice MC, Serruys PW, Sousa JE, Fajadet J, Ban Hayashi E, Perin M, Colombo A, Schuler G, Barragan P, Guagliumi G, Molnar F, Falotico R; RAVEL Study Group. Randomized Study with the Sirolimus-Coated Bx Velocity Balloon-Expandable Stent in the Treatment of Patients with de Novo Native Coronary Artery Lesions. A randomized comparison of a sirolimus-eluting stent with a standard stent for coronary revascularization. N Engl J Med 2002;346:1773-80.

Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, Daubert JP, Higgins SL, Brown MW, Andrews ML; Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877-83.

National Council on Radiation Protection and Measurements. Ionizing radiation exposure of the population of the United States. NCRP Report No. 160. Bethesda, MD: National Council on Radiation Protection and Measurements; 2009.

National Council on Radiation Protection and Measurements. Radiation dose management for fluoroscopically guided interventional medical procedures. NCRP Report No. 168. Bethesda, MD: National Council on Radiation Protection and Measurements; 2010.

Padovani R, Bernardi G, Quai E, Toh HS, Signor M, Morocutti G, Spedicato L. Retrospective evaluation of occurrence of skin injuries in interventional cardiac procedures. Radiat Prot Dosimetry 2005; 117 (1-3):247-250.

Padovani, R., Le Heron, J., Cruz-Suarez, R., Duran, A., Lefaure, C., Miller, D.L., Sim, H.K., Vano, E., Rehani, M., Czarwinski, R., 2010. International project on individual monitoring and radiation exposure levels in interventional cardiology. Radiat Prot Dosimetry 2011; in press.

Peterzol A, Quai E, Padovani R, Bernardi G, Kotre J, Dowling A. Reference levels in PTCA as a function of procedure complexity. Radiat Prot Dosimetry 2005;117 (1-3): 54-58.

Prieto C, Vano E, Fernández JM, Galvan C, Sabate M, Gonzalez L, Martinez D. Six years experience in intracoronary brachytherapy procedures: patient doses from fluoroscopy. Br J Radiol. 2006 Sep; 79(945): 730-733.

Rice MJ, McDonald RW, Li X, Shen I, Ungerleider RM, Sahn DJ. New Technology and Methodologies for Intraoperative, Perioperative, and Intraprocedural Monitoring of Surgical and Catheter Interventions for Congenital Heart Disease Echocardiography 2002; 19:725-734.

Rosenthal LS, Mahesh M, Beck TJ, Saul JP, Miller JM, Kay N, Klein LS, Huang S, Gillette P, Prystowsky E, Carlson M, Berger RD, Lawrence JH, Yong P, Calkins H. Predictors of fluoroscopy time and estimated radiation exposure during radiofrequency catheter ablation procedures. Am J Cardiol 1998;82:451-458.

Salukhe TV, Dimopoulos K, Francis D. Cardiac resynchronisation may reduce all-cause mortality: meta-analysis of preliminary COMPANION data with CONTAK-CD, InSync ICD, MIRACLE and MUSTIC. Int J Cardiol 2004;93:101-3.

The SoS Investigators. Coronary artery bypass surgery versus percutaneous coronary intervention with stent implantation in patients with multivessel coronary artery disease (the Stent or Surgery trial): a randomized controlled trial. Lancet 2002;360:965–70.

Togni M, Balmer F, Pfiffner D, Maier W, Zeiher AM, Meier B, on behalf of the Working Group Interventional Cardiology and Coronary Pathophysiology of the European Society of Cardiology. Percutaneous coronary interventions in Europe 1992–2001. Eur Heart J 2004;25:1208–1213.

Tsapaki, V., Ahmed, N.A., AlSuwaidi, J.S., Beganovic, A., Benider, A., BenOmrane, L., Borisova, R., Economides, S., El-Nachef, L., Faj, D., Hovhannesyan, A., Kharita, M.H., Khelassi-Toutaoui, N., Manatrakul, N., Mirsaidov, I., Shaaban, M., Ursulean, I., Wambani, J.S., Zaman, A., Ziliukas, J., Zontar, D., Rehani, M.M., 2009. Radiation exposure to patients during interventional procedures in 20 countries: initial IAEA project results. AJR. Am. J. Roentgenol. 193, 559-569.

UNSCEAR. Sources and effects of ionizing radiation: volume I, sources: annex D, medical radiation exposure. Report to the General Assembly of the United Nations; 2000; New York, NY Available at:

http://www.unscear.org/unscear/en/publications/2000_1.html Accessed December 31, 2010.

UNSCEAR. Sources of ionizing radiation: volume I. Report to the General Assembly, with scientific annexes; 2010; New York, NY. Available at: http://www.unscear.org/unscear/en/publications/2008_1.html Accessed December 31, 2010.

Vano E, Goicolea J, Galvan C, Gonzalez L, Meiggs L, Ten JI, Macaya C. Skin radiation injuries in patients following repeated coronary angioplasty procedures. Br J Radiol. 2001 Nov;74(887):1023-31.

Vano E, Kleiman NJ, Duran A, Rehani MM, Echeverri D, Cabrera. M. Radiation cataract risk in interventional cardiology personnel. Radiat Res, 2010; 174(4):490-495

Verin V, Popowski Y, de Bruyne B, Baumgart D, Sauerwein W, Lins M, Kovacs G, Thomas M, Calman F, Disco C, Serruys PW, Wijns W, Piessens M, Kurtz J, Simon R, Delafontaine P, Erbel R. Endoluminal Beta-Radiation Therapy for the Prevention of Coronary Restenosis after Balloon Angioplasty. N Engl J Med 2001;344:243-249.

Waksman R, Bhargava B, White L, Chan RC, Mehran R, Lansky AJ, Mintz GS, Satler LF, Pichard AD, Leon MB, Kent KK. Intracoronary beta-radiation therapy inhibits recurrence of in-stent restenosis. Circulation 2000;101:1895-8.

Williams DO, Holubkov R, Yeh W, Bourassa MG, Al-Bassam M, Block PC, Coady P, Cohen H, Cowley M, Dorros G, Faxon D, Holmes DR, Jacobs A, Kelsey SF, King SB, Myler R, Slater J, Stanek V, Vlachos HA, Detre KM. Percutaneous Coronary Intervention in the Current Era Compared With 1985–1986 The National Heart, Lung, and Blood Institute Registries. Circulation 2000;102:2945-2951.

Zanchetta M, Maiolino P. Intracardiac echocardiography. Do we need a new ultrasonographic window? Ital Heart J 2004;5:173-177.

2. THE BIOLOGICAL EFFECTS OF RADIATION

Main Points

- **Deterministic effects are due to injury in populations of cells, characterised by a threshold dose and an increase in the incidence and severity of the reaction as the dose is increased further. Deterministic effects are also termed tissue reactions.**
- **Stochastic effects are malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose without threshold.**
- **Radiation-induced skin injuries may not become fully manifest until months after the radiation dose was administered.**
- **The diagnosis of a radiation induced skin injury is often delayed.**
- **The lens of the eye is a radiosensitive tissue.**
- **In the lens of the eye, ionizing radiation typically causes posterior subcapsular cataract formation.**
- **Surveys of cardiologists and support staff working in catheterization laboratories have found a high percentage of lens opacities attributable to occupational radiation exposure when radiological protection tools have not been used properly.**

2.1 Types of radiation effects

(22) The effects of radiation can be classified into two groups: deterministic effects (harmful tissue reactions) and stochastic effects (cancer and heritable effects).

(23) *Deterministic effects* (e.g. skin injury) are largely caused by the reproductive sterilisation of cells following high radiation doses. The induction of tissue reactions is generally characterised by a threshold dose. The reason for the presence of this threshold dose is that radiation-induced reproductive survival of a critical population of cells in a given tissue needs to be sustained before injury is expressed in a clinically relevant form. Above the threshold dose the incidence and severity of the injury, including impairment of the capacity for tissue recovery, increases with dose (ICRP 103). The threshold is variable, depending on the nature and condition of the exposed tissue (Balter, 2010).

(24) The injury is not expressed clinically until the cells die as a result of an unsuccessfully attempt at cell division or differentiation and are lost as part of the normal process of tissue turnover (Balter, 2010). The incidence as well as the severity of the injury, including impairment of the capacity for tissue recovery, increases with dose. After a high radiation dose, the outcome for the affected individual can be devastating (Balter, 2010).

(25) Eighty percent of reported radiation-induced skin injuries in one large series were from cardiac procedures (Koenig et al 2001). Nonetheless, cardiologists often do not recognise that a radiation injury is related to a cardiac procedure, either because they are unaware of the magnitude of radiation dose delivered or they do not know that radiation can cause skin injuries.

(26) The dose of radiation received by some patients is high and the number of radiation injury cases is increasing (NCI, 2005). However, most currently practising interventional cardiologists have no personal experience of a case of radiation injury. The number of radiation injuries is small compared with the number of fluoroscopically guided cardiology procedures performed worldwide.

(27) *Stochastic effects* The accumulation of cellular and animal data relevant to radiation tumourigenesis has, since 1990, strengthened the view that DNA damage response processes in single cells are of critical importance to the development of cancer after radiation exposure. Epidemiological and experimental studies provide evidence of radiation risk, albeit with uncertainties at doses about 100 mSv or less (ICRP 103).

(28) These effects are probabilistic—there is no identifiable threshold for producing the effect. The likelihood of inducing a stochastic effect increases with dose, but the exact relationship between dose and effect is not known. In the low dose range, below about 100 mSv, it is scientifically plausible to assume that the incidence of cancer or heritable effects will rise in direct proportion to an increase in the equivalent dose in the relevant organs and tissues (the "linear-non-threshold" or LNT model) (ICRP 103). Dose has no relationship to the severity of the effect.

(29) Children are approximately 2-3 times more sensitive to the stochastic effects of radiation than adults (ICRP 1991). They also have a longer potential lifespan than do adults, so they have more time to develop possible radiation related sequelae. In children, the probability of a fatal cancer per fluoroscopically guided procedure is estimated at approximately 0.07-0.08%, but this risk may vary widely depending on patient age, underlying life expectancy and how the procedure is performed (Martinez et al, 2007, Bacher et al, 2005).

(30) While there is compelling evidence that radiation causes heritable effects in experimental animals, there continues to be no direct evidence that exposure of humans to radiation leads to excess heritable disease in offspring (ICRP 103).

2.2 Background

(31) Some months after the discovery of x-rays in 1895, radiation-induced skin changes were observed (Daniel 1896, Codman 1896). Some early radiologists suffered severe dermatitis, radiation cancer and amputation of digits. There was a delay in recognising that x-rays were the cause because they are invisible and do not cause any sensation during exposure. As noted in ICRP Publication 103, the goal of preventing these radiation injuries was the impetus for the formation of what is now the Commission (ICRP 2007).

(32) Following the dramatic rise in the number of percutaneous coronary interventional procedures, cases of patients with deep skin ulceration and necrosis were reported in the 1990s (Shope, 1996). In 1994 the U.S. Food and Drug Administration issued an advisory regarding skin injury from fluoroscopically guided procedures (FDA 1994). Radiation skin injury has also been reported following radiofrequency catheter ablations (Vano, 1998). This is of particular concern because many of these patients are young adults, and some are children. The Commission drew attention to prevention of skin injuries from interventional fluoroscopy procedures in Publication 85 (ICRP 2000), and reiterated the importance of preventing skin injuries in Publication 105 (ICRP 2007).

2.3 Radiation Effects and the Skin

(33) The response of the skin to radiation is dose-related and occurs when this dose is concentrated on one area, usually the site where the x-rays enter the patient. The term "absorbed dose" is used to assess the amount of radiation to which a tissue is exposed (see the Glossary). The skin response follows a characteristic pattern, although the time course is variable (Balter et al, 2010). The threshold doses and time of appearance for various types of skin injury are summarised in **Table 2.1**.

(34) Defects in DNA repair genes may predispose individuals to radiogenic cancer or lower the threshold for the development of deterministic effects. Some patients with serious and unanticipated radiation injuries may be among the 1% of the population heterozygous for the ATM gene, an autosomal recessive gene responsible for ataxia telangiectasia, or may harbour some other ATM abnormality. (Hymes, 2006, Allan, 2008) Other disorders with a genetic component affecting DNA breakage or repair also increase radiation sensitivity, including Fanconi anaemia, Bloom syndrome and xeroderma pigmentosum. Familial polyposis, Gardner syndrome, hereditary malignant melanoma and dysplastic nevus syndrome also increase radiation sensitivity (Hymes, 2006). Certain familial cancer syndromes may increase susceptibility to radiogenic cancer, including neurofibromatosis, Li-Fraumeni syndrome and hereditary retinoblastoma (Allan, 2008).

(35) Autoimmune and connective tissue disorders predispose patients to the development of severe cutaneous radiation effects in an unpredictable fashion. These typically occur in association with the high radiation doses administered during radiation therapy. The aetiology is not known. These disorders include scleroderma, systemic lupus erythematosus and possibly rheumatoid arthritis.((Wagner et al, 1999, Hymes, 2006) Hyperthyroidism and diabetes mellitus are also associated with increased radiation sensitivity (Koenig Part 1, 2001) Diabetes is believed to predispose to radiation injury secondary to small vessel vascular disease and consequent decreased healing capacity (Herold, 1999). A number of drugs increase radiation sensitivity, including actinomycin D, doxorubicin, bleomycin, 5-fluorouracil and methotrexate (Koenig Part 1, 2001) Again, this effect is usually seen only with the high radiation doses delivered during radiation therapy.

(36) It is apparent from the foregoing and from **Table 2.1** that there are no rigid thresholds for dose or time of appearance of radiation-induced skin changes, because individuals vary in their radio-sensitivity and radio-responsiveness (Balter et al, 2010). These ranges are shown graphically in **Figure 2.1**. In the discussion below, threshold doses are given for an average person, but it should be understood that these will vary from individual to individual. For most patients, clinically important skin reactions occur only when the absorbed skin dose is greater than 5 Gy (Balter et al, 2010; ICRP Tissue Reactions, 2011a).

Table 2.1: Tissue reactions from a single-delivery radiation dose to the skin of the neck, torso, pelvis, buttocks or arms. (from Balter et al, 2010)

- This table is applicable to the normal range of patient radiosensitivities in the absence of mitigating or aggravating physical or clinical factors.
- Skin dose refers to absorbed skin dose (including backscatter). This quantity is ***not*** the reference air kerma ($K_{a,r}$) described by the Food and Drug Administration (21 CFR § 1020.32 (2008)) or the International Electrotechnical Commission.(IEC, 2010)
- This table does not apply to the skin of the scalp.
- Abrasion or infection of the irradiated area is likely to exacerbate radiation effects.
- ***The dose and time bands are not rigid boundaries. Signs and symptoms are expected to appear earlier as the skin dose increases.***

Band	Single-site Acute Skin-Dose Range (Gy)[1]	NCI Skin Reaction Grade*	Approximate time of onset of effects			
			(4) **Prompt < 2 weeks**	(5) **Early 2 – 8 weeks**	**Mid term 6 – 52 weeks**	**Long term > 40 weeks**
A1	0-2	N/A	No observable effects expected			
A2	2-5	1	- Transient erythema	- Epilation	- Recovery from hair loss	(6) - None expected
B	5-10	1	- Transient erythema	- Erythema, epilation	- Recovery. - At higher doses; prolonged erythema, permanent partial epilation	(7) - Recovery. - At higher doses dermal atrophy/induration.
C	10-15	1-2	- Transient erythema	- Erythema, epilation. - Possible dry or moist desquamation (8) - Recovery from desquamation	(9) - Prolonged erythema. - Permanent epilation.	(10) - Telangiectasia[2] - Dermal atrophy/induration. - Skin likely to be weak.
D	> 15	3-4	- Transient erythema - After very high doses, edema and acute ulceration; long-term surgical intervention likely to be required.	- Erythema, epilation. (11) - Moist desquamation	(12) - Dermal atrophy, - Secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required. - At higher doses, dermal necrosis; surgical intervention likely to be required..	(13) - Telangiectasia[2]. - Dermal atrophy/induration, - Possible late skin breakdown. - Wound might be persistent and progress into a deeper lesion. - Surgical intervention likely to be required.

[1] ***Skin dosimetry is unlikely to be more accurate than ± 50%***

[2] Refers to radiation-induced telangiectasia. Telangiectasia associated with an area of initial moist desquamation or the healing of ulceration may be present earlier.

*NCI = U.S. National Cancer Institute

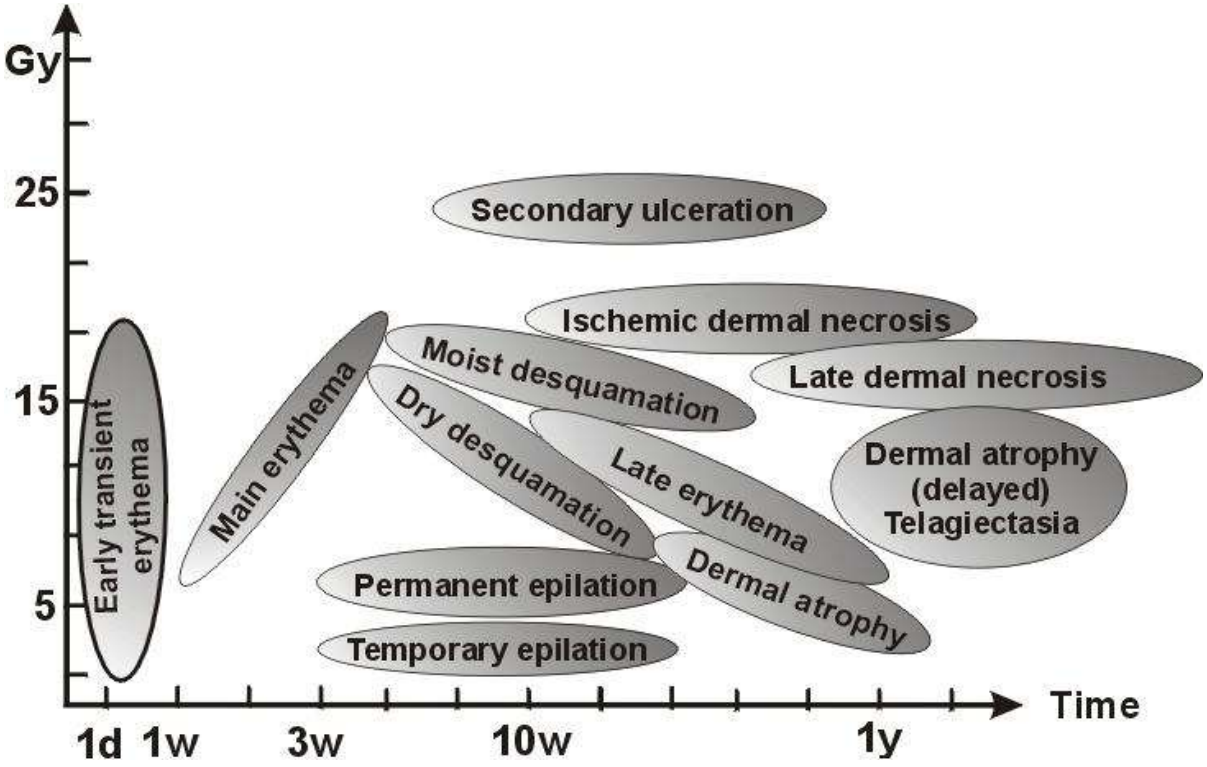


Figure 2.1: Graphical representation of data in Table 2.1 showing overlap in the skin effects with both dose and time.

(37) The lowest dose that may produce a noticeable skin change in individuals with average radiation sensitivity is conventionally considered to be 2 Gy. Histamine-like substances are activated and dilate capillaries, resulting in reddening (transient erythema). This usually occurs within hours of exposure and fades after 24 hours. This effect is likely to be under-reported due to its short duration.

(38) After a dose of 6 Gy, a second hyperaemic phase (main erythema) commences at approximately 10 days. This phase may be apparent earlier after doses > 6 Gy. It results from the destruction of proliferating basal cells in the epidermis. The patient may complain of burning, tenderness and itching, and the skin becomes warm and oedematous. The erythema usually peaks at 2 weeks and fades by 4 weeks (Koenig et al, 2001).

(39) If doses exceed 10 Gy, the erythema may be more prolonged, with hyperpigmentation. At skin doses > 14 Gy the inflammation can progress to dry desquamation—the erythematous skin is covered with scales and flakes of corneum, with an appearance resembling sunburn. Moist desquamation occurs at doses of about 18 Gy. The skin blisters and sloughs with weeping of serum from the deep cutaneous layers.

This is associated with considerable pain and the skin becomes susceptible to infection. Topical antibiotics are often required (Shack et al, 1987). The proliferative cells in the basal layer of the epidermis are damaged and reduced in number. Desquamation usually appears 4 weeks after exposure and can last many weeks, particularly if secondary infection occurs.

(40) A late phase of erythema can develop 8-10 weeks after radiation exposure of approximately 15 Gy. The skin has a mauve or dusky appearance. A skin dose of about 18 Gy may result in vascular insufficiency of the dermis, leading to ischemic dermal necrosis 10-16 weeks following exposure. The damage is greater at higher doses (Koenig et al, 2001).

(41) Dermal atrophy occurs after prolonged erythema, particularly when associated with moist desquamation. This is typically seen in two phases, initially at 3 months and then at 1 year. At doses above 10 Gy, telangiectasia may also develop because of dilation of the dermal capillaries. This is often a late phenomenon, occurring more than a year after exposure, but has been noted earlier and can increase over time (Turreson et al, 1986). Trauma may precipitate late necrosis in skin that shows these late changes. The threshold for this is approximately12 Gy, so it may be seen in the absence of earlier skin desquamation.

(42) The diagnosis of a radiation-induced skin injury is often delayed because these lesions are relatively rare and the cause may not be recognized. Also, there is often a latent period of many months before the lesion is fully apparent (Balter et al, 2010). Patients often seek care from a dermatologist, rather than the physician who performed the interventional procedure. As a result, the history of fluoroscopy may be overlooked or considered irrelevant (Frazier et al 2007). Skin biopsy is frequently performed, although the results are not specific for radiation injury and can lead to a non-healing ulcer, as can other forms of trauma. Misdiagnoses are often made, including contact dermatitis from an electrode pad, allergy to adhesive tape or skin disinfectant, drug eruption, viral or bacterial infection and even insect bite. The deep pain associated with an injury may lead to extensive chest and abdominal evaluation (Vlietstra et al 2004). Severe injuries may extend into muscle (Monaco et al, 2003).

(43) Skin cancer directly related to radiation from an interventional procedure has not been reported. Cases of basal cell carcinoma have been documented following x-ray treatment for scalp ringworm (Shore 2002) with a relative risk of 3.6 after a scalp dose of 4.8 Gy. The relative risk of skin cancer in Chinese medical x-ray workers has been estimated at 4.1 in a cohort studied from 1950 – 1995. (Wang 2002)

2.4 The Lens of the Eye and Radiation

(44) The prevalence of cataract is difficult to estimate, as it depends in part on the definition of cataract. The Framingham Eye Study (Kahn et al, 1977) found a 91% prevalence in 75-85 year olds, although this figure was reduced to 46% if ‘modest visual deficit’ is added to the definition. A more recent Spanish study gave a prevalence of cataract and decreased visual acuity of more than 60% of 75 year olds. (Acosta et al, 2006)

(45) The majority of lens opacities that are not due to radiation are associated with cortical changes in the superficial substance of the lens. The lens is a radiosensitive tissue. Ionizing radiation typically causes posterior subcapsular (PSC) cataract formation (Figure 2.2). Unlike an age-related cataract, which usually interferes initially with visual acuity, a PSC cataract reduces contrast sensitivity before reducing visual acuity.

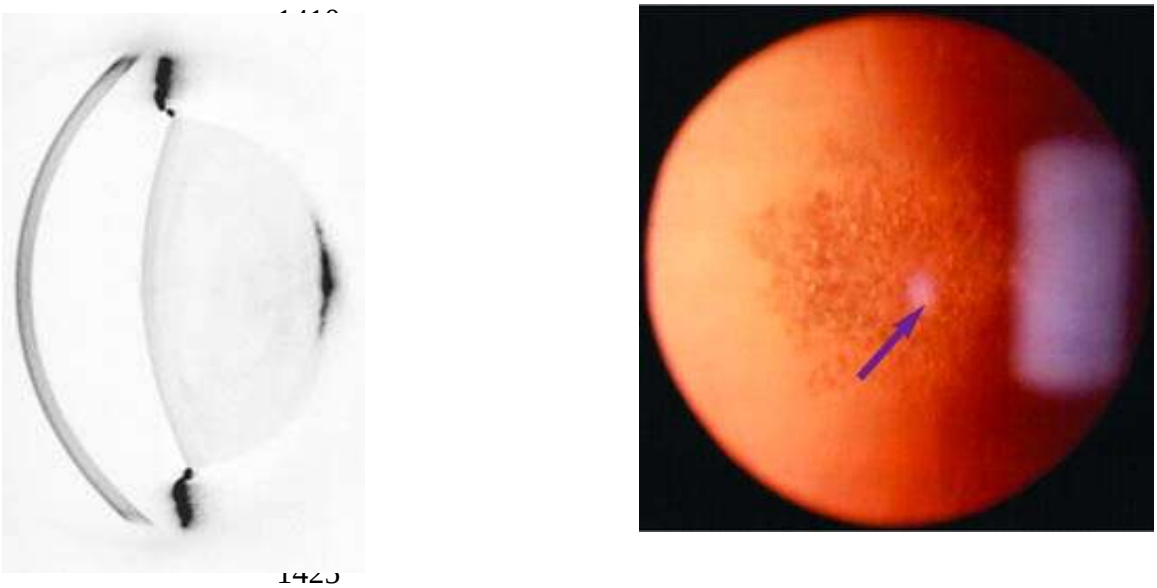


Figure 2.2: a) A radiation-induced posterior subcapsular (PSC) cataract is shown as a central black shadow at the posterior aspect of the lens. b) Retroillumination photograph of a PSC cataract at the posterior aspect of the lens. This causes glare and poor vision in bright light conditions as well as poor reading vision. (From RSNA News, June 2004 (http://www.rsna.org/Publications/rsnanews/upload/jun2004.pdf)) [Permission to be requested from RSNA]

(46) The response of the lens to radiation has traditionally been considered a deterministic effect. The threshold dose for detectable human lens opacities has been considered to be 2 Sv for a single acute exposure and 5 Sv for protracted exposure. For cataract with visual impairment, the thresholds have been considered to be 5 Sv and 8 Sv respectively. (ICRP 1991, NCRP 1993). More recent data in populations exposed to lower doses of radiation suggest that dose related lens opacification occurs at exposures significantly lower than 2 Sv, and that there may be no dose threshold. (Worgul et al, 2007, Kleiman 2007, NCRP 168, 2010, Shore 2010, ICRP XXX [Tissue Reactions], 2011a)

(47) There have been reports of radiation-induced cataracts in interventionalists who have performed procedures for a number of years, and of doses to the lens approaching the annual limit of 150 mSv during angiographic procedures (Figure 2.3)

(Vano et al, 1998, Pages 2000, Hidajat 2006, Vano et al 2010). Recent studies have shown that with typical reported interventional workloads the radiation dose to the lens may exceed the current threshold for deterministic effects after several years of work, if radiological protection tools are not used (Vano et al, 2008, Kim et al, 2008) Several surveys of cardiologists and support staff working in catheterization laboratories, conducted with coordination provided by the International Atomic Energy Agency (IAEA) in Latin America and Asia, have found a high percentage of lens opacities attributable to occupational radiation exposure (Vano et al, 2010, Ciraj-Bjelac et al, 2010).

(48) These recent data and the mechanistic uncertainties regarding cataract development have highlighted the need for a detailed reappraisal of the radiosensitivity of the lens of the eye. This issue is addressed in ICRP Publication **XXX,** on Tissue Reactions and Other Non-Cancer Effects of Radiation and its Statement on Tissue Reactions (ICRP, 2011a, 2011b). The previous Commission recommendation (ICRP, 1991) of a dose limit of 150 mSv per year for occupational exposure in a planned exposure situation (e.g., occupational exposure of interventionalists) has been changed. The Commission now recommends that the lens dose limit for chronic occupational exposure should be 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv, i.e. the same as the annual whole body limit for workers (ICRP, 2011a, 2011b).

(49) The Commission now considers the threshold in absorbed dose to the lens of the eye to be 0.5 Gy (ICRP, 2011b). The Commission judges, based on existing evidence, that an acute dose of up to around 100 mGy produces no functional impairment of tissues, including the lens of the eye with respect to cataract, although the use of a threshold model remains uncertain for this tissue (ICRP, 2011a).

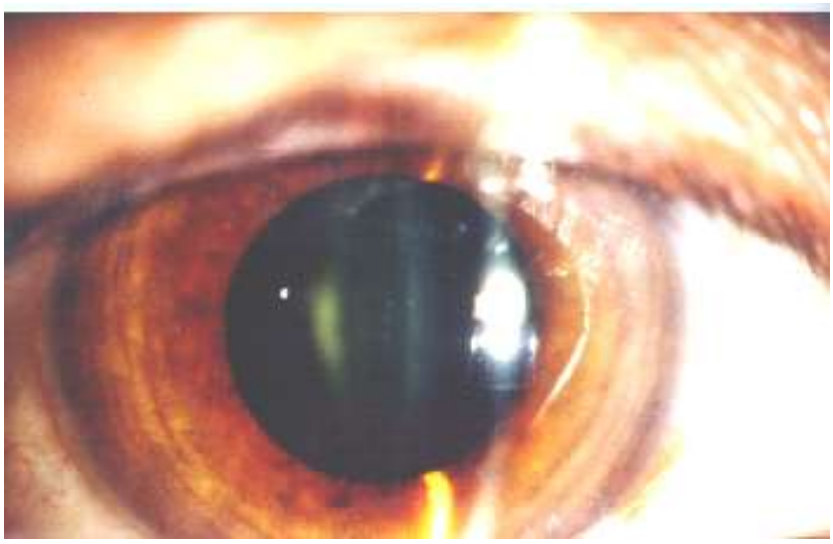


Figure 2.3: PSC cataract in the eye of an interventionist using an old x-ray system and high scatter radiation from improper working conditions (E. Vano BJR 1998)

2.5 Cardiovascular effects of radiation exposure

(50) The mechanisms of heart radiation damage include inflammatory processes, in particular after low doses, and after higher doses there is a progressive reduction in the number of patent capillaries eventually leading to ischemia, myocardial cell death and fibrosis, accelerated atherosclerosis in major blood vessels, decreased cardiac function, and fatal congestive heart failure. There are no known mitigators of radiation-induced cardiovascular disease (ICRP, 2011).

(51) Analyses of the atomic bomb survivors have shown that radiation doses above 0.5 Gy are associated with an elevated risk of both stroke and heart disease (Shimizu et al, 2010). These findings are consistent with other studies that demonstrated an increased risk of heart disease after radiation therapy to the chest (Bhatti et al, 2008). There is compelling evidence that ionizing radiation in the doses using for radiation therapy can increase the risk of heart disease (McGale and Darby, 2008).

(52) Radiation induced heart disease can occur as a result of both microvascular damage to the myocardium, leading to focal myocardial degeneration and fibrosis, and accelerated atherosclerosis in major blood vessels. Cardiovascular radiation effects have been reported to occur at doses > 0.5 Gy (ICRP, 2011). Although uncertainty remains, medical practitioners should be aware that the absorbed dose threshold for circulatory disease may be as low as 0.5 Gy to the heart (ICRP, 2011b). In some complex fluoroscopically guided cardiac procedures, organ doses may be > 0.5 Gy. These radiation effects need to be considered during the optimization process.

(53) At lower doses (below 0.5 Gy) the relationship between radiation dose and increased cardiovascular risk is unclear (Shimizu et al, 2010). McGeoghegan and colleagues (2008) observed an association between mortality from non-cancer causes of death, particularly circulatory system disease, and exposure to ionizing radiation in their analysis of 42,000 radiation workers with low-dose, long-term radiation exposure. Other studies have shown mixed results (McGale and Darby, 2008). Recent reviews of epidemiological studies of populations medically, occupationally or environmentally exposed to relatively low-dose radiation showed that there was substantial heterogeneity in the association between radiation exposure and circulatory disease, with respect to the risk per unit radiation dose, possibly resulting from confounding factors or bias (ICRP, 2011). As there is no clear understanding of the underlying biological mechanisms, it is difficult to interpret these mixed results (Dauer et al, 2010).

2.6 Occupational radiation exposure and intracranial neoplasms

(54) Ionizing radiation is one of the few established causes of neural tumours (Yonehara et al., 2004). Preston and colleagues studied the incidence of nervous system tumours in atomic bomb survivors (Preston et al., 2007; Preston et al., 2002). They found a significant dose-related excess of nervous system tumours. They concluded that exposure to doses of radiation as low as < 1 Sv is associated with an elevated incidence

of nervous system tumours (Preston et al., 2002). It is clear that in children, radiation exposure is associated with the development of brain cancer, but the relationship in individuals exposed as adults is much less clear. The association between benign intracranial tumours and radiation appears to be substantially stronger than for malignant tumours (UNSCEAR, 2000). However, the BEIR-VII report does not explicitly present Lifetime Attributable Risk (LAR) for brain cancer incidence or mortality (NRC, 2006). What is clear is that for operators and staff, the brain is one of the least protected organs during interventional fluoroscopy procedures.

(55) Radiation dose to the brain in fluoroscopists has not been well studied. Wenzl noted that cardiologists may receive the highest radiation doses of any specialists who use fluoroscopy for interventional procedures (Wenzl, 2005). Renaud determined that the annual exposure to cardiologists' heads was approximately 20 – 30 mSv (Renaud, 1992). However, Renaud's study was performed with data from 1984 through 1988, when both cardiac interventions and fluoroscopic equipment were less sophisticated than they are now.

(56) Finkelstein suggested that the occurrence of brain tumours in two Toronto cardiologists in a one-year period might indicate that they were radiation-induced (Finkelstein, 1998). Epidemiologic evidence for radiation-induced brain cancer in fluoroscopists is suggestive, but by no means conclusive. In 1975, Matanoski and colleagues found that the death rate from brain cancer in American radiologists was almost 3 times that of other medical specialists who did not use radiation (Matanoski et al., 1975). In a Swedish case-control study of 233 patients with brain tumours, Hardell and colleagues reported that work as a physician using fluoroscopy increased the risk of developing a brain tumour, with an odds ratio of 6.0 (95% confidence interval, 0.62-57.7), but there were only 3 such individuals among the 233 cases (Hardell et al., 2001). No increased risk was found for other health care workers. In a case-control study of 476 individuals diagnosed with gliomas between 1991 and 1994 in the San Francisco area, Carozza and colleagues observed an increased risk in physicians and surgeons (odds ratio 3.5, 95% confidence interval 0.7-17.6) (Carozza et al., 2000). There were only 6 physicians in the group, and the authors suggested that the increased risk might be due to occupational exposure to numerous biologic agents and chemicals as well as to radiation. On the other hand, Blettner and colleagues conducted a case-control study in Germany of 844 patients with brain tumours and 1737 control subjects, using self-reported medical and occupational data (Blettner et al., 2007). More than 2/3 of the 91 participants occupationally exposed to radiation were in the medical field (physicians, nurses, radiographers). Blettner and colleagues found no significant risk of brain tumours as a result of exposure to medical ionizing radiation. Karipidis and colleagues conducted a case-control study in Australia of 416 patients with gliomas and 422 controls and found no evidence of an association between gliomas and ionizing radiation (Karipidis et al. 2007).

2.7 References

1565 Acosta R, Hoffmeister L, Roman R, Comas M, Castilla M, Castells X. Systematic
1566 review of population-based studies of the prevalence of cataracts. Arch Soc Esp
1567 Oftalmol 2006; 81: 509-516
1568 Allan JM. Genetic susceptibility to radiogenic cancer in humans. Health Phys 2008;
1569 95:677-686.
1570 Bacher K, Bogaert E, Lapere R, De Wolf D, Thierens H. Patient-specific dose and
1571 radiation risk estimation in pediatric cardiac catheterization. Circulation. 2005 Jan
1572 4;111(1):83-9.
1573 Balter S, Hopewell JW, Miller DL, Wagner LK, Zelefsky MJ. Fluoroscopically guided
1574 interventional procedures: A review of radiation effects on patients' skin and hair.
1575 Radiology 2010; 254:326-41.
1576 Bhatti P, Sigurdson AJ, Mabuchi K. Cam low-dose radiation increase risk of
1577 cardiovascular disease? Lancet 2008; 372:697-699.
1578 Blettner M., Schlehofer B., Samkange-Zeeb F., Berg G., Schlaefer K., Schüz J. (2007)
1579 Medical exposure to ionising radiation and the risk of brain tumours: Interphone
1580 study group, Germany. Eur J Cancer 43:1990-8.
1581 Carozza S.E., Wrensch M., Miike R., Newman B., Olshan A.F., Savitz D.A., Yost M.,
1582 Lee M. (2000) Occupation and adult gliomas. Am J Epidemiol 152:838-46.
1583 Finkelstein M.M. (1998) Is brain cancer an occupational disease of cardiologists? Can J
1584 Cardiol 14:1385-8.
1585 Ciraj-Bjelac O, Rehani MM, Sim KH, Liew HB, Vano E, Kleiman NJ. Risk for radiation
1586 induced cataract for staff in interventional cardiology: Is there reason for concern?
1587 Catheter Cardiovasc Interv 2010;76(6):826-834.
1588 Codman EA. The cause of burns from x-rays. (letter) Bos Med Surg J 1896; 136:610-
1589 611
1590 Daniel J. The x-rays. (letter) Science 1896; 3:562
1591 Dauer LT, Brooks AL, Hoel DG, Morgan WF, Stram D, Tran P. Review and evaluation
1592 of updated research on the health effects associated with low-dose ionising radiation.
1593 Radiat Prot Dosim 2010; 140(2):103-136
1594 Frazier TH, Richardson JB, Fabre VC, Callen JP. Fluoroscopy-induced chronic
1595 radiation skin injury: a disease perhaps often overlooked. Arch Dermatol 2007;
1596 143(5): 637-640
1597 Hardell L., Hansson Mild K., Påhlson A., Hallquist A. (2001) Ionizing radiation, cellular
1598 telephones and the risk for brain tumours. Eur J Cancer Prev 10:523-9.
1599 Herold DM, Hanlon AL, Hanks GE. Diabetes mellitus: a predictor for late radiation
1600 morbidity. Int J Radiat Oncol Biol Phys 1999; 43: 475-479
1601 Hidajat N, Wust P, Felix R, Schroder RJ. Radiation exposure to patient and staff in
1602 hepatic chemoembolization: risk estimation of cancer and deterministic effects.
1603 Cardiovasc Intervent Radiol 2006; 29(5): 791-796
1604 Hymes SR, Strom EA, Fife C. Radiation dermatitis: clinical presentation,
1605 pathophysiology, and treatment 2006. J Am Acad Dermatol 2006;54:28-46
1606 IEC. Report 60601 Medical electrical equipment - Part 2-43: Particular requirements for
1607 the safety of X-ray equipment for interventional procedures. 2nd ed. Geneva,
1608 Switzerland: International Electrotechnical Commission; 2010.

ICRP, 1990. The 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann ICRP 1991; 21(1-3):1-201

ICRP, 2000. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann ICRP 30:7-67.

ICRP, 2007a. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann ICRP 37(2-4):1-332

ICRP, 2007b.. Radiological protection in medicine. ICRP Publication 105. Ann ICRP 37:1-63

ICRP Protection 2011a. Tissue Reactions and Other Non-Cancer Effects of Radiation. ICRP Publication **XXX**. Ann ICRP 2011; in press

ICRP 2011b. Statement on Tissue reactions. Approved by the Commission on April 21, 2011. Available at http://www.icrp.org/docs/ICRP%20Statement%20on%20Tissue%20Reactions.pdf Accessed May 9, 2011. (in press)

Kahn, HA, Liebowitz HM, Ganley JP, Kini MM, Colton T, Nickerson RS, Dawber TR. The Framingham Eye Study. I. Outline and major prevalence findings. Am J Epidemiol 1977; 106(1): 17-32

Karipidis KK, Benke G, Sim MR, Kauppinen T, Giles G. (2007) Occupational exposure to ionizing and non-ionizing radiation and the risk of glioma. Occup Med (Lond) 57:518-524.

Kim KP, Miller DL, Balter S, Kleinerman RA, Linet MS, Kwon D, Simon SL. Occupational radiation doses to operators performing cardiac catheterization procedures. Health Phys 2008;94:211-227.

Kleiman NJ. Radiation cataract. In: Working Party on Research Implications on Health and Safety Standards of the Article 31 Group of Experts, ed. Radiation Protection 145 EU Scientific Seminar 2006 New insights in radiation risk and basic safety standards. Brussels: European Commission; 2007:81-95. Available at http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/145_en.pdf Accessed July 28, 2010

Koenig TR, Wolff D, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: Part 1, Characteristics of radiation injury. AJR 2001; 177: 3-11

Martinez LC, Vano E, Gutierrez F, Rodriguez C, Gilarranz R, Manzanas MJ. Patient doses from fluoroscopically guided cardiac procedures in pediatrics. Phys Med Biol 2007; 52: 4749-4759.

Matanoski G.M., Seltser R., Sartwell P.E., Diamond E.L., Elliott E.A. (1975) The current mortality rates of radiologists and other physician specialists: specific causes of death. Am J Epidemiol 101:199-210.

McGale P, Darby SC. Commentary: A dose-response relationship for radiation-induced heart disease—current issues and future prospects. Int J Epidemiol 2008; 37:518-523

McGeoghegan D, Binks K, Gillies M, Jones S, Whaley S. The non-cancer mortality experience of male workers at British Nuclear Fuels plc, 1946-2005. Int J Epidemiol 2008; 37:506-518

1652 Monaco JL, Bowen K, Tadros PN, Witt PD. Iatrogenic deep musculocutaneous radiation
1653 injury following percutaneous coronary intervention. J Invasive Cardiol
1654 2003;15:451-3.
1655 National Cancer Institute, 2005. Interventional fluoroscopy: reducing radiation risks for
1656 patients and staff. NIH Publication No. 05-5286. National Cancer Institute,
1657 Bethesda, MD. Available at: http://www.cancer.gov/images/Documents/45bae965-
1658 697a-4de8-9dae-b77222e0e79d/InterventionalFluor.pdf Accessed December 31,
1659 2010.
1660 National Council on Radiation Protection and Measurements. Limitation of exposure to
1661 ionizing radiation. NCRP Report 116. Bethesda, MD: National Council on Radiation
1662 Protection and Measurements; 1993.
1663 National Council on Radiation Protection and Measurements. Radiation dose
1664 management for fluoroscopically guided interventional medical procedures. NCRP
1665 Report No. 168. Bethesda, MD: National Council on Radiation Protection and
1666 Measurements; 2010.
1667 NRC. (2006) Health risks from exposure to low levels of ionizing radiation: BEIR-VII
1668 Phase 2 National Academy Press, Washington, DC.
1669 Pages J. Effective dose and dose to the crystalline lens during angiographic procedures.
1670 JBR-BTR 2000; 83:108-110
1671 Preston D.L., Ron E., Tokuoka S., Funamoto S., Nishi N., Soda M., Mabuchi K.,
1672 Kodama K. (2007) Solid cancer incidence in atomic bomb survivors: 1958-1998.
1673 Radiat Res 168:1-64.
1674 Preston D.L., Ron E., Yonehara S., Kobuke T., Fujii H., Kishikawa M., Tokunaga M.,
1675 Tokuoka S., Mabuchi K. (2002) Tumors of the nervous system and pituitary gland
1676 associated with atomic bomb radiation exposure. J Natl Cancer Inst 94:1555-63.
1677 Renaud L. (1992) A 5-y follow-up of the radiation exposure to in-room personnel during
1678 cardiac catheterization. Health Phys 62:10-15.
1679 Shack RB, Lynch JB. Radiation dermatitis. Clin Plast Surg 1987; 14: 391-401
1680 Shimizu Y, Kodama K, Nishi N, Kasagi F, Suyama A, Soda M, Grant EJ, Sugiyama H,
1681 Sakata R, Moriwaki H, Hayashi M, Konda M, Shore RE. Radiation exposure and
1682 circulatory disease risk: Hiroshima and Nagaski atomic bomb survivor data, 1950-
1683 2003. BMJ 2010; 340:b5349
1684 Shope, T.B., 1996. Radiation-induced skin injuries from fluoroscopy. Radiographics 16,
1685 1195-1199.
1686 Shore RE, Moseson M, Xue X, Tse Y, Harley N, Pasternack BS. Skin cancer after x-ray
1687 treatment for scalp ringworm. Radiat Res 2002: 157 (4): 410-418
1688 Shore, R.E., Neriishi, K., Nakashima, E., 2010. Epidemiological studies of cataract risk
1689 at low to moderate radiation doses: (not) seeing is believing. Radiat. Res. 174, 889-
1690 894.
1691 Turreson I, Notter G. The predictive value of skin telangiectasia for late radiation effect
1692 in different normal tissues. Int J Radiat Oncol Biol Phys 1986; 12 603-609
1693 UNSCEAR. (2000) Sources and effects of ionizing radiation. United Nations, New
1694 York.

United States Food and Drug Administration . Public Health Advisory. Avoidance of serious x-ray induced skin injuries to patients during fluoroscopically guided procedures. Rockville, MD: Center for Devices and Radiological Health, United States Food and Drug Administration, 1994 Available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm063084.htm Accessed July 29, 2010.

Vano E, Arranz L, Sastre JM, Moro C, Ledo A, Garate MT, Minguez I. Dosimetric and radiation protection considerations based on some cases of patient skin injuries in interventional cardiology. Br J Radiol 1998; 71: 510-516

Vano E, Gonzalez L, Beneytez F, Moreno F. Lens injuries induced by occupational exposure to non-optimized interventional radiology laboratories. Br J Radiol 1998; 71: 728-733

Vano E, Gonzalez L, Fernandez M, Haskal ZJ. Eye lens exposure to radiation in interventional suites: caution is warranted. Radiology 2008; 248: 945-953

Vano E, Kleiman NJ, Duran A, Rehani MM, Echeverri D, Cabrera. M. Radiation cataract risk in interventional cardiology personnel. Radiat Res, 2010; 174(4):490-495

Vlietstra RE, Wagner LK, Koenig T, Mettler F. Radiation burns as a severe complication of fluoroscopically guided cardiological interventions. J Int Cardiol 2004; 17(3): 1-12

Wagner LK, McNesse MD, Marx MV, Siegel EL. Severe skin reactions from interventional fluoroscopy: case report and review of literature. Radiology 1999; 213: 773-776

Wang JX, Zhang LA, Li BX, Zhao YC, Wang ZQ, Zhang JY, Aoyama T. Cancer incidence and risk estimation among medical x-ray workers in China, 1950-1955. Health Phys 2002; 82(4): 455-466

Wenzl T.B. (2005) Increased brain cancer risk in physicians with high radiation exposure. Radiology 235:709-10; author reply 710-1.

Worgul BV, Kundiyev YI, Sergiyenko NM, Chumak VV, Vitte PM, Medvedovsky C, Bakhanova EV, Junk AK, Kryrychenko OY, Musijachenko NV, Shylo SA, Vitte OP, Xu S, Xue X, Shore RE. Cataracts among Chernobyl clean-up workers: implications regarding permissible eye exposures. Radiat Res 2007; 167(2): 233-243

Yonehara S., Brenner A.V., Kishikawa M., Inskip P.D., Preston D.L., Ron E., Mabuchi K., Tokuoka S. (2004) Clinical and epidemiologic characteristics of first primary tumors of the central nervous system and related organs among atomic bomb survivors in Hiroshima and Nagasaki, 1958-1995. Cancer 101:1644-54.

3. CLINICAL EXAMPLES OF DETERMINISTIC INJURY AFTER FLUOROSCOPICALLY GUIDED CARDIAC PROCEDURES

Main Points

- **There is increasing concern about skin radiation dose levels in cardiology.**
- **The cases presented in this chapter provide a clinical context and illustrate skin changes due to radiation injury.**
- **Deterministic injuries may extend into deeper tissues and can cause symptoms that persist for years.**
- **Deterministic injuries may be accompanied by an increase in stochastic risk.**

3.1 Introduction

(57) There is increasing concern about skin radiation dose levels in cardiology. This is because of the discovery of deterministic injuries in patients who have undergone long procedures using suboptimal equipment, performed by individuals inadequately trained in radiological protection (UNSCEAR, 2010). However, high skin doses can occur in obese patients, or patients undergoing complex interventions, even when the procedure is performed by an experienced, well-trained operator using modern, well-maintained equipment (Suzuki, 2008; Bryk, 2006).

(58) The information presented in Chapter 2 (section 2.3) on the radiobiology of the skin can be difficult to interpret without a clinical context. The cases presented in this chapter provide that clinical context and illustrate the skin changes discussed in Chapter 2. It should be apparent that these injuries can be severe and debilitating. Some patients will require life-long therapy and observation. Treatment often requires a multidisciplinary team working in a specialized centre. Pain management and psychological support are important components of treatment.

(59) Methods to optimize patient radiation dose and minimize skin dose are described in Chapter 5 and listed in Table 5.1, but are repeated here because of their importance. Limit fluoroscopy time and the number of cine frames to the least number possible for successful completion of the procedure. Monitor patient radiation dose during the procedure. Use fluoroscopy equipment with pulsed fluoroscopy and use the lowest pulse rate that provides adequate fluoroscopic guidance. Use the lowest fluoroscopic and cine dose rates necessary for each stage of the procedure. When possible, slightly rotate the gantry so that the entrance beam is periodically directed at a different entrance skin site. Keep the image receptor (image intensifier or flat panel detector) as close as possible to the patient, and keep the x-ray tube as far away as possible from the entrance skin site.

3.2 Case 1 (Vliestra et al, 2004)

(60) A 53-year-old man weighing 141 kg (310 lbs) had two previous percutaneous transluminal coronary angioplasties (PTCA) 3 years earlier and now presented with unstable angina. A repeat coronary angiogram was followed immediately by PTCA of the distal circumflex artery. The procedure included use of the left anterior oblique (LAO) projection, biplane cinefluorography runs, high dose fluoroscopy mode and a total fluoroscopy time of 51.4 minutes. The estimated skin dose was 22 Gy.

(61) The patient presented six weeks later with a painful, itchy rash on his lower back in a square pattern (Fig. 3.1). This area developed into a painful ulcer. Debridement and skin grafting were required six months after the PTCA. Local discomfort persists.

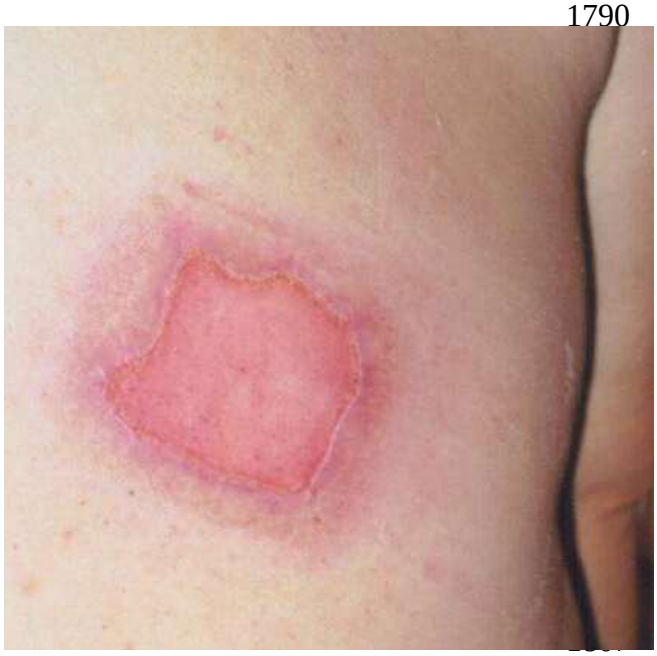


Figure 3.1 Case 1. See text for details. Reprinted from Vliestra, 2004. (Permission needed)

3.3 Case 2 (Koenig et al, 2001)

(62) A 75 year old woman had two previous coronary angiograms, followed by PTCA for a 90% stenosis of the right coronary artery. Ten months after the procedure she developed a skin lesion (Fig. 3.2). Skin dose estimates are not available.

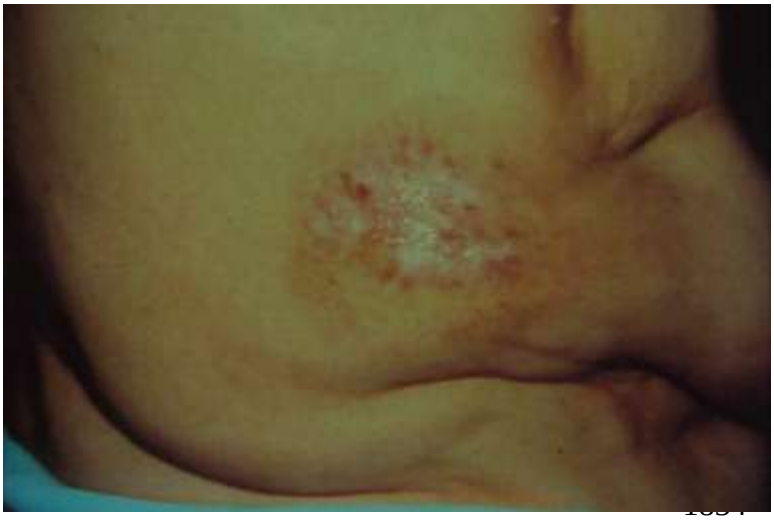
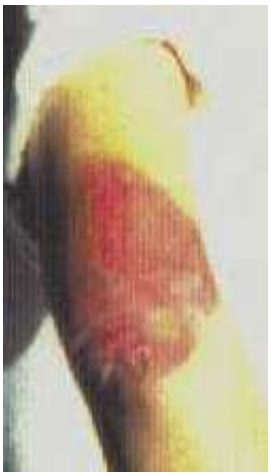
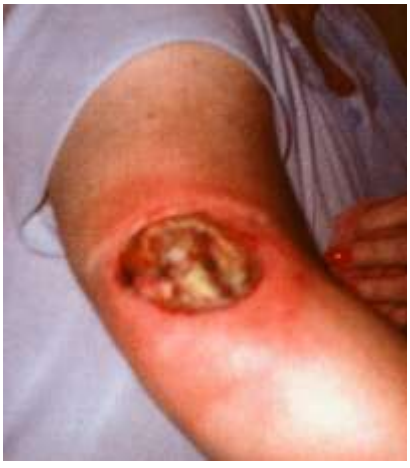


Figure 3.2 Case 2. The right lateral chest demonstrates both hyper- and hypopigmentation, in addition to skin atrophy and telangiectasia. Reprinted from Koenig, 2001. (Permission needed)

3.4 Case 3 (Koenig et al, 2001)

(63) A 49-year-old woman presented with an 8-year history of supraventicular tachycardia. Radiofrequency catheter ablation was performed. During the procedure her right arm was in the x-ray beam near the port. The separator (spacer) had been removed from the tube housing. Fluoroscopy time was approximately 20 minutes. Skin dose data are not available. She presented 3 weeks later with a skin lesion on her right elbow (Fig. 3.3). If the patient's arm had been positioned outside the x-ray beam the injury could have been prevented or its severity decreased.





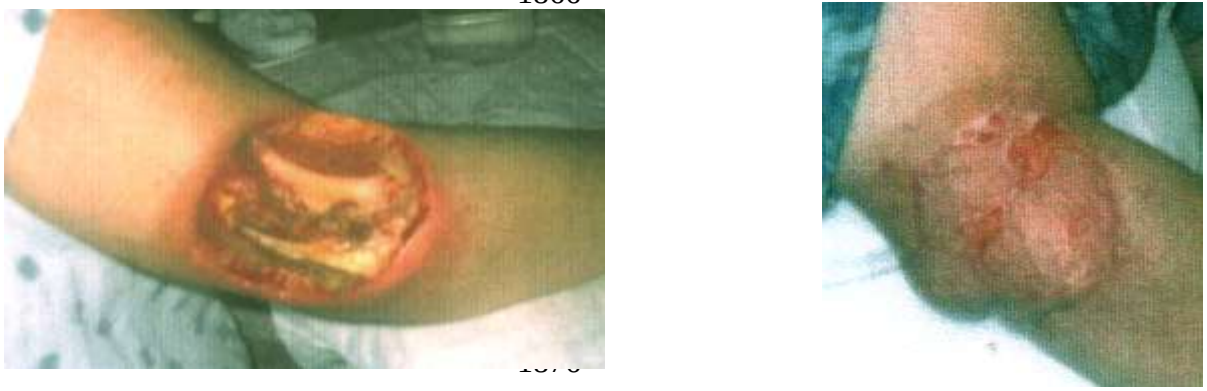


Figure 3.3 Case 3. See text for details. A) 3 weeks: Area of sharply demarcated erythema. B) 5 months: Tissue necrosis. C) 6½ months: Deep ulceration with exposure of the bone. D) Following surgical flap. Reprinted from Koenig, 2001. (Permission needed)

3.5 Case 4 (Vliestra et al, 2004)

(64) A 38-year-old man weighing 114 kg (250 lbs) was diagnosed with Wolff-Parkinson-White syndrome. An attempt at radiofrequency ablation using biplane fluoroscopy was unsuccessful. A few weeks after the procedure, the patient developed areas of brownish-red discolouration on his back, which resolved. A second unsuccessful ablation procedure was performed 2½ months later, with reappearance of the skin discolouration after 1 week. The physician thought the skin lesion was due to the grounding pad used for radiofrequency ablation rather than to radiation. A third unsuccessful ablation procedure was performed; skin lesions appeared 8 days later (Fig 3.4). Each of the three procedures used more than 100 min of fluoroscopy time. Skin dose estimates are not available. The severe injury to the right arm was due to its position. If the arm had been positioned away from the entrance x-ray beam, the injury might have been avoided.

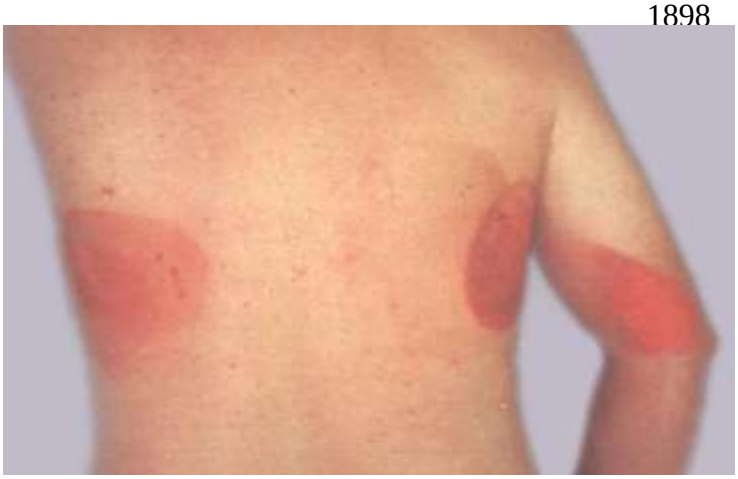


Figure 3.4 Case 4. The right-sided lesions show desquamation. The erythema on the back healed into discoloured scars. The right arm lesion, closer to the x-ray beam, developed necrosis and required a skin graft. Reprinted from Vliestra, 2004. (Permission needed)

3.6 Case 5 (Vañó et al, 1998)

(65) A 17-year-old female underwent an electrophysiology ablation procedure for posterior pathway pre-excitation that lasted 5 hours. Eleven months later she underwent a second procedure that also lasted 5 hours. Both procedures were performed with biplane fluoroscopy. Fluoroscopy time for the lateral plane was estimated at 90-120 minutes. Skin dose estimates are not available. Twelve hours after the second procedure she developed an erythematous plaque in the right axilla. One month later she consulted a dermatologist for red macular and blister lesions on her right side. Twenty-six months after the second procedure an indurated, atrophic plaque with linear edges, 10 x 5 cm^2, was observed (Fig. 3.5). The diagnosis was chronic radiodermatitis. The muscles in her right arm have also been affected, with resultant limitation in the range of motion. Because of the patient's age and the region irradiated, her risk of subsequent breast cancer is also increased.

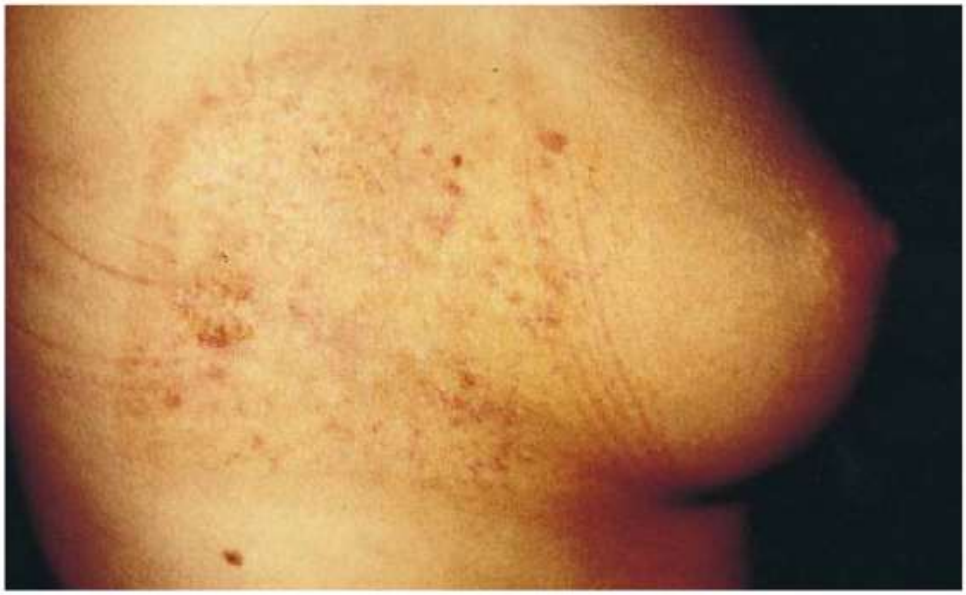


Figure 3.5 Case 5. Indurated, atrophic plaque with linear edges, with areas of hyper- and hypopigmentation. Reprinted from Vañó, 1998. (Permission needed)

3.7 Case 6 (Courtesy of Dr. M. Portas, Buenos Aires, Argentina)

(66) An obese 57-year-old female, a heavy smoker, underwent PTCA. The procedure time was approximately 6 hours. No data on radiation dose are available. Early manifestations were blisters on the skin of the back in the lumbar region. This was diagnosed by a dermatologist as a herpes zoster infection. Two months later, a deep ulcer (Radiation Therapy Oncology Group/European Organisation for Research and Treatment of Cancer [RTOG/EORTC] cutaneous radiotoxicity grade 4) appeared at the same site. (No photographs of the injury at this stage are available.) It was extremely painful. The following year the patient underwent a plastic surgery procedure, with two rotation flaps to close the wound. The rotation flaps subsequently underwent necrosis, leaving an ulcer approximately 20 x 20 cm (Fig. 3.6). During the next several years, conservative treatment was performed at a specialized burn centre. Wound coverage was performed with porcine dermis, skin allografts and autografts, in conjunction with anti-inflammatory and antibacterial therapy and hyperbaric oxygen treatments. This treatment led to progressive wound closure. After 3 years of treatment (5 years after the PTCA), the dimensions of the ulcer were reduced to 3 x 1.5 cm (Fig 3.7). *In vitro* radiosensitivity testing demonstrated that the patient had normal radiosensitivity. The injury and prolonged recovery were attributed to radiation exposure, obesity and heavy smoking.

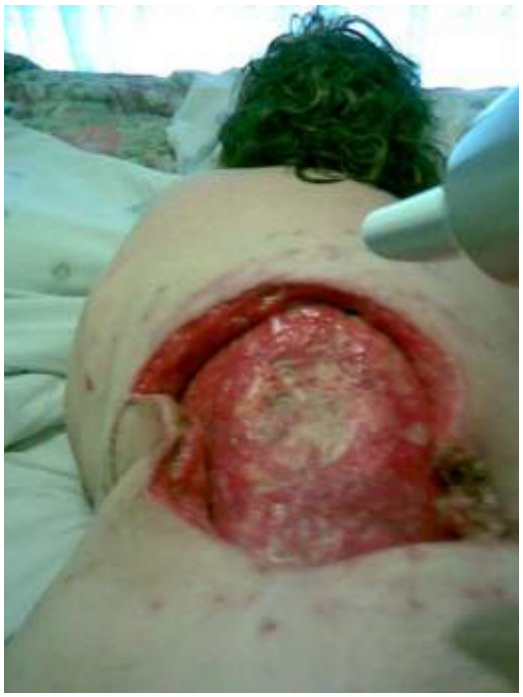


Figure 3.6 Case 6. Appearance of the patient's back following the initial surgery and necrosis of the rotation flaps. The ulcer is approximately 20 x 20 cm.

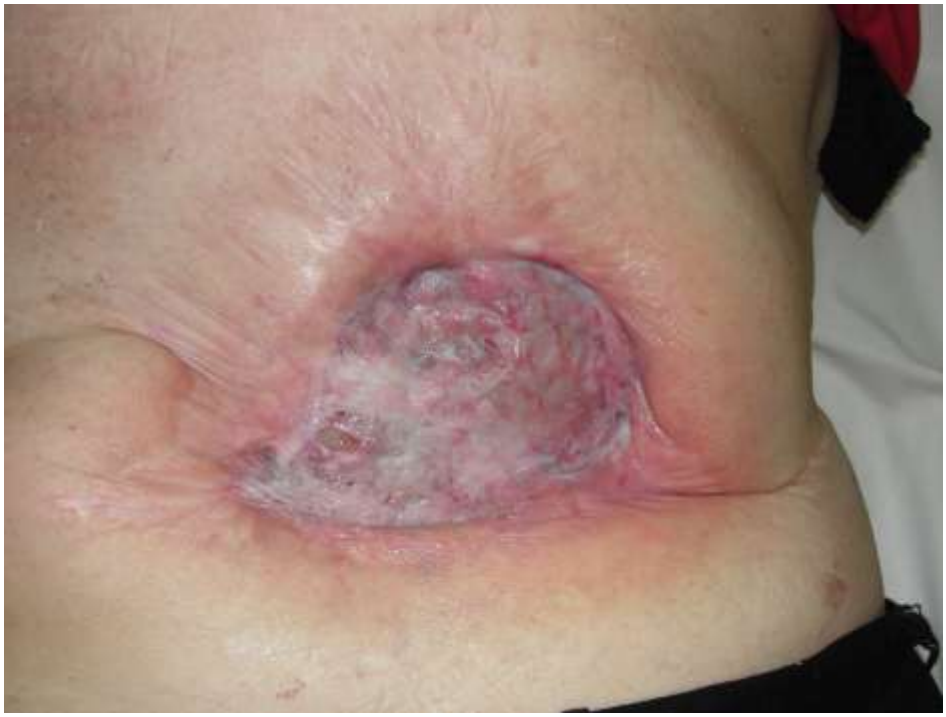


Figure 3.7 Case 6. Appearance of the patient's back 5 years after the PTCA. After 3 years of treatment, the ulcer is reduced in size to 3 x 1.5 cm. The patient's quality of life is much improved.

3.8 References

Bryk, S.G., Censullo, M.L., Wagner, L.K., Rossman, L.L., Cohen, A.M., 2006. Endovascular and interventional procedures in obese patients: a review of procedural technique modifications and radiation management. J. Vasc. Interv. Radiol. 17, 27-33.

Koenig, T.R., Wolff, D., Mettler, F.A., Wagner, L.K., 2001. Skin injuries from fluoroscopically guided procedures: Part 1, Characteristics of radiation injury. AJR. Am. J. Roentgenol. 177, 3-11.

Suzuki, S., Furui, S., Isshiki, T., Kozuma, K., Koyama, Y., Yamamoto, H., Ochiai, M., Asakura, Y., Ikari, Y., 2008. Patients' skin dose during percutaneous coronary intervention for chronic total occlusion. Catheter. Cardiovasc. Interv. 71, 160-164.

UNSCEAR. Sources of ionizing radiation: volume I. Report to the General Assembly, with scientific annexes; 2010; New York, NY. Available at: http://www.unscear.org/unscear/en/publications/2008_1.html Accessed December 31, 2010.

Vañó, E., Arranz, L., Sastre, J.M., Moro, C., Ledo, A., Gárate, M.T., Minguez, I., 1998. Dosimetric and radiation protection considerations based on some cases of patient skin injuries in interventional cardiology. Br. J. Radiol. 71, 510-516.

Vlietstra, R.E., Wagner, L.K., Koenig, T., Mettler, F., 2004. Radiation burns as a severe complication of fluoroscopically guided cardiological interventions. J Interv Cardiol 17, 1-12.

4. PRINCIPLES OF RADIOLOGICAL PROTECTION FOR PATIENTS AND STAFF

Main Points

- **Justification means that a medical procedure should only be performed when it is appropriate for a particular patient— the anticipated clinical benefits should exceed all anticipated procedural risks, including radiation risk.**
- **For CT and nuclear medicine studies, justification is a responsibility shared between the referring clinician and the cardiac imager. For fluoroscopically guided interventions, the responsibility rests with the interventionalist.**
- **Optimization means that the radiation dose to the patient is suitable for the medical purpose, and radiation that is clinically unnecessary or unproductive is avoided.**
- **Patient radiation dose is optimized when imaging is performed with the least amount of radiation required to provide adequate image quality, diagnostic information, and for fluoroscopy, adequate imaging guidance.**
- **Dose limits apply to occupational exposure of cardiologists and staff.**
- **Dose limits do not apply to medical exposures of patients or to carers and comforters.**

4.1 Introduction

(67) The Commission recommends three fundamental principles of radiological protection: justification, optimization of protection, and application of dose limits (ICRP 103, ICRP 105). The first two are source related and apply to all radiation exposure situations. The third applies to staff, but does not apply to medical exposures of patients or to carers and comforters.

4.2 Justification

(68) The principle of justification is that, in general, "any decision that alters the radiation exposure situation should do more good than harm. This means that by introducing a new radiation source, by reducing existing exposure, or by reducing the risk of potential exposure, one should achieve sufficient individual or societal benefit to offset the detriment it causes." (ICRP 103, ICRP 105). The principal aim of medical exposures is to do more good than harm to the patient, subsidiary account being taken of the radiation detriment from the exposure of the radio- logical staff and of other individuals (ICRP 103).

(69) A medical procedure should only be performed when it is appropriate for a particular patient. The RAND Corporation has developed a definition of "appropriate" that is widely used: the expected health benefit (i.e., increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences (i.e., mortality, morbidity, anxiety of anticipating the procedure, pain produced by the procedure, misleading or false diagnoses, time lost from work) by a

sufficiently wide margin that the procedure is worth doing (Sistrom, 2008, NHS, 1993). In other words, the anticipated clinical benefits should exceed all anticipated procedural risks, including radiation risk.

(70) In the United States, appropriateness criteria have been developed for many clinical scenarios (Brindis et al, 2005, Douglas, 2008, Patel, 2009, Hendel 2009, ACR, 2010, Taylor 2010). Similar guidelines have been developed in the United Kingdom, though they are less readily available (RCR, 2007). European guidelines are also available (Hesse, 2005, Schroeder 2008). These recommendations are typically based on a standardized literature review and compilation of evidence tables, followed by rating of each indication by an expert panel with varied composition (Patel et al, 2005). Appropriateness may vary based on national and local norms and practice patterns, as well as well as patient and family values and preferences (Wolk et al, 2004).

(71) The responsibility for the justification of the use of a particular procedure falls on the relevant medical practitioners (ICRP 103). For CT and nuclear medicine studies, justification is a responsibility shared between the referring clinician and the cardiac imager. For the referring clinician, this entails weighing the benefits of a test against its risks, including radiation exposure, and considering such an analysis for all possible alternatives including performing no test. For the cardiac imager, justification entails ensuring that the test has a reasonable indication, given the available information, and discussing the indication with the referring clinician if there is concern in this respect. For fluoroscopically guided interventions, the responsibility rests with the interventionalist.

4.3 Optimization

(72) The principle of optimization of protection is that "the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors. This means that the level of protection should be the best under the prevailing circumstances, maximizing the margin of benefit over harm" (ICRP 103, ICRP 105, NCRP 1993). This is often summarized using the acronym ALARA, which stands for As Low As Reasonably Achievable.

(73) For cardiology procedures, this principle is applied in the design of cardiac facilities that use ionizing radiation, appropriate selection and use of equipment, and in day-to-day working procedures. Optimization is best described as a radiation dose to the patient that is suitable for the medical purpose, and avoidance of radiation that is clinically unnecessary or unproductive.

(74) Dose optimization means delivering a radiation dose to the organs and tissues of clinical interest no greater than that required for adequate imaging and minimizing dose to other structures (e.g., the skin). Patient radiation dose is considered to be optimized when imaging is performed with the least amount of radiation required to provide adequate image quality and, for fluoroscopy, adequate imaging guidance (NCI, 2005). The goal of every imaging procedure is to provide images adequate for the clinical purpose. Imaging requirements depend on the specific patient and the specific procedure. Reducing patient radiation dose to the point where images are inadequate is

counterproductive; it results in radiation dose to the patient without answering the clinical question. Improving image quality beyond what is clinically needed subjects the patient to additional radiation dose without additional clinical benefit. The goal of radiation management is to keep patient radiation dose as low as possible consistent with the use of appropriate equipment and the imaging requirements for a specific patient and a specific procedure.

4.4 Dose limits

(75) The principle of application of dose limits states that "the total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the Commission" (ICRP 103, ICRP 105). This principle does not apply to medical exposure of patients. As noted in ICRP Publication 105, "Provided that the medical exposures of patients have been properly justified and that the associated doses are commensurate with the medical purpose, it is not appropriate to apply dose limits or dose constraints to the medical exposure of patients, because such limits or constraints would often do more harm than good."(ICRP 105) For interventional procedures, the medical condition being treated and the non-radiation risks of the procedure typically present substantially greater morbidity and mortality than do the radiation risks (Miller, 2008, NCRP 168, 2010).

4.5 References

What do we mean by appropriate health care? Report of a working group prepared for the Director of Research and Development of the NHS Management Executive. Qual Health Care 1993;2:117-23.

American College of Radiology. ACR Appropriateness Criteria®. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx Accessed August 3, 2010.

Brindis RG, Douglas PS, Hendel RC, Peterson ED, Wolk MJ, Allen JM, Patel MR, Raskin IE, Bateman TM, Cerqueira MD, Gibbons RJ, Gillam LD, Gillespie JA, Iskandrian AE, Jerome SD, Krumholz HM, Messer JV, Spertus JA, Stowers SA. ACCF/ASNC appropriateness criteria for single-photon emission computed tomography myocardial perfusion imaging (SPECT MPI): a report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group and the American Society of Nuclear Cardiology endorsed by the American Heart Association. J Am Coll Cardiol 2005;46:1587-1605.

Douglas, P.S., Khandheria, B., Stainback, R.F., Weissman, N.J., Peterson, E.D., Hendel, R.C., Blaivas, M., Des Prez, R.D., Gillam, L.D., Golash, T., Hiratzka, L.F., Kussmaul, W.G., Labovitz, A.J., Lindenfeld, J., Masoudi, F.A., Mayo, P.H., Porembka, D., Spertus, J.A., Wann, L.S., Wiegers, S.E., Brindis, R.G., Patel, M.R., Wolk, M.J., Allen, J.M., 2008. ACCF/ASE/ACEP/AHA/ASNC/SCAI/SCCT/SCMR 2008 appropriateness criteria for stress echocardiography: a report of the American College of Cardiology Foundation Appropriateness Criteria Task Force, American Society of Echocardiography, American College of Emergency Physicians,

American Heart Association, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance endorsed by the Heart Rhythm Society and the Society of Critical Care Medicine. J. Am. Coll. Cardiol. 51, 1127-1147. Available at: http://content.onlinejacc.org/cgi/content/full/51/11/1127 Accessed January 1, 2011.

Hendel RC, Berman DS, Di Carli MF, et al. ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009 appropriate use criteria for cardiac radionuclide imaging: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the American Society of Nuclear Cardiology, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the Society of Cardiovascular Computed Tomography, the Society for Cardiovascular Magnetic Resonance, and the Society of Nuclear Medicine. Circulation. 2009;119(22):e561-587.

Hesse, B., Tagil, K., Cuocolo, A., Anagnostopoulos, C., Bardies, M., Bax, J., Bengel, F., Busemann Sokole, E., Davies, G., Dondi, M., Edenbrandt, L., Franken, P., Kjaer, A., Knuuti, J., Lassmann, M., Ljungberg, M., Marcassa, C., Marie, P.Y., McKiddie, F., O'Connor, M., Prvulovich, E., Underwood, R., van Eck-Smit, B., 2005. EANM/ESC procedural guidelines for myocardial perfusion imaging in nuclear cardiology. Eur J Nucl Med Mol Imaging 32, 855-897. Available at: http://www.eanm.org/scientific_info/guidelines/gl_cardio_myocard_perf.pdf Accessed January 1, 2011.

International Commission on Radiological Protection. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann ICRP 2007; 37(2-4):1-332

International Commission on Radiological Protection. Radiological protection in medicine. ICRP Publication 105. Ann ICRP 2007;37:1-63.

Miller DL. Overview of contemporary interventional fluoroscopy procedures. Health Phys 2008; 95:638-644.

NCI. Interventional fluoroscopy: reducing radiation risks for patients and staff. NIH Publication No. 05-5286. Bethesda:National Cancer Institute, 2005. Available at: http://www.cancer.gov/images/Documents/45bae965-697a-4de8-9dae-b77222e0e79d/InterventionalFluor.pdf Accessed January 1, 2011.

NCRP. Limitation of exposure to ionizing radiation. NCRP Report No. 116. Bethesda, MD: National Council on Radiation Protection and Measurements; 1993.

NCRP. Radiation dose management for fluoroscopically guided interventional medical procedures. NCRP Report No. 168. Bethesda, MD: National Council on Radiation Protection and Measurements; 2010.

Patel MR, Spertus JA, Brindis RG, Hendel RC, Douglas PS, Peterson ED, Wolk MJ, Allen JM, Raskin IE. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. J Am Coll Cardiol 2005;46:1606-1613.

Patel, M.R., Dehmer, G.J., Hirshfeld, J.W., Smith, P.K., Spertus, J.A., 2009. ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization: a report by the American College of Cardiology Foundation

Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography. J. Am. Coll. Cardiol. 53, 530-553. Available at: http://content.onlinejacc.org/cgi/content/full/53/6/530 Accessed January 1, 2011.

The Royal College of Radiologists. Making the best use of clinical radiology services: referral guidelines. 6th ed. London:The Royal College of Radiologists, 2007.

Schroeder S, Achenbach S, Bengel F, et al. Cardiac computed tomography: indications, applications, limitations, and training requirements: report of a Writing Group deployed by the Working Group Nuclear Cardiology and Cardiac CT of the European Society of Cardiology and the European Council of Nuclear Cardiology. Eur Heart J 2008;29(4):531-556.

Sistrom CL. In support of the ACR Appropriateness Criteria®. J Am Coll Radiol 2008;5:630-635.

Taylor, A.J., Cerqueira, M., Hodgson, J.M., Mark, D., Min, J., O'Gara, P., Rubin, G.D., Kramer, C.M., Berman, D., Brown, A., Chaudhry, F.A., Cury, R.C., Desai, M.Y., Einstein, A.J., Gomes, A.S., Harrington, R., Hoffmann, U., Khare, R., Lesser, J., McGann, C., Rosenberg, A., Schwartz, R., Shelton, M., Smetana, G.W., Smith, S.C., Jr., 2010. ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 appropriate use criteria for cardiac computed tomography: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the Society of Cardiovascular Computed Tomography, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the American Society of Nuclear Cardiology, the North American Society for Cardiovascular Imaging, the Society for Cardiovascular Angiography and Interventions, and the Society for Cardiovascular Magnetic Resonance. J. Am. Coll. Cardiol. 56, 1864-1894. Available at: http://content.onlinejacc.org/cgi/content/full/56/22/1864 Accessed January 1, 2011.in press.

Wolk MJ, Peterson E, Brindis R, Eagle K. President's page: the appropriate cardiologist: responsible stewardship in a golden era of cardiology. J Am Coll Cardiol 2004;44:933-935.

5. MANAGING PATIENT DOSE IN FLUOROSCOPICALLY GUIDED INTERVENTIONS

Main Points

- **The informed consent process should include information on radiation risk if the risk of radiation injury is thought to be significant.**
- **Important aspects of the patient's medical history that should be considered when estimating radiation risk are genetic factors, co-existing diseases, medication use, radiation history, and pregnancy.**
- **Some of the factors that affect the patient's radiation dose depend on the x-ray system, but many others depend on how the operator uses the x-ray system.**
- **During the procedure, the cardiologist should be kept aware of the fluoroscopy time, the number of cine series and cine frames, and the total patient dose.**
- **As patient radiation dose increases, the operator should consider the radiation dose already delivered to the patient and the additional radiation necessary to complete the procedure.**
- **Patient radiation dose reports should be produced at the end of the procedure, and archived.**
- **Radiation dose data should be recorded in the patient's medical record after the procedure.**
- **When the patient's radiation dose from the procedure is high, clinical follow-up is essential for early detection and management of skin injuries.**
- **Patients who have received a substantial radiation dose should have follow-up at 10-14 days and at one month after the procedure for possible deterministic effects.**

5.1 Introduction

(76) Fluoroscopically guided interventions (FGI) comprise 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). This chapter deals with clinical radiation management before, during and after FGI.

(77) The doses received by patients during fluoroscopically guided cardiac procedures can be high, and some patients may have several procedures carried out in a relatively short period of time. Hence, it is essential that the cardiologist optimises patient radiation dose (Chambers, 2011). If a certain dose threshold is exceeded (see Chapter 2), the procedure could result in deterministic effects (harmful tissue reactions). High radiation doses also increase stochastic risk (cancer and heritable effects).

It is important for medical practitioners to be aware that although uncertainty remains, the absorbed dose threshold for circulatory disease may be as low as 0.5 Gy to the heart and brain (ICRP, 2011a). In some complex fluoroscopically guided cardiac procedures, organ doses may be > 0.5 Gy. Cardiovascular radiation effects have been reported to occur at these doses, including focal myocardial degeneration and fibrosis, and accelerated atherosclerosis in major blood vessels. (ICRP XXX Tissue Reactions, 2011b).

(78) The mean age of patients undergoing cardiac procedures is relatively high. Stochastic risk is not a great concern for older patients because of the latency period for the development of cancer and these patients' relatively shorter life expectancies. Stochastic risk is of greater concern when fluoroscopically guided procedures are performed on children. Children have longer life expectancies and are also more sensitive to the effects of radiation.

(79) Initial and continuous training in dose management and radiological protection has a definitive influence on patient doses, and is essential for interventionalists (Hirshfeld, 2005, Rehani, 2007, ICRP 2009). Several recent publications have demonstrated that this training helps to optimise patient dose and reduce operator dose (Whitby, 2005, Vano, 2006, Bor, 2008, Bernardi, 2008, Kim, 2010, IAEA TECDOC 1641, 2010). Training is discussed further in Chapter 9.

5.2 Before the Procedure

(80) A discussion of radiation risk is an appropriate part of the informed consent process if radiation risk factors are present or a substantial radiation dose is anticipated. ICRP recommends that patients should be counselled before the procedure if the risk of radiation injury is thought to be significant (ICRP Publication 85). Important aspects of the patient's medical history that should be considered when estimating radiation risk are genetic factors, co-existing diseases, medication use, radiation history, and pregnancy (Miller et al, 2010).

(81) Obese patients are at a higher risk of radiation-induced skin injury because of poor radiation penetration and the accompanying closer proximity of the x-ray source to the patient (Bryk, 2006). Absorbed dose at the entrance skin site in obese patients can be as much as 10 times higher than in non-obese patients (Wagner, JVIR 2000). Many of the documented injuries associated with fluoroscopic procedures have been seen in larger patients (Koenig Part 2, 2001).

(82) For some complex procedures, and especially when procedures are repeated in large or obese patients, a medical physicist can provide useful advice to help optimise the procedure. If a previous procedure has resulted in a high peak skin dose, the strategy for further possible procedures in the same patient should include modifying subsequent procedures to reduce skin dose, if possible. Other procedure modifications are often necessary in obese patients (Bryk, 2006).

(83) Except for time-critical emergency procedures, pregnancy status should be determined prior to a fluoroscopically guided intervention (ICRP 105). If possible, elective procedures on pregnant patients should be deferred until the patient is no longer

pregnant. When medically indicated FGI procedures must be performed on pregnant patients, and except for time-critical emergency procedures, the Commission recommends that procedure planning include feasible modifications to minimize conceptus dose, estimation of expected radiation dose to the conceptus, evaluation of the radiogenic risk to the conceptus, and inclusion in the informed consent process of the expected benefits and potential risks of the procedure to both the patient and the conceptus (ICRP 84). Whenever possible, and if time permits, the pre-procedure planning process should involve a qualified physicist.

(84) The Commission has stated that in general, termination of pregnancy at foetal doses of less than 100 mGy is not justified based upon radiation risk (ICRP Publication 84). For comparison, a typical fetal dose from CTA of the coronary arteries is approximately 0.1 mGy (McCollough, 2007).

5.3 During the Procedure

(85) When optimizing patient radiation dose, the first priority must be to obtain a sufficient number of images of a high enough quality to permit diagnosis and guide interventions. This will require a certain minimum amount of fluoroscopy time and number and length of cine series. Optimal management of patient dose requires knowledge and control of the typical fluoroscopic dose rates and values of dose per cine frame for the most common operational modes.

(86) Typical values of skin dose rate (surface entrance air kerma rate) during cardiology procedures for a medium size patient are 15-45 mGy/min for “medium” fluoroscopy mode and 50-150 mGy/min for “high” fluoroscopy mode. Skin dose per cine frame is typically between 0.1 and 1.0 mGy. Skin doses in cardiac procedures can reach several Gy, especially for complex procedures and when several projections with similar C-arm angulations are required (Miller, 2008). Organ doses may reach 100 Gy and effective doses may reach 50 mSv. Variation in patient doses between centres may be substantial. Some of this variation is likely to be due to the settings of the x-ray systems. A study carried out by the IAEA comparing x-ray systems from different countries demonstrated 10-fold differences for dose values when phantoms of the same thickness were imaged (Ortiz at al, 2004).

(87) Several operational factors can substantially modify the radiation dose received by the patients and affect the kerma-area product (KAP) and the patient’s skin dose (Publication 85). These are also discussed and illustrated in an ICRP publication devoted to radiological protection outside the imaging department (reference ICRP TG 78). Some of these factors depend on the x-ray system (e.g. availability of pulsed fluoroscopy, virtual collimation, stored fluoroscopy loops, extra filtration, wedge filters, rotational and cone beam CT acquisition modes, etc.), but others depend on how the operator uses the x-ray system (e.g. collimation to the area of interest, use of low fluoroscopy modes when possible, acquiring cine series at 12.5-15 frames per second when possible, keeping the image detector as close as possible to the patient, avoiding steeply angulated projections, reducing the number of frames per cine series) (NCRP Report 168, 2010). Recommendations for dose optimization in the radiology literature apply equally to

interventional cardiology procedures (Miller, 2002, Miller, 2010, Wagner, JVIR 2000, Wagner 2007). **Table 5.1** provides some practical advice.

(88) During the procedure, the cardiologist should be aware of the fluoroscopy time, the number of cine series and cine frames, and the total patient dose, either as KAP or as Reference Air Kerma (RAK) the cumulative air kerma at the Interventional Reference Point (see Glossary). (The Interventional Reference Point is also known as the Patient Entrance Reference Point.) The need here is to monitor, in real time, whether the threshold doses for deterministic effects are being approached or exceeded (ICRP 105, ICRP XXX 2011b). Modern fluoroscopy systems that are compliant with the international standard for interventional fluoroscopy systems display radiation data to the operator during the procedure (IEC, 2010). The responsibility for monitoring radiation dose may be delegated to a technologist, nurse or other person depending on national or local regulations and the institution's policy and needs (NCRP 168, 2010). A specific individual should be tasked with this responsibility. The purpose of dose monitoring is to ensure that the operator is aware of how much radiation is being administered.

(89) As patient radiation dose increases, the operator should consider the radiation dose already delivered to the patient and the additional radiation necessary to complete the procedure. It may be possible to reduce further radiation usage and control skin dose by limiting the number and length of cine series, decreasing the dose rate for cine or fluoroscopy, using collimation or changing the gantry angle slightly.

(90) Knowledge of the patient's skin dose distribution could help to avoid the risk of skin injuries, but measurement of skin dose distribution is not an easy task in fluoroscopically guided procedures. This is especially true in cardiology, where very different C-arm angulations are used during the procedures and the regions of the irradiated skin can also be very different. However, using different C-arm angulations can help reduce peak skin dose, especially when collimation is also used (Miller, 2002). **Figure 5.1** shows an example of skin dose distribution measured with slow film (Vano et al. 1997) and how overlap of radiation fields can increase the dose to a certain area of the skin.

5.4 After the procedure

(91) Modern fluoroscopy systems that are compliant with the international standard for interventional fluoroscopy systems provide a dose report at the conclusion of the procedure (IEC, 2010). An example of a typical dose report is shown in **Fig 5.2**. Several companies offer dose reports for cardiology procedures that include information on skin dose distribution. Patient radiation dose reports should be produced at the end of the procedure, and archived. Radiation dose data should be recorded in the patient's medical record after the procedure (Chambers, 2011).

(92) Patient doses for cardiac procedures are often reported as kerma-area product (KAP). Skin dose distribution, and especially RAK and peak skin dose (PSD) (defined in the glossary), are sometimes more important, particularly when repeated procedures are performed on the same patient (Miller, 2002). Fluoroscopy time does not include the effect of fluoroscopy dose rate and does not indicate the radiation dose from cine. It is

not a useful descriptor of patient radiation dose (Chida, 2006, Fletcher, 2002). Fluoroscopy time should not be the only dose measurement recorded or audited (Chambers, 2011, NCRP Report 168, 2010).

(93) The management and follow-up of patients who have received a high dose of radiation is also important. The operator should be notified promptly if the substantial radiation dose level (SRDL) was exceeded. (SRDL is defined in the Glossary and discussed further in Section 10.6.) The operator should write an appropriate note in the patient's medical record, stating that a substantial radiation dose has been administered, and indicating the reason (Hirshfeld, 2005). This information may be included in the post-procedure note.

(94) When the SRDL has been exceeded, clinical follow-up is essential for early detection and management of skin injuries (NCRP Report 168, 2010, Chambers, 2011). The patient should be advised of the possibility of a deterministic skin injury, and should be told to examine the beam entrance site at 2 – 4 weeks after the procedure. The operator should be notified if any skin changes are seen. Patients should also be contacted by telephone at approximately 30 days after the procedure. If a skin injury is suspected, the interventionalist should see the patient at an office visit, and should arrange for appropriate follow-up care (NCRP Report 168, 2010, Chambers, 2011). The physician responsible for the patient's care should be informed of the possibility of radiation effects. Ideally, a system should be established to identify and monitor repeated procedures (ICRP 85, 2000).

5.5 Paediatric Patients

(95) Paediatric cardiology procedures require special consideration. These interventions are often challenging, time-consuming and may require multi-stage procedures, leading to high radiation exposure. Contributing factors include the higher heart rates, smaller cardiovascular structures, small body size and wider variety of unusual anatomic variants seen in children (Justino 2006).

(96) Patient radiation dose from paediatric interventional cardiology procedures can be reduced by the use of dedicated radiographic protocols that include tighter collimation, pulsed fluoroscopy frame rates of 25-30 frames/sec and cine frame rates of 25-50 frames/sec. As part of the Step Lightly initiative, the Alliance for Radiation Safety in Pediatric Imaging has published a checklist for use during paediatric interventional fluoroscopy to help reduce patient doses (Sidhu, 2009).

5.6 References

American College of Radiology. ACR practice guideline for imaging pregnant or potentially pregnant adolescents and women with ionizing radiation. Practice Guidelines and Technical Standards 2008. Reston, VA: American College of Radiology, 2008; p. 23-37. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/Pregnancy.aspx Accessed August 11, 2010.

2425 Balter S. Interventional fluoroscopy. Physics, technology and safety. Wiley-Liss, New
2426 York, 2001.
2427 Bernardi G, Padovani R, Morocutti G, Vano E, Malisan MR, Rinuncini M, Spedicato L,
2428 Fioretti PM. Clinical and technical determinants of the complexity of percutaneous
2429 transluminal coronary angioplasty procedures: analysis in relation to radiation
2430 exposure parameters. Catheter Cardiovasc Interv 2000 Sep;51(1):1-9; discussion 10.
2431 Bernardi G, Padovani R, Trianni A, Morocutti G, Spedicato L, Zanuttini D, Werren M,
2432 Wagner LK. The effect of fellows' training in invasive cardiology on radiological
2433 exposure of patients. Radiat Prot Dosimetry 2008, 128(1):72–76.
2434 Bor D, Sancak T, Toklu T, Olgar T, Ener S. Effects of radiologists' skill and experience
2435 on patient doses in interventional examinations. Radiat Prot Dosimetry 2008;129:32-
2436 5.
2437 Bryk SG, Censullo ML, Wagner LK, Rossman LL, Cohen AM. Endovascular and
2438 interventional procedures in obese patients: a review of procedural technique
2439 modifications and radiation management. J Vasc Interv Radiol 2006;17:27-33.
2440 Chambers CE, Fetterly KA, Holzer R, Lin P-JP, Blankenship JC, Balter S, Laskey WK.
2441 Radiation safety program for the cardiac catheterization laboratory. Catheter
2442 Cardiovasc Interv 2011, in press.
2443 Chida K, Saito H, Otani H, Kohzuki M, Takahashi S, Yamada S, Shirato K, Zuguchi M.
2444 Relationship between fluoroscopic time, dose-area product, body weight, and
2445 maximum radiation skin dose in cardiac interventional procedures. Am J Roentgenol.
2446 2006;186:774-8.
2447 Den Boer A, de Feyter PJ, Hummel WA, Keane D, Roelandt JR. Reduction of radiation
2448 exposure while maintaining high-quality fluoroscopic images during interventional
2449 cardiology using novel x-ray tube technology with extra beam filtering. Circulation.
2450 1994 Jun;89(6):2710-4.
2451 Faulkner K, Vano E. Deterministic effects in interventional radiology. Radiat Prot
2452 Dosimetry. 2001;94(1-2):95-8.
2453 Fletcher DW, Miller Dl, Balter S, Taylor MA. Comparison of four techniques to
2454 estimate radiation dose to skin during angiographic and interventional radiology
2455 procedures. J Vasc Interv Radiol 2002;13:391-97.
2456 Guibelalde E, Vano E, Gonzalez L, Prieto C, Fernandez JM, Ten JI. Practical aspects for
2457 the evaluation of skin doses in interventional cardiology using a new slow film. Br J
2458 Radiol. 2003 May;76(905):332-6.
2459 Hirshfeld JW Jr, Balter S, Brinker JA, Kern MJ, Klein LW, Lindsay BD, Tommaso CL,
2460 Tracy CM, Wagner LK, Creager MA, Elnicki M, Lorell BH, Rodgers GP, Weitz
2461 HH; American College of Cardiology Foundation; American Heart Association;
2462 HRS; SCAI; American College of Physicians Task Force on Clinical Competence
2463 and Training. ACCF/AHA/HRS/SCAI clinical competence statement on physician
2464 knowledge to optimize patient safety and image quality in fluoroscopically guided
2465 invasive cardiovascular procedures: a report of the American College of Cardiology
2466 Foundation/American Heart Association/American College of Physicians Task Force
2467 on Clinical Competence and Training. Circulation. 2005;111(4):511-32.

IAEA, 2010. Patient dose optimization in fluoroscopically guided interventional procedures. IAEA-TECDOC-1641. Vienna: International Atomic Energy Agency, 2010.

International Commission on Radiological Protection. Radiological protection and safety in medicine. ICRP Publication 73. Ann ICRP 1996; 26(2):1-47

International Commission on Radiological Protection. Pregnancy and medical radiation. ICRP Publication 84. Ann ICRP 2000; 30:1-43.

International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann ICRP 2000; 30(2):1-67.

International Commission on Radiological Protection. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103. Ann ICRP 2007;37:1-332.

International Commission on Radiological Protection. Radiological protection in medicine. ICRP Publication 105. Ann ICRP 2007; 37:1-63.

ICRP, 2009. Recommendations of the International Commission on Radiological Protection. ICRP Publication 113, Ann. ICRP 39 (5).

International Commission on Radiological Protection 2011a. Statement on Tissue reactions. Approved by the Commission on April 21, 2011. ICRP ref 4825-3093-1464. Available at http://www.icrp.org/docs/ICRP%20Statement%20on%20Tissue%20Reactions.pdf Accessed May 9, 2011.

International Commission on Radiological Protection 2011b. Tissue Reactions and Other Non-Cancer Effects of Radiation. ICRP Publication **XXX**. Ann ICRP 2011; in press

IEC. Medical electrical equipment. Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures. IEC 60601-2-43. 2nd edition, Geneva, Switzerland: International Electrotechnical Commission; 2010.

Justino H. The ALARA concept in pediatric cardiac catheterization: techniques and tactics for managing radiation dose. Pediatr Radiol 2006; 36:146-153

Kim C, Vasaiwala S, Haque F, Pratap K, Vidovich MI. Radiation safety among cardiology fellows. Am J Cardiol 2010;106(1):125-128.

Koenig TR, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: part 2, review of 73 cases and recommendations for minimizing dose delivered to patient. AJR Am J Roentgenol. 2001 Jul;177(1):13-20.

McCollough CH, Schueler BA, Atwell TD, Braun NN, Regner DM, Brown DL, LeRoy AJ. Radiation exposure and pregnancy: when should we be concerned? RadioGraphics 2007; 27:9090-918.

Miller DL, Balter S, Noonan PT, Georgia JD. Minimizing radiation-induced skin injury in interventional radiology procedures. Radiology 2002;225:329-36.

Miller DL. Overview of contemporary interventional fluoroscopy procedures. Health Phys 2008, 95:638-644.

Miller DL, Balter S, Schueler BA, Wagner LK, Strauss KJ, Vañó E. Clinical radiation management for fluoroscopically guided interventional procedures. Radiology 2010, in press.

2512 Neofotistou V, Vano E, Padovani R, Kotre J, Dowling A, Toivonen M, Kottou S,
2513 Tsapaki V, Willis S, Bernardi G, Faulkner K. Preliminary reference levels in
2514 interventional cardiology. Eur Radiol. 2003 Oct;13(10):2259-63.
2515 National Council on Radiation Protection and Measurements. Radiation dose
2516 management for fluoroscopically guided interventional medical procedures. NCRP
2517 Report No. 168. Bethesda, MD: National Council on Radiation Protection and
2518 Measurements; 2010.
2519 Neofotistou V. Review of patient dosimetry in cardiology. Radiat Prot Dosimetry.
2520 2001;94(1-2):177-82.
2521 Ortiz P, Vano E, Padovani R, Cotelo E, Ramirez A, Mota H, Faulkner K, Balter S.
2522 Influence of the interventional equipment performance on patient dose and image
2523 quality. Results of a survey under the IAEA International Action Plan for the
2524 Radiological Protection of Patients. ECR 2004. Vienna. Austria.
2525 Rehani MM. Training of interventional cardiologists in radiation protection—the
2526 IAEA's initiatives. Int J Cardiol 2007;114:256-260.
2527 Sidhu MK, Goske MJ, Coley BJ, Connolly B, Racadio J, Yoshizumi TT, Utley T,
2528 Strauss KJ. Image gently, step lightly: increasing radiation dose awareness in
2529 pediatric interventions through an international social marketing campaign. J Vasc
2530 Interv Radiol 2009; 20:1115-1119.
2531 Tsapaki V, Kottou S, Kollaros N, Dafnomili P, Kyriakidis Z, Neofotistou V. Dose
2532 performance evaluation of a charge coupled device and a flat-panel digital
2533 fluoroscopy system recently installed in an interventional cardiology laboratory.
2534 Radiat Prot Dosimetry. 2004;111(3):297-304.
2535 Tsapaki V, Kottou S, Vano E, Faulkner K, Giannouleas J, Padovani R, Kyrozi E,
2536 Koutelou M, Vardalaki E, Neofotistou V. Patient dose values in a dedicated Greek
2537 cardiac centre. Br J Radiol. 2003 Oct;76(910):726-30.
2538 Vano E, Arranz L, Sastre JM, Moro C, Ledo A, Garate MT, Minguez I. Dosimetric and
2539 radiation protection considerations based on some cases of patient skin injuries in
2540 interventional cardiology. Br J Radiol. 1998 May;71(845):510-6.
2541 Vano E, Goicolea J, Galvan C, Gonzalez L, Meiggs L, Ten JI, Macaya C. Skin radiation
2542 injuries in patients following repeated coronary angioplasty procedures. Br J Radiol.
2543 2001 Nov;74(887):1023-31.
2544 Vano E, Gonzalez L, Ten JI, Fernandez JM, Guibelalde E, Macaya C. Skin dose and
2545 dose-area product values for interventional cardiology procedures. Br J Radiol. 2001
2546 Jan;74(877):48-55.
2547 Vano E, Gonzalez L. Approaches to establishing reference levels in interventional
2548 radiology. Radiat Prot Dosimetry. 2001;94(1-2):109-12.
2549 Vano E, Guibelalde E, Fernandez JM, Gonzalez L, Ten JI. Patient dosimetry in
2550 interventional radiology using slow films. Br J Radiol. 1997 Feb;70:195-200.
2551 Vano E, Prieto C, Fernandez JM, Gonzalez L, Sabate M, Galvan C. Skin dose and dose-
2552 area product values in patients undergoing intracoronary brachytherapy. Br J Radiol.
2553 2003 Jan;76(901):32-8.
2554 Vano E, Gonzalez L, Fernandez JM, Alfonso F, Macaya C.Occupational radiation doses
2555 in interventional cardiology: a 15-year follow-up. Br J Radiol. 2006;79(941):383-8.

Vlietstra RE, Wagner LK, Koenig T, Mettler F. Radiation burns as a severe complication of fluoroscopically guided cardiological interventions. J Interv Cardiol. 2004 Jun;17(3):131-42.

Wagner LK and Archer BR. Minimising risks from fluoroscopic x rays. Third Edition. Partners in Radiation Management (R.M. Partnership). The Woodlands, TX 77381. USA 2000.

Wagner LK, Archer BR, Cohen AM. Management of patient skin dose in fluoroscopically guided interventional procedures. J Vasc Interv Radiol 2000;11:23-33.

Wagner LK. Radiation injury is a potentially serious complication to fluoroscopically-guided complex interventions. In: Biomedical Imaging and Intervention Journal. Lumpur, Malaysia: Dept. of Biomedical Imaging, University of Malaya; 2007:e22. Available at http://www.biij.org/2007/2/e22/ Accessed Aug 9, 2010

Whitby M, Martin CJ. A study of the distribution of dose across the hands of interventional radiologists and cardiologists. Br J Radiol 2005;78:219-29.

Figure 5.1
Example of skin dose distribution in cardiology procedures (measured with slow film at the San Carlos University Hospital in Madrid). Skin dose distribution measured during a conventional PTCA. In this case the peak skin dose was 0.4 Gy.

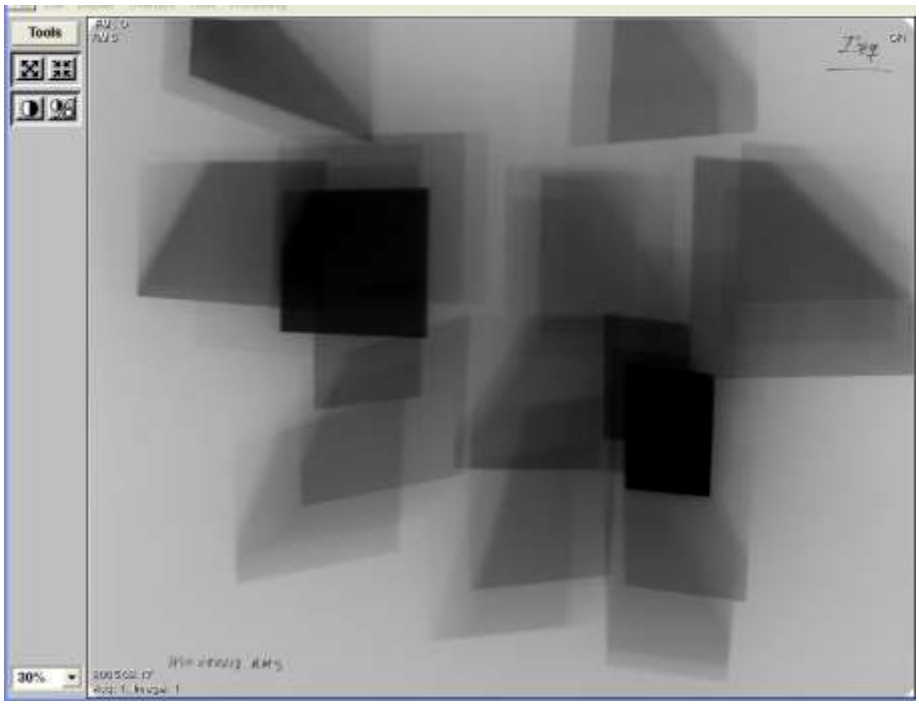
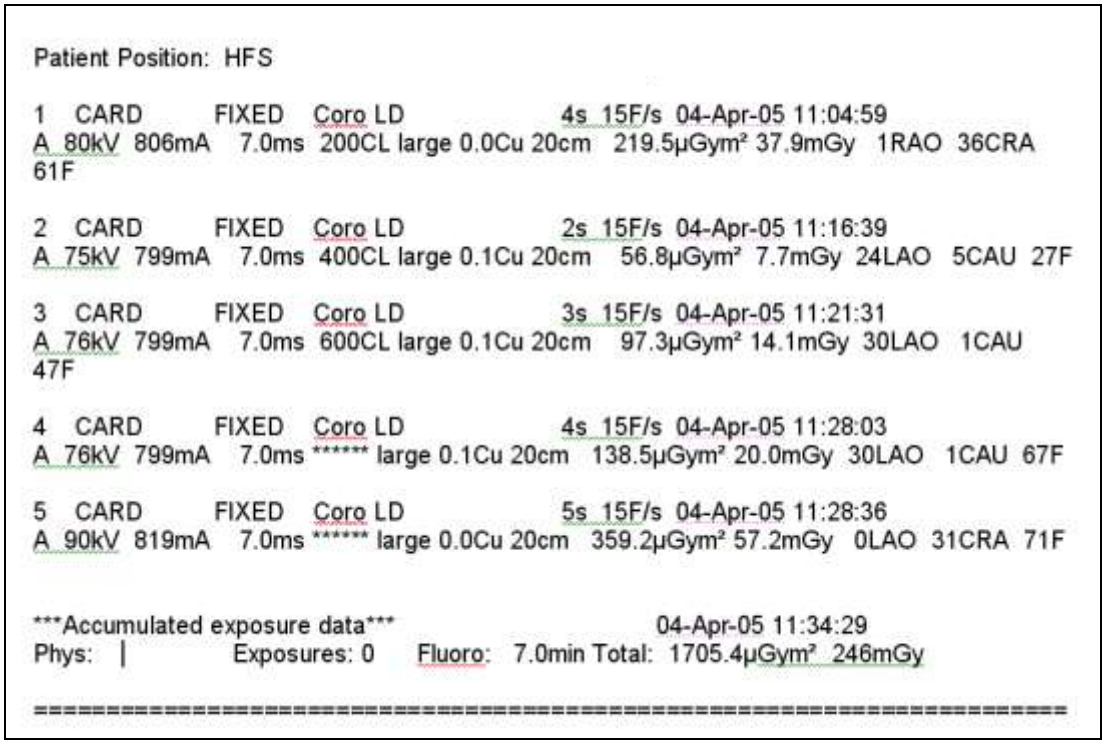


Figure 5.2

Example of a patient dose report produced by a Siemens Axiom Artis X ray system. Entries 1 to 5 indicate the series acquisition order. CARD is the name of the acquisition protocol. FIXED means a constant frame rate during the series run. Coro LD is the acquisition mode. Time in seconds is the duration of the series. Series frame rate, date, time of acquisition, kV, mA peak, pulse time, focus size, extra copper filter, KAP per series, RAK, X-ray beam angulation, and number of frames (for each series) are reported. Total fluoroscopy time, total KAP, and total RAK are also given at the end of the report. The original printing format of the X-ray system is maintained.



Patient Position: HFS

1 CARD FIXED Coro LD 4s 15F/s 04-Apr-05 11:04:59
A 80kV 806mA 7.0ms 200CL large 0.0Cu 20cm 219.5µGym² 37.9mGy 1RAO 36CRA 61F

2 CARD FIXED Coro LD 2s 15F/s 04-Apr-05 11:16:39
A 75kV 799mA 7.0ms 400CL large 0.1Cu 20cm 56.8µGym² 7.7mGy 24LAO 5CAU 27F

3 CARD FIXED Coro LD 3s 15F/s 04-Apr-05 11:21:31
A 76kV 799mA 7.0ms 600CL large 0.1Cu 20cm 97.3µGym² 14.1mGy 30LAO 1CAU 47F

4 CARD FIXED Coro LD 4s 15F/s 04-Apr-05 11:28:03
A 76kV 799mA 7.0ms ****** large 0.1Cu 20cm 138.5µGym² 20.0mGy 30LAO 1CAU 67F

5 CARD FIXED Coro LD 5s 15F/s 04-Apr-05 11:28:36
A 90kV 819mA 7.0ms ****** large 0.0Cu 20cm 359.2µGym² 57.2mGy 0LAO 31CRA 71F

Accumulated exposure data 04-Apr-05 11:34:29
Phys: | Exposures: 0 Fluoro: 7.0min Total: 1705.4µGym² 246mGy

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Table 5.1
Practical advice to reduce patient doses.

Techniques to reduce patient dose
Use a low-dose fluoroscopy mode when possible
Use the lowest-dose mode for image (cine) acquisition that is compatible with the required image quality
Minimize fluoroscopy time—use fluoroscopy only to guide devices and observe motion
Use the last-image-hold image for review when possible, instead of using fluoroscopy
When possible, store a fluoroscopy loop instead of performing a cine run
If it is available, use a stored fluoroscopy loop for review instead of using fluoroscopy
Minimize the number of cine series
Minimize the number of frames per cine series
Never use cine as a substitute for fluoroscopy
Collimate the radiation beam to the area of interest
Use virtual collimation if it is available
Use wedge filters when they are appropriate
Keep the image detector (image intensifier or flat detector) as close as possible to the patient.
Keep the patient as far as possible from the x-ray tube.
Try to avoid steeply angulated projections (especially LAO cranial)
Try to vary the C-arm angulation slightly, to avoid concentrating the radiation dose at a single site on the patient's skin.
Use magnification only when necessary.
Remember that for large patients, and also for steeply angulated projections, the dose to the patient increases substantially.
Pay attention to the patient radiation dose display in the procedure room.
If the patient has had previous similar procedures, try to obtain information about the previous radiation doses to optimise subsequent procedures.

6. RADIATION DOSES AND PROTECTION OF STAFF DURING INTERVENTIONAL FLUOROSCOPY

Main Points

- **In general, reducing patient dose will also reduce operator dose.**
- **The basic tools of occupational radiological protection are time, distance and shielding.**
- **The use of personal protective shielding is necessary in the cardiac catheterization laboratory.**
- **Radiological protection for the eyes is necessary for interventionalists.**
- **Occupational doses can be reduced to very low levels if ceiling suspended lead screens and protective lead curtains suspended from the side of the procedure table are used properly.**
- **Radiation exposure to the operator is neither uniform nor symmetric.**
- **Proper use of personal monitoring badges is necessary in cardiac catheterization laboratories in order to monitor and audit occupational radiation dose.**

6.1 Introduction

(97) Despite regulatory limits on occupational dose, there have been reports of cataracts and of fairly high radiation doses to the hands and legs of staff and hair loss in the portions of the legs not shielded by a protective device (Balter, 2001a). The occurrence of radiation-induced cataracts in operators (Vano et al. 1998a, Vano et al, 2010, ICRP 2000, Ciraj-Bjelac, 2010) and the debate regarding the incidence of brain cancer in interventional cardiologists (Finkelstein, 1998, Klein et al, 2009) highlight the importance of occupational radiological protection for interventionalists, especially for parts of the body not protected by the lead apron.

(98) The operator is not normally exposed to the x-ray beam directly, but is exposed to a considerable amount of scatter radiation. There are a number of techniques, described in Chapter 5, and protective devices, discussed in this Chapter, that, if used appropriately, should result in the operator's annual effective dose being well within regulatory limits. With proper use of radiological protection tools and techniques, the effective dose (E) for an interventionalist is typically 2–4 mSv/year, and is well below the 20 mSv/year limit recommended by the Commission (Dendy, 2008, Tsapaki, 2004, Miller, 2010, ICRP 2007). Proper use of personal monitoring badges is essential in cardiac catheterization laboratories in order to monitor and audit occupational radiation dose. Too often, personal monitoring badges are not worn, or are worn improperly (Padovani, 2011). Training in radiation management and radiological protection, as discussed in Chapter 9, is essential (ICRP 2000).

6.2 Comparison of radiation exposure with that of other staff

(99) The interventionalist encounters much more radiation than most other medical and paramedical staff in a hospital. The radiation intensity from radioisotopes used in nuclear medicine is smaller by a factor of a few tens or even hundred. Nuclear medicine staff are likely to be exposed to much less radiation, whether it emanates from the patient or from external sources (normally in shielded containers). Similarly, while the radiation sources used in radiotherapy are of very high strength (GBq or TBq of radioactivity), staff are exposed only to remnant radiation leaking through the shielding material and scattered through a large distance. Staff in the interventional laboratory who are positioned in the control room are protected by both shielding and distance from the x-ray beam. Typically, in a properly designed facility, the radiation intensity in the control room may be tens of thousands of times less than at the operator's position (Rehani and Ortiz-Lopez, 2005). Exposure factors for the interventionalist are a thousand times higher than for staff working in the control room.

(100) The major protection in nuclear medicine accrues from the lower radiation intensity and in radiotherapy from shielding and distance. The situation in interventional fluoroscopy is very different. First, the operator's working position is quite close to the x-ray source and the source of scatter radiation (the patient). Second, the intensity of the x-ray beam lies in between the radiation intensities observed in nuclear medicine and radiotherapy. Also, beam intensity is 10-fold or 20-fold higher in cine mode than in fluoroscopy mode (NCRP Report 168, 2010). Shielding plays a major role in radiological protection in interventional fluoroscopy, due to variability in the operator's distance from the x-ray source, the relative position of the operator, patient, and x-ray source and the duration of the procedure.

6.3 The essentials of occupational radiological protection

(101) The essentials of occupational radiological protection are time, distance and shielding. Staff radiological protection cannot be handled independently from patient protection, since they correlate in many ways. Both patient and occupational radiological protection are also discussed in an ICRP publication devoted to radiological protection outside the imaging department (reference ICRP TG 78). In general, reducing patient dose will also reduce operator dose.

(102) *Time*, one essential component of radiological protection, is controlled by reducing the time the x-ray beam is on, both for fluoroscopy and for cine. Reducing fluoroscopy time and fluoroscopy dose rate reduces patient dose. Reduced patient dose results in reduced scatter, and therefore in reduced operator dose. Readers are advised to remember all of the factors discussed in Chapter 4.

(103) *Distance* is a valuable tool for radiological protection. Radiation dose decreases as the square of the distance between the radiation source and the operator (the inverse square law). A person who moves away from the x-ray source to three times the original distance will receive only one-ninth of the original dose. During a procedure, the operator cannot normally move further away from the patient than arm's length. This can

result in high operator radiation doses, especially if contrast medium is injected manually for angiographic runs. However, if a mechanical injector is used for contrast medium injection, the operator can move back away from the patient, and ideally behind a shield.

(104) In general, scattered radiation is most intense on the entrance beam side of the patient (Balter, 2001b, Schueler et al, 2006, Stratakis et al, 2006). When using a C-arm in a lateral projection, the operator should be positioned on the image receptor side of the patient, if possible. When using a C-arm in a frontal projection, positioning the x-ray tube below the table will place the area of higher radiation scatter towards the floor, so that the operator's head and neck receive less radiation.

(105) *Shielding* is of three types: architectural shielding, equipment mounted shields, and personal protective devices (Miller et al, 2010). Architectural shielding is built into the walls of the procedure room and is not discussed further here. Rolling and stationary shields that are constructed of transparent leaded plastic and rest on the floor are useful for providing additional shielding for both operators and staff. They are particularly well suited for use by nurses and anaesthesia personnel. The interventionalist is protected by equipment-mounted shields suspended from the ceiling and the procedure table, and by personal protective devices such as a lead apron, leaded glasses and a thyroid shield.

(106) Simple measures, such as standing a little away from the table and patient, limiting the field size (collimation) and carrying out procedures quickly consistent with case complexity can be very effective in reducing occupational radiation dose. **Table 6.1** presents some practical advice to improve occupational protection in the catheterization laboratory and **Table 6.2** presents the relative change in scatter dose rates measured in a typical catheterization laboratory for different changes in technique. The values in **Table 6.2** highlight the large changes in scatter dose associated with changes in technique and patient body size.

6.4 Personal protective devices

(107) The use of personal protective shielding is essential in the cardiac catheterization laboratory. In the past, there has been a trend to use lead aprons of higher lead equivalence (0.5 mm rather than 0.25, 0.3 or 0.35 mm), even though physical measurements did not demonstrate a great difference in attenuation (Table 6.3). The inherently conservative safety factor has always influenced practice in radiation, both for interventionalists and for regulators.

(108) When procedures are performed on thinner patients, and in particular on children, a lead apron of 0.25 mm lead equivalence will suffice for staff protection, but for procedures performed on thicker patients, and for procedures performed by physicians with heavy workload, a 0.5 mm lead apron may be more suitable. Lead is very effective for protecting against radiation, but is heavy. The weight can cause problems for staff who have to wear these aprons for long spans of time (Goldstein, 2004). There are reports of back injuries due to lead aprons among staff who wear these aprons for many years (NCRP, 2010). Some newer aprons are lighter weight while maintaining approximately the same lead equivalence. Newer apron designs distribute weight using a variety of different methods. Two-piece (skirt and vest) wraparound aprons distribute the apron's weight and also provide protection for the wearer's back.

(109) Lead aprons should be properly placed on designated hangers and should not be folded, creased, or crumpled in any way. Sitting on them, folding them or improperly hanging them may result in damage that reduces their effectiveness. Lead aprons, gloves and other leaded protective clothing should be inspected before they are put into service and then periodically re-inspected to determine that they provide the shielding benefit for which they were designed. A combination of visual, physical and fluoroscopic inspection can be employed to ensure the integrity of the garments. Consideration should be given to minimizing the irradiation of inspectors by minimizing unnecessary fluoroscopy (NCRP 168, 2010).

(110) A lead apron does not protect the eyes, the hands, the lower legs or the back (unless the apron is the wrap-around type). Radiation exposure of these parts of the body has become a concern.

(111) Radiological protection for the eyes is essential for interventionalists (Dauer et al, 2010). Preferably, this protection is provided by ceiling-suspended shields (section 6.3), as these devices protect the entire head, and not just the eyes. However, there are many procedures where it is not practical to use ceiling-suspended shields, as they interfere with the operator's ability to perform the procedure (Miller et al., 2010). In these situations, leaded eyeglasses should be worn. Wearing these eyeglasses has been shown to significantly reduce radiation dose to the operator's eyes (Vano et al, 2008; Thornton et al, 2010).

(112) While the dose reduction factor for 0.5 mm lead equivalent protective glasses is approximately 0.03 (i.e., 97% of the radiation is attenuated) the extent of radiation attenuation by the eyeglass lenses is not an adequate descriptor, by itself, of the effectiveness of the eyewear (NCRP report 168, 2010). For maximum effectiveness, radiation protective eyewear should intercept as much as possible of the scattered radiation that is directed at the interventionalist's eyes. During interventional procedures, interventionalists normally turn their heads away from the primary beam to view the fluoroscopy monitor. This results in exposure of the eyes to scattered radiation from the side. Protective eyewear should provide shielding for side exposure, using either side shields or a wrap-around design (NCRP report 168, 2010). Proper fit is necessary to ensure that the lenses and side shields adequately protect the eye and minimize exposure, and is also important to minimize discomfort from the weight of the eyewear (Schueler et al., 2009). Even properly designed and fitted leaded eyewear attenuates scattered radiation by only a factor of 2 or 3 (Moore et al., 1980; Thornton et al, 2010). The net effect of protective eyeglasses is dependent on the design of the glasses, the nature of the clinical procedure, and the wearer's work habits.

(113) In younger individuals, the thyroid gland is relatively sensitive to radiation-induced cancer. However, the cancer incidence risk is strongly dependent on age at exposure, with very little risk after age 30 for males and age 40 for females (NRC, 2006). For younger workers, wearing a thyroid collar and a protective apron reduces effective dose to ~50 % of the effective dose achieved by wearing a protective apron alone (Martin, 2009; von Boetticher et al., 2009). Use of a thyroid collar (or a protective apron with thyroid coverage) is recommended for younger interventionalists and for all

personnel whose personal monitor readings at the collar level (unshielded) exceed 4 mSv (E) in a month (Wagner, 2004).

(114) Flexible, sterile, radiation-attenuating surgical gloves are available to reduce interventionalist hand exposure. A previous recommendation that protective gloves be worn in high exposure situations has been reconsidered (NCRP report 133, 2000, NCRP report 168, 2010). Attenuating surgical gloves may be used to provide a small degree of protection when hands are exposed only to scattered radiation, but the use of these gloves does not permit interventionalists to place their hands safely in the primary beam (NCRP 168, 2010).

(115) There are several factors that could lead to higher hand doses for interventionalists when these gloves are used (Miller et al, 2010). Just as with special tools that allow for increased distance between the hands of the interventionalist and the primary x-ray beam, the reduction in tactile feedback from radiation-attenuating surgical gloves may lead to an increase in fluoroscopy time or CT exposure time for delicate procedures. Because of the increased dose when any shielding is placed in the primary beam, and the false sense of security that these gloves provide, protective gloves can result in increased radiation dose to the hand when the gloved hand is in the primary beam (Wagner, 1996). With or without added protection, the hands should not be placed in the primary x-ray beam, except for those rare occasions when it is essential for the safety and care of the patient. This should be done for the shortest possible time. As a rule, if an operator's hands are visible on the monitor, then practices should be altered (Limacher et al. 1998).

6. 5 Equipment-mounted shields

(116) The standard equipment-mounted shields used in catheterization laboratories at present are ceiling suspended lead screens and protective lead curtains suspended from the side of the procedure table. If these tools are used properly, occupational doses can be reduced to very low levels.

(117) A leaded glass or plastic screen placed between the patient and the operator protects the operator's eyes, head and neck. Properly placed shields have been shown to dramatically reduce operator eye dose (Maeder et al., 2006, Thornton et al, 2010). These screens can effectively replace both leaded eyewear and a thyroid shield. The screens add no weight to the operator, eliminating the ergonomic consequences of the protective equipment they replace.

(118) When a frontal (posteroanterior) projection is used and the x-ray tube is below the procedure table, scatter dose rates under the table are 3-4 times higher than the values over the table (Schueler et al, 2006). Leaded curtains suspended from the procedure table should be used to protect the interventionalist's lower legs. At present, these shields are available in almost all interventional suites.

(119) Disposable, lightweight, sterile, lead-free radiological protection drape or pad shields can be positioned on the patient outside of the beam path to significantly reduce scattered radiation during cardiac interventional procedures (Sawdy et al, 2009, Germano et al, 2005). These contain metallic elements (typically bismuth or tungsten-antimony) and are placed on the patient after the operative site has been prepared and draped. They

have been shown to reduce operator dose substantially, with reported reductions of 12-fold for the eyes, 26-fold for the thyroid and 29-fold for the hands (King et al, 2002, Dromi et al, 2006). While their use adds some cost to the procedure, disposable protective drapes should be considered for complex procedures and procedures where the operator's hands must be near the radiation field (e.g., pacemaker placement) (Miller et al., 2010). In some institutions they are used routinely (Kim et al, 2010). These drapes should not be visible in the fluoroscopic image. If they are, the result will be an increase in patient dose.

6.6 Overall impact of protective devices

(120) The effective dose (E) to the cardiologist per procedure has been reported to range from 0.2 to 18.8 μSv (Padovani and Rodella, 2001). A more recent review demonstrated a range of 0.02 to 38.0 μSv (Kim et al, 2008). The wide dose ranges are most likely due to both the wide variation in procedure complexity and the inconsistent use of shields and personal protective devices. Modest operator dose reductions over time were observed for both diagnostic catheterizations and ablation procedures, due to technological improvements, but doses were not reduced over time for percutaneous coronary interventions. This was believed to be due mainly to the increased complexity of interventions.

(121) Even if one assumes a rather high workload of 1000 angiographic procedures per year, the annual threshold level of 20 mSv will rarely be exceeded. One study reported an estimate of E for the operator of only 0.04–0.05 mSv/year (Efstathopolous et al. 2003), although other studies have reported 2–4 mSv/year (Dendy, 2008, Tsapaki, 2004). The extensive studies by Kuon et al. establish that with proper choice of technique and shielding devices, the operator may be exposed to only 0.8% of typical radiation levels in advanced cardiac catheterization laboratories (Kuon et al. 2002).

(122) When a lateral projection or steep gantry angulation is used, standing on the x-ray tube side of the C-arm increases operator dose. Kuon et al. have estimated the influence of angulation of the X-ray tube on the amount of scatter radiation to the operator (Kuon et al. 2004). Radiation levels have been found to be highest for the left anterior oblique (LAO) position, whereas in posteroanterior (PA) and right anterior oblique (RAO) angulations, levels are much lower (Kuon et al. 2002, 2003, 2004). Simultaneous craniocaudal angulation further increases the dose. The group has shown that the standard view for the left main stem coronary artery (LAO 60°/20°–) is associated with a 7.6-fold increase in dose to the operator and a 2.6-fold increase in dose for the patient as compared to an alternative less frequently used angulation (caudal PA0°/30°–).

(123) Effective dose does not reflect the doses to susceptible, unprotected parts of the body—the hands and the eyes. Radiation exposure to the operator is neither uniform nor symmetric. A right-handed operator performing the procedure via the right femoral artery has his or her left side turned towards the patient. Therefore the left side of the body is exposed to the highest level of scatter radiation (Maeder et al. 2005). This is especially true for the hands, which are at the level where the X-ray beam enters the

patient. During cardiac catheterization, the left hand has been reported to receive twice the dose as compared with the right hand (Vaño et al. 1998b). The left eye also receives higher doses than the right eye. Not surprisingly, a tall operator will receive a lower eye dose than a short operator, because of the greater distance from the tall operator's eyes to the patient.

(124) Unless personal monitoring devices are always worn, and worn properly, it is not possible to estimate occupational dose accurately. Failure to wear personal monitoring devices may lead to the false belief that an individual's occupational dose is low when it is not.

6.7 Personal dosimetry

(125) The Commission recommends the use of two personal dosimeters for occupational dosimetry cardiac catheterization laboratories: one worn on the trunk of the body inside the apron and the other worn outside the apron at the level of the collar or the left shoulder (ICRP 2000). The dosimeter under the apron provides an estimate of the dose to the organs of the shielded region. The dosimeter worn outside the apron supplies an estimate of the dose to the organs of the head and neck, including the thyroid and lens of the eyes (if unshielded), but greatly overestimates the doses to organs of the trunk. Results obtained from both dosimeters can be used to estimate the occupational effective dose as recommended by the NCRP (NCRP, 1995) and ICRP (ICRP, 2000). A dosimeter for the hands may also be useful.

(126) The effective dose, E, can be estimated from the dosimeter values for H_w (under the apron at the waist, although this position is not critical) and H_n (above the apron at the neck) from the equation:

$$E = 0.5\ H_w + 0.025\ H_n$$

(127) NCRP report 122 (NCRP 1995) contains specific recommendations for calculating the effective dose when protective aprons are worn during diagnostic and interventional medical procedures involving fluoroscopy. In addition to the above formula, it states that the effective dose can be estimated as $H_n/21$ if only one dosimeter is worn on the neck outside the apron.

(128) The European Commission DIMOND project addressed the issues regarding optimization of staff doses with an attempt to propose preliminary occupational dose constraints (Tsapaki at al. 2004). The proposed value for cardiologists' annual effective dose was 0.6 mSv. UNSCEAR (UNSCEAR 2000, paragraph 166) reported that cardiologists tend to be the most exposed staff in medicine; their average annual dose was 0.4mSv, and an appreciable proportion received more than 1 mSv. A recent review of radiation exposures to operators from cardiac procedures over a 30 year period highlighted the difficulty in comparing reported dosimetry results because of significant differences in dosimetric methods in each study (Kim et al, Health Physics, 2008). Better standardization of dosimetric methods is recommended.

(129) Many operators not only do not use protective equipment properly, but also do not regularly wear their dosimeters. Failure to wear dosimeters is a problem throughout

the world (Vaño et al. 1998b, McCormick, 2002, Padovani, 2011). In addition to monitoring personal exposure, dosimeter use helps to increase awareness about radiological protection. In the absence of formal training in radiological protection for cardiologists in such countries, physicians in training adopt the practices of their seniors (Rehani and Ortiz-Lopez, 2005).

(130) Compliance with the radiation badge policies is one of the main problems in many interventional cardiology services (Vano 2005). Reported occupational dose values are often surprisingly low, and the reason is likely not a high level of radiological protection, but rather failure to wear personal dosimeters. McCormick et al. (McCormick 2002) reported that before a mandatory radiological protection training programme, compliance with the radiation badge policy for physicians and nurse clinicians was only 36% in 1999, and afterwards reached a maximum of only 77%. A strict policy on the regular use of personal dosimeters should be part of any quality programme in cardiology laboratories.

6.8 References

Balter, S, 2001a. Interventional fluoroscopy – physics, technology, safety. Wiley-Liss, New York.

Balter S., 2001b. Stray radiation in the cardiac catheterization laboratory. Radiat Prot Dosim 94(1-2), 183-188.

Ciraj-Bjelac O, Rehani MM, Sim KH, Liew HB, Vano E, Kleiman NJ. Risk for radiation induced cataract for staff in interventional cardiology: Is there reason for concern? Catheter Cardiovasc Interv 2010;76(6):826-834.

Dauer, L.T., Thornton, R.H., Solomon, S.B., St Germain, J., 2010. Unprotected operator eye lens doses in oncologic interventional radiology are clinically significant: estimation from patient kerma-area-product data. J. Vasc. Interv. Radiol. 21, 1859-1861.

Dendy PP. Radiation risks in interventional radiology. Br J Radiol 2008; 81:1-7.

Dromi, S., Wood, B.J., Oberoi, J., Neeman, Z., 2006. Heavy metal pad shielding during fluoroscopic interventions. J. Vasc. Interv. Radiol. 17, 1201-1206.

Efstathopoulos E, Makrygiannis SS, Kottou S, et al. Medical personnel and patient dosimetry during coronary angiography and intervention. Phys Med Biol 2003;48:3059-68.

Finkelstein MM. Is brain cancer an occupational disease of cardiologists? Can J Cardiol 1998;14,1385-8.

Germano, J.J., Day, G., Gregorious, D., Natarajan, V., Cohen, T., 2005.
A novel radiation protection drape reduces radiation exposure during fluoroscopy guided electrophysiology procedures. J. Invasive Cardiol. 17, 469-72.

Goldstein JA, Balter S, Cowley M, Hodgson J, Klein LW; Occupational hazards of interventional cardiologists: prevalence of orthopedic health problems in contemporary practice. Catheter Cardiovasc Interv. 2004 Dec;63(4):407-11.

ICRP. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann ICRP 2000;30(2).

2946 ICRP. The 2007 Recommendations of the International Commission on Radiological
2947 Protection. ICRP Publication 103. Ann ICRP 2007; 37(2-4):1-332
2948 Kim KP, Miller DL, Balter S, Kleinerman RA, Linet MS, Kwon D, Simon SL.
2949 Occupational radiation doses to operators performing cardiac catheterization
2950 procedures. Health Phys 94: 211-227, 2008.
2951 Kim, C., Vasaiwala, S., Haque, F., Pratap, K., Vidovich, M.I., 2010. Radiation safety
2952 among cardiology fellows. Am. J. Cardiol. 106, 125-128.
2953 King JN, Champlin AM, Kelsey CA, Tripp DA. Using a sterile disposable protective
2954 surgical drape for reduction of radiation exposure to interventionalists. Am J
2955 Roentgenol 2002; 178:153-157.
2956 Klein LW, Miller DL, Balter S, Laskey W, Haines D, Norbash A, Mauro MA, Goldstein
2957 JA. Occupational health hazards in the interventional laboratory: time for a safer
2958 environment. Heart Rhythm 2009, 6:439-444.
2959 Kuon E, Schmitt M, Dahm JB. Significant reduction of radiation exposure to operator
2960 and staff during cardiac interventions by analysis of radiation leakage and improved
2961 lead shielding. Am J Cardiol 2002; 89:44-9.
2962 Kuon E, Dahm J, Empen K, et al. Identification of less-irradiating tube angulations in
2963 invasive cardiology. J Am Coll Cardiol 2004;44:1420-8.
2964 Limacher MC, Douglas PS, Germano G, et al. ACC expert consensus document.
2965 Radiation safety in the practice of cardiology. J Am Coll Cardiol. 1998;31:892-913.
2966 Maeder M. Verdun FR, Stauffer JC et al. Radiation exposure and radiation protection in
2967 interventional cardiology. Kardiovaskuläre Medizin 2005;8:124-132.
2968 Maeder M, Brunner-La Rocca HP, Wolber T, Ammann P, Roelli H, Rohner F, Rickli H.
2969 Impact of a lead glass screen on scatter radiation to eyes and hands in interventional
2970 cardiologists. Catheter Cardiovasc Interv 2006; 67:18-23.
2971 Marshall NW, Faulkner K, Clarke P. An investigation into the effect of protective
2972 devices on the dose to radiosensitive organs in the head and neck. Br J Radiol. 1992
2973 Sep;65(777):799-802.
2974 Martin, CJ. A review of radiology staff doses and dose monitoring requirements. Radiat
2975 Prot Dosim 2009; 136(3), 140-157.
2976 McCormick VA, Schultz CC, Hollingsworth-Schuler V, Campbell JM, O'Neill WW,
2977 Ramos R. Reducing radiation dose in the cardiac catheterization laboratory by
2978 design alterations and staff education. Am J Cardiol 2002; 90:903-905.
2979 Miller DL, Vañó E, Bartal G, Balter S, Dixon R, Padovani R, Schueler B, Cardella JF,
2980 de Baère T. Occupational radiation protection in interventional radiology: A joint
2981 guideline of the Cardiovascular and Interventional Radiology Society of Europe and
2982 the Society of Interventional Radiology. Cardiovasc Interv Radiol 2010; 33:230-
2983 239.
2984 Moore WE, Ferguson G, Rohrmann C. Physical factors determining the utility of
2985 radiation safety glasses. Med Phys 1980; 7(1), 8-12.
2986 NRC. Health risks from exposure to low levels of ionizing radiation: Phase 2, BEIR VII.
2987 Washington, DC: The National Academies Press, 2006.
2988 NCRP. Use of personal monitors to estimate effective dose equivalent and effective dose
2989 to workers for external exposure to low-LET radiation. NCRP report No. 122.

Bethesda, Maryland: National Council on Radiation Protection and Measurements; 1995.

NCRP. Radiation protection for procedures performed outside the radiology department. NCRP Report No. 133. Bethesda, Maryland: National Council on Radiation Protection and Measurements; 2000.

NCRP. Radiation dose management for fluoroscopically guided interventional medical procedures. NCRP Report No. 168. Bethesda, MD: National Council on Radiation Protection and Measurements; 2010.

Padovani R, Rodella CA. Staff dosimetry in interventional cardiology. Radiat Prot Dosimetry 2001;94:99-103.

Padovani, R., Le Heron, J., Cruz-Suarez, R., Duran, A., Lefaure, C., Miller, D.L., Sim, H.K., Vano, E., Rehani, M., Czarwinski, R., 2010. International project on individual monitoring and radiation exposure levels in interventional cardiology. Radiat Prot Dosimetry 2011; in press.

Rehani MM, Ortiz-Lopez P. Radiation effects in fluoroscopically guided cardiac interventions – keeping them under control.(Editorial). Int J Cardiol 2006; 109(2): 147-151.

Sawdy, J.M., Gocha, M.D., Olshove, V., Chisolm, J.L., Hill, S.L., Phillips, A., Galantowicz, M., Cheatham, J.P., Holzer, R.J., 2009. Radiation protection during hybrid procedures: innovation creates new challenges. J. Invasive Cardiol. 21, 437-40.

Schueler BA, Vrieze TJ, Bjarnason H, Stanson AW. An investigation of operator exposure in interventional radiology. RadioGraphics 2006; 26(5), 1533-1541.

Schueler BA, Sturchio G, Landsworth R, Hindal M, Magnuson D. (2009) Does new lightweight leaded eyewear provide adequate radiation protection for fluoroscopists? (abstract) Med Phys 2009; 36(6), 2747-2748.

Stratakis J, Damilakis J, Hatzidakis A, Theocharopoulos N, Gourtsoyiannis N. Occupational radiation exposure from fluoroscopically guided percutaneous transhepatic biliary procedures. J Vasc Interv Radiol 2006; 17(5), 863–871.

Thornton, R.H., Dauer, L.T., Altamirano, J.P., Alvarado, K.J., St. Germain, J., Solomon, S.B., 2010. Comparing strategies for operator eye protection in the interventional radiology suite. J. Vasc. Interv. Radiol. 21, 1703-1707.

Tsapaki V, Kottou S, Vano E, Komppa T, Padovani R, Dowling A, Molfetas M, Neofotistou V. Occupational dose constraints in interventional cardiology procedures: the DIMOND approach. Phys Med Biol. 2004 Mar 21;49(6):997-1005.

United Nations Scientific Committee on the Effects of Atomic Radiation. Sources and effects of ionizing radiation. UNSCEAR 2000 report to the General Assembly, with scientific annexes. Annex E. Occupational radiation exposures. (Available at www.unscear.org). New York: United Nations; 2000.

Vano E, González L, Beneytez F, et al. Lens injuries induced by occupational exposure in non-optimised interventional radiology laboratories. Br J Radiol 1998a;71:728-33.

Vano E, Gonzalez L, Guibelalde E, et al. Radiation exposure to medical staff in interventional and cardiac radiology. Br J Radiol 1998b;71:954-60.

Vano E. Radiation exposure to cardiologists: how it could be reduced. Heart. 2003; 89(10):1123-4.

Vano E, Gonzalez L, Fernandez JM, Alfonso F, Macaya C. Occupational radiation doses in interventional cardiology: a 15 year follow-up. Br J Radiol 2006;79(941):383-388.

Vano E, Gonzalez L, Fernandez JM, Prieto C, Guibelalde E. Influence of patient thickness and operation modes on occupational and patient doses in interventional cardiology. Radiat Prot Dosim 2006; 118(3): 325-330.

Vano E, Gonzalez L, Fernandez M, Haskal ZJ. Eye lens exposure to radiation in interventional suites: caution is warranted. Radiology 2008; 248: 945-953.

Vano E, Kleiman NJ, Duran A, Rehani MM, Echeverri D, Cabrera. M. Radiation cataract risk in interventional cardiology personnel. Radiat Res, 2010; 174(4):490-495

von Boetticher H, Lachmund J, Hoffmann W. Cardiac catheterization: impact of face and neck shielding on new estimates of effective dose. Health Phys 2009; 97(6), 622– 627.

Wagner LK, Mulhern OR. Radiation-attenuating surgical gloves: effects of scatter and secondary electron production. Radiology 1996; 200:45-48.

Wagner LK, Archer BR. Minimizing Risks from Fluoroscopic X-Rays: Bioeffects, Instrumentation, and Examination. 4th Edition. The Woodlands, Texas:(Partners in Radiation Management, 2004.

Table 6.1.

Practical advice for interventionalists to improve staff radiation protection (from Vano et al, 2003 and Miller et al, 2010).

- Increase your distance from the patient (the scatter radiation source) whenever possible. This is obviously only possible when angiographic runs are not performed by hand. Working at 80 cm from the isocenter instead of 40 cm can decrease scattered dose to approximately a quarter of the original dose.
- Try to position yourself in a low scatter area. Scattered radiation is higher at the x-ray tube side of the gantry and lower on the side of the image receptor.
- Use a ceiling suspended screen, a table-suspended screen and other protective shielding, such as a lead apron, thyroid collar and lead glasses, when possible.
- When appropriate, use a dose reduction pad or drape at the catheter entrance site to reduce your hand dose.
- Minimise the use of fluoroscopy and use low-dose fluoroscopy modes (for example, pulsed fluoroscopy) when possible.
- Minimize the number of cine series and the number of frames per cine series.
- Use magnification as little as possible.
- Collimate the x-ray beam as tightly as possible.
- Obtain appropriate training in radiation management and radiation protection.
- Wear your dosimeters and know your own dose.
- In addition, a final general concept: reduce the patient's radiation and you will also be reducing your own dose.

Table 6.2

Relative increases in staff doses with changes in different operational features in a Philips Integris 5000 fluoroscopy unit (Vano et al, 2006).

Action	*Increase in staff dose*
Changing from low to high fluoroscopy mode (for a 20 cm thick patient)	× 2.6
Changing II format from 23 cm to 17 cm (for a 20 cm thick patient)	× 1.0
Changing patient thickness from 16 to 28 cm	× 4.2
Changing from low fluoroscopy mode to cine (for a 20 cm thick patient)	× 8.3

Table 6.3

Protection of different lead aprons for X-ray beams filtered with 3 mm Al and generated at the kVp indicated (Vano et al, 2006).

kVp	Protective apron Pb equivalent (mm)	Fraction of energy transmitted (%)
90	0.25	8.3
90	0.35	4.9
90	0.50	2.4
80	0.25	5.7
80	0.35	3.0
80	0.50	1.3
70	0.25	3.3
70	0.35	1.5
70	0.50	0.5

7. RADIOLOGICAL PROTECTION FOR NUCLEAR CARDIOLOGY

Main Points

- **Appropriate use criteria and guidelines that help to set standards for justification have been developed through consensus efforts of professional societies.**
- **Optimization of nuclear cardiology procedures involves the judicious selection of radiopharmaceuticals and administered activities to ensure diagnostic image quality while minimizing patient dose.**
- **For SPECT protocols, Tc-99m-based agents yield lower effective doses than Tl-201, and are preferred on dosimetric grounds.**
- **Administered activities should be within pre-specified ranges, as provided in international and national guidelines, and should reflect patient habitus.**
- **If stress imaging is normal, rest imaging can be omitted to minimize total dose.**
- **Practitioners need good quality dosimetry data to perform proper benefit-risk analyses for their patients.**

7.1 Introduction

(131) More than 90% of nuclear cardiology studies are myocardial perfusion scintigraphy studies for the assessment of myocardial perfusion and/or viability. The vast majority of nuclear cardiology procedures are performed with single photon emission computed tomography (SPECT). A small but growing number of laboratories perform positron emission tomography (PET) studies.

(132) An estimated 32.7 million diagnostic nuclear medicine procedures are performed annually worldwide (UNSCEAR 2008). Of these, approximately 14 million are nuclear cardiology procedures, and this number has increased rapidly (Davis, 2006). More nuclear cardiology procedures are performed in the United States than in the rest of the world combined. In the U.S., nuclear medicine procedures accounted for 26% of the medical exposure of patients in 2006, and cardiac studies accounted for 85% of the nuclear medicine exposure (NCRP report 160, 2009).

7.2 Radiopharmaceuticals

(133) The radiopharmaceuticals used most commonly for nuclear cardiology studies are summarized in **Table 7.1**. In Europe, most studies are performed using Tc-99m-based agents, while in the United States, a sizable minority of studies are performed using Tl-201, usually in the context of a dual isotope study with rest Tl-201 imaging followed by stress Tc-99m imaging. The use of thallium results in a higher dose to the patient (Einstein et al, 2007).

Table 7.1. Commonly Used Radiopharmaceuticals for Nuclear Cardiology

Agent	Modality	Role			Physical Half-Life	Effective Dose (10^{-3} mSv/MBq)	ICRP Publication
		(14) erfusion	(15 unctio n	(16 iabilit y			
Tc-99m sestamibi	SPECT	+++	++	+	6h	9.0 rest/7.9 stress	80(1998)
Tc-99m tetrofosmin	SPECT	+++	++	+	6h	7.6 rest/7.0 stress	80(1998)
Tl-201	SPECT	+++	+	++	73h	140	106(2008)
Tc-99m red blood cells	Planar or SPECT MUGA	-	+++	-	6h	7.0	80(1998)
Rb-82	PET	+++	++	-	75s	3.4*	(17) 80(1998)*
N-13 ammonia	PET	+++	++	-	10m	2.0	80(1998)
F-18 fluorodeoxyglucose	PET	-	-	+++	110m	19	(18) 80(1998)

SPECT: single photon emission computed tomography, PET: positron emission tomography: MUGA: multiple gated acquisition

* ICRP's dose coefficients for Rb-82, dating to Publication 53 (1987) and reiterated in Publication 80 (1998), reflect for some organs "worst case" conditions, as was stated in Publication 53, and thus dose estimates deriving therefrom might be overly conservative. Three groups have recently suggested lower dose coefficients (Senthamizhchelvan et al 2010, 1.11 μSv/MBq; Hunter 2010, 0.74 μSv/MBq; and Stabin 2010, 1.7 μSv/MBq); the Commission is currently revisiting the issue of Rb-82 dosimetry.

(134) Recommended administered activities for nuclear cardiology procedures vary markedly among the professional societies and accrediting bodies in various countries (Hesse et al., 2005). Guidelines have been published by both the American Society of Nuclear Cardiology (ASNC) (DePuey, 2006; Henzlova, 2009) and the European Council on Nuclear Cardiology (ECNC) (Hesse et al., 2005), a joint group of the European Association of Nuclear Medicine (EANM) and the European Society of Cardiology (ESC). Injected activity from these guidelines is summarized in **Table 7.2**.

Table 7.2. Recommended Injected Activity (MBq) for Standard Cardiac SPECT and PET Protocols

		ASNC	EANM/ESC
SPECT	Thallium 1 injection	92 to 148	74 to 111
	Thallium 2 injections	92 to 148 (stress) 37 to 74 (reinjection)	74 to 111 (stress) 37 (reinjection)
	Technetium-99m 1 day	296 to 444 (1st dose) 888 to 1332 (2nd dose)	400 to 500 (1st dose) 1200 to 1500 (2nd dose)
	Technetium-99m 2 day	888 to 1332 each day	600 to 900 each day
	Dual Isotope	92 to 148 (Tl) 888 to 1332 (^{99m}Tc)	not specified
	MUGA	925 to 1295*	not specified
PET	Rubidium-82 2 injections	1480 to 2220 per dose**	1100 to 2200 per dose
	N-13 ammonia 2 injections	370 to 740 per dose	370 to 740 per dose
	F-18 FDG	185 to 555	200 to 350

*740 to 925 for planar imaging

**for 2 dimensional acquisition using camera with bismuth germanate or lutetium oxyorthosilicate crystals

7.3 Dosimetry for nuclear cardiology

(135) Two types of dose coefficients can be determined: 1) tissue dose coefficients, which can be used to estimate the dose to a particular tissue or organ, and 2) effective dose coefficients, which can be used to estimate effective dose to the individual. Note however that effective dose is intended for use as a radiological protection quantity. Effective dose is not recommended for epidemiological evaluations, nor should it be used for detailed specific retrospective investigations of individual exposure and risk (ICRP, 2007a).

(136) Estimates of organ dose and estimates of effective dose to patients are generally obtained by using mathematical biokinetic models that quantify the distribution and metabolism of a radiopharmaceutical in the body. These models incorporate biokinetic data from humans and/or animals and enable the determination of dose coefficients.

(137) *Tissue dose coefficients* quantify absorbed doses to a specific organ in a typical patient, per unit activity administered. For example, ICRP's current liver dose coefficient

in an adult for the PET tracer F-18 fluorodeoxyglucose is 1.1×10^{-2} mGy per MBq (ICRP, 1998). Thus, a 200 MBq injection of F-18 fluorodeoxyglucose is associated with an estimated dose to the liver of 2.2 mGy.

(138) *Effective dose coefficients* quantify effective dose per unit activity administered. ICRP's current effective dose coefficient in an adult for F-18 fluorodeoxyglucose is 1.9×10^{-2} mSv per MBq (ICRP, 1998), and therefore the same 200 MBq injection of F-18 fluorodeoxyglucose would be associated with an estimated effective dose of 3.8 mSv.

(139) Several systems provide mathematical frameworks for estimating dose coefficients, including those of ICRP Publication 30 (ICRP, 1979) and those of the Society of Nuclear Medicine's Medical Internal Radiation Dose committee (Loevinger et al., 1988) and Radiation Dose Assessment Resource task group (Stabin et al., 2001). These approaches are essentially equivalent (Stabin, 2006). They estimate radiation dose as energy per unit mass. Energy is generally determined from biokinetic models of the radiopharmaceutical's time-activity curve, from tables of the mean energy per nuclear transition, and from Monte Carlo computer models. Organ masses are determined from a model of a representative person.

(140) There are numerous collections of dose coefficients for specific radiopharmaceuticals. The most extensive compilations are those of the Commission, for which current estimates can be found in Publications 53 (ICRP, 1987), 80 (ICRP, 1998), and 106 (ICRP, 2008). Effective doses for commonly used radiopharmaceuticals for nuclear cardiology, based on the most recent ICRP effective dose coefficients for these radiopharmaceuticals, are listed in **Table 7.1**. These effective doses reflect ICRP Publication 60 tissue weighting factors; updated effective dose coefficients reflecting Publication 103 tissue weighting factors will be included in a forthcoming ICRP publication. In many countries there is a regulatory requirement that dose coefficients be provided in manufacturers' package inserts/product information (PI) sheets for radiopharmaceuticals.

7.4 Current dosimetry estimates

(141) The dose to a typical patient from a nuclear cardiology study can be estimated by multiplying dose coefficients by the administered activity. These estimates are illustrated in **Figure 7.1**, using the most recent ICRP dose coefficients for each agent and administered activities in the middle of the range specified in **Table 7.2**.

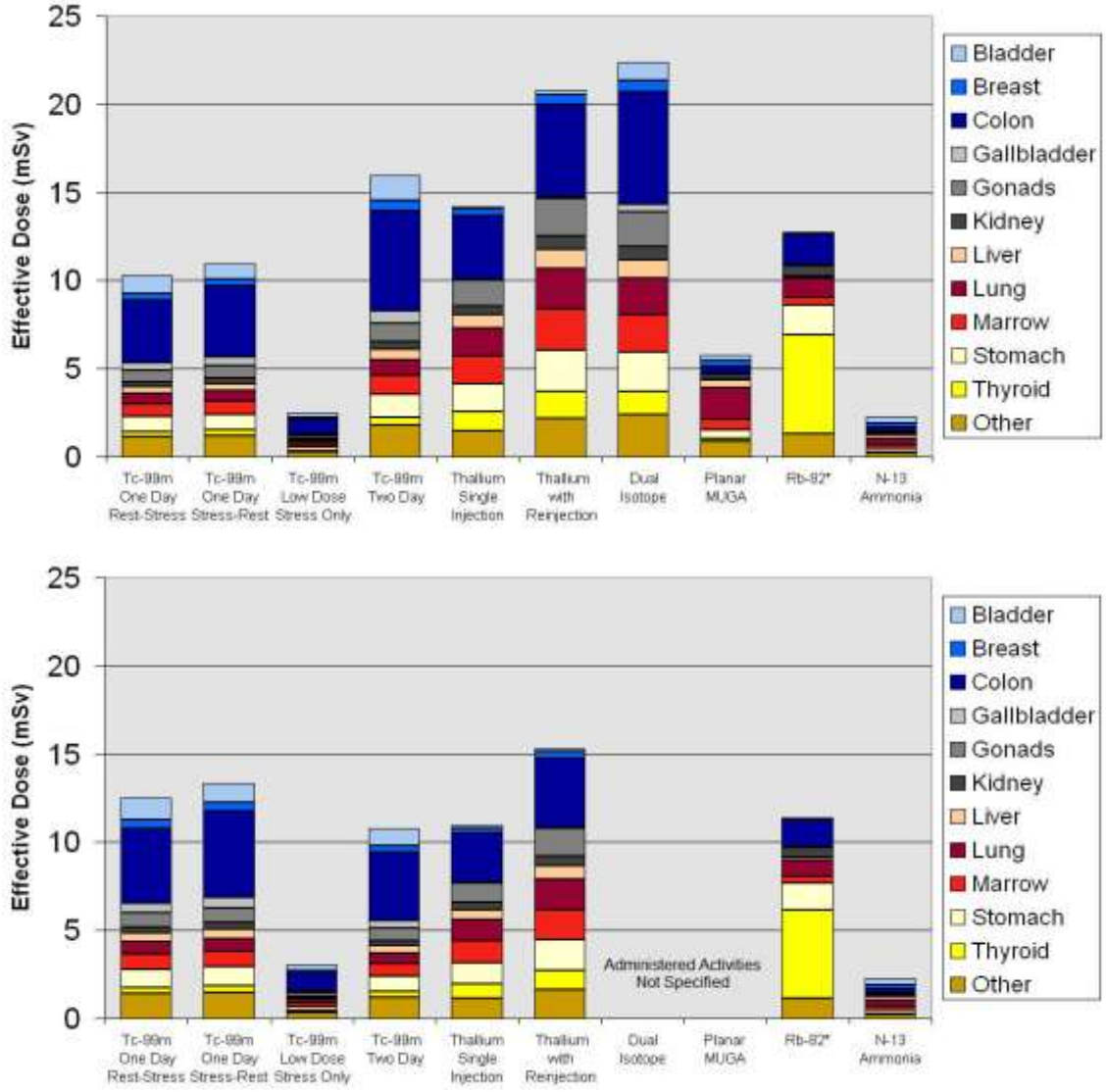


Figure 7.1. Effective doses from standard nuclear cardiology procedures, estimated using the most recent ICRP dose coefficients and Publication 103 tissue weighting factors (ICRP, 2007a). Stacked bars represent organ weighted equivalent doses contributing to effective dose. Doses for Tc-99m represent the average of Tc-99m sestamibi and tetrofosmin. Top: Using average recommended administered activities from American Society of Nuclear Cardiology guidelines (Henzlova, 2009; DePuey, 2006). Bottom: Using average recommended administered activities from European Council on Nuclear Cardiology guidelines (Hesse et al., 2005).

*Note that ICRP's dose coefficients for Rb-82, dating to Publication 53 (1987) and reiterated in Publication 80 (1998), reflect for some organs "worst case" conditions, as was stated in Publication 53, and thus dose estimates derived therefrom might be overly conservative. Three groups have recently suggested lower dose coefficients (Senthamizhchelvan et al 2010, 1.11 μSv/MBq; Hunter 2010, 0.74 μSv/MBq; and Stabin 2010, 1.7 μSv/MBq); the Commission is currently revisiting the issue of Rb-82 dosimetry.

7.5 Uncertainty in dosimetry

(142) Because many terms are estimated and multiplied together to determine dose coefficients, there are numerous potential sources of uncertainty in these dose estimates. Differences between planned and actual administered activity are considered to be minor contributors to the total uncertainty, if regular quality control is performed (ICRP, 1987). The three most sizable contributors to uncertainty are inter-individual variability in organ masses, absorbed fractions, and total activity in each organ. Uncertainties in organ activity reflect differences in biokinetics. (Stabin, 2008b) Experimental validation of calculated absorbed doses has indicated agreement within 20% to 60%, with the larger value applicable to patients who differed considerably from the body size and shape assumed in the calculations (Roedler, 1981). More recent publications contend that the combined uncertainties for any given dose estimate of a radiopharmaceutical are generally at least a factor of 2 (Stabin, 2008b).

7.6 Discrepancies between ICRP dosimetry and information from manufacturers

(143) The most readily available source of dosimetric data about a radiopharmaceutical is typically the information provided by the manufacturer. In several cases, dose coefficients vary considerably between those given in ICRP publications and those provided by manufacturers. These discrepancies may affect the choice of diagnostic tests and the choice of radiopharmaceuticals, since radiation risk is one factor that should be incorporated into benefit-risk analyses.

(144) One recent report evaluating package inserts in the United States found that effective doses for Tl-201 estimated from a single manufacturer's information were less than half of those estimated from ICRP tables, while doses estimated from package inserts from two other manufacturers were greater than or similar to ICRP effective doses.(Einstein et al., 2007) These discrepancies are due, in part, to the numerous sources of uncertainty incorporated into dose coefficients. However, they may also be due to the use of limited and older data by manufacturers (Gerber et al., 2009; Stabin, 2008a).

(145) The Commission recommends that national regulatory authorities implement programs to ensure the quality of dosimetric data in package inserts and product information. Aspects of quality include inclusion of effective dose coefficients (as opposed to total body dose coefficients), periodic post-approval updates to reflect the available dosimetric data, and transparency in the data sources and sample sizes used to obtain dose coefficients.

7.7 Radiological protection of patients in nuclear cardiology

(146) The general principles of radiological protection (chapter 4), i.e. justification and optimisation, can be applied to the protection of patients in nuclear cardiology. Dose limitation is not appropriate, but diagnostic reference levels should be used to help manage the radiation dose so that the dose is commensurate with the clinical purpose (ICRP, 1977, ICRP, 2007a, ICRP, 2007b).

7.7.1 Justification

(147) Nuclear cardiology studies should always be justified on clinical grounds (Gerber et al., 2009). Even in highly expert institutions, sizable percentages of nuclear cardiology studies performed may not meet standardized criteria for appropriateness. To a certain degree this may reflect limitations with appropriateness criteria, which may not incorporate all the information included in decision making for a particular patient. However, in a recent retrospective analysis of 284 patients undergoing nuclear stress testing at the Mayo Clinic, 25% had inappropriate or uncertain indications (Gibbons et al., 2008). Four inappropriate indications accounted for 88% of inappropriate studies. The most common inappropriate indication was stress testing in an asymptomatic low-risk patient.

(148) Pre-test classification of patients by indication, with a requirement for specific justification for patients with no identified appropriate indication, offers an approach to decrease the number of nuclear stress tests performed that are not justified. The Commission encourages the development and validation of national and regional appropriateness criteria for utilization of cardiac imaging. For clinical scenarios in which more than one imaging modality might be used, appropriateness criteria should simultaneously address these multiple modalities. (ACR, 2010). Alternative techniques (such as stress-echocardiography) are available, and should be considered whenever possible.

7.7.2 Optimization

(149) Several methods can be used to control patient dose in nuclear cardiology. These include choosing the most appropriate radiopharmaceutical(s), optimizing injected activity, avoiding rest imaging when stress imaging is normal and encouraging hydration and early micturition after radiopharmaceutical administration. Hydration and early micturition may halve the dose to the bladder wall (Einstein et al., 2007).

(150) The choice of protocols is particularly critical. As illustrated in Table 2 and Figure 1, a variety of standard protocols are available for the performance of myocardial perfusion imaging. Their effective doses can range from 2 mSv to nearly 30 mSv. The lowest dose myocardial perfusion imaging protocols use N-13 ammonia. N-13 ammonia is a PET tracer that requires an on-site cyclotron due to its 10-minute half-life. This limits its availability.

(151) SPECT protocols may require one or two injections of a radiopharmaceutical. The radiopharmaceutical may be Tl-201, a Tc-99m-based agent (sestamibi or tetrofosmin), or both. The effective dose depends on the radiopharmaceutical(s) and

injected activities selected. In general, Tc-99m is preferable to Tl-201 on dosimetric grounds. Effective doses are typically considerably higher for protocols using Tl-201, and lowest for stress-only Tc-99m protocols. A protocol employing Tl-201 may be optimal for some patients, e.g. those with a history of Tc-99m images obscured by increased sub-diaphragmatic tracer uptake, if an alternative imaging modality is not used. For patients with a low- or low-intermediate pre-test probability of a perfusion defect, in whom it is expected that stress imaging will be normal, a stress-first/stress-only protocol is recommended, since rest imaging can be omitted if stress images are normal (Hesse et al., 2005; Mahmarian, 2010). This approach may be especially useful in conjunction with attenuation correction, which decreases the percentage of studies with perfusion defects due to artefact (Gibson et al., 2002).

(152) The Commission recommends formal training in radiological protection, and in particular in the application of methods to minimize patient dose in accordance with ALARA principles, for all physicians involved in nuclear cardiology studies, regardless of their medical specialty. The recommended training is described in ICRP Publication 113 (ICRP, 2009). Additional recommendations are available from the IAEA (IAEA, 2001).

7.7.3 Diagnostic Reference Levels in Nuclear Cardiology

(153) Diagnostic reference levels are used in medical imaging to indicate whether, in routine conditions, the levels of patient dose from, or administered activity for, a specified imaging procedure are unusually high or low for that procedure (ICRP, 2007a). They are discussed further in Chapter 10. If so, a local review should be initiated to determine whether protection has been adequately optimised or whether corrective action is required.

(154) Professional medical bodies (in conjunction with national health and radiological protection authorities) are encouraged to set diagnostic reference levels that best meet their specific needs and that are consistent for the regional, national, or local area to which they apply (ICRP, 2007b). In nuclear medicine, reference levels usually have been derived from pragmatic values of administered activity based on accepted custom and practice (ICRP, 2007b). Sources of diagnostic reference levels for nuclear cardiology include ASNC, ECNC, and national guidelines, which provide a range of administered activities for each protocol. The activity administered to a given patient can be adjusted within these ranges to reflect patient habitus. For example, while up to 1332 MBq of technetium-99m is recommended per injection in a two-day protocol, this upper limit should be restricted to larger patients.

7.8 Advice to patients

(155) In recent years, the threat of nuclear terrorism has led to the widespread use of radiation detectors for security screening at airports and other public facilities. Patients who have received radiopharmaceuticals for nuclear cardiology studies may retain sufficient activity to trigger these detectors (Dauer, 2007b). In particular, patients who

have received Tl-201 may trigger these detectors for up to 51 days following the procedure (Dauer, 2007a). Patients should be advised of this possibility and should be given information cards that indicate the potential time for triggering security radiation detectors after diagnostic cardiac procedures involving the use of Tl-201 or other radiopharmaceuticals (Dauer, 2007a)

7.9 Current research areas

(156) Recent technological developments in nuclear cardiology, such as more sophisticated noise-reducing image reconstruction algorithms and new camera designs that employ arrays of solid-state detectors, offer the possibility to improve camera efficiency. Research efforts using these technologies have largely focused on decreasing acquisition time and improving image quality. These technologies also offer the potential to markedly decrease administered activity and thereby patient dose, while maintaining comparable diagnostic performance in comparison to conventional scanners. Further investigation and clinical validation is required (Patton et al., 2007).

7.10 References

ACR, 2010. American College of Radiology ACR Appropriateness Criteria®. Clinical Condition: Chronic Chest Pain — High Probability of Coronary Artery Disease. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx Accessed January 2, 2011.

Dauer LT, Williamson MJ, St. Germain J, Strauss HW, 2007a. Tl-201 stress tests and homeland security. J Nucl Cardiol 14(4):582-588.

Dauer LT, Williamson MJ, St. Germain J, Strauss HW, 2007b. Nuclear granny—reply. J Nucl Cardiol 14(6):904-905.

Davis W. Mapping improvements in molecular imaging. Medical Imaging. 2006;May 2006. Available at: http://www.imagingeconomics.com/issues/articles/MI_2006-05_01.asp Accessed December 31, 2010.

DePuey, E.G., 2006. Imaging guidelines for nuclear cardiology procedures. 13, e21.

Earls, J.P., Berman, E.L., Urban, B.A., Curry, C.A., Lane, J.L., Jennings, R.S., McCulloch, C.C., Hsieh, J., Londt, J.H., 2008. Prospectively gated transverse coronary CT angiography versus retrospectively gated helical technique: improved image quality and reduced radiation dose. Radiology 246, 742-753.

Earls, J.P., Schrack, E.C., 2008. Prospectively gated low-dose CCTA: 24 months experience in more than 2,000 clinical cases. Int J Cardiovasc Imaging.

Einstein, A.J., Moser, K.W., Thompson, R.C., Cerqueira, M.D., Henzlova, M.J., 2007. Radiation dose to patients from cardiac diagnostic imaging. Circulation 116, 1290-1305.

Gerber, T.C., Carr, J.J., Arai, A.E., Dixon, R.L., Ferrari, V.A., Gomes, A.S., Heller, G.V., McCollough, C.H., McNitt-Gray, M.F., Mettler, F.A., Mieres, J.H., Morin, R.L., Yester, M.V., 2009. Ionizing Radiation in Cardiac Imaging. A Science

3428 Advisory from the American Heart Association Committee on Cardiac Imaging of
3429 the Council on Clinical Cardiology and Committee on Cardiovascular Imaging and
3430 Intervention of the Council on Cardiovascular Radiology and Intervention.
3431 Circulation 119, 1056-1065.
3432 Gibbons, R.J., Miller, T.D., Hodge, D., Urban, L., Araoz, P.A., Pellikka, P., McCully,
3433 R.B., 2008. Application of appropriateness criteria to stress single-photon emission
3434 computed tomography sestamibi studies and stress echocardiograms in an academic
3435 medical center. J Am Coll Cardiol 51, 1283-1289.
3436 Gibson, P.B., Demus, D., Noto, R., Hudson, W., Johnson, L.L., 2002. Low event rate for
3437 stress-only perfusion imaging in patients evaluated for chest pain. J Am Coll Cardiol
3438 39, 999-1004.
3439 Gutstein, A., Wolak, A., Lee, C., Dey, D., Ohba, M., Suzuki, Y., Cheng, V., Gransar, H.,
3440 Suzuki, S., Friedman, J., Thomson, L.E., Hayes, S., Pimentel, R., Paz, W., Slomka,
3441 P., Berman, D.S., 2008. Predicting success of prospective and retrospective gating
3442 with dual-source coronary computed tomography angiography: development of
3443 selection criteria and initial experience. Journal of Cardiovascular Computed
3444 Tomography 2, 81-90.
3445 Henzlova, M.J., Cerqueira, M.D., Hansen, C.L., Taillefer, R., Yao, S.-S., 2009. ASNC
3446 imaging guidelines for nuclear cardiology procedures. Stress prorocols and tracers.
3447 Available at:
3448 http://www.asnc.org/imageuploads/ImagingGuidelinesStressProtocols021109.pdf
3449 Accessed January 2, 2011,
3450 Hesse, B., Tagil, K., Cuocolo, A., Anagnostopoulos, C., Bardies, M., Bax, J., Bengel, F.,
3451 Busemann Sokole, E., Davies, G., Dondi, M., Edenbrandt, L., Franken, P., Kjaer, A.,
3452 Knuuti, J., Lassmann, M., Ljungberg, M., Marcassa, C., Marie, P.Y., McKiddie, F.,
3453 O'Connor, M., Prvulovich, E., Underwood, R., van Eck-Smit, B., 2005. EANM/ESC
3454 procedural guidelines for myocardial perfusion imaging in nuclear cardiology. Eur J
3455 Nucl Med Mol Imaging 32, 855-897.
3456 Hunter, C., Ziadi, M., Etele, J., Hill, J., Beanlands, R., deKemp, R., 2010. New effective
3457 dose estimates for Rubidium-82 based on dynamic PET/CT imaging in humans. J
3458 Nucl Med. 2010; 51(Suppl 2):1429. Available at:
3459 http://jnumedmtg.snmjournals.org/cgi/content/meeting_abstract/51/2_MeetingAbstra
3460 cts/1429 Accessed January 2, 2011.
3461 Husmann, L., Valenta, I., Gaemperli, O., Adda, O., Treyer, V., Wyss, C.A., Veit-
3462 Haibach, P., Tatsugami, F., von Schulthess, G.K., Kaufmann, P.A., 2008. Feasibility
3463 of low-dose coronary CT angiography: first experience with prospective ECG-
3464 gating. Eur Heart J 29, 191-197.
3465 IAEA, 2001. Training in radiation protection and the safe use of radiation sources.
3466 Safety Report Series No. 20. Vienna: International Atomic Energy Agency, 2001.
3467 ICRP, 1977. Recommendations of the International Commission on Radiological
3468 Protection. ICRP publication 26. Ann ICRP 1(3), 1-53.
3469 ICRP, 1979. ICRP publication 30: limits for intakes of radionuclides by workers. Ann
3470 ICRP 2, 1-116.

3471 ICRP, 1987. Radiation dose to patients from radiopharmaceuticals. A report of a Task
3472 Group of Committee 2 of the International Commission on Radiological Protection.
3473 ICRP Publication 53. Ann.ICRP 18, 1-29.
3474 ICRP, 1998. Radiation dose to patients from radiopharmaceuticals (addendum 2 to ICRP
3475 publication 53). ICRP Publication 80. Ann.ICRP 28, 1-123.
3476 ICRP, 2001. Radiation dose to patients from radiopharmaceuticals. A report of a Task
3477 Group of Committees 2 and 3 of the International Commission on Radiological
3478 Protection. Addendum 5 to ICRP Publication 53.
3479 ICRP, 2007a. The 2007 recommendations of the International Commission on
3480 Radiological Protection. ICRP Publication 103. Ann.ICRP 37, 1-332.
3481 ICRP, 2007b. Radiological Protection in Medicine. ICRP Publication 105. Ann.ICRP
3482 37(6), 1-64.
3483 ICRP, 2008. Radiation dose to patients from radiopharmaceuticals. Addendum 3 to
3484 ICRP Publication 53. ICRP Publication 106. Approved by the Commission in
3485 October 2007. Ann ICRP 38, 1-197.
3486 ICRP, 2009. Radiological protection education and training for healthcare staff and
3487 students (diagnostic imaging and interventional procedures). ICRP Publication 113.
3488 Ann ICRP 39 (5).
3489 Loevinger, R., Budinger, T., Watson, E., 1988. MIRD primer for absorbed dose
3490 calculations. Society of Nuclear Medicine, New York.
3491 Mahmarian, J.J., 2010. Stress only myocardial perfusion imaging: Is it time for a
3492 change? J Nucl Cardiol 17, 529-535.
3493 National Council on Radiation Protection and Measurements. Ionizing radiation
3494 exposure of the population of the United States. NCRP Report No. 160. Bethesda,
3495 MD: National Council on Radiation Protection and Measurements; 2009.
3496 Patton, J.A., Slomka, P.J., Germano, G., Berman, D.S., 2007. Recent technologic
3497 advances in nuclear cardiology. J Nucl Cardiol 14, 501-513.
3498 Roedler, H.D., 1981. Accuracy of internal dose calculations with special consideration of
3499 radiopharmaceutical biokinetics, Third International Radiopharmaceutical Dosimetry
3500 Symposium, HHS Publication FDA 81-8166. Department of Health and Human
3501 Welfare, Bureau of Radiological Health, Rockville, MD.
3502 Rybicki, F.J., Otero, H.J., Steigner, M.L., Vorobiof, G., Nallamshetty, L., Mitsouras, D.,
3503 Ersoy, H., Mather, R.T., Judy, P.F., Cai, T., Coyner, K., Schultz, K., Whitmore,
3504 A.G., Di Carli, M.F., 2008. Initial evaluation of coronary images from 320-detector
3505 row computed tomography. Int J Cardiovasc Imaging 24, 535-546.
3506 Senthamizhchelvan, S., Bravo, P.E., Esaias, C., Lodge, M.A., Merrill, J., Hobbs, R.F.,
3507 Sgouros, G., Bengel, F.M., 2010. Human biodistribution and radiation dosimetry of
3508 ^{82}Rb. J. Nucl. Med. 51, 1592-1599.
3509 Stabin, M., 2006. Nuclear medicine dosimetry. Phys Med Biol 51, R187-202.
3510 Stabin, M., Siegel, J., Hunt, J., Sparks, R., Lipsztein, J., Eckerman, K., 2001. RADAR:
3511 the radiation dose assessment resource—an online source of dose information for
3512 nuclear medicine and occupational radiation safety [abstract]. J Nucl Med 42(suppl),
3513 243P.

Stabin, M.G., 2008a. Radiopharmaceuticals for nuclear cardiology: radiation dosimetry, uncertainties, and risk. J Nucl Med 49, 1555-1563.

Stabin, M.G., 2008b. Uncertainties in internal dose calculations for radiopharmaceuticals. J Nucl Med 49, 853-860.

Stabin, M.G., 2010. Proposed revision to the radiation dosimetry of 82Rb. Health Phys. 99, 811-813.

UNSCEAR. Sources and effects of ionizing radiation: volume I, sources: annex D, medical radiation exposure. Report to the General Assembly of the United Nations; 2000; New York, NY Available at: http://www.unscear.org/unscear/en/publications/2000_1.html Accessed December 31, 2010.

8. RADIOLOGICAL PROTECTION FOR CARDIAC CT

Main Points

- **Appropriate use criteria and guidelines for justification have been developed through consensus efforts of professional societies.**
- **Justification needs to be performed on an individualized, patient-by-patient basis, weighing the benefits and risks of each imaging test under consideration as well as of doing no test. Assessment of radiation risk is one part of this process.**
- **Dose from cardiac CT is strongly dependent on scanner mode, tube current, and tube voltage.**
- **For patients with a heart rate less than 65-70 bpm and a regular rhythm, diagnostic image quality can generally be maintained while using dose-reduction methods such as ECG-controlled tube current modulation and axial imaging. The maximum tube current should be appropriate for the patient's habitus.**
- **Further research is needed to develop and validate methods, such as newer scan modes and low-voltage scanning, to minimize radiation dose to patients and practitioners.**

8.1 Introduction

(157) The possibility of CT of the coronary arteries was suggested by Sir Godfrey Hounsfield, inventor of the CT scanner, in his 1979 Nobel Lecture when he stated "A further promising field may be the detection of the coronary arteries. It may be possible to detect these under special conditions of scanning." (Hounsfield, 1979). Unlike nuclear cardiology technology, which has remained largely static, cardiac CT technology has evolved rapidly in recent years. These advancements have enabled a variety of types of cardiac CT studies to be performed. Today, cardiac CT encompasses several distinct procedures, including coronary artery calcium (CAC) scoring, CT coronary angiography (CTCA), pulmonary vein CT angiography, and CT attenuation correction of nuclear cardiology image data. Recent technological advances have been associated with an increase in the number of procedures performed, although reliable statistics on worldwide numbers are not available at present.

8.2 Types of CT scanners

(158) Each new generation of CT scanners has varied from its predecessors in terms of technical parameters (e.g., temporal resolution, spatial resolution, craniocaudal coverage) and also in patent radiation dose. The first scanner capable of performing cardiac studies, the dynamic spatial reconstructor, used 14 x-ray sources that rotated around the patient, resulting in patient doses approaching 100 Gy (Block et al., 1984). The electron beam CT scanner, also called "ultrafast" CT due to its excellent temporal resolution, superseded this machine. Patient dose from electron beam CT was markedly

lower, with typical effective doses of approximately 1 mSv for both CAC scoring and CTCA (Morin et al., 2003). Electron beam CT scanners had low spatial resolution, and have been supplanted by multiple-detector-row CT (MDCT) scanners. The improved spatial resolution of MDCT scanners enables a more accurate assessment of coronary stenosis and plaque visualization. Initial efforts at CTCA were performed with 4-slice scanners. The technology gained popularity with subsequent generations of faster 16- and 64-slice scanners and became even more widespread with the advent of 128- and 256-slice scanners. MDCT is the focus of ICRP Publication 102 (ICRP, 2007a).

8.3 Dosimetric Quantities

(159) Currently, three types of dosimetric quantities are utilized for CT. These are: i) weighted CT dose index ($CTDI_w$) and volume CT dose index ($CTDI_{vol}$), ii) dose-length product (DLP), and iii) effective dose. $CTDI_w$ and $CTDI_{vol}$ are estimates of the average dose within the central portion of the scan volume. DLP integrates the $CTDI_{vol}$ over the length of the anatomy scanned, and reflects the increased patient dose when a longer portion of the patient is scanned (e.g., chest vs. heart). Effective dose is a calculated quantity used to reflect the risk of a radiation exposure to a portion of the body in terms of a uniform whole-body exposure. Effective dose was developed as a radiological protection quantity, and is used to compare radiation risk among different diagnostic examinations (ICRP, 2007b; McCollough, 2008)

(160) Current MDCT scanners typically report $CTDI_{vol}$ and DLP for each study. Effective dose can be estimated by multiplying DLP by a body-region-specific conversion factor (*k* factor). For cardiac studies, the most commonly used conversion factor is of 0.017 $mSv \cdot mGy^{-1} \cdot cm^{-1}$, the European Guidelines on Quality Criteria for Computed Tomography chest factor (i.e., effective dose is estimated as 0.017·DLP) (Bongartz et al., 2000). This conversion factor does not reflect the more recent ICRP Publication 103 tissue weighting factors, is derived from data from single-slice scanners, and was developed for chest scans rather than cardiac scans (Christner et al., 2010; Einstein et al., 2010). This method provides a useful approximation of effective dose from cardiac CT based on easily available data, but it typically underestimates effective dose. Alternative, more complex approaches for determining effective dose are Monte Carlo simulations and determination of organ doses in physical anthropomorphic phantoms. These are discussed in more detail in ICRP Publication 102 (ICRP, 2007a).

8.4 Factors affecting patient dose

(161) Factors affecting patient dose in cardiac CT include both those intrinsic to the scanner, such as scanner generation, model and manufacturer, and parameters selected by the operator. Hausleiter et al, in an observational study of 50 sites performing CTCA, observed a marked difference between scanner manufacturers in effective dose (Hausleiter et al., 2009). Reported doses from CTCA vary depending on which generation of MDCT scanners was used (Einstein et al., 2007). The most recent generation of scanners incorporates technology with the potential to decrease patient

doses considerably. Operator-selectable parameters that affect dose include x-ray tube current (mA) or tube current-time product (mAs), tube peak voltage (kVp), pitch (IEC, 2009), scan length (craniocaudal coverage), scan mode, and in some cases the number of x-ray tubes employed.

8.4.1 Tube Current

(162) The choice of an appropriate mA and kVp for a given study reflects a trade-off between image noise and radiation dose. Increasing the tube current results in both a decrease in image noise and an increase in radiation dose. Dose increases in a roughly linear fashion with increased tube current (Gerber et al., 2005). Baseline tube current should be adjusted to reflect patient habitus, as larger patients will require a higher tube current to obtain images with standard levels of noise. For the same tube current, different scanners will produce images with different amounts of noise, so protocols must be tailored to each scanner. A sensible balance is required—overly aggressive reductions in radiation dose may render the scan non-diagnostic. New image reconstruction algorithms incorporating an iterative noise-reduction methodology may maintain image quality while decreasing tube current.

8.4.2 Tube Voltage

(163) For cardiac MDCT applications, a tube voltage of 120 kVp is common. For smaller patients, a lower voltage, e.g. 100 kVp, is used in some centres. Dose varies approximately with voltage to the 2.5 power, so a 37% dose reduction would be expected with this decrease in tube voltage. The evidence supporting low-voltage CTCA (Abada et al., 2006; Bischoff et al., 2009; Hausleiter et al., 2010) is not as robust as that supporting 120 kVp CTCA (Abdulla et al., 2007). However, many sites have obtained excellent image quality using reduced voltage (**Figure 8.1**).

Figure 8.1. CT coronary angiogram, obtained using a tube voltage of 100 kVp and single-heartbeat volume scanning. Courtesy Andrew J. Einstein, MD, PhD, Columbia University Medical Centre, New York, NY, USA

8.4.3 Scan Length

(164) Patient dose is linearly related to the length of the portion of the body irradiated, which is basically equal to the scan length. Typically CTCA is performed with scanning from the carina to the base of the heart, with a small margin of error on each side to allow for patient motion. A scan length of 11-15 cm is typical. Excessively large margins result in increased patient dose without additional diagnostic information. Greater craniocaudal coverage is necessary when the aorta must be included and in cases where the patient has undergone coronary artery bypass grafting, in which case the upper limit of the scan is above the aortic arch. For pulmonary vein CT angiography, the scan length can be reduced. In this case the structures of interest are the left atrium, pulmonary veins, and their anatomic relationship to the oesophagus and aorta; these can be visualized without scanning caudally to the cardiac apex.

8.4.4 Scan Mode

(165) Scan modes include conventional helical (spiral) imaging with constant tube current, conventional helical imaging with ECG-gated tube current modulation (EGTCM), high-pitch helical imaging and axial imaging, including both step-and-shoot and volume imaging (**Figure 8.2**). CTCA using MDCT was first performed using helical mode and a constant tube current, with a typical pitch of 0.2 for 64-slice scanners (**Figure. 8.2 (a)**). All current cardiac scanners offer EGTCM, which keeps tube current at its maximum during diastasis, when coronary movement is generally minimized, and decreases tube current during the remainder of the cardiac cycle (**Figure 8.2 (b)**). This limits the number of phases of the cardiac cycle in which image reconstructions can be performed without excessive noise, but for patients with low heart rates (<65 bpm) and regular heart rhythms, this generally does not pose a problem. Generally, patients should receive beta blockers or calcium channel blockers to lower heart rate and improve the efficacy of EGTCM. For patients who do not meet these conditions, reconstructions at end-systole are often quite useful for visualizing the proximal- and mid-right coronary artery (Sanz et al., 2005). If EGTCM is applied in these patients, it may be advisable to widen the period of time during which tube current is maintained at its maximal value. EGTCM typically decreases effective dose by about one-third. For single-source scanners, this decrease in dose is more pronounced with lower heart rates (Jakobs et al., 2002).

(166) More recently, axial CTCA protocols have been incorporated into some MDCT scanners. This approach to scanning acquires image data only during a pre-specified phase of the cardiac cycle, and the x-ray beam is off during the remainder of the cardiac cycle. In step-and-shoot (sequential) scanning, x-rays are delivered in one cardiac cycle, the patient couch is advanced with the beam off during the next cardiac cycle, and the process is repeated until the entire craniocaudal volume of interest has been scanned. For 64-detector-row scanners, this generally requires 3 or 4 iterations, i.e. 5 or 7 heartbeats (5 heartbeats illustrated in **Figure 8.2 (c)**). For step-and-shoot imaging to generate interpretable cardiac images, it is generally thought that heart rate should be less than 70 beats per minute and heart rhythm should be regular, although this has not been well studied. An advantage of step-and-shoot imaging is reduced dose due to the elimination of radiation exposure during much of the cardiac cycle and the absence of the overlap of irradiated areas characteristic of helical CTCA. Disadvantages include the inability to retrospectively perform image reconstruction at additional phases of the cardiac cycle and the attendant inability to assess cardiac function and wall motion.

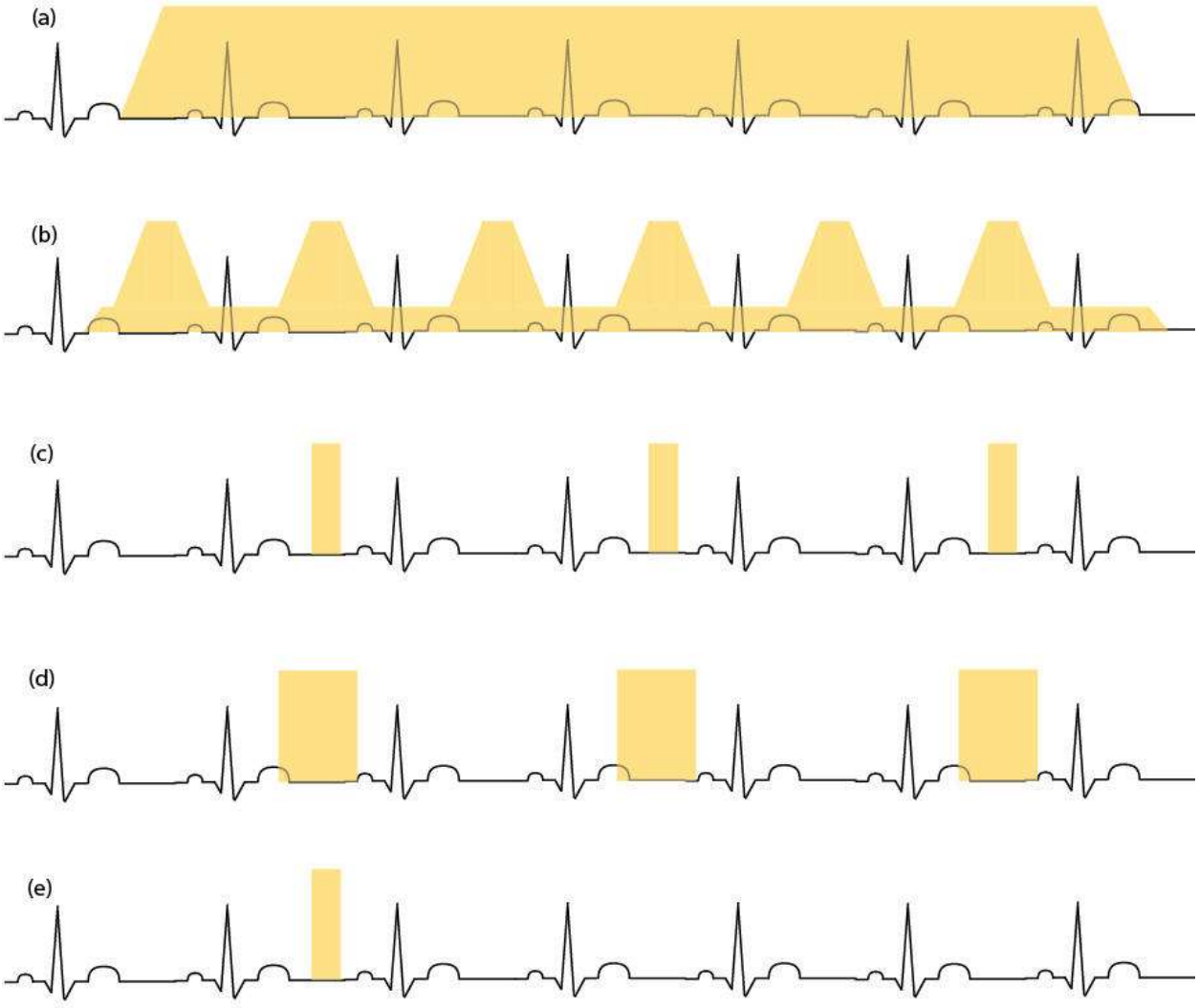
(167) One modification of axial imaging is to increase the length of time that the x-ray tube is on, thus increasing dose but enabling reconstructions within a range of phases of the cardiac cycle (**Figure 8.2 (d)**). Thus, rather than obtaining only images in a single portion of diastasis, a variety of strategies can be employed, such as obtaining images in a range of diastolic phases, or covering from end-systole through diastasis. Dose is proportional to exposure time. The optimal strategy for implementation of axial imaging has not yet been determined.

(168) Two recently-introduced scan modes offer the potential for significant dose reductions. Both cover the entire heart with x-rays delivered for only a fraction of a single heartbeat (**Figure 8.2 (e)**). The extreme case of axial imaging is volume scanning,

which uses a cone-beam x-ray source and a large detector array that covers the entire heart without requiring table motion (Einstein et al., 2010). The extreme case of helical imaging is high-pitch helical scanning, in which two x-ray sources mounted at 90° from each other are used with a rapid table speed to enable the entire heart to be covered in a fraction of a beat.(Achenbach et al., 2010) Each of these modes currently requires a low heart rate to obtain excellent image quality at minimal radiation dose.

(169) The clinical literature evaluating axial CTCA and the single-heartbeat modes is limited (Earls et al., 2008; Gutstein et al., 2008; Husmann et al., 2008; Rybicki et al., 2008). There are no multicentre studies evaluating diagnostic accuracy efficacy in comparison to gold-standard diagnosis by invasive angiography. These scan modes require more rigorous validation.

Figure 8.2



Scan modes used in cardiac CT. Black line denotes electrocardiographic signal, shaded region represents tube current. (a) helical scan, (b) helical scan with

electrocardiographically-gated tube current modulation, (c) axial step-and-shoot scan, (d) axial step-and-shoot scan, with extending exposure time ("padding") to permit reconstruction of multiple cardiac phases, (e) axial single heartbeat scan (volume and high-pitch helical scans, illustrated here with no padding). Not all modes are available on all MDCT scanners.

8.5 Current Dosimetry Estimates

(170) Dosimetry from CTCA depends on many factors, and thus varies markedly between protocols. Einstein et al reviewed the published literature on effective dose from cardiac CT in 2007(Einstein et al., 2007). Effective doses from calcium scoring ranged from 1.0 to 6.2 mSv using helical technique and from 0.5 to 1.8 mSv using axial technique. For helical 64-slice CTCA, effective dose ranged from 8 to 21.4 mSv without and from 6.4 to 14 mSv with EGTCM. In a 15 centre study performed in the U.S., median effective dose, estimated using a k factor of 0.014 $mSv \cdot mGy^{-1} \cdot cm^{-1}$, was 21 mSv prior to a best-practice dose reduction educational intervention (Raff et al., 2009). In a 50-centre worldwide study, median effective dose was 12 mSv (Hausleiter et al., 2009). In Hausleiter et al's study, there was a 6-fold range in median doses among sites performing CTCA. EGTCM was associated with a reduction in dose-length product and effective dose of 25% (95% confidence interval 23-28%), use of an x-ray tube voltage of 100 kV was associated with a reduction of 46% (95% confidence interval 42-51%), and use of axial step-and-shoot scanning was associated with a reduction of 78% (95% confidence interval 77-79%) (Hausleiter et al., 2009). Other single-centre studies have evaluated axial step-and-shoot scanning, and typically report effective doses in the 2-4 mSv range (Earls and Schrack, 2008). In comparison to conventional helical scanning, volume scanning has been associated with a dose reduction of 84%, (Einstein et al., 2010), and high-pitch helical scanning has been associated with effective dose of <1 mSv for patients with a slow (≤60 bpm) heart rate who weigh ≤100 kg (Achenbach et al., 2010), using a k factor of 0.014 $mSv \cdot mGy^{-1} \cdot cm^{-1}$.

(171) The wide range of values for effective dose seen in clinical practice makes it impossible to provide "typical" values for cardiac CT. Effective dose is dependent on both the CT scanner and the protocol used. Estimates of approximate average values are presented in Table 8.1, but it must be appreciated that these values should not be considered as typical values, target values, or representative of clinical practice at any one institution.

Table 8.1 Estimated Approximate Average Effective Dose for Various Types of Cardiac CT Examinations

Examination	Effective Dose (mSv)*
CT coronary angiography (CTCA) (helical)	19
CT coronary angiography (CTCA) (tube current modulation)	13
CT coronary angiography (CTCA) (prospectively gated)	4
Coronary artery calcium scoring (CAC)	2

*The data in the Table are reproduced from Einstein, 2009. For other estimates of effective dose, see, e.g., Einstein et al, 2007; Hausleiter et al, 2009; Kim et al, 2009; Smith-Bindman et al, 2009; Earls and Schrack, 2009; Raff et al, 2009.

(172) Effective doses reported in many of the studies assessing CT protocols are determined on a patient-by-patient basis. The existence of conversion factors, such as those in the European Guidelines on Quality Criteria for CT (Bongartz et al., 2000; Bongartz et al.), make it easy for an investigator to estimate an "effective dose" for a single study from the DLP reported on the scanner, but this is not the intended use of effective dose (Einstein et al., 2008; Gerber et al., 2009; ICRP 2007b). Citation of these studies is not an endorsement of this approach by the Commission. When the Commission introduced effective dose in 1990 (ICRP, 1991), it was defined for populations, not for specific individuals. This has not changed.

8.6 Radiological Protection of Patients in Cardiac CT

(173) The general principles of radiological protection (chapter 4), i.e., justification and optimisation, can be applied to the protection of patients in cardiac CT. Dose limitation is not appropriate, but diagnostic reference levels should be used to help manage the radiation dose so that the dose is commensurate with the clinical purpose (ICRP, 2007b, ICRP, 2007c).

8.6.1 Justification

(174) The Commission recommends the development and application of appropriate use criteria for cardiac CT. Appropriate indications for cardiac CT are available from professional organizations and should be used (Taylor et al, 2010; Schroeder et al., 2008).

(175) In reports from one institution, 46% of CTCA studies but only 11% of stress SPECT studies were unclassifiable in terms of appropriateness, and of the remaining classifiable studies, 51% of CTCA studies and 72% of stress SPECT studies were appropriate.(Gibbons et al., 2008; Miller et al.) It is unclear from these data whether the difference between modalities primarily reflects a limitation with the first version of the U.S. CTCA appropriateness criteria, which left many studies unclassifiable, or whether CTCA studies are less likely to be performed for appropriate indications that SPECT studies. Further investigation is required, and programs to ensure maximal adherence to appropriate use criteria are also encouraged.

8.6.2 Optimization

(176) As discussed in section 8.3, the operator controls numerous scan parameters that affect patient dose. The operator should be provided with appropriate guidelines for mAs and kVp selection as a function of patient body habitus. Special consideration should be given to reducing mAs and/or kVp when evaluation of coronary plaques and stenoses is not the primary aim, e.g. for evaluation of possible anomalous coronaries, or prior to repeat cardiac surgery to assess the course of bypass grafts in relation to the sternum. Scan length should be limited to that needed to reliably image the volume of interest.

(177) The operator should be provided with appropriate guidelines for selection of the scan mode. Scan modes that reduce dose should be employed as appropriate (Gerber et al., 2009). Scans performed for calcium scoring should be performed using axial imaging, and in combined studies should be reviewed prior to performance of CTCA. The presence of widespread, heavy coronary calcification may suggest that CTCA should not be performed, due to the high likelihood of unevaluable coronary segments. For all patients, with the possible exception of patients scanned on a multiple-source scanner with variable pitch, rate-control agents should be given as needed with the goal of decreasing heart rate to approximately 60 beats per minute.

(178) The Commission recommends formal training in radiological protection, and in particular in the application of the principles of justification and optimization, for all physicians who refer patients for, or perform, cardiac CT studies (ICRP 113, 2011). This includes cardiologists, radiologists, nuclear medicine specialists, and internists.

(179) Quality improvement programs have been shown to decrease radiation dose substantially for CTCA (Raff et al., 2009), and thus their implementation is encouraged.

8.6.3 Diagnostic Reference Levels

(180) Diagnostic reference levels are used in medical imaging to indicate whether, in routine conditions, the levels of patient dose from, or administered activity for, a specified imaging procedure are unusually high or low for that procedure (ICRP, 2007b). They are discussed further in Chapter 10. If so, a local review should be initiated to determine whether protection has been adequately optimised or whether corrective action is required.

(181) Professional medical bodies (in conjunction with national health and radiological protection authorities) are encouraged to set diagnostic reference levels that best meet their specific needs and that are consistent for the regional, national, or local area to which they apply (ICRP, 2007c). At present, no diagnostic reference levels exist for cardiac CT.

8.7 References

Abada, H.T., Larchez, C., Daoud, B., Sigal-Cinqualbre, A., Paul, J.F., 2006. MDCT of the coronary arteries: feasibility of low-dose CT with ECG-pulsed tube current modulation to reduce radiation dose. AJR Am J Roentgenol 186, S387-390.

Abdulla, J., Abildstrom, S.Z., Gotzsche, O., Christensen, E., Kober, L., Torp-Pedersen, C., 2007. 64-multislice detector computed tomography coronary angiography as potential alternative to conventional coronary angiography: a systematic review and meta-analysis. Eur Heart J 28, 3042-3050.

Achenbach, S., Marwan, M., Ropers, D., Schepis, T., Pflederer, T., Anders, K., Kuettner, A., Daniel, W.G., Uder, M., Lell, M.M., 2010. Coronary computed tomography angiography with a consistent dose below 1 mSv using prospectively electrocardiogram-triggered high-pitch spiral acquisition. Eur Heart J 31, 340-346.

Bischoff, B., Hein, F., Meyer, T., Hadamitzky, M., Martinoff, S., Schomig, A., Hausleiter, J., 2009. Impact of a reduced tube voltage on CT angiography and radiation dose: results of the PROTECTION I study. JACC Cardiovasc Imaging 2, 940-946.

Block, M., Bove, A.A., Ritman, E.L., 1984. Coronary angiographic examination with the dynamic spatial reconstructor. Circulation 70, 209-216.

Bongartz, G., Golding, S.J., Jurik, A.G., Leonardi, M., van Meerten, E.v.P., Geleijns, J., Jessen, K.A., Panzer, W., Shrimpton, P.C., Tosi, G., 2000. European Guidelines on Quality Criteria for Computed Tomography. EUR 16262. The European Commission's Study Group on Development of Quality Criteria for Computed Tomography.

Bongartz, G., Golding, S.J., Jurik, A.G., Leonardi, M., van Meerten, E.v.P., Rodríguez, R., Schneider, K., Calzado, A., Geleijns, J., Jessen, K.A., Panzer, W., Shrimpton, P.C., Tosi, G., 2004 CT Quality Criteria, European Commission.

Christner, J.A., Kofler, J.M., McCollough, C.H., 2010. Estimating effective dose for CT using dose-length product compared with using organ doses: consequences of adopting International Commission on Radiological Protection publication 103 or dual-energy scanning. AJR Am J Roentgenol 194, 881-889.

Earls, J.P., Schrack, E.C., 2009. Prospectively gated low-dose CCTA: 24 months experience in more than 2,000 clinical cases. Int. J. Cardiovasc. Imaging 25, 177-187.

Einstein, A.J., Elliston, C.D., Arai, A.E., Chen, M.Y., Mather, R., Pearson, G.D.N., DeLaPaz, R.L., Nickoloff, E., Dutta, A., Brenner, D.J., 2010. Radiation dose from single heartbeat coronary CT angiography performed using a 320 detector-row volume scanner. Radiology 254, 698-704.

3900 Einstein, A.J., 2009. Medical imaging: the radiation issue. Nat. Rev. Cardiol. 6, 436-438.
3901 Einstein, A.J., Moser, K.W., Thompson, R.C., Cerqueira, M.D., Henzlova, M.J., 2007.
3902 Radiation dose to patients from cardiac diagnostic imaging. Circulation 116, 1290-
3903 1305.
3904 Einstein, A.J., Sanz, J., Dellegrottaglie, S., Milite, M., Sirol, M., Henzlova, M.,
3905 Rajagopalan, S., 2008. Radiation dose and cancer risk estimates in 16-slice computed
3906 tomography coronary angiography. J Nucl Cardiol 15, 232-240.
3907 Gerber, T.C., Carr, J.J., Arai, A.E., Dixon, R.L., Ferrari, V.A., Gomes, A.S., Heller,
3908 G.V., McCollough, C.H., McNitt-Gray, M.F., Mettler, F.A., Mieres, J.H., Morin,
3909 R.L., Yester, M.V., 2009. Ionizing Radiation in Cardiac Imaging. A Science
3910 Advisory From the American Heart Association Committee on Cardiac Imaging of
3911 the Council on Clinical Cardiology and Committee on Cardiovascular Imaging and
3912 Intervention of the Council on Cardiovascular Radiology and Intervention.
3913 Circulation 119, 1056-1065.
3914 Gerber, T.C., Stratmann, B.P., Kuzo, R.S., Kantor, B., Morin, R.L., 2005. Effect of
3915 acquisition technique on radiation dose and image quality in multidetector row
3916 computed tomography coronary angiography with submillimeter collimation.
3917 Invest.Radiol. 40, 556.
3918 Gibbons, R.J., Miller, T.D., Hodge, D., Urban, L., Araoz, P.A., Pellikka, P., McCully,
3919 R.B., 2008. Application of appropriateness criteria to stress single-photon emission
3920 computed tomography sestamibi studies and stress echocardiograms in an academic
3921 medical center. J Am Coll Cardiol 51, 1283-1289.
3922 Hausleiter, J., Meyer, T., Hadamitzky, M., Huber, E., Zankl, M., Martinoff, S., Kastrati,
3923 A., Schomig, A., 2006. Radiation dose estimates from cardiac multislice computed
3924 tomography in daily practice: impact of different scanning protocols on effective
3925 dose estimates. Circulation 113, 1305.
3926 Hausleiter, J., Meyer, T., Hermann, F., Hadamitzky, M., Krebs, M., Gerber, T.C.,
3927 McCollough, C., Martinoff, S., Kastrati, A., Schömig, A., Achenbach, S., 2009.
3928 Estimated radiation dose associated with cardiac CT angiography. JAMA 301, 500-
3929 507.
3930 Hausleiter, J., Martinoff, S., Hadamitzky, M., Martuscelli, E., Pschierer, I., Feuchtner,
3931 G.M., Catalan-Sanz, P., Czermak, B., Meyer, T.S., Hein, F., Bischoff, B., Kuse, M.,
3932 Schomig, A., Achenbach, S., 2010. Image quality and radiation exposure with a low
3933 tube voltage protocol for coronary CT angiography. Results of the PROTECTION II
3934 Trial. JACC Cardiovasc Imaging 3, 1113-1123.
3935 Hounsfield, G.N., 1979. Computed medical imaging. Nobel lecture, 8 December 1979.
3936 ICRP, 1991. 1990 Recommendations of the International Commission on Radiological
3937 Protection. ICRP Publication 60. Ann. ICRP 21, 1-201.
3938 ICRP, 2007a. Managing patient dose in multi-detector computed tomography (MDCT).
3939 ICRP Publication 102. Ann. ICRP 37(1), 1-79.
3940 ICRP, 2007b. The 2007 recommendations of the International Commission on
3941 Radiological Protection. ICRP Publication 103. Ann. ICRP 37, 1-332.
3942 ICRP, 2007c. Radiological Protection in Medicine. ICRP Publication 105. Ann. ICRP
3943 37(6), 1-64.

IEC, 2009. Medical Electrical Equipment - Part 2-44: Particular Requirements for the Safety of X-ray Equipment for Computed Tomography. International Standard IEC 60601-2-44. 3rd Edition. International Electrotechnical Commission, Geneva.

Jakobs, T.F., Becker, C.R., Ohnesorge, B., Flohr, T., Suess, C., Schoepf, U.J., Reiser, M.F., 2002. Multislice helical CT of the heart with retrospective ECG gating: reduction of radiation exposure by ECG-controlled tube current modulation. Eur.Radiol. 12, 1081.

Kim, K.P., Einstein, A.J., Berrington de Gonzalez, A., 2009. Coronary artery calcification screening: estimated radiation dose and cancer risk. Arch. Intern. Med. 169, 1188-1194.

McCollough, C.H., 2008. CT dose: how to measure, how to reduce. Health Physics 95, 508-517.

Miller, J.A., Raichlin, E., Williamson, E.E., McCully, R.B., Pellikka, P.A., Hodge, D.O., Miller, T.D., Gibbons, R.J., Araoz, P.A., 2010. Evaluation of coronary CTA Appropriateness Criteria in an academic medical center. J Am Coll Radiol 7, 125-131.

Morin, R.L., Gerber, T.C., McCollough, C.H., 2003. Radiation dose in computed tomography of the heart. Circulation 107, 917.

Raff, G.L., Chinnaiyan, K.M., Share, D.A., Goraya, T.Y., Kazerooni, E.A., Moscucci, M., Gentry, R.E., Abidov, A., 2009. Radiation dose from cardiac computed tomography before and after implementation of radiation dose-reduction techniques. JAMA 301, 2340-2348.

Sanz, J., Rius, T., Kuschnir, P., Fuster, V., Goldberg, J., Ye, X.Y., Wisdom, P., Poon, M., 2005. The importance of end-systole for optimal reconstruction protocol of coronary angiography with 16-slice multidetector computed tomography. Invest.Radiol. 40, 155.

Schroeder, S., Achenbach, S., Bengel, F., Burgstahler, C., Cademartiri, F., de Feyter, P., George, R., Kaufmann, P., Kopp, A.F., Knuuti, J., Ropers, D., Schuijf, J., Tops, L.F., Bax, J.J., 2008. Cardiac computed tomography: indications, applications, limitations, and training requirements: report of a Writing Group deployed by the Working Group Nuclear Cardiology and Cardiac CT of the European Society of Cardiology and the European Council of Nuclear Cardiology. Eur Heart J 29, 531-556.

Smith-Bindman, R., Lipson, J., Marcus, R., Kim, K.P., Mahesh, M., Gould, R., Berrington de Gonzalez, A., Miglioretti, D.L., 2009. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. Arch. Intern. Med. 169, 2078-2086.

Taylor, A.J., Cerqueira, M., Hodgson, J.M., Mark, D., Min, J., O'Gara, P., Rubin, G.D., Kramer, C.M., Berman, D., Brown, A., Chaudhry, F.A., Cury, R.C., Desai, M.Y., Einstein, A.J., Gomes, A.S., Harrington, R., Hoffmann, U., Khare, R., Lesser, J., McGann, C., Rosenberg, A., Schwartz, R., Shelton, M., Smetana, G.W., Smith, S.C., Jr., 2010. ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 appropriate use criteria for cardiac computed tomography: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the Society of Cardiovascular Computed Tomography, the American College of Radiology, the

American Heart Association, the American Society of Echocardiography, the American Society of Nuclear Cardiology, the North American Society for Cardiovascular Imaging, the Society for Cardiovascular Angiography and Interventions, and the Society for Cardiovascular Magnetic Resonance. J. Am. Coll. Cardiol. 56, 1864-1894.

9. RADIOLOGICAL PROTECTION TRAINING FOR INTERVENTIONAL FLUOROSCOPY

Main Points

- **Interventional cardiologists worldwide typically have little or no training in radiological protection (RP).**
- **Legislation in most countries requires that individuals who take responsibility for medical exposures must be properly trained in RP.**
- **Training activities in RP should be followed by an evaluation of the knowledge acquired from the training programme (a formal examination system).**
- **Physicians who have completed training should be able to demonstrate that they possess the knowledge specified by the curriculum by passing an appropriate certifying examination.**
- **In addition to the training recommended for other physicians who use X-rays, interventionalists, including interventional cardiologists, should receive a second, higher level of RP training.**
- **Nurses and other healthcare professionals who assist during fluoroscopic procedures should be familiar with radiation risks and radiological protection principles, in order to minimise their own exposure and that of others.**
- **Training programmes should include both initial training for all incoming staff and regular updating and retraining.**
- **Scientific congresses should include refresher courses on RP, attendance at which could be a requirement for continuing professional development**

9.1 Introduction

(182) Despite the extensive and routine use of x-rays in their clinical practice, interventional cardiologists (IC) worldwide typically have little or no training in radiological protection (RP). Traditionally, medical students do not receive training in RP during medical school. Medical professionals who subsequently specialise in radiological specialties, such as diagnostic radiology, nuclear medicine and radiotherapy, are taught radiological physics and RP as part of their specialty training. In many countries, there is no teaching of RP during training in other specialties, such as medicine and cardiology.

(183) In the past, training in radiological physics and RP was not necessary for non-radiologists, as x-rays and other radiation sources were employed only in radiology departments, by staff with reasonable training in RP. Although x-ray fluoroscopy has been in use for more than a century now, its early application involved visualization of body anatomy, movement of structures or passage of contrast media through the body. Radiologists normally performed these procedures. When fluoroscopically guided interventions were introduced, other specialists (cardiologists and an increasing number

of clinicians in other medical specialties) began performing these procedures. Initially, they did so jointly with radiologists, in radiology departments. Over the years, x-ray equipment was installed in other clinical departments and used by non-radiologists without radiologist participation. These non-radiologists were not subject to the training requirements of radiological physics and RP that were mandatory for radiologists. It is now clear that this training is essential; hence the need for specific guidance for cardiology.

(184) The Commission has addressed the specifics of training for interventionalists and nuclear medicine specialists, among others, in ICRP Publication 113 (ICRP 113, 2009). Further information on training in nuclear medicine is presented in Section 7.7.2.

9.2 Requirements on Radiological protection

(185) In its Publications 85 and 113, the Commission recommends a second level of RP training for interventional radiologists and cardiologists, in addition to the training recommended for other physicians who use X-rays (ICRP 85, 2000, ICRP 113, 2009). The Commission also recommends that nurses and other healthcare professionals who assist during fluoroscopic procedures should be familiar with radiation risks and precautions, in order to minimise their own exposure and that of others.

(186) Training activities in RP should be followed by an evaluation of the knowledge acquired from the training programme. Education and training in RP should be complemented by formal examination systems to test competency before the person is awarded certification. If certification in RP is required for some medical specialties (e.g. interventional cardiology), certification should be obtained before the professional practices the specialty.. Training programmes should include both initial training for all incoming staff and regular updating and retraining. Scientific and professional societies should contribute to the development of the training syllabuses to ensure a consistent approach, and to promote and support the education and training. Scientific congresses should include refresher courses on RP, attendance at which could be a requirement for continuing professional development for professionals using ionising radiation. (ICRP 113, 2009).

(187) The International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources (BSS), published by the International Atomic Energy Agency (IAEA) and jointly sponsored by the Food and Agriculture Organization (FAO), the International Labour Organization (ILO), the Pan American Health Organization (PAHO) and the World Health Organization (WHO) (IAEA, 1996), require appropriate training that is sufficient to perform assigned tasks in the conduct of diagnostic or therapeutic procedures involving radiation.

(188) The Medical Exposure Directive of EC 97/43/Euratom considers interventional radiology (Article 9) as a special practice involving high doses to patients (EU, 1997). According to Article 7, Member States shall ensure that the practitioner has adequate theoretical and practical training for the purpose of radiological practice as well as relevant competence in radiological protection. No special mention is made of interventional cardiology.

(189) Legislation in most countries requires that individuals who take responsibilities for medical exposure must be properly trained in RP. However, a training system and accreditation mechanism is still lacking in many countries.

9.3 Training guidelines, curricula and materials

(190) The Commission, in Publication 85 (ICRP, 2000), states that interventional procedures are complex and demanding and that radiation dose tends to be operator dependent. It is particularly important that individuals performing these procedures are adequately trained both in clinical techniques and in radiological protection. It further states that special additional training should be planned when new x-ray systems or techniques are implemented in a centre. Basic and continuing training in radiological protection should be an integral part of this education. Training requirements are addressed in Publication 113 (ICRP 113, 2009).

(191) In view of the number of radiation-induced injuries reported in recent years among patients undergoing interventional procedures (Rehani and Ortiz-Lopez, 2005, Vano and Gonzalez, 2005, ICRP, 2000, Koenig et al, 2001), a number of organizations have begun to provide recommendations for training requirements. Published guidelines were initially for interventional radiologists, but they are gradually becoming available from cardiology societies.

9.3.1 USA

(192) The Food and Drug Administration (FDA) advisory of 1994 (FDA, 1994) alerted facilities to ensure proper training. FDA's specific recommendations for facilities in which invasive procedures are performed included the following:

- Assure appropriate credentials and training for physicians performing fluoroscopy.
- All operators of the system must be trained and understand the operation of the fluoroscopic system, including the implications for radiation exposure from each mode of operation.
- Facilities should ensure that physicians performing fluoroscopic procedures are educated so that they may, on a case-by-case basis, assess risks and benefits for individual patients, considering variables such as age, beam location and direction, tissues in the beam and previous fluoroscopic procedures or radiation therapy.

(193) In 1995, the American College of Cardiology Cardiac Catheterization Committee published a Position Statement indicating that appropriate training of staff is imperative, and that ‘‘Proper instruction in the principles of radiation physics and safety should be a part of every cardiologist's education" (Brinker et al., 1995). The American

College of Cardiology Consensus Document further clearly delineated the need for a radiation safety knowledge base for cardiology staff (Limacher et al., 1998).

(194) In 2004, an American College of Cardiology/American Heart Association/ American College of Physicians (ACC/AHA/ACP) Task Force published a further report on clinical competence and training as a companion to the ACC's 1998 report (Hirshfeld et al, 2004; Limacher et al, 1998). The proposed curriculum in the 2004 document specifies the knowledge that a qualified physician should possess in order to be credentialed to use x-ray fluoroscopic machines, but does not specify a minimum number of hours of training. Physicians who have completed training should be able to demonstrate that they possess the knowledge specified by the curriculum by passing an appropriate certifying examination.

(195) The necessary knowledge depth varies, depending upon the types of fluoroscopically guided procedures a particular physician performs. The ACC/AHA/ACP document outlines two different curricula—basic and advanced. The basic curriculum is appropriate for physicians who perform simpler fluoroscopically guided critical-care unit procedures such as right heart catheterization, temporary pacemaker placement, and intra-aortic balloon pump placement. The advanced curriculum is appropriate for physicians who perform angiographic, interventional, and electrophysiological procedures that employ greater amounts of radiation in more complex circumstances with different purposes and a greater attendant risk of patient and personnel injury.

(196) The National Council on Radiation Protection and Measurements (NCRP) in the U.S. recently published a report on radiation dose management for fluoroscopically guided interventional medical procedures (NCRP, 2010). This report makes a number of specific recommendations, including:

- Each individual present in a fluoroscopically guided interventional (FGI) procedure room shall have appropriate radiological protection training.
- Every person who operates or supervises the use of FGI equipment shall have current training in the safe use of that specific equipment.
- Interventionalists who perform FGI procedures or other procedures with the potential for high patient doses require additional knowledge and training beyond that necessary for interventionalists whose practice is limited to low-dose FGI procedures.
- Clinical training and experience is not an acceptable substitute for formal training in radiation management.

9.3.2 European Commission

(197) In compliance with European Commission requirements, an outline for specific training in radiological protection for interventional radiology has been developed (EC, 2000; Vañó et al. 1997). Although there is no special mention of interventional cardiology in the group of professionals, the table giving suggested number of training hours has a column for interventional cardiology specialists; 20-30 hours of training are suggested. The initial Spanish experience, based on these guidelines, has been reported (Vañó, 2003). This included development of a training CD (MARTIR, 2002).

9.3.3 International Atomic Energy Agency

(198) The International Atomic Energy Agency (IAEA) has developed a curriculum with educational objectives specifically for interventional cardiologists. It is directed primarily at developing countries where the cardiology professional societies are not yet sufficiently robust to develop their own separate modules for basic and advanced curricula in the field of radiological protection. For these countries a "sandwich" module is ideal, particularly in view of the lack of individuals with sufficient expertise in radiological protection in diagnostic imaging to teach the subject. IAEA has also prepared educational material in the form of an electronic presentation on CD. This IAEA training material on Radiation Protection in Cardiology is available without cost and can be obtained by writing to patient.protection@iaea.org or downloaded from the website http://rpop.iaea.org.

9.3.4 WHO

(199) The World Health Organization (WHO) has stated that specific training in interventional radiology is required in addition to basic training and has provided training requirements (WHO 2000). WHO further stated that the training process must be continued when new techniques are introduced, when new radiological systems are installed and when new staff are appointed. It also recommended continuous training and refresher courses at regular intervals. However, interventional cardiology was outside the scope of this document.

9.4 Credentialing

(200) There is a distinction between the credentialing of a physician as technically competent to perform a procedure versus the credentialing of the same physician as competent to safely use a fluoroscope. Since the amount of radiation employed by the interventional cardiologist both per patient and annually is no less than that used by an interventional radiologist, the training standards of radiation physics and radiological protection in interventional cardiology should be the same as for other interventionalists (ICRP 113, 2009).

9.5 References

Brinker, J.A. et al, 1995. Position paper of the American College of Cardiology Cardiac Catheterization Committee. JACC 26, 319-325.

EU, 1997. Council Directive 97/43 Euratom, on health protection of individuals against the dangers ionizing radiation in relation to medical exposure, and repealing Directive 84/466 Euratom. Official Journal of the European Communities No L 180, 9th July 1997:22-7.
http://europa.eu.int/comm/energy/nuclear/radioprotection/legislation_en.htm

EC, 2000. Guidelines on education and training in radiation protection for medical exposures. Radiation Protection 116, European Commission. Directorate General Environment, Nuclear Safety and Civil Protection. Luxembourg, 2000. Available at: http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/116.pdf Accessed January 2, 2011.

FDA, 1994. Avoidance of serious x-ray-induced skin injuries to patients during fluoroscopically-guided procedures. Statement 9 Sept. 1994, Food and Drug Administration, Rockville, MD, USA.

Hirshfeld, J.W., Jr., Balter, S., Brinker, J.A., Kern, M.J., Klein, L.W., Lindsay, B.D., Tommaso, C.L., Tracy, C.M., Wagner, L.K., 2004. ACCF/AHA/HRS/SCAI clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures: a report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training. J. Am. Coll. Cardiol. 44, 2259-2282.

IAEA, 1996. International Basic Safety Standards against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, Vienna: IAEA.

ICRP, 2000. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85, Annals of the ICRP 30 (2).

ICRP, 2009. Radiological protection education and training for healthcare staff and students (diagnostic imaging and interventional procedures). ICRP Publication 113. Ann ICRP 39 (5).

Koenig TR, Wolff D, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: Part 1, Characteristics of radiation injury. AJR 2001; 177: 3-11

Limacher, M.C. et al, 1998. Radiation safety in the practice of cardiology. JACC 31, 892-913.

MARTIR (Multimedia and Audiovisual Radiation Protection Training in Interventional Radiology), 2002. CD-ROM. Radiation Protection 119, European Commission. Directorate General Environment, Nuclear Safety and Civil Protection. Luxembourg (free availability at http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm; go to publication 119).

NCRP, 2010. Radiation dose management for fluoroscopically guided medical procedures. Report No. 168. National Council on Radiation Protection and Measurements, Bethesda, MD.

Rehani, M.M. and Ortiz-Lopez, P., 2006. Radiation effects in fluoroscopically guided cardiac interventions - keeping them under control. Int. J. Cardiol. 109(2), 147-151.

Vano E, and Gonzalez L. 2005. Accreditation in radiation protection for cardiologists and interventionalists. Radiat Prot Dosimetry. 117(1-3):69-73.

Vañó, E., Gonzalez, L., Faulkner, K. et al, 1997. Specific training objectives in radiation protection for medical staff in interventional radiology installations. Draft document. DIMOND European Concerted Action.

Vañó, E., Gonzalez, L., Canis, M. et el., 2003. Training in radiological protection for interventionalists. Initial Spanish experience. BJR 76, 217-219.

WHO, 2000. Efficacy and radiation safety in interventional radiology. World Health Organisation, Geneva.

10. QUALITY ASSURANCE PROGRAMMES

Main Points

- **Two basic objectives of the radiological protection quality assurance programme (QAP) are to evaluate patient radiation dose on a periodic basis and to monitor occupational radiation dose for workers in cardiology facilities where radiation is used.**
- **Training in RP (both initial and retraining) should be included in the QAP for all staff involved in interventional cardiology procedures.**
- **A cardiologist should be in charge of the QAP aspects of RP for cardiology procedures, and should be assisted by a medical physicist.**
- **A senior interventionalist and a medical physicist should be included in the planning for a new interventional fluoroscopy laboratory, installation of a new x-ray or nuclear medicine system and the upgrade of existing equipment.**
- **Periodic evaluation of image quality and procedure protocols should be included in the QAP.**
- **The QAP should ensure the regular use of personal dosimeters and include a review of all abnormal dose values.**
- **The QAP should establish a trigger level for individual clinical follow-up when there is a risk of radiation-induced skin injuries.**
- **Patient dose reports should be produced at the end of procedures, archived and recorded in the patient's medical record. If dose reports are not available, dose values should be recorded in the patient's medical record together with procedure and patient identification.**
- **Patient dose audits (including comparison with DRLs) and reporting are important components of the QAP.**

10.1 Introduction

(201) Quality assurance programs in cardiology should cover all of the planned and systematic actions necessary to provide confidence that optimum quality has been achieved in the entire diagnostic process, i.e. there is consistent production of adequate diagnostic information with the lowest acceptable exposure of patients and personnel (WHO 1982).

(202) A quality assurance programme (QAP) for interventional cardiology includes all of the aspects of radiological protection (RP) of patients and staff in addition to the usual clinical aspects. Only the RP aspects are discussed here. Two basic objectives of the QAP are to evaluate patient radiation dose on a periodic basis and to monitor occupational radiation dose for workers in cardiology facilities where radiation is used. Table 10.1 summarizes the 10 key points to be included in a RP QAP. The RP component of the QAP for interventional cardiology should be an independent portion of the general QAP for x-ray installations in a particular health centre.

(203) A cardiologist should be in charge of the QAP aspects of RP for cardiology, and should be assisted by a medical physicist. The RP QAP for cardiology should be reviewed at least annually, to allow the opportunity for updates and periodic follow up. Self-audit of the QAP is also advisable. Table 10.2 presents some questions to be answered as part of this internal audit of the QAP.

10.2 Facilities

(204) The design of a new interventional fluoroscopy laboratory, the selection and installation of a new x-ray or nuclear medicine system and the upgrade of existing equipment are all complex and expensive processes. Planning for these processes should include RP. Both a senior physician (interventionalist, nuclear medicine specialist or CT imaging specialist, as appropriate) and a medical physicist should be included in this planning. Physicians representing all of the medical specialties who will be using the new room should be involved in specifying the equipment for the room. Important aspects to consider are shown in Table 10.3.

(205) Suggested architectural specifications for catheterization laboratories have been published by scientific societies (ACC/AHA 1991): adequate dimensions (50 m^2), a sufficiently large control room with a wide leaded window, sufficient ceiling height (3 m, allowing for ceiling suspended support of the C-arm, monitors, etc.), appropriate radiation shielding (including window and doors), easy access for personnel and patients, etc. New x-ray rooms should be of sufficient size to allow personnel to be positioned at a distance from the patient when inside the X ray room during the procedures. The installation should include a control room with a wide shielded glass window, so that other clinicians and other personnel can follow the procedures without radiation exposure.

(206) Appropriate shielding, access to the x-ray room and RP tools (aprons, thyroid protectors, protective gloves and glasses, protective screens, ceiling-suspended and under-table shields), should be part of the planning for catheterization laboratories.

Dose reduction technology, including the capabilities to measure, record, and transfer patient dose data to the patient's medical record, should be considered an important factor in the selection of new fluoroscopy and CT equipment. Appropriate standards should be taken into account (IEC 2010).

10.3 Acceptance and constancy testing

(207) Acceptance tests shall be made by the company supplying the equipment in the presence of technical personnel from the centre buying the system, or by centre technical personnel. Commissioning of the new equipment before its clinical use should be the responsibility of the personnel of the centre.

(208) Periodic quality controls (QC), including dosimeter calibration, should be planned taking into account international standards, local recommendations and the recommendations of the x-ray system manufacturer. These should also include practical results for the appropriate management of patient doses by the cardiologists (e.g. dose rate

in the different fluoroscopy modes, dose per frame during cine acquisition, CT scan protocols).

(209) Periodic evaluation of image quality and procedure protocols should also be included in the QAP. Image quality should be measured with test objects during the acceptance and constancy tests. With the new digital imaging detectors it is possible to select a wide range of dose values to obtain the required level of quality in the images. It is easy to specify excessive dose rates, as these do not impair image quality and are not easily detected from inspection of the image. Cardiologists, in cooperation with the medical physicist and the industry engineer should set the fluoroscopic or CT system doses to achieve the appropriate balance between image quality and dose.

(210) It is possible to perform this periodic evaluation of image quality using clinical criteria. The European consortium DIMOND (DIMOND 2008) has proposed a set of criteria to evaluate fluoroscopic cardiac imaging (Bernardi 2001a and 2001b).

(211) Cardiologists should learn the dose required to obtain a certain level of diagnostic information. For interventional fluoroscopy, this is related to fluoroscopy time, number of series, number of frames/series, fluoroscopy and cine modes and dose rates, etc.). It is also important to verify that wedge filters, collimation and C-arm angulations are used properly. CT scan protocols, modes, and technique factors, and their effect on patient dose, are discussed in Chapter 8. Concerns related to nuclear medicine doses are discussed in Chapter 7.

10.4 Staff

(212) An important aspect of the QAP is a description of the roles and responsibilities of personnel. There should be enough staff to avoid an excessive number of procedures per specialist, and sufficient nursing and technologist support. Support by network specialists (for new digital systems), maintenance and service personnel and medical physics specialists is advised.

(213) Analysis of staff radiation dose should be included in the QAP. Calibrated dosimeters for staff must be available. In addition to the dosimeter in the x-ray system for the evaluation of patient dose, personnel working in the catheterization laboratories should wear appropriate dosimeters, and a strict policy for their use should be implemented. Additional electronic dosimeters may also be useful, especially for RP training of students and inexperienced personnel. The QAP should ensure the regular use of personal dosimeters and include a review of all abnormal dose values.

10.5 Training

(214) Training in RP is another important item to be included in the QAP. Initial accreditation in RP should follow local requirements. Special attention to training in RP should be given to fellows and residents. Seminars to analyse patient and staff dose results can be an excellent educational tool as well as a useful QA activity. Training is discussed in more detail in chapter 9 and in ICRP Publication 113 (ICRP, 2009).

10.6 Follow-up for possible radiation-induced skin injuries for interventional fluoroscopy procedures

(215) The QAP should establish a trigger level for individual clinical follow-up when there is a risk of radiation-induced skin injuries (ICRP 2000; WHO 2000; NCRP 168). The Substantial Radiation Dose Level (SRDL) is a threshold value that is used to trigger additional dose management actions, including patient follow-up (NCRP 2010). There is no implication that a radiation dose below the SRDL is completely safe or that a radiation dose above the SRDL will always cause an injury. Some suggested values are a skin dose of 3 Gy, a KAP of 500 Gy·cm^2, or an air kerma at the interventional reference point of 5 Gy (NCRP 168). For cardiology procedures, a KAP between 150 and 250 Gy·cm^2 may be more appropriate, depending on the radiation field size and the specific protocols. These values could indicate peak skin doses greater than 2 Gy in a single procedure. These values are intended to trigger follow-up for a radiation dose that might produce a clinically relevant injury in an average patient. Lower values may be used at the discretion of the facility, especially when previously irradiated skin is involved (NCI 2005).

(216) If the trigger level has been exceeded, the patient's personal physician should be informed about the patient's radiation dose and the possibility of ionising radiation effects. Appropriate clinical follow up should be arranged. If the dose estimate after the procedure is close to the threshold for deterministic effects then the patient should be informed of possible symptoms or observable skin effects by the interventionist or his/her staff. Information about what the patient should do in case these effects appear should be provided.

10.7 Dose audits

(217) Patient dose audits and reporting are important components of the QAP. Patient dose reports should be produced at the end of procedures, archived, and transferred to the patient's medical record. An example of a patient dose report is presented in chapter 5, Fig 5.2. If such reports are not available, dose values should be recorded together with the procedure and patient identification (Miller et al, 2004). If the reports are available only in hard copy (printed), relevant data should be transferred to an electronic database for further analysis. If the reports are available in electronic format, the files should be archived together with the images. For interventional fluoroscopy, quantities to be measured and recorded periodically for a significant number of patients include: KAP, reference point air kerma (if available in the x-ray system), fluoroscopy time, number of series, and number of frames (NCRP, 2010). Reference point air kerma measurement capability has become widely available in fluoroscopic equipment manufactured after mid-2006. For CT examinations, the quantities are $CTDI_w$, $CTDI_{vol}$ or DLP (section 8.3). For nuclear medicine studies, the quantity is administered activity.

(218) Dose audits should include an evaluation of the centre's performance with respect to established reference levels (section 10.7.1). Dose audits for interventional cardiology procedures require additional analyses (sections 10.7.3, 10.7.4), because these procedures also present a risk of deterministic injury.

10.7.1 Diagnostic Reference Levels

(219) Dose guidelines were first introduced in the U.S and the U.K. in the late 1980s and early 1990s (Wall, 1998). They were introduced into ICRP recommendations as "investigation levels" in Publication 60 (ICRP, 1990) and as "diagnostic reference levels" (DRLs) in Publication 73 (ICRP, 1996). DRLs are now an established method of defining feedback levels for high volume examinations such as chest radiographs or mammograms. The Commission continues to recommend their use (ICRP 85, ICRP 103, ICRP 105).

(220) DRLs are used to help avoid radiation dose to the patient that does not contribute to the medical imaging task. They provide practitioners with a straightforward tool for comparing the radiation doses that they deliver to their patients with the radiation doses delivered by their colleagues. They are a guide to good practice, but are neither dose limits nor thresholds that define competent performance of the operator or the equipment. They are intended to provide guidance on what is achievable with current good practice rather than optimum performance, and help identify unusually high radiation doses or exposure levels. A mean dose for a procedure that is less than the reference level does not guarantee that the procedure is being performed optimally.

(221) To use DRLs as a quality improvement tool, an institution or individual practitioner collects radiation dose data for cases of a procedure performed in their own practice. The recommended number of cases varies from 10 to >50, with the latter number suggested for interventional fluoroscopy procedures because of the high individual variability in patient dose of cases of image-guided interventional procedures (Wall, 1998, Vano 2008). The mean radiation dose for the procedure is then compared to the DRL. If local practice results in a mean radiation dose that is greater than the DRL, the fluoroscopic equipment should be investigated. If the fluoroscopic equipment is functioning properly and within specification, operator technique and procedure protocols should be examined (Vano, 2001). Investigations are also appropriate where local values are substantially below the DRL, as excessively low doses may be associated with poor image quality.

10.7.2 Application of Diagnostic Reference Levels in interventional fluoroscopy procedures

(222) At present, there is little evidence to indicate that dose levels are decreasing in interventional cardiology. If anything, dose levels are increasing due to the increased complexity of fluoroscopically guided procedures. As the Commission has noted, reference levels, in principle, could be useful for dose optimization in interventional fluoroscopy procedures (ICRP 105). However, patient dose distributions for interventional fluoroscopy procedures extend over a wide range and are very variable due to the differing complexity of the procedures, different patient sizes and different operational modes. The Commission has suggested that a potential approach to this problem is to take into account

the relative "complexity" of the procedure (ICRP 105). Other methods have also been proposed (NCRP 2010).

(223) Recent studies have provided DRLs for cardiovascular procedures (Peterzol et al 2005, Neofotistou et al 2003, Balter et al 2008, D'Helft et al 2009). Some diagnostic invasive procedures (e.g., routine coronary angiography) are done in a relatively standardized way and in sufficient volumes that a valid DRL might be constructed.

(224) The European DIMOND consortium proposed provisional RLs for radiation doses delivered to patients during two types of invasive cardiology procedures, coronary angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA). The proposed DRLs for CA and PTCA were KAP values of 45 $Gy \cdot cm^2$ and 75 $Gy \cdot cm^2$, fluoroscopy times of 7.5 min and 17 min and 1250 and 1300 frames, respectively. The consortium concluded that more studies were required to establish "tolerances" from the proposed levels, taking into account the complexity of the procedure and the patient's size.

(225) Bernardi and co-workers performed studies in Udine, Italy (Bernardi, 2000) and later in several European hospitals (Neofotistou, 2003), with quantitative assessments of complexity in relation to a patient's exposure to radiation. The relationships between several clinical factors, anatomic factors and technical factors versus fluoroscopy time were evaluated for PTCA. A scoring system was developed, and two complexity indexes were conceived, based on which the procedures were divided into three groups: simple, medium, and complex. The relative complexity of procedures carried out in different centres should be taken into account when comparing typical patient doses with reference levels.

(226) The IAEA carried out an international project to determine the feasibility of establishing guidance levels for cardiac catheterization and percutaneous coronary interventions (IAEA, 2009). The IAEA report has been summarized in a separate publication (Balter et al, 2008). For PTCA procedures, the report recommended the use of a reference level, using KAP, of 100 $Gy \cdot cm^2$ for simple procedures, 125 $Gy \cdot cm^2$ for moderate complexity procedures and 200 $Gy \cdot cm^2$ for complex procedures. Unfortunately, methods for quantifying complexity have not yet been developed for other interventional cardiology procedures, such as electrophysiology ablation or pacemaker insertion.

10.7.3 Evaluation of high dose interventional fluoroscopy procedures

(227) Reference levels are used to evaluate the average dose per procedure. Because of the lognormal dose distribution that is characteristic of fluoroscopically guided interventions, an additional process is needed to evaluate the high dose "tail". The high dose tail is of particular interest, because this tail represents the cases where patient doses may be high enough to cause deterministic effects.

(228) Cases that required a radiation dose greater than the SRDL (section 10.6) should be identified and reported to the laboratory director and laboratory quality manager on a periodic basis. A monthly report is helpful, to ensure that patients with high radiation doses receive appropriate education and follow-up.

(229) For each such procedure, the report should include patient identifier(s), the dose delivered during the procedure, the type of procedure, the room in which the procedure was performed, the operator's name, a count of the patient's previous invasive procedures

(essential for estimating total skin dose), and any special notes. The goal of this report is to help assure that all patients who received a high radiation dose have been appropriately educated, and that appropriate follow-up is scheduled and performed (Miller et al, 2010).

(230) Cases resulting in possible radiation injuries should be discussed at the next laboratory QA meeting. This discussion should include any available diagnoses, planned patient follow-up, and outcomes. Unless it is clear that the injury was not radiation-induced, the procedure should be reviewed for the appropriate use of radiation in the clinical context (Miller et al, 2010).

10.7.4 Evaluation of skin dose for interventional fluoroscopy procedures

(231) It is advisable to measure the skin dose distribution in a sample of patients, to verify that basic aspects of patient protection are being followed (e.g. appropriate collimation, use of wedge filter, avoidance of a high concentration of radiation fields in the same skin area). (Vano 1997; Guibelalde 2003). Skin dose may be measured with special film, with dosimeters placed directly on the patient's skin, and by other means (Miller et al, 2004). A qualified physicist should be consulted for these measurements.

Table 10.1. Some key aspects to be included in the section of radiological protection of the quality assurance programme for cardiac facilities using ionising radiation.

1. Facility design.
2. X ray equipment (selection criteria).
3. Radiological protection tools.
4. Availability of dosimeters.
5. Availability of personnel and their responsibilities.
6. Training in radiological protection (initial and continuing).
7. Patient dose audit and reporting.
8. Clinical follow up for high patient doses
9. Image quality and procedure evaluation.
10. Staff doses.

Table 10.2. Examples of quality indicators

Can your centre report patient dose values from the last year?
Do you have a procedure for the clinical follow-up of high doses to patients?
Do you know the results of your x-ray system QCs?
Are you following your staff dose values?
Do you have a continuous training programme in RP?

Table 10.3 Facility procurement considerations (ICRP, 2000)

Analysis of clinical need	Workload
Equipment specification	General requirements
	Major equipment components
	Functional requirements
	Specific equipment requirements
Computer capabilities	Image display matrix
	Processing times
	Memory/image storage
	PACS linkages*
	HIS linkages†
Systems performance	Image quality
	Patient dose
	Dose control measures
User manuals	Technical training
	Operational training
Compliance with national and international standards	Electrical safety
	Mechanical safety
	Radiation safety
	Room design/shielding
Service and warranty	Maintenance programme
	Quality control programmes
	Access to service software protocols/ rationale for service schedules
Operation costs	Cost of consumables - projected over 5 years

*PACS=picture archiving and communication system
†HIS=hospital information system

REFERENCES

American College of Cardiology/American Heart Association ad hoc Task Force on Cardiac Catheterization. ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. JACC 1991; 18 (5): 1149 82.

Balter, S., Miller, D.L., Vano, E., Ortiz Lopez, P., Bernardi, G., Cotelo, E., Faulkner, K., Nowotny, R., Padovani, R., Ramirez, A., 2008. A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures. Med Phys 35, 673-680.

Bernardi G, Padovani R, Morocutti G, Vano E, Malisan MR, Rinuncini M, Spedicato L, Fioretti PM. Clinical and technical determinants of the complexity of percutaneous transluminal coronary angioplasty procedures: analysis in relation to radiation exposure parameters. Catheter Cardiovasc Interv 2000 Sep;51(1):1-9; discussion 10.

Bernardi G, Padovani R, Morocutti G, Spedicato L, Giannuleas JD, Neofotistou E, Manginas A, Goicolea JC, McNeill J, Vano E, Marzocchi A, Tsapaki V, Fioretti PM, Malone J. Quality criteria for cardiac images in diagnostic and interventional cardiology. Br J Radiol. 2001 Sep;74(885):852-5.

Bernardi G, Padovani R, Morocutti G, Spedicato L, Giannuleas JD, Neofotistou E, Maginas A, Goicolea JC, McNeill J, Vano E. A method based on DIMOND quality criteria to evaluate imaging in diagnostic and interventional cardiology. Radiat Prot Dosimetry. 2001;94(1-2):167-72.

D'Helft CJ, Brennan PC, McGee AM, et al. Potential Irish dose reference levels for cardiac interventional examinations. Br J Radiol 2009; 82:296-302

DIMOND. Available at http://www.dimond3.org/ Last updated October, 2008. Accessed May 9, 2011.

EC, 2000. Guidelines on education and training in radiation protection for medical exposures. Radiation Protection 116, European Commission. Directorate General Environment, Nuclear Safety and Civil Protection. Luxembourg, 2000. Available at: http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/116.pdf Accessed January 2, 2011.

Guibelalde E, Vano E, Gonzalez L, Prieto C, Fernandez JM, Ten JI. Practical aspects for the evaluation of skin doses in interventional cardiology using a new slow film. Br J Radiol. 2003 May;76(905):332-6.

Hirshfeld JW Jr, Balter S, Brinker JA, Kern MJ et al. American College of Cardiology Foundation; American Heart Association/; HRS; SCAI; American College of Physicians Task Force on Clinical Competence and Training. ACCF/AHA/HRS/SCAI clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures: a report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training. Circulation. 2005 Feb 1;111(4):511-32.

IAEA, 2009. Establishing guidance levels in x ray guided medical interventional procedures: A pilot study. Safety Reports Series No. 59. International Atomic Energy Agency, Vienna.

IEC, 2010. Medical electrical equipment. Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures. IEC 60601-2-43. 2nd edition. International Electrotechnical Commission. Geneva, Switzerland.

ICRP, 1990. The 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann ICRP 1991; 21(1-3):1-201

ICRP, 1996. Radiological protection and safety in medicine. ICRP Publication 73. Ann ICRP 26(2):1-47

ICRP, 2000. Avoidance of radiation injuries from medical interventional procedures. ICRP Publication 85. Ann ICRP 30(2):1-67

ICRP, 2007a. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103. Ann. ICRP 37, 1-332.

ICRP, 2007b. Radiological protection in medicine. ICRP Publication 105. Ann ICRP 37:1-63.

ICRP, 2009. Radiological protection education and training for healthcare staff and students (diagnostic imaging and interventional procedures). ICRP Publication 113. Ann ICRP 39 (5).

Miller, D.L., Balter, S., Wagner, L.K., Cardella, J.F., Clark, T.W.I., Neithamer, C.D., Jr., Schwartzberg, M.S., Swan, T.L., Towbin, R.B., Rholl, K.S., Sacks, D., 2004. Quality improvement guidelines for recording patient radiation dose in the medical record. J Vasc Interv Radiol 15, 423-429.

Miller DL, Balter S, Schueler BA, Wagner LK, Strauss KJ, Vano E. Clinical radiation management for fluoroscopically guided interventional procedures. Radiology 2010; 257(2):321-332.

NCI. Interventional fluoroscopy: reducing radiation risks for patients and staff. NIH Publication No. 05-5286. Bethesda, MD: National Cancer Institute, 2005. Available at: http://www.cancer.gov/images/Documents/45bae965-697a-4de8-9dae-b77222e0e79d/InterventionalFluor.pdf Accessed January 1, 2011.

Neofotistou V, Vano E, Padovani R, et al. Preliminary reference levels in interventional cardiology. Eur Radiol 2003; 13:2259-2263.

NCRP, 2010. Radiation dose management for fluoroscopically guided medical procedures. NCRP Report No. 168. National Council on Radiation Protection and Measurements, Bethesda, MD.

Padovani R, Bernardi G, Malisan MR, Vano E, Morocutti G, Fioretti PM. Patient dose related to the complexity of interventional cardiology procedures. Radiat Prot Dosimetry. 2001;94(1-2):189-92.

Peterzol A, Quai E, Padovani R, Bernardi G, Kotre J, Dowling A. Reference levels in PTCA as a function of procedure complexity. Radiat Prot Dosimetry 2005; 117(1-3); 54-58.

Vano E, Guibelalde E, Fernandez JM, Gonzalez L, Ten JI. Patient dosimetry in interventional radiology using slow films. Br J Radiol. 1997 Feb;70:195-200.

Vano E, Gonzalez E. Approaches to establishing reference levels in interventional radiology. Radiat Prot Dosim 2001; 94:109-112.
Vano E, Gonzalez L, Canis M, Hernandez-Lezana A. Training in radiological protection for interventionalists. Initial Spanish experience. Br J Radiol. 2003 Apr;76(904):217-9.
Vano E, Järvinen H, Kosunen A, et al. Patient dose in interventional radiology: a European survey. Radiat Prot Dosimetry 2008; 129:39-45.
Wall BF, Shrimpton PC. The historical development of reference doses in diagnostic radiology. Radiat Prot Dosimetry 1998; 80:15-19.
WHO, 1982. Quality Assurance in Diagnostic Radiology. Geneva.
WHO, 2000. Efficacy and Radiation Safety in Interventional Radiology. Geneva.

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