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Radiological Protection in Cardiology

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GUEST EDITORIAL

RADIOLOGICAL PROTECTION IN CARDIOLOGY: KNOWLEDGE ASSISTED BY TECHNOLOGY

Cardiology is one of the largest single users of medical radiation. The appropriate use of radiation supports procedures with enormous clinical benefits. The guidance given in this report will help maximise patient benefits while minimising clinically unnecessary irradiation.

Medical practice may unavoidably use substantial amounts of ionising radiation to achieve optimum clinical goals. Some individual patients currently receive radiation doses during the course of diagnosis, treatment, and follow-up that that are high enough to be of concern regarding an increase in the incidence of cancer. In a few patients, skin doses have been high enough to cause minor or major tissue reactions. Justification of clinical necessity and optimisation of radiological protection for each medical exposure is essential to obtain appropriate patient benefits at an acceptable risk for individual patients, clinical staff, and society in general.

Knowledge, assisted by technology, is required to achieve optimum radiological protection. Engineering controls such as structural shielding, preprogramed imaging protocols, and dose displays only increase safety if they are used appropriately. Each person directly or indirectly involved in patient care must have radiation protection knowledge, and must actively use this information to improve both patient care and worker safety. Job-specific educational resources and formal credentialling processes are needed to ensure necessary knowledge levels.

All non-clinical stakeholders (governments, regulators, equipment owners, physicists, etc.) should possess the formal and practical information needed to understand clinical requirements. Radiation protection officers may find it helpful to observe clinical procedures periodically. This is particularly important in the interventional area because of many real-time interactions between available equipment, the choice of settings, the operators' actual working methods, and the patient's clinical needs.

Justification is a responsibility shared between the healthcare provider who orders a procedure and the actual service provider. The individual ordering an imaging procedure is best equipped to evaluate, and has the primary responsibility for evaluating, the expected information gain against the radiological and other risks of the proposed procedure. The service provider shares responsibility for ensuring that the test has a reasonable indication, given the available information.

Optimisation of protection is the responsibility of equipment owners (by arranging the purchase and maintenance of appropriate equipment), medical physicists (through participation in equipment testing and other aspects of the quality process), and radiographers/technologists (through selecting patient- and procedure-specific protocols), as well as the supervising physician. Protocols should be configured in consultation with the interpreting physician to optimise the probability of obtaining the necessary clinical information with the use of as little radiation as possible.

Optimisation of both patient and staff protection during interventional procedures also requires the performing physician to pay active attention to equipment settings and radiation use during the course of the procedure. At present, staff irradiation is unavoidable in many interventional procedures. Optimisation of protection includes minimising staff irradiation when this can be accomplished without placing the patient in jeopardy.

In this report, background information for justification and optimisation is supplied in concise reviews of relevant radiobiology along with operational radiological protection materials for interventional fluoroscopy, nuclear cardiology, and cardiac computed tomography. Additional relevant materials are available in the documents and training resources published by the International Commission on Radiological Protection and the International Atomic Energy Agency over the past decade. The bibliography of the present publication provides further selected references that can be used to expand these topics into a comprehensive institutional programme.

A formal quality assurance programme is needed to ensure appropriate use of radiation over time. Periodical evaluation of image quality and procedural protocols should be included in the quality assurance programme. Patient dose monitoring and review is an essential addition to the actions described above. All available dosimetric information for all procedures (diagnostic and therapeutic) from all modalities should be collected into an institutional database. These data should be evaluated statistically for intra-institutional variability and compared with published external norms. Procedures that resulted in substantial skin or other organ doses require additional individual patient surveillance and communication.

This publication will be of interest and value to a wider audience than the title suggests. Most of its contents are also relevant to interventional radiology, vascular surgery, and all of the other clinical specialties where advanced imaging or fluoroscopically guided therapeutic procedures are performed. Referring healthcare providers, physicians, nurses, radiographers and radiological technologists, healthcare administrators, medical and health physicists, regulators, equipment suppliers, and others will benefit from careful reading of this publication.

Stephen Balter

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Radiological Protection in Cardiology

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Approved by the Commission in October 2011

Abstract–Cardiac nuclear medicine, cardiac computed tomography (CT), interventional cardiology procedures, 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 that are high enough to cause radiation injury and an increased risk of cancer. Treatment of congenital heart disease in children is of particular concern. Additionally, staff[1] in cardiac catheterisation laboratories may receive high doses of radiation if radiological protection tools are not used properly.

The Commission provided recommendations for radiological protection during fluoroscopically guided interventions in *Publication 85*, for radiological protection in CT in *Publications 87* and *102*, and for training in radiological protection in *Publication 113* (ICRP, 2000b,c, 2007a, 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 procedures and optimisation of protection in cardiac CT studies, cardiac nuclear medicine studies, and fluoroscopically guided cardiac interventions. It includes discussions of

[1] As indicated in the Glossary, the term 'worker' is defined by the Commission in *Publication 103* (ICRP, 2007b) as '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'. In a hospital, these persons are part of the staff. The term 'staff' is preferred in this report because the intended audience is more familiar with this term.

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.

As 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 programmes for interventional fluoroscopy.

Keywords: Cardiology; Computed tomography; Nuclear medicine; Cardiac catheterisation; Radiological protection

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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. *Publication 105* is a general overview of this area (ICRP, 2007c). These reports summarise 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, 2000b,c, 2007a, 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 primarily to nuclear medicine, computed tomography, percutaneous coronary interventions, and electrophysiology procedures. This rapidly expanding field of medicine, both in numbers and complexity, requires guidance for practitioners.

At its 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.

The membership of the Task Group during the preparation of this report was:

C. Cousins (Co-Chair)	D.L. Miller (Co-Chair)	G. Bernardi
M.M. Rehani	P. Schofield	E. Vañó

Corresponding members were:

B. Geiger	P. Heintz	R. Padovani
K-H. Sim	A.J. Einstein	

In addition, Jacques Lochard and John Boice, Main Commission members, made important contributions as critical reviewers.

The membership of Committee 3 during the period of final preparation of this report was:

E. Vañó (Chair)	M.M. Rehani (Secretary)	M.R. Baeza
J.M. Cosset	L.T. Dauer	I. Gusev
J.W. Hopewell	P-L. Khong	P. Ortiz López
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MAIN POINTS

- **Individuals who request, perform, or interpret cardiology imaging procedures should be aware of the radiation risks of the procedures.**
- **Criteria and guidelines for appropriate use have been developed through the consensus efforts of professional societies, and should be used in clinical practice.**
- **As with all other medical exposures, nuclear cardiology examinations, cardiac computed tomography examinations, interventional cardiology procedures, and electrophysiology procedures should be optimised, and dose reduction techniques should be used whenever applicable.**
- **The informed consent process should include information on radiation risk if the risk of radiation injury is thought to be significant.**
- **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 Gycm^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 tissue reactions should be able to recognise these skin injuries.**
- **Individuals who perform interventional cardiology or electrophysiology procedures should be familiar with methods to reduce radiation dose to patients and staff.**
- **Nurses, radiographers/technologists, and other healthcare professionals who assist during imaging procedures (fluoroscopy, computed tomography, and scintigraphy) should be familiar with radiation risks and radiological protection principles in order to minimise their own exposure and that of others.**
- **When there is a risk of occupational radiation exposure, staff should use appropriate personal protective shielding.**
- **In addition to the training recommended for all physicians who use ionising radiation, interventional cardiologists and electrophysiologists should receive a second, higher level of radiological protection training.**
- **Training programmes in radiological protection should include both initial training for all incoming staff, and regular updating and retraining.**
- **A cardiologist should have management responsibility for 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 for fluoroscopy, computed tomography, and scintigraphy.**
- **Quality assurance programmes should ensure the regular use of personal dosimeters, and should include a review of all abnormal dose values.**

EXECUTIVE SUMMARY

(a) In cardiology, patient radiation exposure is due primarily to nuclear medicine, computed tomography (CT), interventional cardiology procedures 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 an increased risk of cancer. Treatment of congenital heart disease in children is of particular concern. Additionally, staff in cardiac catheterisation and electrophysiology laboratories may receive high radiation doses if radiological protection tools are not used properly.

1. The biological effects of radiation

(b) Stochastic effects (malignant disease and heritable effects) are effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose with no 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 two to three times more sensitive to the stochastic effects of radiation than adults. They also have a longer potential life span than adults, so they have more time to develop possible radiation-related sequelae.

(c) Tissue reactions (e.g. skin injury) are due to injury in populations of cells, and are characterised by a threshold dose and an increase in the incidence and severity of the reaction as the dose is increased. Tissue reactions are also termed 'deterministic effects'. 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. Skin injuries may extend into deeper tissues and can cause symptoms that persist for years. Tissue reactions may be accompanied by an increase in the risk of stochastic effects.

(d) The mechanisms of cardiac radiation damage include inflammatory processes. After higher doses, there is also a progressive reduction in the number of patent capillaries, eventually leading to ischaemia, 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. At low doses, there is a latency period of 10–20 years.

(e) The lens of the eye is a radiosensitive tissue. Ionising radiation typically causes posterior subcapsular cataract formation in the lens of the eye. Surveys of cardiologists and support staff working in catheterisation laboratories have found a high percentage of lens opacities attributable to occupational radiation exposure when

radiological protection garments and devices have not been used properly, and radiation protection principles have been ignored.

2. Application of the principles of radiological protection in medicine

(f) The Commission recommends three principles of radiological protection: justification, optimisation of protection, and application of dose limits (ICRP, 2007b). 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, carers, or comforters.

(g) Justification in medicine 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. Justification is a responsibility shared by the referring clinician and the cardiac imager or interventionalist.

(h) Optimisation in medicine 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 protection is optimised when imaging is performed with the least amount of radiation required to provide adequate image quality, diagnostic information and, for fluoroscopy, imaging guidance.

3. Managing patient dose in fluoroscopically guided interventions

(i) The informed consent process should include information on radiation risk if the risk of radiation injury is thought to be significant (ICRP, 2000b). 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.

(j) Some of the factors that affect a 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.

(k) 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 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 $Gycm^2$, or an air kerma at the patient entrance reference point of 5 Gy. Patients who have received a substantial radiation dose should have follow-up 2–4 weeks after the procedure for detection of potential radiation injuries.

4. Protection of staff during interventional fluoroscopy

(l) The basic tools of occupational radiological protection are time, distance, and shielding. The use of personal protective shielding is necessary in interventional cardiology and electrophysiology laboratories. Occupational doses can be reduced to very low levels with proper use of ceiling-suspended lead shields and protective lead curtains suspended from the side of the procedure table. In general, reducing patient dose will also reduce operator dose. With proper use of radiological protection devices and techniques, the effective dose for an interventionalist is typically 2–4 mSv/y, and is well below the dose limit of 20 mSv/y, averaged over a 5-year period, recommended by the Commission.

(m) Radiation exposure to the operator is neither uniform nor symmetrical. Radiological protection for the eyes is necessary for interventionalists. Proper use of personal monitoring badges is necessary in interventional cardiology laboratories in order to monitor and audit occupational radiation dose.

5. Radiological protection for nuclear cardiology

(n) Criteria and guidelines for appropriate use have been developed through the consensus efforts of professional societies. These criteria and guidelines help to set standards for justification of nuclear cardiology procedures. Justification needs to be performed on an individualised, patient-by-patient basis, and should weigh the benefits and risks of each imaging test under consideration as well as the benefits and risks of not performing a test. Assessment of radiation risk is one part of this process.

(o) Optimisation of protection in nuclear cardiology procedures involves the judicious selection of radiopharmaceuticals and administered activities to ensure diagnostic image quality while minimising patient dose. Administered activities should be within prespecified ranges, as provided in international and national guidelines, and should reflect patient habitus. If stress imaging is normal, rest imaging can be omitted to minimise total dose. For single-photon emission CT protocols, ^{99m}Tc-based agents yield lower effective doses than ^{201}Tl, and are preferred on dosimetric grounds. Practitioners need good-quality dosimetric data to perform proper benefit–risk analyses for their patients.

6. Radiological protection for cardiac computed tomography

(p) As with nuclear cardiology, criteria and guidelines for appropriate use of cardiac CT have been developed, and justification needs to be performed in the same fashion. Dose from cardiac CT is strongly dependent on scanner mode, tube current, and tube potential. For patients with a heart rate <65–70 beats/min and a regular rhythm, diagnostic image quality can generally be maintained while using dose reduction methods such as axial imaging or electrocardiogram (ECG)-controlled tube current modulation. For non-obese patients, diagnostic image quality can generally be maintained using low-voltage (e.g. 100 kVp) scanning. The maximum tube

current should be appropriate for the patient's habitus. Further research is needed to develop and validate methods to reduce patient radiation dose.

7. Radiological protection training for cardiologists

(q) Legislation in most countries requires that individuals who take responsibility for medical exposures must be properly trained in radiological protection. Cardiologists worldwide typically have little or no training in radiological protection. The Commission recommends that, in addition to the training recommended for other physicians who use ionising radiation, interventional cardiologists and electrophysiologists should receive a second, higher level of radiological protection training (ICRP, 2009).

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

(s) Training activities in radiological protection 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.

(t) 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. The training should be commensurate with the individual's role (ICRP, 2009).

8. Quality assurance programmes

(u) Two basic purposes of a radiological protection quality assurance programme (QAP) are to evaluate patient radiation dose periodically and to monitor occupational radiation dose for workers in cardiology facilities where radiation is used. A cardiologist should have management responsibility for the QAP aspects of radiological protection for cardiology procedures, and should be assisted by a medical physicist. The radiation protection advisor/radiation safety officer should also be involved in monitoring occupational radiation dose.

(v) The planning process for a new interventional fluoroscopy laboratory, CT scanner or nuclear medicine system in a cardiology facility, or the upgrade of existing equipment should include the participation of a medical physicist, a senior radiographer, and a senior cardiologist. These individuals should have experience with the procedures that will be performed using the new equipment.

(w) Periodical evaluation of image quality and procedure protocols should be included in the QAP. The QAP should establish trigger levels 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.

(x) 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 the procedure and patient identification. Patient dose audits (including comparison with diagnostic reference levels) and reporting are important components of the QAP.

GLOSSARY

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 dm by ionising radiation. The SI unit for absorbed dose is joule per kilogram (J/kg). Its special name is gray (Gy) (ICRP, 2007b). In layman's terms, absorbed dose is the measure of energy absorbed by a unit mass of tissue from ionising 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 or equipment standards.

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 ($\approx 2.7\ 10^{-11}$ Ci).

Brachytherapy

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

Bradycardia

Heart rate <60 beats/min. Depending on the heart rate and the presence or absence of an underlying abnormality, bradycardias may or may not require treatment.

Cardiomyopathy

A disease of the heart muscle that often, but not always, results in a weakening of the pumping strength of the ventricles.

Cardioverter-defibrillator

A device typically implanted similarly to a pacemaker, which can monitor heart rate and rhythm, and deliver electrical therapy such as shocks in response to certain tachycardias as specified by the cardiologist.

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, 2007b).

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

A series of tests performed 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, see Tissue reaction

Diagnostic reference level (DRL)

Used in medical imaging with ionising 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, 2007b).

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 to express 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, 2007b).

Dose limit

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

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:

$$E = \sum_{\mathrm{T}} w_{\mathrm{T}} \sum_{\mathrm{R}} w_{\mathrm{R}} D_{\mathrm{T,R}} \quad \text{or} \quad E = \sum_{\mathrm{T}} w_{\mathrm{T}} H_{\mathrm{T}}$$

where H_{T} or $w_{\mathrm{R}} D_{\mathrm{T,R}}$ 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. Its special name is sievert (Sv) (ICRP, 2007b). 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 optimisation of radiation protection and dose limitation for stochastic effects.

Electrophysiology

Cardiac electrophysiology is directed at evaluation and treatment of 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 alone, 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 recognised 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, 2007b).

Equivalent dose (H_T)

The dose in a tissue or organ T given by:

$$H_T = \sum_R w_R D_{T,R}$$

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. This unit's special name is sievert (Sv) (ICRP, 2007b). 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, 2000b).

Gray (Gy)

The special name for the SI unit of absorbed dose: 1 Gy = 1 J/kg.

Justification

The process of determining whether either: (1) a planned activity involving radiation is, overall, beneficial (i.e. 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 protection strategy 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 protection strategy outweigh its cost and any harm or damage it causes (ICRP, 2007b)].

Interventional reference point, see Patient entrance reference point

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 expected value of the sum of the kinetic energies. The unit for kerma is joule per kilogram (J/kg). This unit's special name is gray (Gy) (ICRP, 2007b). 'Kerma' is an acronym for 'kinetic energy released in a mass'.[2]

Kerma-area product (KAP)

(More accurately, air kerma-area product, since this quantity is usually determined in air.) The integral of air kerma across the entire x-ray beam emitted from an 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 $Gycm^2$. The International Commission on Radiation Units and Measurements' notation for this quantity is P_{KA}(ICRU, 2005). Earlier publications used the abbreviation 'DAP' for dose-area product (Stecker et al., 2009) (see also the remark accompanying the definition of kerma).

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:

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

[2] Remark on air kerma vs dose in air. For many years, dosimetric values in air for diagnostic radiology have been given in terms of absorbed dose to air. Although the values of both quantities are equal when equilibrium of secondary electrons exists, they are different near the interface between air and tissue or air and phantom, where there is no such equilibrium. In this region, absorbed dose in air cannot be determined by ordinary means, while air kerma is easily measured, as dosimetric equipment is calibrated in terms of air kerma. Thus, all reported values of absorbed dose in air are actually values of air kerma. In addition, organ doses can be obtained by using available conversion coefficients, which convert from air kerma to organ doses. There is, therefore, no practical value in trying to determine the absorbed dose in air. For these reasons, for quantities determined in air, the International Commission on Radiation Units and Measurements recommend the use of air kerma rather than absorbed dose to air, entrance surface air kerma rather than entrance surface dose, kerma-area product rather than dose–area product, and computed tomography air kerma index rather than computed tomography dose index (ICRU, 2005). In this report, absorbed dose in air has been retained for historical reasons and because most readers are more familiar with the term 'dose' as it appears in the literature, and less familiar with 'air kerma'.

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, 2007b).

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, 2007b).

Myocardial perfusion

Blood flow to the heart muscle.

Occupational exposure

This refers to all exposures incurred by workers in the course of their work. However, because of the ubiquity of radiation, the Commission therefore limits its use of 'occupational exposures' to radiation exposures incurred at work as a result of situations that can reasonably be regarded as being the responsibility of the operating management. Excluded exposures and exposures from exempt practices or exempt sources generally do not need to be accounted for in occupational protection (ICRP, 2007b).

Optimisation of protection (and safety)

The principle of optimisation of protection is defined by the Commission as the source-related process to keep the likelihood of incurring exposures (where these are not certain to be received), the number of people exposed, and the magnitude of individual doses as low as reasonably achievable, taking economic and societal factors into account. This means that the level of protection should be the best under the prevailing circumstances, maximising the margin of benefit over harm (ICRP, 2007b). In medical imaging and radiotherapy procedures, optimisation of protection 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 protection is optimised when imaging is performed with the least amount of radiation required to provide adequate image quality, diagnostic information and, for fluoroscopy, imaging guidance.

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 isocentre 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 isocentre of the gantry.

Peak skin dose

The maximum absorbed dose to the most heavily irradiated localised region of skin (i.e. the localised region of skin that lies within the primary x-ray beam for the longest period of time during a fluoroscopically guided procedure). The

International Commission on Radiation Units and Measurements, notation for this quantity is $D_{skin,local}$ (ICRU, 2005). The notation used by the National Council on Radiation Protection and Measurements is $D_{skin,max}$ (NCRP, 2010). Peak skin dose is measured in units of Gy (NCRP, 2010).

Percutaneous coronary intervention (PCI)

Percutaneous coronary intervention 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 to radiation sources and to the individual in controllable exposure situations. The principle of justification and the principle of optimisation of protection are source related and apply in all exposure situations. The principle of application of dose limits is individual related and only applies in planned exposure situations (ICRP, 2007b).

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-linear energy transfer (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, 2007b).

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 or conduct abnormal electrical signals.

Radiographer

Radiographers use medical x-ray equipment to produce images of the tissues, organs, bones, and vessels of the body, as prescribed by physicians, to assist in the diagnosis of disease or injury. They apply knowledge of anatomy, physiology, positioning, radiographic technique, radiation biology, and radiological protection in the performance of their responsibilities. 'Radiographer' and 'radiological technologist' are synonyms.

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, 2010). It is the air kerma accumulated at a specific point in space relative to the fluoroscopic gantry (see Patient entrance reference point) during a procedure. Reference air kerma does not include backscatter and is measured in units of Gy. It is a special case of the quantity with the ICRU notation $K_{a,i}$, and has

the NCRP notation $K_{a,r}$ (ICRU, 2005; NCRP, 2010). 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 et al., 2009).

Scintigraphy
: Nuclear medicine imaging procedures.

Sievert (Sv)
: The special name for the SI unit of equivalent dose, effective dose, and operational dose quantities. The unit is joule/kilogram (J/kg).

Staff
: In the context of this document, staff are healthcare workers (see Workers) who participate in the care of a patient during a radiological procedure (e.g. physicians, nurses, radiographers) or who may be exposed to radiation from medical imaging equipment during the course of their work (e.g. equipment service personnel, janitorial staff).

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 with no threshold (ICRP, 2007b).

Stenosis
: Narrowing of a hollow structure. With respect to coronary artery anatomy, this refers to narrowing of the inner diameter of a coronary artery.

Stress test
: A standardised procedure for assessing the effect of stress on cardiac haemodynamics, electrical activity, perfusion, and/or function. Stress may be induced by exercise or simulated by administration of drugs.

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, 2010).

Tachycardia
: Heart rate >100 beats/min. Depending on the heart rate and the presence or absence of an underlying abnormality, tachycardias may or may not require treatment.

Threshold dose for tissue reactions
: Dose estimated to result in 1% incidence of tissue reactions (ICRP, 2007b).

Tissue reaction

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. Tissue reactions are also termed 'deterministic effects'. In some cases, tissue reactions are modifiable by postirradiation procedures including biological response modifiers (ICRP, 2007b).

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 (ICRP, 2007b) such that:

$$\sum_T w_T = 1$$

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. Workers in medical professions involving radiation are occupationally exposed (ICRP, 2007b).

1. INTRODUCTION

- **In cardiology, patient radiation exposure is due to nuclear medicine, computed tomography, diagnostic cardiac catheterisation, 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, computed tomography, interventional cardiology procedures, and electrophysiology procedures are increasing in number and account for a large share of patient radiation exposure.**
- **Both interventional cardiology and electrophysiology procedures can result in patient skin doses that are high enough to cause radiation injury and an increased risk of cancer.**
- **Complex percutaneous coronary interventions and cardiac electrophysiology procedures can be associated with high radiation doses.**
- **Treatment of congenital heart disease in children is of particular concern due to their greater sensitivity to radiation.**
- **Staff in cardiac catheterisation laboratories may receive high radiation doses if radiological protection garments and devices are not used properly.**

1.1. Introduction

(1) In cardiology, patients are exposed to ionising radiation from different modalities: radiography, fluoroscopy (including cineangiography), computed tomography (CT), and nuclear medicine. These 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. Radiography is not discussed further in this report; the other three modalities are the subject of this publication.

1.2. 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, and 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, 2000b), but advances in technology and in our understanding of radiation effects have occurred over the past decade.

1.2.1. Percutaneous coronary interventions

(3) Despite the continuing development of non-invasive cardiac imaging techniques over the past decade, including echocardiography, cardiac CT, cardiac

scintigraphy, and cardiac magnetic resonance imaging, an increasing number of patients undergo fluoroscopically guided invasive cardiac diagnostic and therapeutic procedures. In Europe, there was a three-fold increase in coronary angiography and a five-fold increase in percutaneous coronary interventions (PCIs) 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 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 PCIs, 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 USA declined by approximately 2% (NCRP, 2010), and also appears to be declining in some European countries (Meier, 2010). A number of factors are probably responsible, including increased use of cardiac CT, the results of the COURAGE trial (Boden et al., 2007), and changes in reimbursement for these procedures.

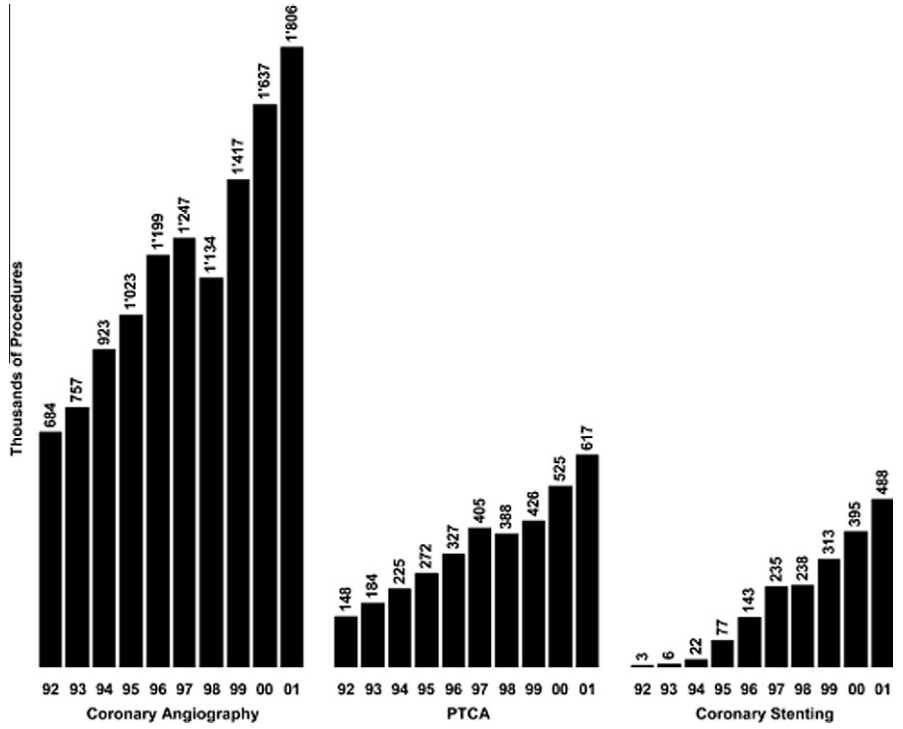


Fig. 1.1. Coronary angiograms, percutaneous transluminal coronary angioplasty (PTCA) and coronary stenting in Europe from 1992 to 2001 in thousands of procedures. Reproduced, with permission, from Togni et al. (2004).

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

(6) This growth has mainly involved the Western world, but a similar trend has been seen in other countries; in China, for instance, the annual increment rate for PCIs is around 40% (Cheng, 2004). The total number is relatively small compared with the population of China, and may reflect the lower prevalence of coronary artery disease in the Chinese population (3–7%, approximately one-quarter of that of Western Caucasians), but the number is expected to grow as a consequence of changing dietary habits, lifestyle, and cigarette smoking (Cheng, 2004; Moran et al., 2010). A survey of developing countries revealed that approximately 30% of the 20 participating countries demonstrated a doubling of workload in the 3-year period from 2004 to 2007 (Tsapaki et al., 2009). The same study indicated that the number of paediatric interventional procedures can be as high as the number of adult interventional procedures.

1.2.2. Skin injuries

(7) Both PCIs and interventional electrophysiology procedures can result in patient skin doses high enough to cause skin injuries (tissue reactions, see Chapters 2 and 3) (Miller, 2008). At one centre, the frequency of skin injuries was estimated to be 0.03% (Padovani et al., 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 practising clinicians of the potential risks involved with these procedures.

(8) 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. Vañó et al. (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 et al., 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.

(9) Patient radiation dose is related to procedure complexity (Bernardi et al., 2000; Peterzol et al., 2005; Balter et al., 2008; IAEA, 2009). Multivessel PCI is considered to be a complexity factor, but this may not always be the case (Bernardi et al., 2000). Other factors that appear to affect complexity for PCIs include the type of lesion, the chronicity of the occlusion, the degree of vessel tortuosity, and the involvement of vessel bifurcations (Balter et al., 2008; IAEA, 2009).

1.2.3. Cardiac electrophysiology procedures

(10) 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 approximately 50% worldwide (Mond et al., 2004). More recently, biventricular 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 USA in 2008 (NCRP, 2010).

(11) 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. If fluoroscopic technical factors are not optimised, these patients can be exposed to very high doses of radiation and a substantial risk of tissue reactions due to the long fluoroscopy times required for these procedures (Rosenthal et al., 1998; McFadden et al., 2002).

1.2.4. Congenital and valvular heart diseases

(12) Congenital and valvular heart diseases comprise two other groups of cardiac disease where catheter techniques are used and where new catheter techniques continue to be developed. An increase in the number of percutaneous interventions performed is likely in the near future. 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 compared with adults (Hall, 2009).

(13) These techniques to treat congenital and valvular heart diseases are largely justified as they may replace very-high-risk surgical procedures. Although transoesophageal and intracardiac ultrasound may partially replace fluoroscopy (Rice et al., 2002; Zanchetta and Maiolino, 2004), radiation risk still remains a problem and is often underestimated. Fluoroscopy times as long as 129 min 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).

1.2.5. Paediatric patients

(14) It has been estimated that approximately 7% of all cardiac angiography procedures are carried out in children aged 0–15 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 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). 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.

(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 1.9–8.6 $Gycm^2$ for diagnostic procedures. Mean dose values for therapeutic procedures, in both extremes of the paediatric age group, ranged from 2.4 to 17.8 $Gycm^2$ (Martinez et al., 2007). In a series of 205 children (mean age 4.1 years) who underwent diagnostic cardiac catheterisation, the mean dose was 17 $Gycm^2$ (Chida et al., 2010). In comparison with proposed diagnostic reference levels (DRLs) for fluoroscopically guided cardiac interventions in adults of 50 $Gycm^2$ for diagnostic procedures and 125 $Gycm^2$ for therapeutic procedures (Balter et al., 2008), paediatric patients have typically received <20% of the dose received by adult patients. Nonetheless, radiation doses from paediatric cardiac catheterisation procedures are of concern (Andreassi et al., 2006; Andreassi, 2009). The 90^{th} percentile dose for a 30–40-kg patient undergoing an intervention in a paediatric catheterisation laboratory can be as high as 200 $Gycm^2$ (NCRP, 2010).

1.3. Cardiac computed tomography

(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. Today, cardiac CT encompasses several distinct procedures, including coronary artery calcium scoring (coronary calcium scans), coronary CT angiography (coronary CTA), pulmonary vein CT angiography, myocardial CT perfusion, and CT attenuation correction of nuclear cardiology image data (Weigold et al., 2011). 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. In the USA, CT was the largest source of medical exposure to patients in 2006, accounting for 49% of the medical exposure of patients according to a report of the National Council on Radiation Protection and Measurements (NCRP, 2009). In this report, cardiac CT (including coronary CTA and coronary calcium scans) accounted for 4.7% of CT examinations, but 12.1% of patient

exposure from CT. The most recent generation of scanners incorporates technology with the potential to decrease patient dose, and thus the radiation burden, to this population considerably.

1.4. 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; 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 use single-photon emission CT (SPECT), although a small but growing number of laboratories perform positron emission tomography (PET) studies.

(18) In the USA, 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, 2009). Nuclear medicine procedures were the second largest source of medical exposure to the US population after CT.

(19) More nuclear cardiology procedures are performed in the USA 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 US 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 et al., 2008; Hendel et al., 2010). Cardiologists should incorporate the principle of justification into their clinical decision making and, based on individual patient circumstances and diagnostic needs, should consider using alternative methodologies that do not require ionising radiation, such as stress echocardiography.

1.5. Occupational radiation risk

(20) Radiation risk is not limited to patients. Operators and staff may receive substantial 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 et al., 2008). There is considerable variation in operator doses observed for the same type of procedure, indicating that radiological protection practices can be improved (Kim and Miller, 2009). Recent studies have shown that there is an increased incidence of radiation-related cataracts in interventional cardiologists when radiological protection devices are not used properly and radiological protection principles are not followed (Ciraj-Bjelac et al., 2010; Vañó et al., 2010). Unfortunately, there is lack of proper monitoring of radiation doses to staff and lack of reliable data on occupational doses (Padovani, 2011).

1.6. Summary

(21) In summary, cardiology procedures that use ionising radiation 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 tissue reactions (skin injuries) should be taken into account. Interventional cardiologists are among the 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.

2. BIOLOGICAL EFFECTS OF RADIATION

- **Tissue reactions are due to injury in populations of cells, and are characterised by a threshold dose and an increase in the incidence and severity of the reaction as the dose is increased further. Tissue reactions are also termed 'deterministic effects'.**
- **Stochastic effects (malignant disease and heritable effects) are effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose with no 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, ionising radiation typically causes posterior subcapsular cataract formation.**
- **Surveys of cardiologists and support staff working in catheterisation 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: tissue reactions (harmful tissue effects) and stochastic effects (cancer and heritable effects).

(23) Tissue reactions (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 loss of reproductive survival of a critical population of cells in a given tissue must occur before the injury is expressed in a clinically relevant form. Above the threshold dose, the severity of the injury, including impairment of the capacity for tissue recovery, increases with dose (ICRP, 2007b). The threshold is variable, depending on the nature and condition of the exposed tissue (Balter et al., 2010).

(24) The injury is not expressed clinically until the cells die as a result of an unsuccessful attempt at cell division or differentiation, and are lost as part of the normal process of tissue turnover (Balter et al., 2010). After a high radiation dose, the outcome for the affected individual can be devastating (Balter et al., 2010).

(25) Eighty percent of reported radiation-induced skin injuries in one large series were from cardiac procedures (Koenig et al., 2001a). Nonetheless, cardiologists often do not recognise that a radiation injury is related to a cardiac procedure, either because they do not know that radiation can cause skin injuries, they are unaware of the magnitude of radiation dose delivered, they do not provide follow-up for patients who have received substantial amounts of radiation, or they do not consider the possibility of a radiation-related aetiology when a patient returns with a skin injury.

(26) The dose of radiation received by some patients is high and the number of cases of radiation injury is increasing (NCI, 2005). However, most currently practis-

ing 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) For 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 of approximately 100 mSv or less (ICRP, 2007b; Linet et al., 2012).

(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 approximately 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' model) (ICRP, 2007b). Dose has no relationship to the severity of the effect.

(29) Children are approximately two to three times more sensitive to the stochastic effects of radiation than adults (ICRP, 1991). They also have a longer potential life span than 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 (Bacher et al., 2005; Martinez et al., 2007).

(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, 2007b).

2.2. Background

(31) Some months after the discovery of x rays in 1895, radiation-induced skin changes were observed (Codman, 1896; Daniel, 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 *Publication 103*, the goal of preventing these radiation injuries was the impetus for the formation of what is now the Commission (ICRP, 2007b).

(32) Following the dramatic rise in the number of PCIs, cases of patients with deep skin ulceration and necrosis were reported in the 1990s (ACR, 1992; Shope, 1996). In 1994, the US Food and Drug Administration (FDA) issued advice regarding skin injury from fluoroscopically guided procedures (FDA, 1994). Radiation skin injury has also been reported following radiofrequency catheter ablations (Vañó et al., 1998a). This is of particular concern because many of these patients are young adults, and some are children. The Commission drew attention to the prevention of skin injuries from interventional fluoroscopy procedures in *Publication 85* (ICRP,

2000b), and re-iterated the importance of preventing skin injuries in *Publication 105* (ICRP, 2007c).

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 energy absorbed per unit mass of tissue (see Glossary). The skin response follows a characteristic pattern, although the time course is variable (Balter et al., 2010). The threshold dose and time of appearance for various types of skin injury are summarised in Table 2.1.

(34) Defects in DNA repair genes, such as the *ATM* gene responsible for ataxia telangiectasia, may predispose individuals to radiation-induced cancer, or lower the threshold for the development of tissue reactions (Hymes et al., 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 et al., 2006). Certain familial cancer syndromes may increase susceptibility to radiation-induced cancer, including neurofibromatosis, Li-Fraumeni syndrome, and hereditary retinoblastoma (Allan, 2008).

(35) Auto-immune 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 et al., 2006). Hyperthyroidism and diabetes mellitus are also associated with increased radiation sensitivity (Koenig et al., 2001a). Diabetes is believed to predispose to radiation injury secondary to small vessel vascular disease and consequent decreased healing capacity (Herold et al., 1999). A number of drugs increase radiation sensitivity, including actinomycin D, doxorubicin, bleomycin, 5-fluorouracil, and methotrexate (Koenig et al., 2001a). Again, this effect is usually only seen 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 radiosensitivity and radioresponsiveness (Balter et al., 2010). These ranges are shown graphically in Fig. 2.1. In the discussion below, threshold doses are given for an average person, but it should be understood that these vary from individual to individual. For most patients, clinically important skin reactions only occur when the absorbed skin dose is >5 Gy (Balter et al., 2010; ICRP, 2012).

(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 h. This effect is likely to be under-reported due to its short duration.

Table 2.1. Tissue reactions from a single-delivery radiation dose to the skin of the neck, torso, pelvis, buttocks, or arms.

Band	Single-site acute skin-dose range (Gy)[*]	NCI skin reaction grade	Approximate time of onset of effects			
			Prompt <2 weeks	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	– None expected
B	5–10	1	– Transient erythema	– Erythema, epilation	– Recovery – At higher doses; prolonged erythema, permanent partial epilation	– Recovery – At higher doses, dermal atrophy/ induration
C	10–15	1–2	– Transient erythema	– Erythema, epilation – Possible dry or moist desquamation – Recovery from desquamation	– Prolonged erythema – Permanent epilation	– Telangiectasia[†] – Dermal atrophy/induration – Skin likely to be weak
D	>15	3–4	– Transient erythema – After very high doses, oedema and acute ulceration; long-term surgical intervention likely to be required	– Erythema, epilation – Moist desquamation	– 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	– Telangiectasia[†] – Dermal atrophy/induration – Possible late skin breakdown – Wound might be persistent and progress into a deeper lesion – Surgical intervention likely to be required

Sources: Balter et al. (2010) and NCRP (2010).
NCI, US National Cancer Institute; NA, not applicable.
* Skin dosimetry is unlikely to be more accurate than ± 50%.
† Refers to radiation-induced telangiectasia. Telangiectasia associated with an area of initial moist desquamation or the healing of ulceration may be present earlier.
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 US Food and Drug Administration [Performance Standards for Ionizing Radiation Emitting Products. Fluoroscopic equipment. 21 C. F. R. pt. 1020.32 (2012)] 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.

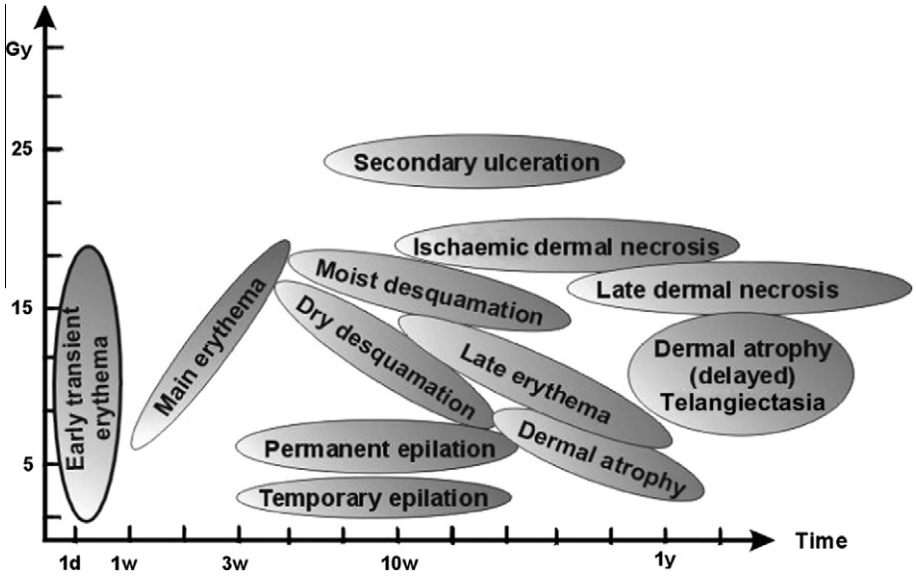


Fig. 2.1. Graphical representation of data in Table 2.1 showing overlap of tissue effects in the skin with both dose and time.

(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., 2001b).

(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 approximately 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 and Lynch, 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 a radiation exposure of approximately 15 Gy. The skin has a mauve or dusky appearance. A skin dose of approximately 18 Gy may result in vascular insufficiency of the dermis, leading to ischaemic dermal necrosis 10–16 weeks following exposure. The damage is greater at higher doses (Koenig et al., 2001a).

(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 >10 Gy, telangiectasia may also develop because of dilation of the dermal capillaries. This is often a late phenomenon, occurring >1 year after exposure, but has been noted earlier and can increase over time (Turreson and Notter, 1986). Trauma may precipitate late necrosis in skin that shows these late changes. The threshold for this is approximately 12 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 recognised. 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 (Vliestra et al., 2004). Severe injuries may extend into underlying 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 et al., 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 to 1995 (Wang et al., 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 prevalence of 91% in 75–85 year olds, although this figure was reduced to 46% if 'modest visual deficit' was added to the definition. A more recent review of prior studies by a Spanish group gave a prevalence of cataract and decreased visual acuity of $\geq$60% in subjects aged $\geq$75 years (Acosta et al., 2006).

(45) The majority of lens opacities that are not due to radiation are associated with cortical changes in the outer cellular layers of the lens. The lens is a radiosensitive tissue. Ionising radiation typically causes posterior subcapsular (PSC) cataract formation (Fig. 2.2). Unlike age-related cortical or nuclear cataracts, which primarily cause a change in visual acuity, a PSC cataract is more likely to result in changes in both visual acuity and contrast sensitivity (Stifter et al., 2006).

(46) The response of the lens to ionising radiation exposure has traditionally been considered a deterministic tissue reaction. Until recently, the threshold dose for detectable human lens opacities has been considered to be 2 Gy for a single acute exposure and 5 Gy for a protracted exposure. For cataract with visual impairment, the thresholds have been considered to be 5 Gy and 8 Gy, respectively (ICRP, 1991;

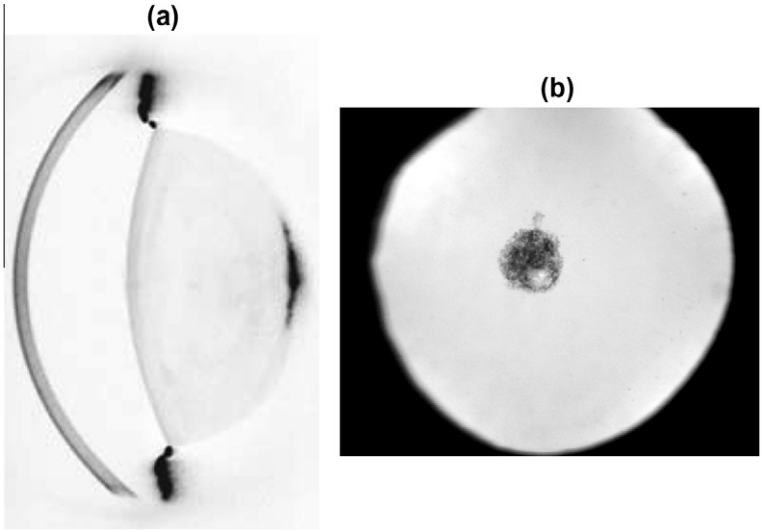


Fig. 2.2. (a) A typical radiation-induced posterior subcapsular (PSC) cataract is depicted in this Scheimpflug image of the lens as a bright reflective plaque in the central PSC lens region (far right). The corneal surface is shown on the far left. The bright reflections at top and bottom at the lens equator are from the dilated iris. (b) Retro-illumination photograph of a PSC cataract along the posterior visual axis of the lens. This central opacity may cause glare and poor vision under bright lighting conditions, as well as poor reading vision.

NCRP, 1993). More recent data in populations exposed to lower doses of radiation suggest that lens opacification occurs at exposures significantly lower than 2 Gy, and that there may be no dose threshold (Kleiman, 2007; Worgul et al., 2007; NCRP, 2010; Shore et al., 2010; ICRP, 2012).

(47) There have been reports of radiation-induced cataract in interventionalists who have performed procedures for a number of years, and of equivalent doses to the lens approaching the annual limit of 150 mSv during angiographic procedures (Fig. 2.3) (Vañó et al., 1998b, 2010; Pages, 2000; Hidajat et al., 2006). Recent studies have shown that with typical reported interventional workloads, the radiation dose to the lens may exceed the current threshold for tissue reactions after several years of work if radiological protection devices are not used and radiological protection principles are not followed (Kim et al., 2008; Vañó et al., 2008a). Several surveys of cardiologists and support staff working in catheterisation laboratories, conducted with co-ordination provided by the International Atomic Energy Agency (IAEA) in Latin America and Asia, have found a high prevalence of lens opacities of the type associated with occupational radiation exposure (Ciraj-Bjelac et al., 2010; Vañó et al., 2010).

(48) These recent data and the mechanistic uncertainties regarding cataract development highlighted the need for a detailed re-appraisal of the radiosensitivity of the lens of the eye. This issue is addressed in *Publication 118* and in the Commission's

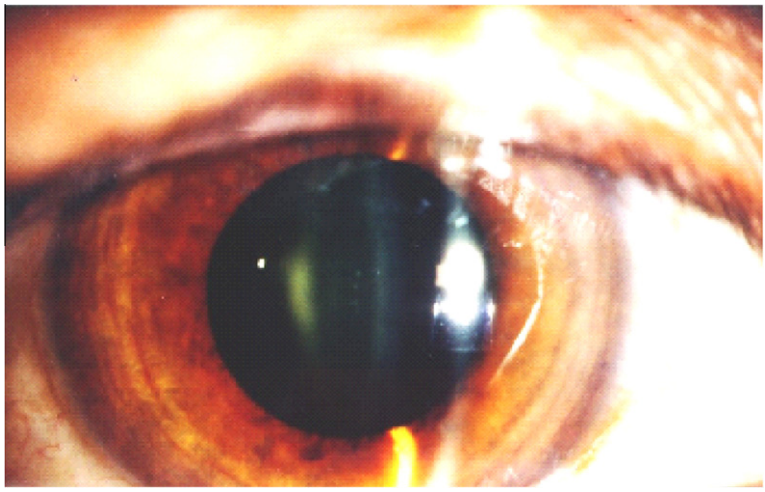


Fig. 2.3. Posterior subcapsular cataract in the eye of an interventionist who used an old x-ray system and experienced high scatter radiation due to improper working conditions. Source: Vañó et al. (1998b).

statement on tissue reactions (ICRP, 2011, 2012). The previous Commission recommendation (ICRP, 1991) of an equivalent dose limit of 150 mSv/y for occupational exposure in a planned exposure situation (e.g. occupational exposure of interventionalists) has been changed. The Commission now recommends that the lens-equivalent dose limit for chronic occupational exposure should be 20 mSv/y, averaged over a defined 5-year period, with no single year exceeding 50 mSv (i.e. the same as the annual whole-body limit for workers) (ICRP, 2011, 2012). Note that a study performed with data from 1984 through 1988, when both cardiac interventions and fluoroscopic equipment were less sophisticated than they are now, determined that the annual equivalent dose to cardiologists' heads was approximately 20–30 mSv (Renaud, 1992).

(49) The Commission considers the threshold for absorbed dose to the lens of the eye to be 0.5 Gy (ICRP, 2011). The Commission judges, based on existing evidence, that an acute dose of up to around 0.1 Gy (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, 2011).

2.5. Cardiovascular effects of radiation exposure

(50) The mechanisms of heart radiation damage include inflammatory processes. After higher doses, there is also a progressive reduction in the number of patent capillaries eventually leading to ischaemia, 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 >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 ionising radiation in the range of doses used for radiation therapy can increase the risk of heart disease (McGale and Darby, 2008). Excess risks of cardiovascular disease only become apparent 10–20 years after exposure at low doses (1–2 Gy) (ICRP, 2011). The epidemiology of the cardiovascular effects of radiation is reviewed extensively in Annex B of the 2006 UNSCEAR report (UNSCEAR, 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 might be as low as 0.5 Gy to the heart (ICRP, 2011). In some complex fluoroscopically guided cardiac procedures, organ doses may be >0.5 Gy. These radiation effects need to be considered during the process of optimisation of protection.

(53) At lower doses (<0.5 Gy), the relationship between radiation dose and increased cardiovascular risk is unclear (Shimizu et al., 2010). In their analysis of 42,000 radiation workers with low-dose, long-term radiation exposure, McGeoghegan et al. observed an association between mortality from non-cancer causes of death, particularly circulatory system disease, and exposure to ionising radiation (McGeoghegan et al., 2008). 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., 2010b).

2.6. Occupational radiation exposure and intracranial neoplasms

(54) Ionising radiation is one of the few established causes of neural tumours (Yonehara et al., 2004). Preston et al. studied the incidence of nervous system tumours in atomic bomb survivors (Preston et al., 2002, 2007), and found a significant dose-related excess of nervous system tumours. They concluded that exposure to equivalent 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 that for malignant tumours (UNSCEAR, 2000). However, the BEIR-VII report does

not explicitly present lifetime attributable risk 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 equivalent dose to cardiologists' heads was approximately 20–30 mSv (Renaud, 1992). Renaud's study was performed with data from 1984 to 1988, when cardiac interventions were less complex but fluoroscopic equipment had fewer protective features than at present. The two trends counteract each other, with variable effect. Kim et al. observed a decrease in cardiologist dose per procedure over time for diagnostic cardiac catheterisation and for electrophysiology procedures, but an increase for PCIs (Kim et al., 2008). Changes in workload also affect an individual's annual equivalent dose. The total number of procedures performed worldwide has increased in recent years (Section 1.1.1).

(56) Finkelstein suggested that the occurrence of brain tumours in two Toronto cardiologists in a 1-year period might indicate that they were induced by radiation (Finkelstein, 1998). Epidemiological evidence for radiation-induced brain cancer in fluoroscopists is suggestive but by no means conclusive. In 1975, Matanoski et al. found that the death rate from brain cancer in American radiologists was almost three 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 et al. 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 three such individuals among the 233 cases (Hardell et al., 2001). No increased risk was found for other healthcare workers. In a case–control study of 476 individuals diagnosed with gliomas between 1991 and 1994 in the San Francisco area, Carozza et al. 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 six physicians in the group. The authors suggested that the increased risk might be due to occupational exposure to numerous biological agents and chemicals as well as radiation.

(57) On the other hand, Blettner et al. 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 two-thirds of the 91 participants occupationally exposed to radiation were in the medical field (physicians, nurses, radiographers). Blettner et al. found no significant risk of brain tumours as a result of exposure to medical ionising radiation. Karipidis et al. 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 ionising radiation (Karipidis et al., 2007).

3. CLINICAL EXAMPLES OF TISSUE REACTIONS DUE TO FLUOROSCOPICALLY GUIDED CARDIOLOGY PROCEDURES

- **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.**
- **Tissue reactions may extend into deeper tissues and can cause symptoms that persist for years.**
- **Tissue reactions may be accompanied by an increase in the risk of stochastic effects.**

3.1. Introduction

(58) There is increasing concern about skin radiation dose levels in cardiology. This is because of the discovery of tissue reactions 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 (Bryk et al., 2006; Suzuki et al., 2008).

(59) The information presented in 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 specialised centre. Pain management and psychological support are important components of treatment.

(60) Methods to optimise patient radiation dose and minimise 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.
- Use the lowest fluoroscopy pulse rate and lowest fluoroscopy dose rate that provide adequate fluoroscopic guidance.
- Use the lowest fluoroscopic and cine dose rates necessary for each stage of the procedure.
- When possible, rotate the gantry slightly 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.

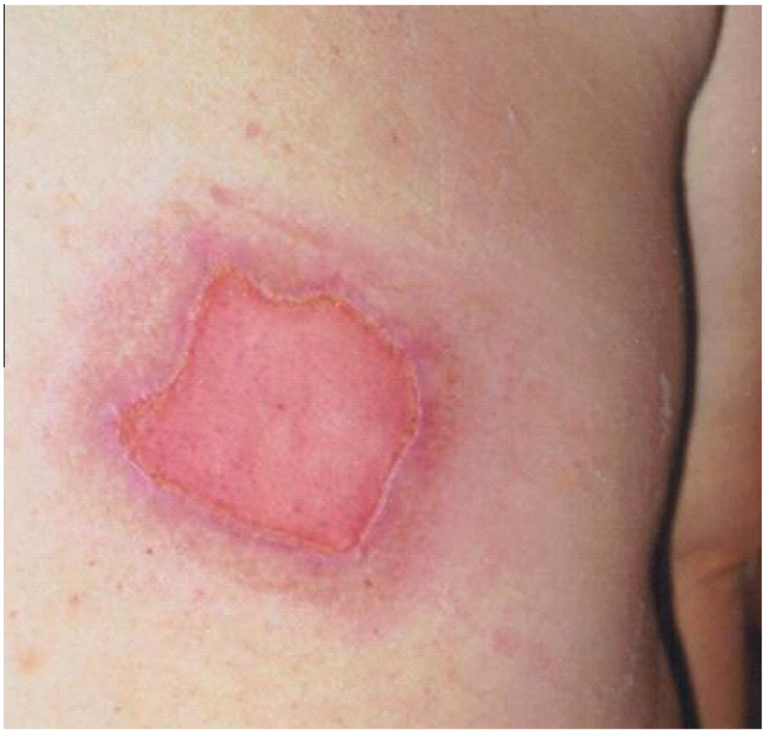


Fig. 3.1. Case 1. See text for details. Source: Vliestra et al. (2004).

3.2. Case 1 (Vliestra et al., 2004)

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

(62) The patient presented 6 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 6 months after PCI. Local discomfort persists.

3.3. Case 2 (Koenig et al., 2001a)

(63) A 75-year-old woman had two previous coronary angiograms, followed by PCI 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.

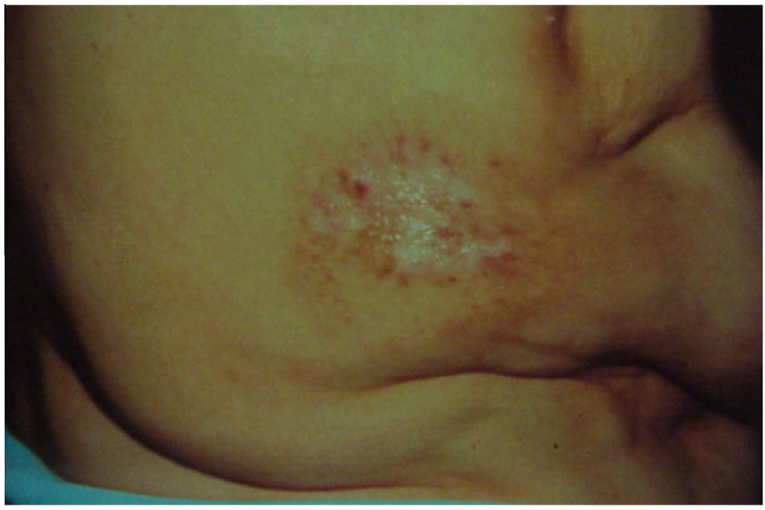


Fig. 3.2. Case 2. The right lateral chest demonstrates both hyper- and hypopigmentation, in addition to skin atrophy and telangiectasia. Source: Koenig et al. (2001a).

3.4. Case 3 (Wagner and Archer, 1997)

(64) A 49-year-old woman presented with an 8-year history of supraventicular tachycardia. Radiofrequency catheter ablation was performed. During the electrophysiology 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 min. 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.

3.5. Case 4 (Vliestra et al., 2004)

(65) 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 electrophysiology ablation procedure was performed 2.5 months later, with re-appearance 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 radiation. A third unsuccessful ablation procedure was performed; skin lesions appeared 8 days later (Fig 3.4). Each of the three procedures involved >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 to the arm might have been avoided.

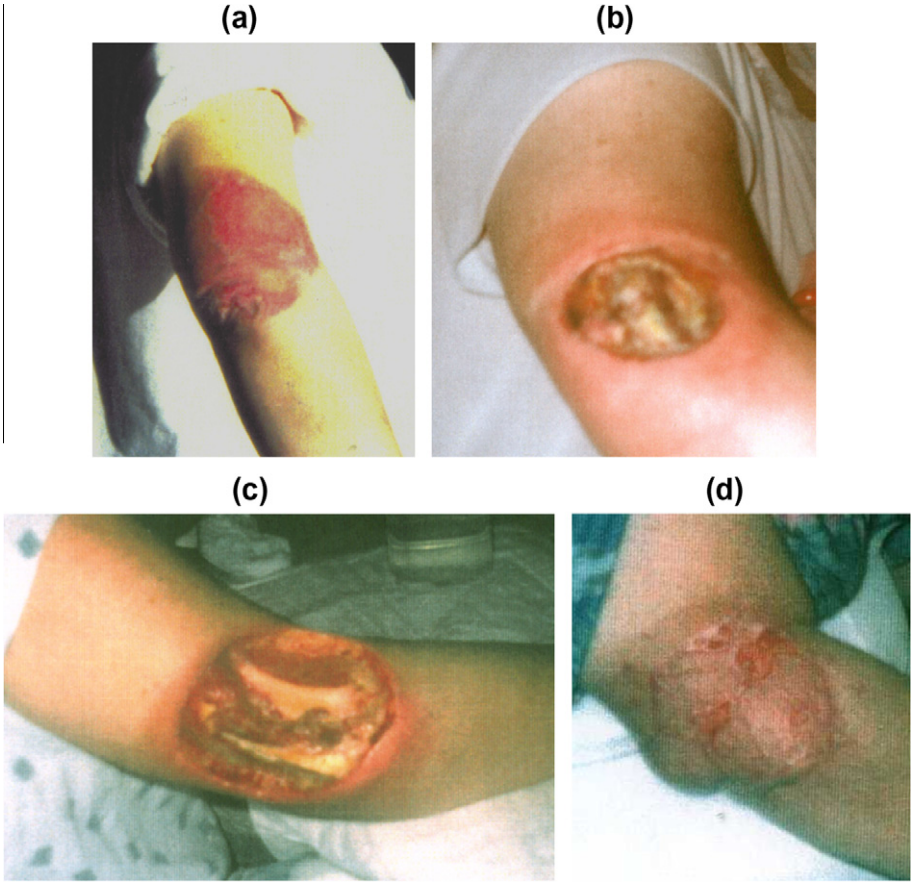


Fig. 3.3. Case 3. See text for details. (a) 3 weeks: area of sharply demarcated erythema. (b) 5 months: tissue necrosis. (c) 6.5 months: deep ulceration with exposure of the bone. (d) Following surgical flap. Source: Wagner and Archer (1997).

3.6. Case 5 (Vañó et al., 1998a)

(66) A 17-year-old female underwent an electrophysiology ablation procedure for posterior pathway pre-excitation that lasted 5 h. Eleven months later, she underwent a second procedure that also lasted 5 h. Both procedures were performed with bi-plane fluoroscopy. Fluoroscopy time for the lateral plane was estimated at 90–120 min. 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, 10×5 cm^2, was observed (Fig. 3.5). The diagnosis was chronic radiodermatitis. The muscles in her right arm have also been affected, with resultant

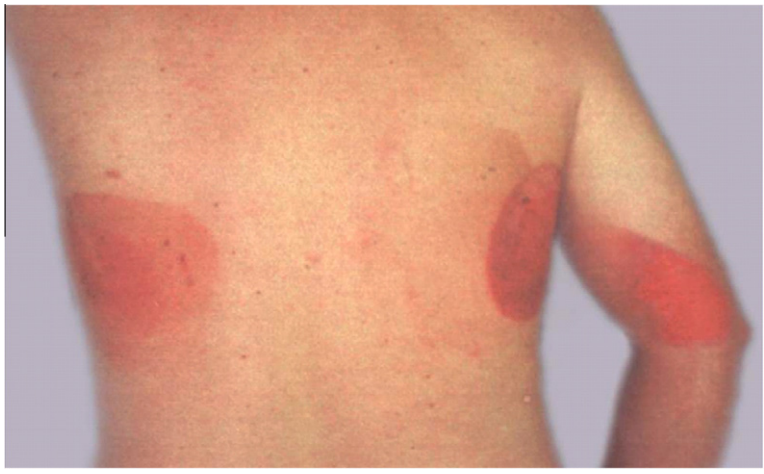


Fig. 3.4. Case 4. The right-sided lesions show desquamation. The erythema on the back healed into discoloured scars. The right arm lesion, closer to the x-ray beam, developed necrosis and required a skin graft. Source: Vliestra et al. (2004).

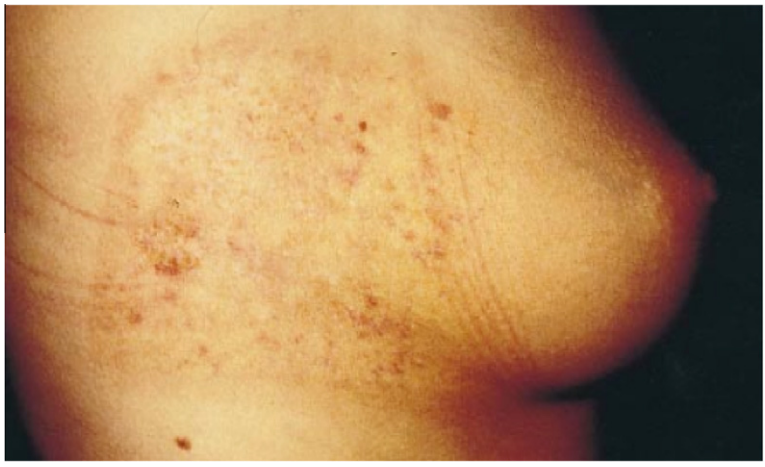


Fig. 3.5. Case 5. Indurated, atrophic plaque with linear edges, with areas of hyper- and hypopigmentation. Source: Vañó et al. (1998a).

limitation in the range of motion. Due to the patient's age and the region irradiated, her risk of subsequent breast cancer is also increased.

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

(67) An obese 57-year-old female, a heavy smoker, underwent PCI. The procedure time was approximately 6 h. No data on radiation dose are available. Early

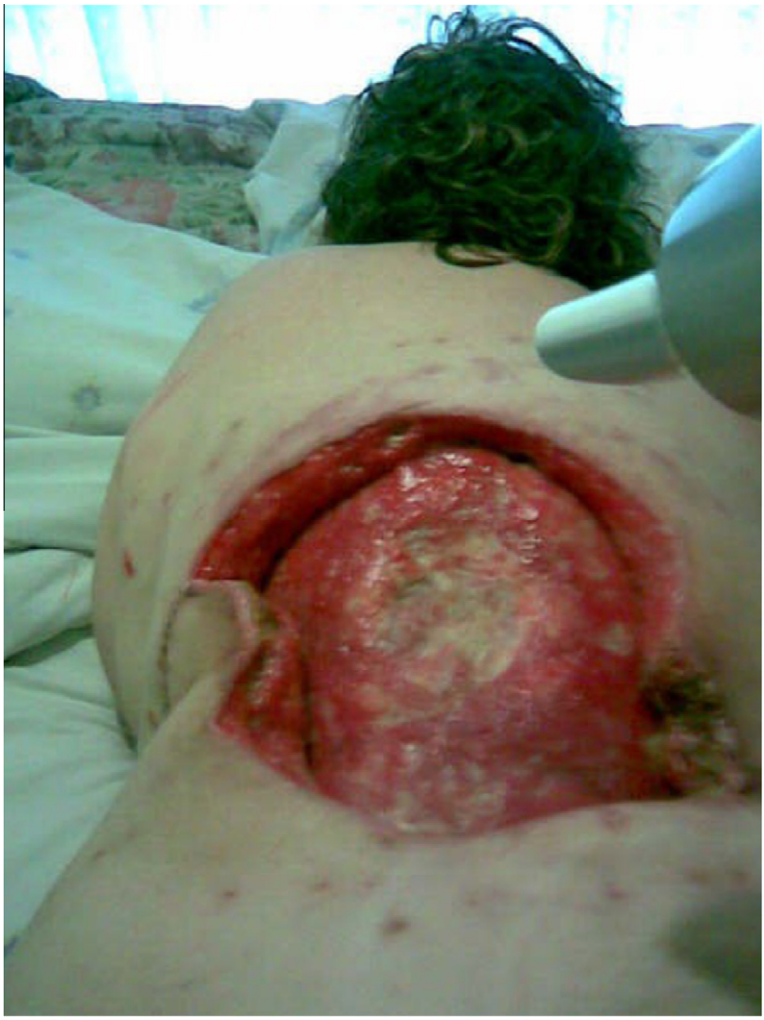


Fig. 3.6. Case 6. Appearance of the patient's back following the initial surgery and necrosis of the rotation flaps. The ulcer is approximately 20×20 cm (courtesy of Dr. M. Portas, Buenos Aires, Argentina).

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 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 20×20 cm (Fig. 3.6). During the next several years, conservative treatment was performed at a specialised burn centre. Wound

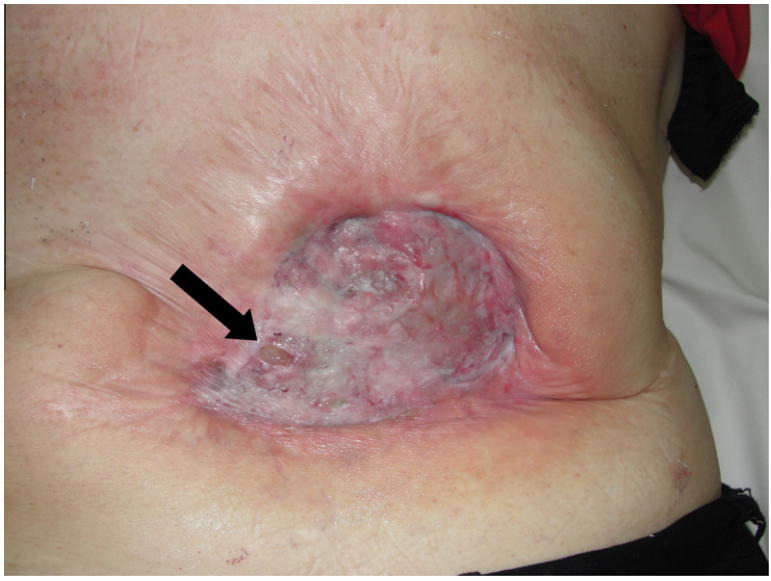


Fig. 3.7. Case 6. Appearance of the patient's back 5 years after percutaneous coronary intervention. After 3 years of treatment with porcine dermis, skin allografts, and autografts, in conjunction with anti-inflammatory and antibacterial therapy, and hyperbaric oxygen treatment, the ulcer is reduced in size to 3×1.5 cm (arrow). The patient's quality of life is much improved (courtesy of Dr. M. Portas, Buenos Aires, Argentina).

coverage was performed with porcine dermis, skin allografts, and autografts, in conjunction with anti-inflammatory and antibacterial therapy, and hyperbaric oxygen treatment. This treatment led to progressive wound closure. After 3 years of treatment (5 years after PCI), the dimensions of the ulcer were reduced to 3×1.5 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.

4. APPLICATION OF THE PRINCIPLES OF RADIOLOGICAL PROTECTION IN MEDICINE

- **Justification in medicine 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.**
- **Justification is a responsibility shared by the referring clinician and the cardiac imager or interventionalist.**
- **Optimisation of protection in medicine means that the radiation dose to the patient is suitable for the medical purpose, and radiation that is clinically unnecessary or unproductive is avoided.**
- **As with all other medical exposures, protection in nuclear cardiology examinations, cardiac computed tomography examinations, interventional cardiology procedures, and electrophysiology procedures should be optimised, and dose reduction techniques should be used whenever applicable.**
- **Patient radiation protection is optimised 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, carers, or comforters.**

4.1. Introduction

(68) The Commission recommends three fundamental principles of radiological protection: justification, optimisation of protection, and application of dose limits (ICRP, 2007b,c). 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, carers, or comforters.

4.2. Justification

(69) 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, 2007b,c). 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 radiological staff and other individuals (ICRP, 2007b).

(70) A medical procedure should only be performed when it is appropriate for a particular patient. A definition of 'appropriate' that is widely used is: 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 (NHS, 1993; Sistrom, 2008). In other words, the anticipated clinical benefits should exceed all anticipated procedural risks, including radiation risk.

(71) In the USA, appropriateness criteria have been developed for many clinical scenarios (Brindis et al., 2005; Douglas et al., 2008; Patel et al., 2009; Hendel et al., 2009a; ACR, 2010; Taylor et al., 2010). Similar guidelines have been developed in the UK, although they are less readily available (RCR, 2007). European guidelines are also available (Hesse et al., 2005; Schroeder et al., 2008). These recommendations are typically based on a standardised 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 patient and family values and preferences (Wolk et al., 2004).

(72) The responsibility for justification of the use of a particular procedure falls on the relevant medical practitioners (ICRP, 2007b). This is a responsibility shared by the referring clinician and the cardiac imager or interventionalist. For the referring clinician, this entails weighing the benefits of a test against its risks, including radiation exposure, and performing this analysis for all possible alternatives, including not performing a test. For the cardiac imager or interventionalist, 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.

4.3. Optimisation of protection

(73) The principle of optimisation 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, maximising the margin of benefit over harm' (NCRP, 1993; ICRP, 2007b,c). This is often summarised using the acronym 'ALARA',[3] which stands for 'as low as reasonably achievable'.

(74) For cardiology procedures, this principle is applied in the design of cardiac facilities that use ionising radiation; appropriate selection, set-up, and use of equipment; and day-to-day working procedures. Optimisation of protection is best

[3] The abbreviation 'ALARA' is often used as equivalent to or instead of the term 'optimisation of protection'. However, the expression 'as low as reasonably achievable' is only part of the concept of optimisation. The entire concept implies keeping patient exposure to the minimum necessary to achieve the required medical objective (diagnostic or therapeutic). In diagnostic imaging and x-ray-guided interventions, it means that the number and quality of images are adequate to obtain the information needed for diagnosis or intervention. In radiation therapy, ALARA only applies to normal tissue, since the dose to the target is not expected to be as low as reasonably achievable, but rather the opposite. Use of the abbreviation 'ALARA' alone and out of this context may be misleading and raise unnecessary controversy.

described as the process leading to a radiation dose to the patient that is suitable for the medical purpose, and avoidance of radiation that is clinically unnecessary or unproductive.

(75) Optimisation of protection means delivering a radiation dose to the organs and tissues of clinical interest no greater than that required for adequate imaging, and minimising dose to other structures (e.g. the skin). Patient radiation protection is optimised 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

(76) 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, 2007b,c). This principle does not apply to medical exposure of patients. As noted in *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, 2007c). For interventional procedures, the medical condition being treated and the non-radiation risks of the procedure typically present substantially greater morbidity and mortality than the radiation risks (Miller, 2008; NCRP, 2010).

5. MANAGING PATIENT DOSE IN FLUOROSCOPICALLY GUIDED INTERVENTIONS

- **Individuals who perform interventional cardiology or electrophysiology procedures should be familiar with methods to reduce radiation dose to patients and staff.**
- **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 operator 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 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 Gycm^2, or an air kerma at the patient entrance reference point of 5 Gy.**

5.1. Introduction

(77) Fluoroscopically guided interventions 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, 2000b). This chapter deals with clinical radiation management before, during, and after fluoroscopically guided interventions.

(78) The doses received by patients during fluoroscopically guided cardiology procedures can be high, and some patients may have several procedures performed in a relatively short period of time. Hence, it is essential that the cardiologist works with the radiographer and other staff to optimise patient radiation protection (Chambers et al., 2011). If a certain dose threshold is exceeded (see Chapter 2), the procedure could result in tissue reactions. For fluoroscopically guided interventions, the typical tissue reaction is skin injury. High radiation doses also increase the risk of stochastic effects (cancer and heritable effects).

(79) 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, 2011). 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, 2012). Excess risks of cardiovascular disease only become apparent 10–20 years after exposure at low doses (1–2 Gy) (ICRP, 2011).

(80) The mean age of patients undergoing PCI is relatively high. The risk of stochastic effects is not a great concern for older patients because of the latency period (10 years or more) for the development of most cancers, and these patients' shorter life expectancies. Patients undergoing electrophysiology procedures tend to be younger. The risk of stochastic effects is of greater concern when fluoroscopically guided procedures are performed on younger adults or children. Children have longer life expectancies than adults, and are also two to three times more sensitive to the effects of radiation than adults.

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

5.2. Before the procedure

(82) 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, 2000b). 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., 2010a).

(83) 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 et al., 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 et al., 2000). Many of the documented injuries associated with fluoroscopic procedures have been seen in larger patients (Koenig et al., 2001b). It is possible to reduce skin dose by raising the table and imaging off-isocentre. Other procedural modifications are also often necessary for obese patients (Bryk et al., 2006).

(84) A medical physicist can provide useful advice to help optimise interventional procedures. During the procedure, a radiographer can provide sound optimisation strategies. Attention to optimisation of protection is especially important for complex procedures and when procedures are repeated, particularly if the patient is obese. 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. When procedures are repeated, a delay between procedures is advisable if clinical circumstances permit. After the skin is irradiated, DNA repair processes are essentially complete within 1 day of exposure. Repopulation, on the other hand, can take up to several months to complete, depending on the radiation dose (Balter et al., 2010).

(85) Except for time-critical emergency procedures, pregnancy status should be determined prior to a fluoroscopically guided intervention (ICRP, 2007c; ACR, 2008). If possible, elective procedures on pregnant patients should be deferred until the patient is no longer pregnant. When medically indicated fluoroscopically guided interventions must be performed on pregnant patients, and except for time-critical emergency procedures, the Commission recommends that procedure planning should include feasible modifications to minimise conceptus dose, estimation of expected radiation dose to the conceptus, evaluation of the radiation 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, 2000a). Whenever possible, and if time permits, the preprocedure planning process should involve a qualified medical physicist (Dauer et al., 2012).

(86) The Commission has stated that, in general, termination of pregnancy at fetal doses <100 mGy is not justified based upon radiation risk (ICRP, 2000a). For comparison, a typical fetal dose from CTA of the coronary arteries is approximately 0.1 mGy and a typical fetal dose from CT of the abdomen is 4 mGy (McCollough et al., 2007).

5.3. During the procedure

(87) When optimising patient radiation protection, the first priority must be to obtain a sufficient number of images of sufficient 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.

(88) Typical values of skin dose rate (surface entrance air kerma rate) during interventional 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. Beam intensity is 10-fold or 20-fold higher in cine mode than in fluoroscopy mode (NCRP, 2010). Skin doses in interventional cardiology and electrophysiology procedures can reach several Gy, especially for complex procedures, steep C-arm angulations, and when several projections with similar C-arm angulations are required (Miller, 2008). These may result in severe skin injuries (Chapter 3). Organ doses may exceed 10 Gy and effective doses may exceed 50 mSv (UNSCEAR, 1993; Stern et al., 1995; Bogaert et al., 2008). 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 IAEA comparing x-ray systems from different countries demonstrated 10-fold differences

for dose values when phantoms of the same thickness were imaged (Ortiz et al., 2004).

(89) Several operational factors can substantially modify the radiation dose received by the patients and affect the kerma-area product (P_{KA} or KAP) and the patient's skin dose (ICRP, 2000b). These are also discussed and illustrated in an ICRP publication devoted to radiological protection outside the imaging department (ICRP, 2010). 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/s 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, 2010). Recommendations for optimisation of protection in the radiology literature apply equally to interventional cardiology procedures (Wagner et al., 2000; Miller et al., 2002, 2010a; Wagner, 2007). Table 5.1 provides practical advice to help reduce patient dose.

(90) During the procedure, the cardiologist should monitor available dose metrics – reference air kerma (RAK), KAP, fluoroscopy time, and the number of cine series

Table 5.1. Practical advice to reduce patient dose.

Use a low-dose-rate fluoroscopy mode when possible
Use a low-pulse-rate fluoroscopy mode when possible
Remove the grid when performing procedures on small children
Use the lowest-dose mode for image (cine) acquisition that is compatible with the required image quality
Minimise 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 available, use a stored fluoroscopy loop for review instead of using fluoroscopy
Minimise the number of cine series
Minimise 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 left anterior oblique 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

and cine frames. (RAK and KAP are defined in the Glossary.) It is important to monitor, in real time, whether the threshold doses for tissue reactions are being approached or exceeded (ICRP, 2007c; NCRP, 2010). Modern fluoroscopy systems, if they are compliant with the international standard for interventional fluoroscopy systems, display radiation data to the operator during the procedure (IEC, 2010). The task of 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, 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.

(91) 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.

(92) 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. Using different C-arm angulations can help reduce peak skin dose, especially when collimation is also used (Miller et al., 2002).

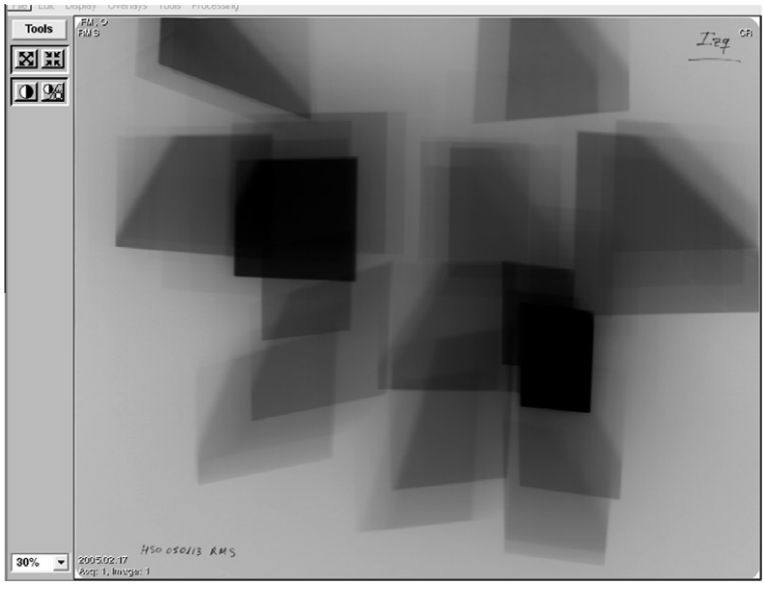
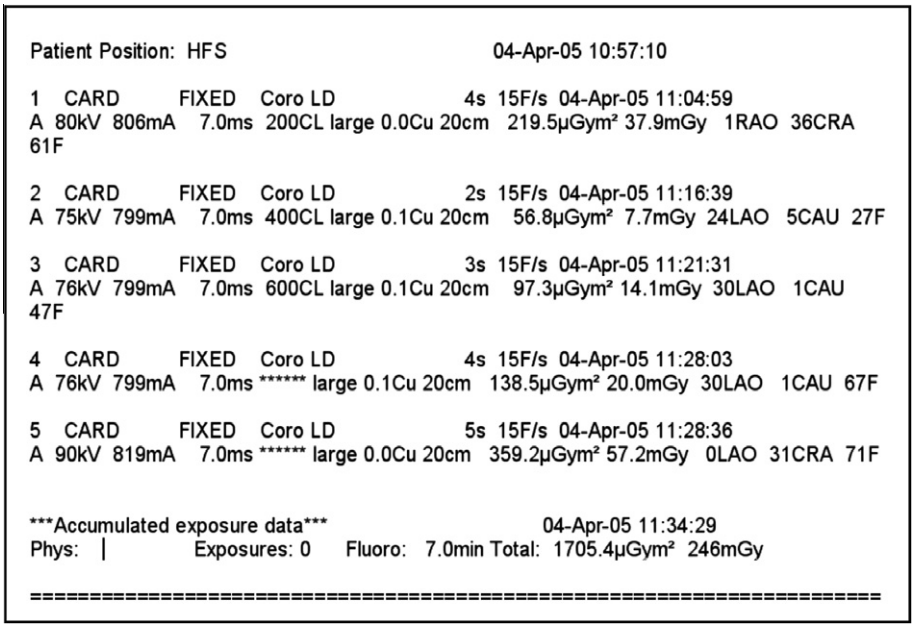


Fig. 5.1. Example of skin dose distribution in cardiology procedures (measured with slow film at the San Carlos University Hospital, Madrid). Skin dose distribution measured during a conventional percutaneous coronary intervention. In this case, the peak skin dose was 0.4 Gy.

However, this must be planned from the beginning of the procedure for maximal effect (Pasciak and Jones, 2011). Fig. 5.1 shows an example of a skin dose distribution mapped and measured with slow film (Vañó et al., 1997a), and demonstrates how overlap of radiation fields can increase the dose to a certain area of the skin.

5.4. After the procedure

(93) 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 fluoroscopically guided 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 et al., 2011).



```
Patient Position: HFS                                  04-Apr-05 10:57:10

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

=========================================================================
```

Fig. 5.2. Example of a patient dose report produced by a Siemens Axiom Artis x-ray system. Entries 1–5 indicate the series acquisition order. Each acquisition is a single cine series. 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, kerma-area product (KAP) per series, reference air kerma (RAK), x-ray beam angulation, and number of frames (for each series) are reported. Total fluoroscopy time and total KAP and RAK (including both fluoroscopy dose and cine acquisitions dose) are also given at the end of the report. The original printing format of the x-ray system is maintained.

(94) Reports of cardiology procedures should document radiation dose (Douglas et al., 2012). All available dose information should be recorded (NCRP, 2010; Miller et al., 2012). Patient doses for cardiac procedures are often reported as KAP. Skin dose distribution, and especially RAK and peak skin dose (defined in the Glossary), are sometimes more important, particularly when repeated procedures are performed on the same patient (Miller et al., 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 (Fletcher et al., 2002; Chida et al., 2006). Fluoroscopy time should not be the only dose-related metric recorded or audited (NCRP, 2010; Chambers et al., 2011).

(95) The management and follow-up of patients who have received a high dose of radiation is also important. If the task of monitoring radiation dose has been delegated to an assistant, that individual should notify the operator at the conclusion of the case if the substantial radiation dose level (SRDL) was exceeded. The SRDL is a trigger level to initiate follow-up of a radiation dose that might produce a clinically relevant injury in an average patient. (SRDL is defined in the Glossary and discussed further in Section 10.6.) Some suggested values for the SRDL are a skin dose of 3 Gy, a KAP of 500 $Gycm^2$, or an air kerma at the interventional reference point of 5 Gy (NCRP, 2010). For cardiology procedures, a KAP of 125–250 $Gycm^2$ may be more appropriate, depending on the radiation field size and the specific protocols. These values could indicate peak skin doses >2 Gy in a single procedure (Bogaert et al., 2009; Bor et al., 2009). 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 et al., 2005; NCRP, 2010). This information may be included in the postprocedure note.

(96) When the SRDL has been exceeded, clinical follow-up is essential for early detection and management of skin injuries (NCRP, 2010; Chambers et al., 2011). The patient should be advised of the possibility of a skin injury due to a tissue reaction, and should be told to examine the beam entrance site 2–4 weeks after the procedure. The operator should be notified if any skin changes are seen. Patients who have not previously notified the operator should be contacted by telephone approximately 30 days after the procedure in order to ensure that a skin injury is not missed. 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, 2010; Chambers et al., 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, 2000b).

5.5. Paediatric patients

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

(98) 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/s, and cine frame rates of 25–50 frames/s. As part of the Step Lightly initiative, the Alliance for Radiation Safety in Pediatric Imaging has published a checklist and guidance for use during paediatric interventional fluoroscopy to help reduce patient doses (Sidhu et al., 2009; Hernanz-Schulman et al., 2011).

6. PROTECTION OF STAFF DURING INTERVENTIONAL FLUOROSCOPY

- **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 interventional cardiology and electrophysiology laboratories.**
- **Radiological protection for the eyes is necessary for operators.**
- **Occupational doses can be reduced to very low levels if ceiling-suspended lead screens and protective lead curtains suspended from the sides of the procedure table are used properly.**
- **Radiation exposure to the operator is neither uniform nor symmetrical.**
- **Proper use of personal monitoring badges is necessary in interventional cardiology and electrophysiology laboratories in order to monitor and audit occupational radiation dose.**
- **Individuals who perform interventional cardiology or electrophysiology procedures should be familiar with methods to reduce radiation dose to patients and staff.**

6.1. Introduction

(99) Despite the Commission's recommendations on occupational dose, there have been reports of cataracts, 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 (Vañó et al., 1998b, 2010; ICRP, 2000b; Ciraj-Bjelac et al., 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 cardiologists who use fluoroscopy, especially for parts of the body not protected by the lead apron.

(100) 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 devices, tools, and techniques, the effective dose for an interventionalist is typically 2–4 mSv/y, and is well below the 20 mSv/y limit recommended by the Commission (Tsapaki et al., 2004; ICRP, 2007b; Dendy, 2008; Miller et al., 2010b). Proper use of personal monitoring badges is essential in cardiac catheterisation laboratories in order to monitor and audit occupational radiation dose. Too often, personal monitoring badges are not worn or are worn improperly (Padovani et al., 2011). Training in radiation management and radiological protection, as discussed in Chapter 9, is essential (ICRP, 2000b, 2009).

6.2. Comparison of radiation exposure with that of other staff

(101) The interventionalist encounters much more radiation than most other medical and paramedical staff in a hospital, even those working in nuclear medicine or radiation therapy. First, the interventionalist'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. Third, 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.

(102) When differences in the working environment between operators and radiographers (technologists) in the catheterisation laboratory are considered – location with respect to shielding and to the patient, number of hours worked in the catheterisation laboratory – exposure factors for the interventionalist are 1000 times higher than for staff working in the control room (Rehani and Ortiz-Lopez, 2006). 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 that at the operator's position (Rehani and Ortiz-Lopez, 2006).

6.3. The essentials of occupational radiological protection

(103) The tools of occupational radiological protection are time, distance, and shielding. Staff radiological protection cannot be handled independently from patient protection as 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 (ICRP, 2010). In general, reducing patient dose will also reduce operator dose.

(104) Time – an essential component of radiological protection for both fluoroscopy and cine – is controlled by reducing the time for which the x-ray beam is on. Reducing fluoroscopy time and fluoroscopy dose rate reduces patient dose. Reduced patient dose results in reduced scatter and therefore reduced operator dose. Readers are advised to remember all of the factors discussed in Chapter 5.

(105) 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). The dose decreases rapidly when a person moves away from the x-ray source (for scatter radiation, this is the patient's irradiated volume). 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 may be able to move away from the patient, ideally behind a shield.

(106) 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.

(107) There are three types of shielding: architectural shielding, equipment-mounted shields, and personal protective devices (Miller et al., 2010b). 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 often particularly well suited for use by nurses and anaesthesia personnel. The interventionalist is protected by equipment-mounted shields suspended from the procedure table; by personal protective devices such as a lead apron, leaded glasses, and a thyroid shield; and sometimes by shields suspended from the ceiling.

(108) Simple measures, such as standing a little distance away from the table and patient, limiting the field size (collimation), and performing 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 catheterisation laboratory, and Table 6.2 presents the relative change in scatter dose rates measured in a typical catheterisation 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

(109) The use of personal protective shielding is essential in the cardiac catheterisation 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 do not demonstrate increases in attenuation that are proportional to the increase in weight (Table 6.3). An inherently conservative safety factor has always influenced practice in radiation protection, both for interventionalists and for regulators.

(110) Lead is very effective for protecting against radiation but it is heavy. The weight can cause problems for staff who wear these aprons for long periods of time (Goldstein et al., 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 have replaced lead with other elements as the attenuating material, and are lighter in 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, provide protection for the wearer's back, and are recommended.

(111) When procedures are performed on smaller patients, particularly on children, a lead apron of 0.25-mm lead equivalence may suffice for staff protection, but for procedures performed on larger patients and procedures performed by physicians with a heavy workload, a greater lead-equivalent thickness may be more

Table 6.1. Practical advice for interventionalists to improve staff radiation protection (from Vañó, 2003a; Miller et al., 2010b; ORAMED [http://www.oramed-fp7.eu/]).

- Increase your distance from the patient (the source of scatter radiation) whenever possible. This is obviously only possible when angiographic runs are not performed by hand. Scatter radiation levels decrease drastically with increased distance from the irradiated volume of the patient.
- 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 shield, a table-suspended screen, and other protective shielding – such as a lead apron, thyroid collar, and leaded glasses with side shields –whenever possible.
- The ceiling-suspended shield should be placed as close to the patient as possible.
- If biplane systems are used, proper use of lateral shields is very important for eye protection.
- 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 (e.g. low-dose-rate pulsed fluoroscopy) when possible.
- Minimise the number of cine series and the number of frames in each cine series.
- Use magnification as little as possible.
- Collimate the x-ray beam as tightly as possible.
- Avoid direct exposure of the hands to primary radiation.
- 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 dose and you will also reduce your own dose.

Table 6.2. Relative increases in staff doses with changes in certain operational features in a Philips Integris 5000 fluoroscopy unit (Vañó et al., 2006b).

Action	Increase in staff dose
Changing from low to high fluoroscopy mode (for a 20-cm-thick patient)	× 2.6
Changing image receptor 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

suitable. Periodical dose monitoring can be implemented to ensure that individuals who use lead aprons are adequately protected (NCRP, 2010).

(112) 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

Table 6.3. Protection of different lead aprons for x-ray beams filtered with 3-mm Al and generated at the kVp indicated (Vañó et al., 2006a).

kVp	Lead equivalence of protective apron (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

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 minimising the irradiation of inspectors by minimising unnecessary fluoroscopy (NCRP, 2010).

(113) A lead apron does not protect the eyes, the hands, the lower legs, or the back (the back is protected if the apron is the wraparound type). Radiation exposure of these parts of the body has become a concern.

(114) Radiological protection for the eyes is essential for interventionalists (Dauer et al., 2010a). Preferably, this protection is provided by ceiling-suspended shields (see 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., 2010b). In these situations, leaded eyeglasses should be worn. They must have side shields and must fit properly (NCRP, 2010). Ill-fitting glasses are uncomfortable and do not provide as much protection as well-fitted glasses. Wearing these eyeglasses has been shown to significantly reduce radiation dose to the operator's eyes (Vañó et al., 2008a; Thornton et al., 2010).

(115) While the dose reduction factor for the lenses of 0.5-mm lead-equivalent protective glasses is approximately 0.03 (i.e. 97% of the radiation is attenuated), the radiation attenuation factor of the eyeglass lenses is not an adequate descriptor, by itself, of the effectiveness of the eyewear (NCRP, 2010). The area covered by the lenses is important. For maximum effectiveness, radiation protective eyewear should intercept as much of the scattered radiation that is directed at the interventionalist's eyes as possible. 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 wraparound design (NCRP, 2010).

(116) Protective eyewear must fit properly to ensure that the lenses and side shields adequately protect the eyes and minimise exposure, and also to minimise 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 two or three

(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.

(117) Wearing a thyroid collar and a protective apron reduces effective dose to approximately 50% of the effective dose achieved by wearing a protective apron alone (Martin, 2009; von Boetticher et al., 2009). In younger individuals, the thyroid gland is relatively sensitive to radiation-induced cancer. The cancer incidence risk is strongly dependent on age at exposure, with very little risk after 30 years of age for males and 40 years of age for females (NRC, 2006). Use of a thyroid collar (or a protective apron with thyroid coverage) should be based on a risk assessment. In general, thyroid protection is necessary for all personnel whose personal monitor readings at the collar level (unshielded) exceed 4 mSv [$H_p(10)$] in a month (Wagner and Archer, 2004; NCRP, 2010). This group includes most interventionalists. Many cardiology laboratories require all staff to wear thyroid shields.

(118) 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, 2000, 2010). Attenuating surgical gloves may be used to provide a small degree of protection when hands are only exposed to scattered radiation, but the use of these gloves does not permit interventionalists to place their hands safely in the primary beam (NCRP, 2010).

(119) There are several factors that could lead to higher hand doses for interventionalists when these gloves are used (Miller et al., 2010b). Just as with special devices 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. Due to 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 and Mulhern, 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, work practices should be altered (Limacher et al., 1998).

6.5. Equipment-mounted shields

(120) At present, the standard shields supplied with fluoroscopy systems for use in cardiology laboratories are ceiling-suspended lead screens and protective lead curtains suspended from the side of the procedure table. If these shields are used properly, occupational doses can be reduced to very low levels.

(121) A leaded glass or plastic screen placed between the patient and the operator protects the operator's eyes, head, and neck. Properly placed shields (as close to the image receptor and as low on the patient as possible, and tilted slightly away from the operator, so as to cast the largest shadow possible on the operator) have been

shown to reduce operator eye dose dramatically (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.

(122) When a frontal (postero-anterior) projection is used and the x-ray tube is below the procedure table, scatter dose rates under the table are three to four 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.

(123) Disposable, lightweight, sterile, lead-free, radiological protection shields, in drape or pad form, can be positioned on the patient outside of the beam path to significantly reduce scattered radiation during cardiac interventional procedures (Germano et al., 2005; Sawdy et al., 2009). 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., 2010b). 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. Occupational exposure from fluoroscopy

(124) The effective dose 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 0.02–38.0 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 catheterisations and ablation procedures due to technological improvements, but doses were not reduced over time for PCIs (Kim et al., 2008). This was believed to be due mainly to the increased complexity of interventions.

(125) Even if one assumes a rather high workload of 1000 angiographic procedures per year, the annual effective dose limit of 20 mSv will rarely be exceeded. One study reported an estimate of effective dose for the operator of only 0.04–0.05 mSv/y (Efstathopoulos et al., 2003), although other studies have reported 2–4 mSv/y (Tsapaki et al., 2004; Dendy, 2008). The extensive studies by Kuon et al. established 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 catheterisation laboratories (Kuon et al., 2002).

(126) 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 position. With postero-anterior and right anterior oblique 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 mainstem coronary artery (left anterior oblique 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 compared with an alternative less-frequently used angulation (caudal postero-anterior 0°/-30°).

(127) Effective dose does not reflect the doses to susceptible, unprotected parts of the body (i.e. the hands and the eyes). Radiation exposure to the operator is neither uniform nor symmetrical. A right-handed operator performing the procedure via the right femoral artery has his/her left side turned towards the patient. Therefore, the left side of the operator's 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 exits the patient. During cardiac catheterisation, the left hand has been reported to receive twice the dose received by the right hand (Vañó et al., 1998c). 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 between the tall operator's eyes and the patient.

(128) 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 a false belief that an individual's occupational dose is low.

6.7. Personal dosimetry

(129) The Commission recommends the use of two personal dosimeters for occupational dosimetry in cardiac catheterisation 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, 2000b). At least one dosimeter (the collar dosimeter) should always be worn. 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. The estimate of lens dose provided by the collar dosimeter is usually acceptable if the x-ray tube is positioned below the patient (Kim et al., 2008), but will overestimate eye dose if protective eyewear is worn. A dosimeter for the hands may also be useful.

(130) The advice of a medical physicist should be sought to interpret monitoring results. Results obtained from both dosimeters can be used to estimate occupational effective dose as recommended by NCRP (NCRP, 1995) and the Commission (ICRP, 2000b). 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:

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

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

(132) The European Commission DIMOND project addressed the issues regarding optimisation of staff protection with an attempt to propose preliminary occupational dose constraints (Tsapaki et al., 2004). UNSCEAR (2000) reported that cardiologists tend to be the most exposed staff in medicine. A recent review of radiation exposures to operators from cardiac procedures over a 30-year period highlighted the difficulty in comparing reported dosimetric results because of significant differences in dosimetric methods in each study (Kim et al., 2008). Better standardisation of dosimetric methods is recommended.

(133) Reported occupational dose values are often surprisingly low, and the reason is not likely to be a high level of radiological protection, but rather failure to wear personal dosimeters. Failure to wear dosimeters is a problem throughout the world (Vañó et al., 1998c; McCormick et al., 2002; Padovani et al., 2011). Lack of compliance with radiation badge policies is a problem in many interventional cardiology services (Vañó and Gonzalez, 2005). For example, McCormick et al. 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% (McCormick et al., 2002).

(134) 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, physicians in training tend to adopt the practices of their seniors (Rehani and Ortiz-Lopez, 2006). A strict policy on the regular use of personal dosimeters should be part of any quality programme in cardiology laboratories. Failure to wear monitoring equipment could be a breach of the employer's procedures and/or local regulatory or legislative requirements.

7. RADIOLOGICAL PROTECTION FOR NUCLEAR CARDIOLOGY

- **Criteria and guidelines for appropriate use have been developed through the consensus efforts of professional societies in order to help set standards for justification in nuclear cardiology.**
- **Optimisation of protection in nuclear cardiology procedures involves the judicious selection of radiopharmaceuticals and administered activities to ensure diagnostic image quality while minimising patient dose.**
- **For single-photon emission computed tomography protocols, ^{99m}Tc-based agents yield lower effective doses than ^{201}Tl, and are preferred on dosimetric grounds.**
- **Administered activities should be within prespecified ranges, as provided in international and national guidelines, and should reflect patient habitus.**
- **If stress imaging is normal, rest imaging can be omitted to minimise total dose.**
- **Practitioners need high-quality dosimetric data to perform proper benefit–risk analyses for their patients.**

7.1. Introduction

(135) 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 SPECT. A small but growing number of laboratories perform PET studies.

(136) 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 USA than in the rest of the world combined. In the USA, 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, 2009). Decreasing use of thallium may have modestly decreased this latter figure since 2006.

7.2. Radiopharmaceuticals

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

(138) Recommended administered activities for nuclear cardiology procedures vary markedly among the professional societies and accrediting bodies in various countries (Hesse et al., 2005). Detailed guidelines on protocols have been published by the American Society of Nuclear Cardiology (ASNC) (DePuey, 2006; Henzlova et al., 2009), the European Council on Nuclear Cardiology (ECNC) (Hesse et al.,

Table 7.1. Commonly used radiopharmaceuticals for nuclear cardiology.

Agent	Modality	Role			Physical half-life	Effective dose per unit activity (10^{-3} mSv/MBq)	ICRP Publication
		Perfusion	Function	Viability			
^{99m}Tc sestamibi	SPECT	+++	++	+	6 h	9.0 rest/7.9 stress	80 (1998)
^{99m}Tc tetrofosmin	SPECT	+++	++	+	6 h	6.9 rest/6.9 stress	106 (2008)
^{201}Tl chloride	SPECT	+++	+	++	73 h	140	106 (2008)
^{99m}Tc red blood cells	Planar or SPECT MUGA	-	+++	-	6 h	7.0	80 (1998)
^{82}Rb chloride	PET	+++	++	-	75 s	3.4*	80 (1998)*
^{13}N ammonia	PET	+++	++	-	10 min	2.0	80 (1998)
^{18}F fluorodeoxyglucose	PET	-	-	+++	110 min	19	106 (2008)

SPECT, single-photon emission computed tomography; PET, positron emission tomography; MUGA, multiple gated acquisition.

* The Commission's dose coefficients for ^{82}Rb, dating to *Publication 53* (ICRP, 1988) and re-iterated in *Publication 80* (ICRP, 1998), reflect 'worst-case' conditions for some organs, as was stated in *Publication 53*, and thus dose estimates derived from these dose coefficients might be overly conservative. Three groups have recently suggested lower dose coefficients [Senthamizhchelvan et al., 2010 (1.11 μSv/MBq); Hunter et al., 2010 (0.74 μSv/MBq); Stabin, 2010 (1.7 μSv/MBq)]; the Commission is currently revisiting the issue of ^{82}Rb dosimetry.

Table 7.2. Recommended injected activity (MBq) for standard cardiac single-photon emission computed tomography (SPECT) and positron emission tomography (PET) protocols according to the American Society of Nuclear Cardiology (ASNC), and a joint group of the European Association of Nuclear Medicine (EANM) and the European Society of Cardiology (ESC).

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

MUGA, multiple gated acquisition; FDG, fluorodeoxyglucose.

* 740–925 for planar imaging.

† For two-dimensional acquisition using camera with bismuth germanate or lutetium oxyorthosilicate crystals.

2005), and a joint group of the European Association of Nuclear Medicine and the European Society of Cardiology. Injected activity from these guidelines is summarised in Table 7.2. Some recommendations on administered activities for individual radiopharmaceuticals are also provided in a joint document of the American College of Radiology, the Society of Nuclear Medicine, and the Society for Pediatric Radiology (ACR, 2009).

7.3. Dosimetry for nuclear cardiology

(139) 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 only 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, 2007b).

(140) Estimates of organ dose and 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.

(141) Tissue dose coefficients quantify absorbed doses to a specific organ in a typical patient, per unit activity administered. For example, the Commission's current liver dose coefficient in an adult for the PET tracer ^{18}F fluorodeoxyglucose is

2.1×10^{-2} mGy/MBq (ICRP, 1998). Thus, a 200-MBq injection of ^{18}F fluorodeoxyglucose is associated with an estimated dose to the liver of 4.2 mGy.

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

(143) Several systems provide mathematical models for estimating dose coefficients, including those of *Publication 30* (ICRP, 1979), the Society of Nuclear Medicine's Medical Internal Radiation Dose Committee (Loevinger et al., 1988) and the 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.

(144) 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, 1988), *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 tissue weighting factors from *Publication 60* (ICRP, 1991). Updated effective dose coefficients reflecting tissue weighting factors from *Publication 103* (ICRP, 2007b) 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 sheets for radiopharmaceuticals.

(145) While these dose coefficients describe radiation exposure to patients, and the evidence base characterising radiation doses to nuclear cardiology workers such as technologists and physicians is more limited (Lundberg et al., 2002; Smart, 2004), it is also important to ensure that radiation dose to workers remains as low as reasonably achievable. Workers should adhere to known radiation safely requirements with respect to use of radiation badges, dose limits, personnel pregnancy, material spills, and other such issues, and should undergo continuing education with regards to radiological protection.

7.4. Current dosimetric estimates

(146) 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 Fig. 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.

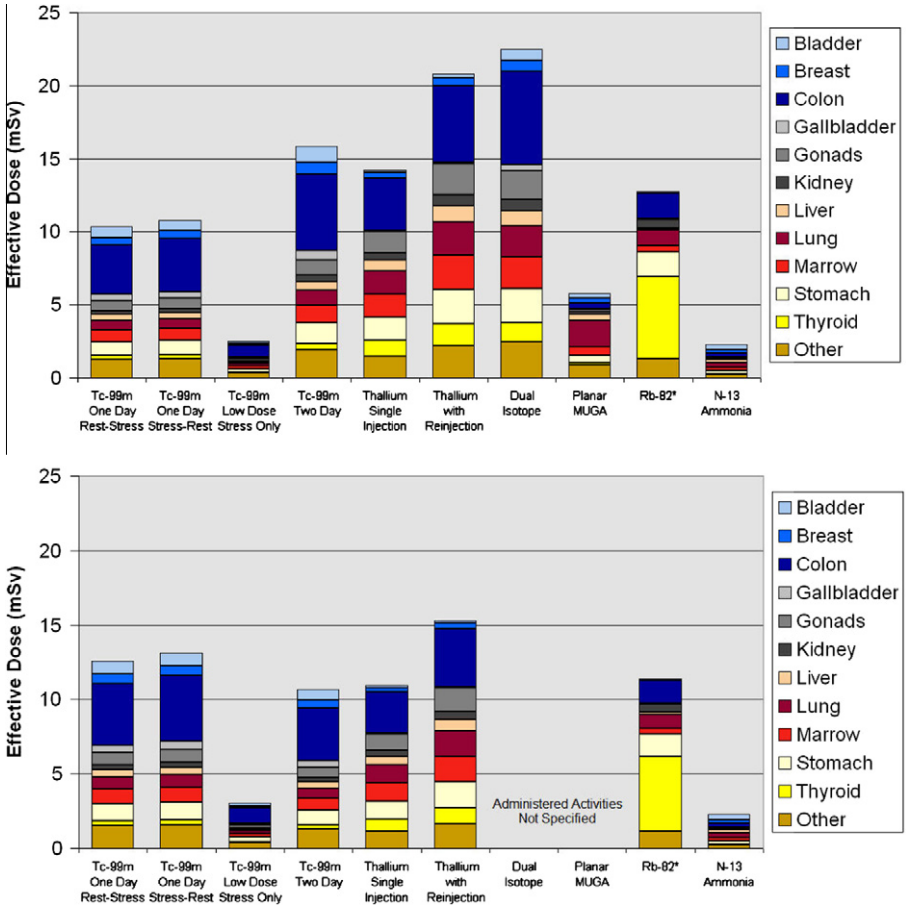


Fig. 7.1. Effective doses from standard nuclear cardiology procedures, estimated using the most recent ICRP dose coefficients and tissue weighting factors from *Publication 103* (ICRP, 2007b). Stacked bars represent organ weighted equivalent doses contributing to effective dose. Doses for ^{99m}Tc represent the average of ^{99m}Tc sestamibi and tetrofosmin. Top: Using average recommended administered activities from the American Society of Nuclear Cardiology guidelines (DePuey, 2006; Henzlova et al., 2009). Bottom: Using average recommended administered activities from the European Council on Nuclear Cardiology guidelines (Hesse et al., 2005). *The Commission's dose coefficients for ^{82}Rb, dating to *Publication 53* (ICRP, 1988) and re-iterated in *Publication 80* (ICRP, 1998), reflect 'worst-case' conditions for some organs, as was stated in *Publication 53*, and thus dose estimates derived from these dose coefficients might be overly conservative. Three groups have recently suggested lower dose coefficients [Senthamizhchelvan et al., 2010 (1.11 μSv/MBq); Hunter et al., 2010 (0.74 μSv/MBq); Stabin, 2010 (1.7 μSv/MBq)]; the Commission is currently revisiting the issue of ^{82}Rb dosimetry.

7.5. Uncertainty in dosimetry

(147) As 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, 1988). The three most sizable contributors to uncertainty are interindividual variability in organ masses, absorbed fractions, and total activity in each organ. Uncertainties in organ activity reflect differences in biokinetics (Stabin, 2008a). Experimental validation of calculated absorbed doses has indicated agreement within 20–60%, 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 two (Stabin, 2008a).

7.6. Discrepancies between ICRP dosimetry and information from manufacturers

(148) 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 test and the choice of radiopharmaceutical, since radiation risk is one factor that should be incorporated into benefit–risk analyses.

(149) One recent report evaluating package inserts in the USA found that effective doses for ^{201}Tl estimated from a single manufacturer's information were less than half of those estimated from the Commission's tables, while doses estimated from package inserts from two other manufacturers were greater than or similar to the Commission's effective doses (Einstein et al., 2007a). 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 (Stabin, 2008b; Gerber et al., 2009).

(150) The Commission recommends that national regulatory authorities should implement programmes 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), periodical postapproval 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

(151) The general principles of radiological protection (Chapter 4) – justification and optimisation – can be applied to the protection of patients in nuclear cardiology. The application of dose limits is not appropriate, but DRLs (Section 7.7.3 and Chapter 10) should be used as an aid to optimisation of protection to help manage the radiation dose so that it is commensurate with the clinical purpose (ICRP, 1977, 2007b,c).

7.7.1. Justification

(152) 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 standardised 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 the inappropriate studies. The most common inappropriate indication was stress testing in an asymptomatic low-risk patient.

(153) Pretest classification of patients by indication (Hendel et al., 2009b), 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 utilisation of cardiac imaging. Appropriateness criteria used to support clinical decisions should be evidence based, and rigorously developed and reviewed by physician organisations with the requisite expertise in the specific services and diseases addressed. For clinical scenarios in which more than one imaging modality might be used, appropriateness criteria should address these multiple modalities simultaneously (ACR, 2010). In clinical scenarios where more than one imaging modality may be considered, physicians should weigh the benefits and risks of each option, and determine which modality would be expected to provide the best balance of diagnostic information quality and risks for the individual patient.

7.7.2. Optimisation of protection

(154) Several methods can be used to control patient dose in nuclear cardiology. These include choosing the most appropriate radiopharmaceutical(s), optimising 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., 2007a).

(155) The choice of protocols is particularly critical. As illustrated in Table 7.2 and Fig. 7.1, 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 ^{13}N ammonia. ^{13}N ammonia is a PET tracer that requires an on-site or nearby cyclotron due to its 10-min half-life. This limits its availability.

(156) SPECT protocols may require one or two injections of a radiopharmaceutical. The radiopharmaceutical may be ^{201}Tl, a ^{99m}Tc-based agent (sestamibi or tetrofosmin), or both. The effective dose depends on the radiopharmaceutical(s) and injected activities selected. In general, ^{99m}Tc is preferable to ^{201}Tl on dosimetric grounds. Effective doses are typically considerably higher for protocols using ^{201}Tl, and lowest for stress-only ^{99m}Tc protocols. A protocol employing ^{201}Tl may be optimal for some patients (e.g. those with a history of ^{99m}Tc images obscured by increased subdiaphragmatic tracer uptake) if an alternative imaging modality is

not used. For patients with a low or low–intermediate pretest probability of a perfusion defect, in whom it is expected that stress imaging will be normal, a stress-first/stress-only protocol is recommended as 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).

(157) Equipment quality control is important in nuclear medicine, just as it is with all other diagnostic and interventional modalities, because radiation protection can only be optimised when the imaging equipment is functioning as intended. Quality control programmes with appropriate medical physics supervision are recommended as one aspect of optimisation of protection.

(158) The Commission recommends formal training in radiological protection for all physicians involved in nuclear cardiology studies, regardless of their medical specialty. This formal training should include training in the application of methods to minimise patient dose, in accordance with the principle of optimisation of protection. The recommended training is described in *Publication 113* (ICRP, 2009). Additional recommendations are available from IAEA (IAEA, 2001).

7.7.3. Diagnostic reference levels in nuclear cardiology

(159) DRLs 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 optimised adequately or whether corrective action is required.

(160) Professional medical bodies (in conjunction with national health and radiological protection authorities) are encouraged to set DRLs 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 have usually been derived from pragmatic values of administered activity based on accepted custom and practice (ICRP, 2007b). Sources of DRLs 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 ^{99m}Tc is recommended per injection in a 2-day protocol, this upper limit should be restricted to larger patients.

7.7.4. The pregnant or nursing patient

(161) Except for time-critical emergency procedures, pregnancy status should be determined prior to any nuclear cardiology study (ICRP, 2000a; ACR, 2008). The patient must be interviewed carefully to assess the likelihood of pregnancy, and urine or serological testing of pregnancy status is recommended for all women of childbearing age. In order to minimise the frequency of unintentional radiation exposure

of the embryo or fetus, advisory notices should be posted in several places within the nuclear cardiology laboratory, and particularly in its reception area. An example of such a notice is:

IF IT IS POSSIBLE THAT YOU MIGHT BE PREGNANT, NOTIFY THE PHYSICIAN OR TECHNICIAN BEFORE YOU RECEIVE ANY RADIOACTIVE MATERIAL.

(162) When a nuclear cardiology examination is proposed for a pregnant woman, care has to be taken to ascertain that the examination is indeed indicated for a medical condition that requires prompt diagnosis and/or therapy. For those diagnostic examinations, the risk to the mother of not performing the examination is greater than the radiation risk to the fetus. If possible, elective procedures on pregnant patients should be deferred until the patient is no longer pregnant.

(163) As for all patients, it is important to ensure that a nuclear cardiology study in the pregnant patient is performed with careful attenuation to implementation of the principle of optimisation of protection. Use of a low-dose protocol is advisable in the pregnant patient (e.g. low-dose stress-first imaging using a ^{99m}Tc-based radiopharmaceutical), with subsequent low-dose rest imaging on a second day only performed if an abnormality is noted on stress imaging. Since radionuclides in maternal tissues contribute to fetal dose, maternal hydration and frequent voiding can reduce the fetal dose after the administration of a number of radiopharmaceuticals.

(164) Occasionally, questions arise about the advisability of becoming pregnant after a nuclear medicine examination. The Commission has recommended that a woman should not become pregnant until the potential fetal dose from remaining radionuclides is <1 mGy. This is not usually a consideration for patients undergoing nuclear cardiology studies.

(165) Since many radiopharmaceuticals are secreted in breast milk, it is safest to assume that, unless there are data to the contrary, some radioactive compound will be found in the breast milk when a radiopharmaceutical is administered to a lactating female. The child should not be breast fed until it is estimated that the amount of secreted radiopharmaceutical will give an effective dose of <1 mSv to the child. It is therefore advised that breast feeding should be interrupted, and that milk expressed during this interruption period should be discarded, for 4 h for ^{99m}Tc sestamibi, tetrofosmin, and red blood cells (in vitro); for 12 h for ^{99m}Tc-labelled red blood cells (in vivo); and for 48 h for ^{201}Tl (ICRP, 2008). For PET tracers with short half-lives, such as ^{13}N ammonia, interruption is not essential due to the short physical half-life. Recommendations for additional radiopharmaceuticals can be found in Annex D of *Publication 106* (ICRP, 2008).

(166) Further guidelines for nuclear medicine procedures in patients who are or may be pregnant can be found in *Publication 84* (ICRP, 2000a).

7.8. Advice to patients

(167) 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 et al., 2007a). In particular, patients who have received ^{201}Tl may trigger these detectors for up to 2 months following the procedure (Dauer et al., 2007b). 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 ^{201}Tl or other radiopharmaceuticals (Dauer et al., 2007b).

7.9. Current research areas

(168) 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 with conventional scanners. Further investigation and clinical validation is required (Patton et al., 2007).

8. RADIOLOGICAL PROTECTION FOR CARDIAC COMPUTED TOMOGRAPHY

- **Criteria and guidelines for appropriate use have been developed through the consensus efforts of professional societies in order to help set standards for justification in cardiac computed tomography.**
- **Justification needs to be performed on an individualised, patient-by-patient basis, weighing the benefits and risks of each imaging test under consideration and the benefits and risks of not performing a test. Assessment of radiation risk is one part of this process.**
- **Dose from cardiac computed tomography is strongly dependent on scanner mode, tube current, and tube potential.**
- **For patients with a heart rate <65–70 beats/min and a regular rhythm, diagnostic image quality can generally be maintained while using dose-reduction methods such as electrocardiogram-based 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, to minimise radiation dose to patients.**

8.1. Introduction

(169) 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 calcium scanning, coronary CTA, 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 computed tomography scanners

(170) 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 patient 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 mGy (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

coronary calcium scanning and coronary CTA (Morin et al., 2003). Electron beam CT scanners had low spatial resolution, and have been supplanted by multidetector row CT (MDCT) scanners. The improved spatial resolution of MDCT scanners enables a more accurate assessment of coronary stenosis and plaque visualisation. Initial efforts at coronary CTA were performed with four-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 more advanced scanners, such as dual source and volume scanners. MDCT is the focus of *Publication 102* (ICRP, 2007a).

8.3. Dosimetric quantities

(171) Currently, three types of dosimetric quantities are utilised for CT. These are: (1) weighted CT dose index ($CTDI_w$) and volume CT dose index ($CTDI_{vol}$), (2) dose–length product (DLP), and (3) 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).

(172) Current MDCT scanners typically report $CTDI_{vol}$ and DLP for each study. Effective dose has been estimated by multiplying DLP by a body-region-specific conversion factor (*k* factor). For cardiac studies, the most commonly used conversion factor is 0.014 mSv mGy^{-1} cm^{-1}; the European Commission's 2004 CT Quality Criteria chest factor (i.e. effective dose is estimated as $0.014 \times DLP$) (Bongartz et al., 2004). This conversion factor does not reflect the more recent *Publication 103* tissue weighting factors (ICRP, 2007b). In addition, it 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 *Publication 102* (ICRP, 2007a).

8.4. Factors affecting patient dose

(173) Factors affecting patient dose in cardiac CT include those intrinsic to the scanner (e.g. scanner generation, model, and manufacturer) and parameters selected by the operator. Hausleiter et al., in an observational study of 50 sites performing coronary CTA, observed a marked difference in effective dose between scanner manufacturers (Hausleiter et al., 2009). Reported doses from coronary CTA vary depending on which generation of MDCT scanners was used (Einstein et al.,

2007a). 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 potential (kV), pitch (IEC, 2009), scan length (craniocaudal coverage), and scan mode.

8.4.1. Tube current

(174) The choice of an appropriate tube current 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 an approximately 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, scan modes, and reconstruction algorithms will produce images with different amounts of noise, so protocols must be tailored. 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 permitting decreased tube current.

8.4.2. Tube potential

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

8.4.3. Scan length

(176) Patient dose is linearly related to the length of the portion of the body irradiated, which is essentially equal to the scan length. Typically, coronary CTA 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.

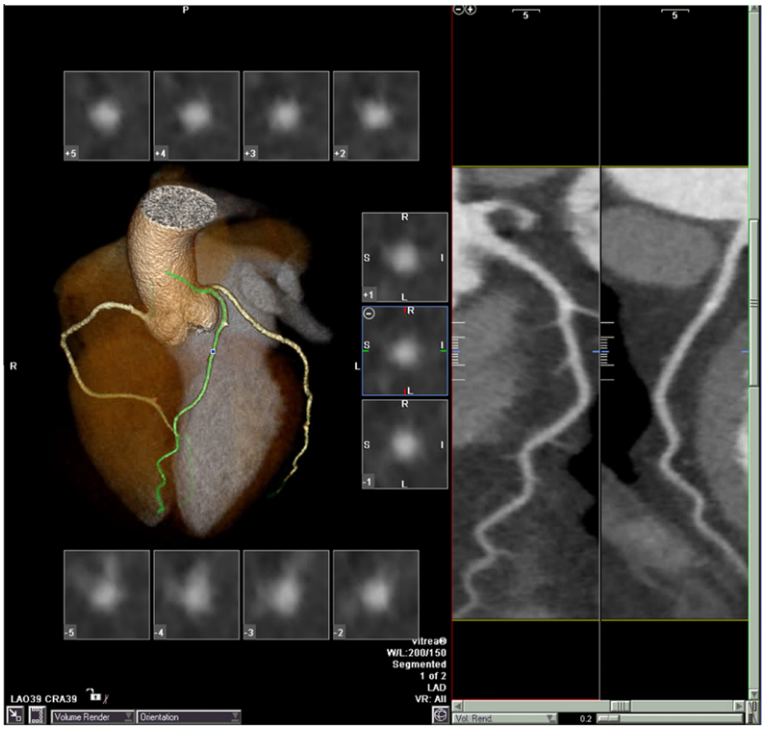


Fig. 8.1. Coronary computed tomography angiogram, obtained using a tube potential of 100 kV and single-heartbeat volume scanning. Source: A.J. Einstein, Columbia University Medical Centre, New York, NY, USA.

8.4.4. Scan mode

(177) Scan modes include conventional helical (spiral) imaging with constant tube current, conventional helical imaging with ECG-based tube current modulation (EBTCM), high-pitch helical imaging, and axial imaging, including both step-and-shoot and volume imaging (Fig. 8.2). Coronary CTA using MDCT was first performed using helical mode and a constant tube current, with a typical pitch of 0.2 for 64-slice scanners (Fig. 8.2a). All current cardiac scanners offer EBTCM, which keeps tube current at its maximum during diastasis, when coronary movement is generally minimised, and decreases tube current during the remainder of the cardiac cycle (Fig. 8.2b). 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 beats/min) and regular heart rhythms, this does not generally pose a problem. Generally, patients should receive beta-blockers or calcium channel blockers to lower heart rate and improve the efficacy of EBTCM. For patients who do not meet these conditions, reconstructions at end-systole are often quite useful for visualising the proximal and mid-right coronary artery (Sanz et al., 2005). If EBTCM is

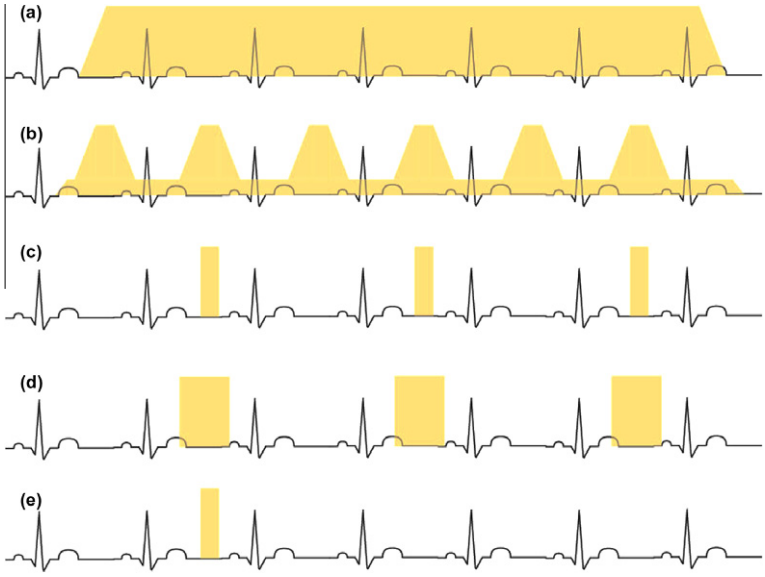


Fig. 8.2. Scan modes used in cardiac computed tomography (CT). Black line denotes electrocardiographic (ECG) signal, shaded region represents tube current. (a) helical scan, (b) helical scan with ECG-based tube current modulation, (c) axial step-and-shoot (prospectively ECG-triggered) scan, (d) axial step-and-shoot (prospectively ECG-triggered) scan with widened exposure/data acquisition time to permit reconstruction of multiple cardiac phases, and (e) axial single heartbeat scan (volume and high-pitch helical scans, illustrated here with minimal exposure time). Not all modes are available on all multidetector row CT scanners.

applied in these patients, it may be advisable to widen the period of time during which tube current is maintained at its maximal value. EBTCM typically decreases effective dose by approximately one-third. For single-source scanners, this decrease in dose is more pronounced with lower heart rates (Jakobs et al., 2002).

(178) More recently, axial coronary CTA protocols have been incorporated into some MDCT scanners. This approach to scanning only acquires image data during prespecified phases of the cardiac cycle, and the x-ray beam is off during the remainder of the cardiac cycle. In step-and-shoot (prospectively ECG-triggered) axial 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 three or four iterations [i.e. five or seven heart beats (five heartbeats illustrated in Fig. 8.2c)]. For step-and-shoot imaging to generate interpretable cardiac images, it is generally thought that heart rate should be <70 beats/min 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 coronary CTA. Disadvantages

include the inability to perform image reconstruction retrospectively at additional phases throughout the cardiac cycle, and the attendant inability to assess cardiac function and wall motion.

(179) One parameter that can be adjusted in axial imaging is the length of time for which the x-ray tube is on, thus increasing dose but acquiring additional data enabling reconstructions within a range of phases of the cardiac cycle (Fig. 8.2d). Thus, rather than only obtaining images in a single portion of diastole, 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.

(180) 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 (Fig. 8.2e). 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 approximately 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.

(181) The clinical literature (Sun and Ng, 2011) evaluating axial coronary CTA and the single-heartbeat modes is more limited than that of helical coronary CTA, lacking multicentre studies evaluating the efficacy of diagnostic accuracy in comparison with gold-standard diagnosis by invasive angiography. Further validation of these scan modes is desirable (von Ballmoos et al., 2011).

8.5. Current dosimetric estimates

(182) Dosimetry from coronary CTA depends on many factors, and thus varies markedly among protocols. Einstein et al. reviewed the published literature on effective dose from cardiac CT in 2007 (Einstein et al., 2007a). Effective doses from coronary calcium scanning ranged from 1.0 to 6.2 mSv using the helical technique, and from 0.5 to 1.8 mSv using the axial technique. For helical 64-slice coronary CTA, effective dose ranged from 8 to 21.4 mSv without EBTCM, and from 6.4 to 14 mSv with EBTCM. In a 15-centre study performed in the USA, median effective dose, estimated using a k factor of 0.014 mSv mGy^{-1} 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 six-fold range in median doses among sites performing coronary CTA. EBTCM was associated with a reduction in DLP and effective dose of 25% (95% confidence interval 23–28%), use of an x-ray tube potential 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 scanning, and many have reported effective doses in the 2–4-mSv range (Earls and Schrack, 2009), although the largest meta-analysis as of 2011

found a mean effective dose of approximately 5 mSv (Sun and Ng, 2011). In comparison with 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 an effective dose of <1 mSv for patients with a slow (≤60 beats/min) heart rate who weigh ≤100 kg (Achenbach et al., 2010) using a k factor of 0.014 mSv mGy^{-1} cm^{-1}.

(183) The very wide range of values for effective dose seen in clinical practice makes it impossible to provide generally applicable 'typical' values of effective dose for cardiac CT. Effective dose is dependent on both the CT scanner and the protocol used. One set of estimates of typical values is presented in Table 8.1, but it must be appreciated that these values should not be considered as target values or representative of clinical practice at any one institution.

(184) Effective doses are determined on a patient-by-patient basis in many of the studies that have assessed CT protocols. The existence of conversion factors, such as those in the European Guidelines on Quality Criteria for CT (Bongartz et al., 2000, 2004), 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 (ICRP, 2007b; Einstein et al., 2008; Gerber et al., 2009). Effective dose is defined for an average person, and should not be used to assess risk for an individual. Citation of these studies is not an endorsement of this approach by the Commission.

(185) The greatest contributions to effective dose from coronary CTA are the weighted equivalent doses to the lungs and female breasts. Absorbed doses from coronary CTA have been reported to be approximately 40–90 mGy to the lungs and breasts using helical scanning, but only 10–12 mGy using axial scanning (Einstein et al., 2007b; Huang et al., 2010).

8.6. Radiological protection of patients in cardiac computed tomography

(186) The general principles of radiological protection (Chapter 4) – justification and optimisation of protection – can be applied to the protection of patients in cardiac CT. The application of dose limits is not appropriate, but DRLs (Section 8.6.3 and Chapter 10) should be used as an aid to optimisation of protection in order to

Table 8.1. Estimated approximate average effective dose for various types of cardiac computed tomography (CT) examinations.

Examination	Effective dose (mSv)*
CT coronary angiography (helical)	19
CT coronary angiography (tube current modulation)	13
CT coronary angiography (prospectively gated)	4
Coronary calcium scanning	2

* Source: Einstein (2009). For other estimates of effective dose, see Einstein et al. (2007a), Earls and Schrack (2009), Gerber et al. (2009), Hausleiter et al. (2009), Kim et al. (2009), Raff et al. (2009), Smith-Bindman et al. (2009), and Sun and Ng (2011).

help manage the radiation dose, so that it is commensurate with the clinical purpose (ICRP, 2007b,c).

8.6.1. Justification

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

(188) In reports from one institution, 46% of coronary CTA studies but only 11% of stress SPECT studies were unclassifiable in terms of appropriateness. Of the remaining classifiable studies, 51% of coronary CTA studies and 72% of stress SPECT studies were appropriate (Gibbons et al., 2008; Miller et al., 2010c). It is unclear from these data whether the difference between modalities primarily reflects a limitation with the first version of the US coronary CTA appropriateness criteria, which left many studies unclassifiable, or whether coronary CTA studies are less likely to be performed for appropriate indications than SPECT studies. Further investigation is required, and programmes to ensure maximal adherence to appropriate use criteria are also encouraged.

8.6.2. Optimisation of protection

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

(190) 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). Coronary calcium scanning should be performed using axial imaging, and should be reviewed in combined studies prior to performance of coronary CTA. The presence of widespread, heavy coronary calcification may suggest that coronary CTA should not be performed due to the high likelihood of coronary segments that cannot be evaluated. 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/min, both to improve image quality and to lower radiation dose.

(191) As noted in Chapter 9, the Commission recommends formal training in radiological protection for all physicians who refer patients for, or perform, cardiac CT studies, including cardiologists, radiologists, nuclear medicine specialists, and internists (ICRP, 2011). This formal training should include training in the application of the principles of justification and optimisation of protection.

(192) Quality improvement programmes (Chapter 10) have been shown to decrease radiation dose substantially for coronary CTA (Raff et al., 2009), and thus their implementation is encouraged. Experts in medical physics can assist in optimisation of protection.

8.6.3. Diagnostic reference levels

(193) DRLs are discussed further in Chapter 10. They 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). If so, a local review should be initiated to determine whether protection has been adequately optimised or whether corrective action is required.

(194) Professional medical bodies (in conjunction with national health and radiological protection authorities) are encouraged to set DRLs 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 DRLs exist for cardiac CT.

8.6.4. The pregnant patient

(195) Except for time-critical emergency procedures, pregnancy status should be determined prior to a CT examination (ICRP, 2000a; ACR, 2008). If possible, elective procedures on pregnant patients should be deferred until the patient is no longer pregnant. Coronary CTA typically involves a scan range extending caudally approximately to the level of the diaphragm, with the uterus positioned outside of the region directly irradiated. As such, in a pregnant patient, the conceptus is generally exposed to a minimal dose of scattered radiation alone (e.g. 0.1 mGy) (McCollough et al., 2007). At such a dose, the attributable risk of fetal malformation or childhood cancer is exceedingly small, and therefore an appropriate, justified coronary CTA examination that may provide significant diagnostic information needed during pregnancy should not be withheld from a pregnant patient. As for all patients, it is important to ensure that coronary CTA in the pregnant patient is performed with careful attenuation to implementation of the principle of optimisation.

9. RADIOLOGICAL PROTECTION TRAINING FOR CARDIOLOGISTS

- **Cardiologists worldwide typically have little or no training in radiological protection.**
- **Legislation in most countries requires that individuals who take responsibility for medical exposures must be properly trained in radiological protection.**
- **Training activities in radiological protection 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 all physicians who use ionising radiation, interventional cardiologists and electrophysiologists should receive a second, higher level of radiological protection 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.**
- **Medical physicists should become familiar with the clinical aspects of the specific procedures performed at the local facility.**
- **Training programmes should include both initial training for all incoming staff, and regular updating and retraining.**
- **Scientific congresses should include refresher courses on radiological protection, attendance at which could be a requirement for continuing professional development.**

9.1. Introduction

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

(197) In the past, training in radiological physics and radiological protection was not necessary for non-radiologists, as x rays and other radiation sources were only employed in radiology departments by staff with reasonable training in radiological protection. Although x-ray fluoroscopy has been in use for more than a century now, its early application involved visualisation 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, equipment

(CT, fluoroscopy, nuclear medicine and radiography equipment) was installed in other clinical departments and outpatient facilities, and used by non-radiologists without radiologist participation. These non-radiologists were not subject to the training requirements of radiological physics and radiological protection that were mandatory for radiologists. It is now clear that this training is essential (Douglas et al., 2012), hence the need for specific guidance for cardiology.

(198) The Commission has addressed the specifics of training for interventionalists, nuclear medicine specialists, medical physicists, nurses, and radiographers/technologists, among others, in *Publication 113* (ICRP, 2009).

9.2. Requirements on radiological protection

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

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

(201) Training activities in radiological protection should be followed by an evaluation of the knowledge acquired from the training programme. Education and training in radiological protection should be complemented by formal examination systems to test competency before the person is awarded certification. If certification in radiological protection is required for some medical specialties (e.g. interventional cardiology, electrophysiology), certification should be obtained before the individual is permitted to practice 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 syllabi to ensure a consistent approach, and to promote and support education and training. Scientific congresses should include refresher courses on radiological protection, attendance at which could be a requirement for continuing professional development for professionals who use ionising radiation (ICRP, 2009).

9.3. Interventional fluoroscopy

(202) The Commission, in *Publication 85* (ICRP, 2000b), stated 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 in both clinical techniques and radiological protection. The Commission further stated 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, 2009).

(203) 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.

(204) In *Publications 85* and *113*, the Commission recommended a second level of radiological protection training for interventionalists, in addition to the training recommended for all physicians who use ionising radiation (ICRP, 2000b, 2009). The Commission also recommended 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. Medical physicists should become familiar with the clinical aspects of the procedures performed at the local facility, as the practical advice offered by medical physicists will almost always be enhanced if they have a working knowledge of the clinical procedure and its imaging requirements.

(205) In view of the number of radiation-induced injuries reported in recent years among patients undergoing interventional procedures (ICRP, 2000b; Koenig et al., 2001a; Vañó and Gonzalez, 2005; Rehani and Ortiz-Lopez, 2006), a number of organisations have started 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

(206) The US FDA advisory of 1994 (FDA, 1994) alerted facilities to ensure proper training. The FDA's specific recommendations for facilities in which invasive procedures are performed include 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.

(207) 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' (American College of

Cardiology Cardiac Catheterization Committee, 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).

(208) 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 (Limacher et al., 1998; Hirshfeld et al., 2004). The proposed curriculum in the 2004 document specifies the knowledge that a qualified physician should possess in order to be credentialled 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.

(209) The necessary knowledge depth varies, depending upon the types of fluoroscopically guided procedures that 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 catheterisation, temporary pacemaker placement, and intra-aortic balloon pump placement. The advanced curriculum is appropriate for physicians who perform angiographic, interventional, and electrophysiology procedures that employ greater amounts of radiation in more complex circumstances with different purposes, and a greater attendant risk of patient and personnel injury.

(210) In the USA, NCRP 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 room during a fluoroscopically guided intervention shall have appropriate radiological protection training.
- Every person who operates or supervises the use of equipment during a fluoroscopically guided intervention shall have current training in the safe use of that specific equipment.
- Interventionalists who perform fluoroscopically guided interventions 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 fluoroscopically guided interventions.
- Clinical training and experience is not an acceptable substitute for formal training in radiation management.

9.3.2. European Commission

(211) In compliance with European Commission requirements, an outline for specific training in radiological protection for interventional radiology has been developed (Vañó et al., 1997b; EC, 2000). Although there is no specific mention of interventional cardiology in the group of professionals, the table giving the suggested number of training hours has a column for interventional cardiology specialists;

20–30 h of training are suggested. The initial Spanish experience, based on these guidelines, has been reported (Vañó et al., 2003). This included development of a training CD [MARTIR (Multimedia and Audiovisual Radiation Protection Training in Interventional Radiology), 2002].

9.3.3. International Atomic Energy Agency

(212) IAEA has developed a curriculum with educational objectives specifically for interventional cardiologists. It is directed primarily at developing countries where the cardiology 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. World Health Organization

(213) 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.

9.3.5. Credentialling

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

10. QUALITY ASSURANCE PROGRAMMES

- **Two basic objectives of the radiological protection quality assurance programme are to evaluate patient radiation dose periodically, and to monitor occupational radiation dose for workers in cardiology facilities where radiation is used.**
- **Training in radiological protection (both initial and retraining) should be included in the quality assurance programme for all staff involved in imaging procedures and interventional cardiology procedures.**
- **A cardiologist should have management responsibility for the quality assurance programme aspects of radiological protection 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 and installation of a new cardiology interventional fluoroscopy laboratory, computed tomography scanner, x-ray or nuclear medicine system, or upgrade of existing equipment.**
- **Quality assurance programmes in cardiology should include patient dose audits for fluoroscopy, computed tomography, and scintigraphy.**
- **Periodical evaluation of image quality and procedure protocols should be included in the quality assurance programme.**
- **The quality assurance programme should ensure the regular use of personal dosimeters and include a review of all abnormal dose values.**
- **The quality assurance programme 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 the procedure and patient identification.**
- **The quality assurance programme should include patient dose audits (including comparison with diagnostic reference levels) for fluoroscopy, computed tomography, and scintigraphy.**

10.1. Introduction

(215) Quality assurance programmes (QAPs) 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. that there is consistent production of adequate diagnostic information with the lowest acceptable exposure of patients and personnel) (WHO, 1982).

(216) A QAP for cardiology includes all of the aspects of radiological protection of patients and staff in addition to the usual clinical aspects. Only the radiological protection aspects are discussed here. Two basic objectives of the QAP are to evaluate patient radiation dose periodically and to monitor occupational radiation dose for workers in cardiology facilities where radiation is used. The radiological protection component of the QAP for cardiology should be an independent portion of the gen-

eral QAP for x-ray and nuclear medicine installations in a particular health centre. The following list summarises 10 key points to be included in a radiological protection QAP:

- Facility design.
- X-ray equipment (selection criteria).
- Radiological protection tools.
- Availability of dosimeters.
- Availability of personnel and their responsibilities.
- Training in radiological protection (initial and continuing).
- Patient dose audit and reporting.
- Clinical follow-up for high patient radiation doses.
- Image quality and procedure evaluation.
- Staff radiation doses.

(217) A cardiologist should have management responsibility for the QAP aspects of radiological protection for cardiology, and should be assisted by a medical physicist. The radiation protection advisor/radiation safety officer should also be involved in monitoring occupational radiation dose. The radiological protection QAP for cardiology should be reviewed at least annually to allow the opportunity for updates and periodical follow-up. Self-audit of the QAP is also advisable. The following list presents some questions to be answered as part of this internal audit of the QAP:

- Can your centre report patient radiation 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 the quality control tests of your x-ray system?
- Are you following your staff radiation dose values?
- Do you have a continuous training programme in radiological protection?

10.2. Facilities

(218) 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 radiological protection. A senior physician (interventionalist, electrophysiologist, nuclear medicine specialist, or CT imaging specialist, as appropriate), a medical physicist, and a senior radiographer/technologist 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 given in Table 10.1.

(219) Suggested architectural specifications for catheterisation laboratories have been published by scientific societies (ACC/AHA, 1991), and include 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), and easy

Table 10.1. Facility procurement considerations (ICRP, 2000b).

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
	Ability for user to optimise dose settings and protocols
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.

access for personnel and patients. 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.

(220) Appropriate shielding, access to the x-ray room, and radiological protection devices (aprons, thyroid protectors, protective gloves and glasses, protective screens, ceiling-suspended and under-table shields) should be part of the planning for catheterisation and electrophysiology 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

(221) Acceptance testing is performed by the company supplying the equipment in the presence of technical personnel from the centre buying the system, or by centre technical personnel. This should include tests to determine the functionality of the radiation safety features of the equipment. Commissioning of the new equipment before its clinical use should be the responsibility of the personnel of the centre.

(222) Periodical quality control, including dosimeter calibration, should be planned taking into account international standards, local regulatory requirements, local recommendations, and the recommendations of the x-ray system manufacturer. These should also include practical results to assist the cardiologist in appropriate management of patient doses (e.g. dose rate in different fluoroscopy modes, dose per frame during cine acquisition, CT scan protocols).

(223) Periodical 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 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 radiographers/technologists, 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.

(224) It is possible to perform this periodical evaluation of image quality using clinical criteria. For example, the European DIMOND (Consortium (http://www.dimond3.org/WEB_DIMOND3/home.htm) has proposed a set of criteria to evaluate fluoroscopic cardiac imaging (Bernardi et al., 2001a,b).

(225) For each imaging modality they use, cardiologists should learn the dose required to obtain an adequate level of diagnostic information. For interventional fluoroscopy, the relevant factors are discussed in Chapter 5. Concerns related to nuclear medicine doses are discussed in Chapter 7. CT scan protocols, modes, technique factors, and their effect on patient dose are discussed in Chapter 8.

10.4. Staff

(226) 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. Medical physicists should be active in cardiology departments where radiation is used. They should work with cardiologists to ensure that proper equipment is purchased and utilised. Physicists can guide cardiologists in achieving the proper balance of dose and image quality, and oversee the training of all members of the department.

(227) 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 fluoroscopy laboratories should wear appropriate dosimeters, and a strict policy for their use should be implemented. Additional electronic dosimeters may also be useful, especially for radiological protection 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

(228) Training in radiological protection (see Chapter 9) should be included in the QAP. Initial accreditation in radiological protection should follow local requirements. Special attention to training in radiological protection 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 quality assurance activity. Training is discussed in more detail in *Publication 113* (ICRP, 2009).

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

(229) The QAP should establish a trigger level for individual clinical follow-up when there is a risk of radiation-induced skin injuries (ICRP, 2000b; WHO, 2000; NCRP, 2010). The 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. Suggested values have included a skin dose of 3 Gy, a KAP of 500 $Gycm^2$, or an air kerma at the interventional reference point of 5 Gy (NCRP, 2010). For cardiology procedures, a KAP between 150 and 250 $Gycm^2$ may be more appropriate, depending on the radiation field size and the specific protocols. These values could indicate peak skin doses >2 Gy in a single procedure. SRDL 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).

(230) 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 tissue reactions, 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. Subsequent evaluation of cases where the SRDL is exceeded should be part of the QAP, as should follow-up of these patients (Section 10.7.3).

10.7. Dose audits

(231) 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 Fig. 5.2. If such reports are not available, dose values should be recorded together with the procedure and patient identification (Miller et al., 2012). If the reports are only available as printed copies, 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.

(232) For interventional fluoroscopy, the 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.

(233) 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 and 10.7.4) because these procedures also present a risk of tissue reactions.

10.7.1. Diagnostic reference levels

(234) Dose guidelines were first introduced in the USA and the UK in the late 1980s and early 1990s (Wall and Shrimpton, 1998). They were introduced into ICRP recommendations as 'investigation levels' in *Publication 60* (ICRP, 1991) and as 'diagnostic reference levels' 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, 2000b, 2007b,c).

(235) 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 to 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.

(236) 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 and Shrimpton, 1998; Vañó et al., 2008b). The mean radiation dose for the procedure is then compared with the DRL. If local practice results in a mean radiation dose that is greater than the DRL, the equipment should be investigated. If the equipment is functioning properly and within specification, procedure protocols and operator technique should be examined (Vañó and Gonzalez, 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

(237) At present, there is little evidence to indicate that dose levels are decreasing in interventional cardiology and electrophysiology. 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 optimisation of protection in interventional fluoroscopy procedures (ICRP, 2007c). 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 the relative 'complexity' of the procedure into account (ICRP, 2007c). Other methods have also been proposed (NCRP, 2010).

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

(239) The European SENTINEL Consortium proposed reference levels for radiation doses delivered to patients during two types of invasive cardiology procedures: coronary angiography and percutaneous transluminal coronary angioplasty (PTCA) (Padovani et al., 2008). The proposed DRLs for coronary angiography and PTCA were KAP values of 45 $Gycm^2$ and 85 $Gycm^2$, fluoroscopy times of 6.5 min and 15 min, and 700 frames and 1000 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.

(240) Bernardi et al. performed studies in Udine, Italy (Bernardi et al., 2000) and later in several European hospitals (Neofotistou et al., 2003), with quantitative assessments of complexity in relation to a patient's exposure to radiation. The relationships between several clinical factors, anatomical factors, and technical factors vs 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.

(241) IAEA carried out an international project to determine the feasibility of establishing guidance levels for cardiac catheterisation and PCIs (IAEA, 2009). The IAEA report has been summarised in a separate publication (Balter et al., 2008). For PTCA procedures, the report recommended the use of a reference level using KAP of 100 $Gycm^2$ for simple procedures, 125 $Gycm^2$ for moderately complex procedures, and 200 $Gycm^2$ 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

(242) Reference levels are used to evaluate the average dose per procedure. Due to 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 sufficiently high to cause tissue reactions.

(243) Cases that require a radiation dose greater than the SRDL (Section 10.6) should be identified and reported to the laboratory director and laboratory quality manager periodically. A monthly report is helpful to ensure that patients with high radiation doses receive appropriate education and follow-up.

(244) 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 ensure that all patients who receive a high radiation dose have been appropriately informed, and that appropriate follow-up is scheduled and performed (Miller et al., 2010a).

(245) Cases resulting in possible radiation injuries should be discussed at the next laboratory quality assurance 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., 2010a).

10.7.4. Evaluation of skin dose for interventional fluoroscopy procedures

(246) It is helpful 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) (Vañó et al., 1997a; Guibelalde et al., 2003), and to establish the relationship between KAP and skin dose for procedures performed at the facility (IAEA, 2010). Skin dose may be measured with special film, with dosimeters placed directly on the patient's skin, and by other means (Miller et al., 2012). A qualified physicist should be consulted for these measurements. In the near future, it may be possible to obtain skin dose estimates and skin dose maps in real-time using automated methods (Khodadadegan et al., 2010; Miller et al., 2012).

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