ICRP ref 4850-2328-1208
2017 March 20
MC Critical reviewers: D. Cool, C. Cousins

Annals of the ICRP

ICRP PUBLICATION 1XX

Occupational Radiological Protection in Interventional Procedures

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PUBLISHED FOR

The International Commission on Radiological Protection

by

[Sage logo]

Please cite this issue as 'ICRP, 201X. Occupational radiological protection in interventional procedures. ICRP Publication 1XX. Ann. ICRP XX(X).'

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110 ICRP Publication 1XX

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112 Approved by the Commission in Month20XX

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115 **Abstract**–to be drafted.

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119 *Keywords:* Word 1; Word 2; Word 3; Word 4; Word 5

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PREFACE

Over the years, the International Commission on Radiological Protection (ICRP), referred to below as 'the Commission', has issued recommendations and guidance on protection against the risks associated with ionising radiation. *Publication 103* (ICRP, 2007) contains the most recent update of these recommendations and *Publication 105* (ICRP, 2007) summarises the application of the principles to medical exposures.

These reports are of a general nature, but the Commission decided to also address specific problems and difficulties that have been observed, especially in the rapidly evolving use of radiation in medicine. This has been achieved by means of concise reports focused and written in a style which is accessible to those directly involved in the procedures and are therefore, directly concerned in their daily work, and by taking effort to ensure wide circulation of such reports.

Examples of these concise reports are publications concerned with interventional procedures, such as *Publication 85* (ICRP, 2000b) on avoiding radiation injuries, *Publication 117* (ICRP, 2010a) on radiological protection from fluoroscopically guided procedures outside the imaging department and *Publication 120* (ICRP, 2013a) on radiological protection in cardiology. These reports provide practical advice aimed at protecting all members of the staff involved in the interventions.

However, a reader audience composed of hospital administrators, staff in charge of radiological protection of the hospital, dosimetry services staff, clinical applications specialists from the suppliers and maintenance companies as well as regulators, need knowledge on occupational exposure assessment and tools and methods for occupational protection. They also need advice on specific issues, such as extremity and eye dose assessment, with and without eye protection, selection of protective garment (e.g. aprons, thyroid shielding, protective eyeglasses), estimation of effective dose when apron is worn, and auditing the interventional procedures when occupational doses are unusually high or low (the latter meaning that the dosimeter may not have been worn). Provision of guidance on these issues is the purpose of this report.

The membership of the Working Party was as follows:

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EXECUTIVE SUMMARY

Background

(a) Physicians in many medical and surgical specialties, assisted by nurses and radiographers (radiological technologists), perform interventions guided by radiological imaging as an alternative to open surgery. On average, these interventions are less invasive, their recovery periods are shorter, and for many types of interventions the complication rate is lower than for the equivalent open surgery. In addition, some patients who may not tolerate anaesthesia and open surgery, as well as lesions that were not previously accessible can now be treated by less invasive image guided interventions.

(b) The number of interventions guided by imaging is increasing steeply in both developed and developing countries. New types of interventions are also of increased complexity, require extensive use of x-ray imaging and raise new issues of occupational protection. Not only interventional radiologists and cardiologists but also other specialists, usually with little or no training in radiological protection, are becoming users of interventional guidance.

(c) The considerable variation in occupational exposures observed for the same type of procedure, suggests that radiological protection practices can be improved. Some recent ophthalmological studies, such as those performed under the coordination of the International Atomic Energy Agency (IAEA) programme, the Retrospective Evaluation of Lens Injuries and Dose (RELID), have shown an increased incidence of radiation-related eye lens opacities in interventionalists when radiological protection devices were not used properly and radiological protection principles were not followed.

Purpose and scope of the report

(d) In *Publications 117* (ICRP, 2010a) and *120* (ICRP, 2013a), the Commission provided practical advice on occupational radiological protection for physicians and other health care personnel involved in fluoroscopically-guided interventions. The current document provides guidance on exposure monitoring strategies, methods and options, radiological protection approaches and garments, their use and testing, the development of a radiological protection programme, education and training and quality assurance of the programme implementation. The guidance is meant for medical physicists and other healthcare professionals in charge of occupational protection, personnel working in dosimetry services, clinical applications support personnel, regulators and all those having an influence on the overall safety culture and on quality assurance and improvement. In addition, the guidance will be useful to those engaged in training, standardisation of equipment and procedures, to those with responsibilities for occupational health and to hospital managers and administrators responsible for providing financial support for protection purposes and to professional bodies (interventionalists, medical physicists, nurses, radiographers).

Uses of image guided interventions, ccupational exposures and observed effects

Uses

(e) Interventions are usually guided by fluoroscopy, and radiographic cine-like series of images are taken to document the lesion and outcome of the intervention. Interventions can also be guided by CT imaging, with images taken while the interventionalist can step behind a mobile shield or out of the room, or by CT fluoroscopy, in which the interventionalist stays in the room when exposing the patient for obtaining images during device manipulation. The principal advantage of CT fluoroscopy over ordinary CT images is the real-time monitoring to access lesions that move within the body as a result of patient breathing or other motion. Its use allows interventions to be performed more rapidly and efficiently. On the other hand, CT fluoroscopy also may result in relatively high radiation doses to both the patient and the physician operator.

(f) X-ray image guided therapeutic interventions such as radioembolisation with ^{90}Y-labeled microspheres (selective internal radiation therapy, SIRT) are an alternative method to treat patients with unresectable primary or secondary liver tumours. Several hospitals are exploring the use of real-time PET-CT-guidance during interventional procedures, such as for biopsies and/or radiofrequency ablations. The use of ^{18}F-FDG PET/CT imaging within the suite to identify where the embolisation or biopsy should be performed as well as to check on effectiveness of interventions and to detect residual disease early after radiofrequency ablation allows ablation to be repeated, if necessary, to obtain the maximum therapeutic benefit.

The occupational exposures

(g) With the appropriate protection, it is possible for active interventionalists to keep their annual occupational effective dose below 10 mSv, and typically within a range of 2–4 mSv or less. Some surveys, however, have shown that individual occupational doses may exceed these values and have considerable variation.

(h) The dose to the lens of the eye has received increased attention as evidence has become available that cataract development may have a much lower threshold for occurrence than was historically believed. The Commission's recommendations have lowered the equivalent dose limit for the lens of the eye from 150 mSv per year to 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv. The nature of interventions guided by radiological imaging is such that, without protective measures for the eyes, personnel with a medium or high workload would receive eye lens doses that would exceed the new annual dose limit, and over time could result in eye lens opacities.

(i) Dose to the hand of the physician nearest to the x-ray irradiated patient volume can be high thus causing the need for specific hand monitoring. Values for annual lower extremity doses up to 110 mSv have been found, despite the use of a protective curtain hanging on the side of the treatment couch. This exposure is attributed to the gap between the protective curtain and the floor, the size of which being dependent on the height of the x-ray table during exposure.

The observed effects

(j) Several ophthalmological studies were conducted on a sample of interventional cardiologists and nurses who were attending cardiology congresses and who voluntarily participated in the studies under the coordination of the IAEA programme, the RELID). About 40–50% of interventionalists, an incidence rate which was 4–5 times higher than that of the unexposed individuals of control group, and 20–40% of technicians and nurses participating in the studies were found to have posterior subcapsular opacities compatible with injuries derived from exposure to ionising radiation. The control group, consisting of similar-aged unexposed individuals, had only this kind of opacities in around 10% of the cases. Professional lifetime lens doses were estimated to reach several Gy in some cases.

Occupational exposure monitoring and exposure evaluation

(k) A survey performed within the IAEA Information System on Occupational Exposure in Medicine, Industry and Research (ISEMIR) (IAEA, 2014b) showed that 76% of interventional cardiologists always used their dosimeters and 45% used two dosimeters. This survey relies on self-reporting and may over-estimate true dosimeter use. In addition, in a number of places of the world, there is a lack of proper monitoring of radiation doses to professionals involved in interventional procedures and often individual dosimeters are not regularly worn.

(l) In addition to assessing the effective dose, occupational exposure monitoring in interventions guided by radiological imaging need to evaluate doses received by the lens of the eyes and in some cases the extremities.

Assessment of effective doses

(m) The combination of the readings of two dosimeters, one shielded by the apron and one unshielded above the apron at the collar level, provides the best available estimate of effective dose (as already stated by the Commission in previous reports). The dosimeter under the apron also provides evidence that an apron of sufficient shielding was regularly worn.

Assessment of eye doses

(n) The dosimeter above the apron, at collar level, not only contributes to assessing effective dose but also provides a reasonable estimation of the dose to the eye lens and the head dose.

(o) Improved methodologies need to be developed to assess eye lens doses when lead glasses are worn. Research programmes should pursue the development of computational technologies (not requiring dosimeters), with personnel position sensing, to assess personnel doses, including eye doses.

Extremity doses

(p) Assessment of dose to the hands in some specific complex interventional procedures needs more attention in the future. Wrist dosimeters may not be able to reflect real finger doses, if part of the hand is very close to or is introduced into the direct x-ray beam, and therefore finger dosimeters may be needed in those cases. Similarly, assessment of exposure to the lower extremities including

that of feet will also require increased attention, especially when protective curtains are not available or there is a gap between the curtains and the floor, depending on the height of the table during the intervention.

Examples of errors with the use of dosimeters and indirect approaches to correct the situation

(q) Examples of incorrect use include wearing a dosimeter over an apron that was intended for use under an apron, wearing a ring dosimeter on the incorrect hand, wearing a dosimeter issued to another person or losing a dosimeter.

(r) Indirect approaches of dose assessment may be useful in identifying the lack of compliance in wearing personal dosimeters and in estimating occupational doses when personal dosimeters have not been used. These approaches may be based on area dosimetry of the scatter dose near the patient (e.g. at the C-arm), using coefficients between occupational lens doses and patient-related quantities such as kerma-area product, for different kind of procedures and the geometries in use.

Guidance on occupational radiological protection

Relationship between patient and staff doses

(s) Occupational protection in interventions guided by radiological imaging is closely related to patient protection and most actions to protect the patient also protect the staff. There are, however, additional measures and protective devices that protect the staff only. The use of these devices should not interfere with the manipulations of the procedure, nor increase patient exposure.

Protection by shielding devices

(t) Shielding aprons should be worn by all interventional staff working inside the x-ray room. The aprons usually contain the equivalent of 0.25 mm, 0.35 mm, or 0.5 mm of lead and some designs have an overlap at the front to provide protection of 0.5 mm lead equivalence with 0.25 mm lead equivalence elsewhere. Transmission is typically between 0.5% and 5% in the range 70 kV to 100 kV (i.e. attenuation factor between 20 and 200). Although they shield the trunk against scattered radiation, parts of the body, including the head, arms, hands and legs are not protected by the apron and these need to be considered in the radiological protection programme.

(u) The most important factor in protection of the head is the proper use of shields. Ceiling suspended lead acrylic shields should always be included for interventional installations, as they can reduce doses to the whole head and neck by factors of 2–10, depending on how efficiently they are positioned.

(v) Staff such as nurses and anesthesia personnel who need to remain near the patient, may benefit from the additional protection provided by movable (rolling) shields that can be positioned between them and the source of scattered radiation.

(w) As described in point (h), under the occupational exposure, the dose to the eye lens can exceed the new dose limit, if protective measures are lacking. Over time it could result in eye lens opacities. Conversely, if the interventional fluoroscopy equipment is operating correctly, procedure protocols have been optimised, the

operator has been trained, and protective tools for the eyes are being used, the dose to the eye lens should be lower than the dose limit.

(x) A close fit of leaded glasses to the facial contours, particularly around the side and underside, is important because the clinician is looking at the image monitor during the x-ray exposures and the eyes may be irradiated from the side and below.

(y) Lead drapes attached to the bottom edge of the ceiling suspended shield as well as shielding drapes and pads can be effective in protecting the hands in some procedures. This type of protection should be considered for procedures where the operator needs to be close to the source of scattered radiation (i.e., the irradiated volume of the patient).

(z) Staff who stand near the couch during interventions should be aware that the radiation field is more intense in the region adjacent to the beam entrance side and when projections are oblique and lateral. Doses to the head, upper body, and hands of the interventionalist from fluoroscopy with the tube positioned under the couch will be substantially lower than the doses received by the lower extremities.

(aa) Where no shielding curtains for the lower extremities are available, the doses to the legs can be greater than those to the hands in an X-ray tube undercouch arrangement and when the couch is at a higher position, the feet may stay unprotected even if the curtains are in place. Rolling lead shields, when available, decrease the body dose to staff by more than 90% if properly used. Stepping back from the couch during cine or radiographic image series, such as digital subtraction angiography (DSA) acquisition appears to be an effective method of reducing toe dose.

(bb) In summary, all professionals in the room should wear protective aprons; the interventionalist should be protected by ceiling suspended screens, table suspended curtains and shielding drapes when feasible. The interventionalist can reduce doses received during the use of high-dose acquisition modes, such as cine and DSA, by stepping back and increasing distance to the patient. Staff such as nurses and anesthesia personnel who need to remain near the patient, can benefit from protection by movable screens and the rest of the personnel should increase protection by distance.

Protection of the embryo and foetus

(cc) After a pregnant woman has declared her pregnancy, her working conditions should ensure that the additional dose to the conceptus does not exceed 1 mSv during the remainder of the pregnancy.

(dd) However, current data do not justify precluding pregnant woman from performing interventions guided by radiological imaging completely if they follow proper procedures. Pregnancy, in any case, requires that the employer carefully reviews the exposure conditions and other aspects of occupational hazards (e.g. back pain with lead apron use) of the pregnant worker.

Quality assurance

(ee) Quality assurance with regular documented checks to confirm that professionals involved in interventions guided by radiological imaging always

wear the dosimeters and protective equipment including eyewear is very important.

(ff) Acceptance tests for protective devices are crucial; some supplies of defective protective clothes have been documented. In addition, handling them with care (e.g. avoid folding) and regular tests, are required as part of the quality assurance and improvement programme, as described in Section 5.

Education and training

(gg) Initial and continuing education and training of professionals in occupational safety and radiological protection is required. This is especially important regarding safety culture, the proper use of the imaging equipment, the radiological protection tools, such as ceiling suspended shields and/or leaded eyewear and the shielding curtains.

(hh) The use of real-time active dosimeters, not only helps in optimising protection of specific high dose procedures, but also contributes to educating professionals on the level of doses being received.

(ii) Hospital staff in charge of occupational protection, dosimetry services staff, clinical applications specialists from suppliers and regulators, need not only knowledge of general radiological protection but also of the clinical practice, the x-ray equipment used in interventions, strategies for occupational exposure assessment, the protection methods and selection and testing protective garments.

Availability of key professionals for radiological protection

(jj) The role of the medical physicists and those in charge of creating and maintaining a radiological protection and training programme is crucial. They are part of the team that ultimately designs and implements optimal radiological protection and care by the interventionalists, radiographers, and nurses.

GLOSSARY

Absorbed dose (D)

The quotient of the mean energy, imparted to an element of matter by ionising radiation and the mass of the element.

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m}$$

Absorbed dose is the basic physical dose quantity and is applicable to all types of ionising radiation and to any material. Absorbed dose is a measurable quantity for which primary standards exist. In the International System of Units, SI, the unit for absorbed dose is the ratio J(joule)/kg(kilogram) to which the special name of gray (Gy) is given.

Carers and comforters

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

Deterministic effect

See Tissue reaction.

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, 2007).

Dose limit

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

Effective dose (E)

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

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

where w_T is the tissue weighting factor for tissue or organ T, and w_R is the radiation weighting factor. The unit for the effective dose is the same as for absorbed dose, J kg^{-1}, and its special name is sievert (Sv). The sum is performed over all organs and tissues of the human body considered to be sensitive to the induction of stochastic effects. The tissue weighting factors are age- and sex-averaged, and intended to apply as rounded values to a population of both sexes and all ages.

Employer

An organisation, corporation, partnership, firm, association, trust, estate, public or rivate 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, 2007).

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^{-1}, and its special name is sievert (Sv).

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^{-1}.

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

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

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

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

Medical exposure

Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly, while voluntarily helping in the support and comfort of patients; and by volunteers.

Occupational exposure

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

Operational quantities

Quantities used in practical applications for monitoring and investigating situations involving external exposure. They are defined for measurements and assessment of doses in the body. In internal dosimetry, no operational dose quantities have been defined which directly provide an assessment of equivalent or effective dose. Different methods are applied to assess the equivalent or effective dose due to radionuclides in the human body. They are mostly based on various activity measurements and the application of biokinetic models (computational models).

Optimisation of protection (and safety)

The process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable, economic and societal factors being taken into account. (ICRP, 2007). In medical imaging and radiotherapy procedures, optimisation of radiological protection means keeping the doses 'as low as reasonably achievable, economic and societal factors being taken into account', and is best described as management of the radiation dose to the patient to be commensurate with the medical purpose.

Personal dose equivalent

The operational quantity for individual monitoring is the personal dose equivalent Hp(d) which is the dose equivalent in soft tissue (commonly interpreted as the "ICRU sphere") at an appropriate depth, d, below a specific point on the human body. The unit of personal dose equivalent is joule per kilogram (J kg^{-1}) and its special name is sievert (Sv). The specified point is usually given by the position where the individual's dosimeter is worn. For monitoring the effective dose the operational quantity Hp(d), and for the assessment of the dose to the skin and to the hands and feet the personal dose equivalent, Hp(0.07) is used. A depth d=3 mm is adequate for monitoring the dose to the lens of the eye. In practice, however, in many countries,

calibration of dosimeters in terms Hp(3) has not been implemented, but Hp(0.07) can be used for the same monitoring purpose for photon radiation, which is the case in interventions guided by radiological imaging.

Principles of protection

A set of principles that apply to radiation sources and to the individual in controlable 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, 2007).

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, 2007).

Sievert (Sv)

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

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 but not its severity, is regarded as a function of dose without threshold.

Threshold dose for tissue reactions

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

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, 2007).

Tissue weighting factor (w_T)

A 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

586 detriment resulting from uniform irradiation of the body (ICRP, 1991). It is
587 weighted (ICRP, 2007) such that:

588 $$\sum_{T} w_T = 1$$

589 Worker

590 Any person who is employed, whether full time, part time or temporarily, by
591 an employer, and who has recognised rights and duties in relation to
592 occupational radiological protection. Workers in medical professions
593 involving radiation are occupationally exposed (ICRP, 2007).

1. INTRODUCTION

1.1. Main points

- There are many advantages of the minimally invasive interventions guided by radiological imaging over open surgery.
- There is considerable variation in occupational doses observed for the same type of procedure, suggesting that radiological protection practices can be improved.
- Recent studies have shown that there is high incidence of radiation-related eye lens opacities (pre-cataracts) in interventionalists and other professionals involved in interventions guided by radiological imaging.
- There is a lack of proper monitoring of radiation doses to professionals in the interventional room in many parts of the world and often individual dosimeters are not regularly worn. For these reasons, data on occupational doses may not always be reliable.
- There is a need for guidance to hospital administrators, medical physicists and those in charge of occupational protection, staff from dosimetry services, regulators, and to all those having an influence on the overall safety culture of the hospital. This guidance includes specific approaches for occupational protection, exposure monitoring strategies, use and testing of protective garments, development of a radiological protection programme, as well as education and training and quality assurancefor the programme implementation.

1.2. Background

(1) Physicians in many medical and surgical specialties, usually assisted by nurses and radiographers (radiologic technologists), perform interventions guided by radiological imaging (NCRP, 2010) as an alternative to more complex and higher risk open surgery. This approach has many advantages: the interventions are less invasive than open surgery, recovery periods are shorter, and for some procedures the complication rate is lower (NCRP, 2010).

(2) Some physicians perform interventions involving multiple organ systems (e.g. radiologists), and some others perform procedures only within one or two organ systems (e.g. cardiologists, gastroenterologists and urologists). Some interventions once performed primarily by radiologists, such as endovascular procedures to treat lower extremity arterial disease, are now increasingly performed by vascular surgeons and cardiologists (Goodney et al., 2009; Harris et al., 2011). In the U.S., radiologists now perform less than 20% of these procedures (Goodney et al., 2009), and less than 35% of all fluoroscopically guided interventional procedures (NCRP, 2009).

(3) The increasing number, diversity and complexity of new types of interventions guided by radiological imaging keep their benefits expanding. On the other hand, they lead to an increase in exposure that appears to offset dose reductions obtained from improvements in technology (Kim et al., 2008). Moreover, occupational doses to interventionalists are among the highest observed in personnel working in medicine (Padovani et al., 2011). In a number of healthcare settings,

there is lack of proper monitoring of occupational radiation doses to professionals, and as a consequence, there is a lack of reliable data on occupational doses (Padovani et al., 2011; ISEMIR, 2014). Too often, personal monitoring badges are worn intermittently, or are worn improperly (Padovani et al., 2011) or are not provided. In some developing countries, no dose monitoring system is in place (Tsapaki et al., 2009). In addition, there is difficulty in comparing reported dosimetry results because of significant differences in dosimetric methods used in each study (Kim et al., 2008), as well lack of consensus on the number of dosimeters that may be used, and where the dosimeters should be worn on the body. The fact that none of the algorithms adequately estimates effective dose for all types of procedures, poses difficulties to reaching a worldwide consensus about which of them should be used.

(4) The Commission reviewed recent epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are or might be lower than previously considered. This is the case of the lens of the eye (ICRP, 2011). Recent studies have shown that there is an increased incidence of radiation-related eye lens opacities in interventional cardiologists when radiological protection devices are not used properly and radiological protection principles are not followed (Ciraj-Bjelac et al., 2010; Jacob et al., 2012; Rehani et al., 2011; Vañó et al., 1998, 2010, 2013a). Fairly high radiation doses to the hands and legs of interventionalists and hair loss in the portions of the legs not shielded by a protective device (Balter, 2001) have been observed. The considerable variation in operator doses observed for the same type of procedure indicates that radiological protection practices can be improved (Kim and Miller, 2009).

(5) Physicians involved in interventional procedures vary in their level of training in radiological protection. For example, in many countries, all radiologists receive training in radiation physics, radiation biology and radiological protection and safety as part of the radiology education, but physicians in other medical disciplines receive variable amounts of education in radiation-related topics, and may or may not be examined in these areas as part of the certification process. *Publication 113* (ICRP, 2009) provides advice and recommendations on education and training, the professionals to be trained, objectives, contents, management approaches, approximate time needed to educate and train a wide variety of health professionals, accreditation and certification.

(6) Several national and international medical societies have adopted guidelines to improve occupational protection and to avoid occupational radiation injuries, such as eye-lens opacities (Duran et al., 2013; Miller, 2010).

(7) The Commission has provided practical advice regarding occupational radiological protection for interventionalists and other health care workers involved in x-ray guided interventions in *Publications 85* (ICRP, 2000a), *117* (ICRP, 2010a) and *120* (ICRP, 2013a).

1.3. Purpose of the report

(8) The purpose of this report is to provide guidance on occupational protection to hospital administrators, medical physicists and those in charge of occupational protection, clinical applications support personnel from supplier companies, staff

from dosimetry services, regulators, and all those having an influence on the overall safety culture of the hospital.

(9) This guidance includes tools and methods for occupational protection and exposure monitoring strategies, selection, use and testing of protective garments, development of a radiological protection programme, as well as education and training and quality assurancefor the programme implementation.

1.4. Scope of the report

(10) The guidance provided in this document applies to interventions guided by radiological imaging, including computed tomography (CT) and, positron emission tomography (PET)-CT guided interventional procedures as well as selective internal radiation therapy (SIRT). However, as the vast majority of interventional procedures relates to interventions guided by x-ray fluoroscopy and image acquisition series, the text of the report report refers to x-ray imaging, unless otherwise specifically stated, such as in the sections devoted to CT and PET-CT and SIRT. Quantities and units relevant to interventional procedures are summarised in Annex B.

(11) For the purpose of this report, interventional procedures are guided diagnostic and therapeutic interventions performed via percutaneous or other access routes, usually with local anesthesia and/or intravenous sedation, which use external ionising radiation in the form of fluoroscopy or computed tomography to localise or characterise a lesion, diagnostic and/or treatment site; monitor the procedure; and/or control and document therapy.

2. THE ISSUES

2.1. Main points

- The number of interventions guided by radiological imaging is steeply increasing in both developed and developing countries. New types of interventions being undertaken are also of increased complexity, thus requiring extensive use of x-ray imaging and raising new issues of occupational protection. Not only interventional radiologists and cardiologists but also other specialists, in some cases not trained in radiological protection, use interventional techniques.
- The dose to the lens of the eye has received recent attention as evidence has become available that cataract development may have a much lower threshold for occurrence than was historically believed. As a consequence, the recommended occupational limit of equivalent dose for the lens of the eye was lowered to 20 mSv per year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv. Without protection of the eyes, the lens dose may become the operationally restrictive dose.
- A few recent studies of interventional cardiology staff revealed that 40–50% of interventional cardiologists (an incidence rate which was 4–5 times higher than that of the unexposed individuals of the control group) and 20–40% of nurses and technicians attending cardiology congresses and voluntarily participating in an ophthalmological examination, showed posterior subcapsular lens changes characteristic of damage due to ionising radiation exposure. With proper protection, the risk of radiation cataract can be decreased substantially.
- Without reliable monitoring data, radiation safety professionals will not have the information needed to offer improvements to reduce doses and optimise radiological protection.
- Interventions involving PET and interventions for SIRT pose new radiological protection challenges as protective devices that are effective for fluoroscopy may not be as effective for PET and SIRT. As novel PET radiopharmaceuticals involving radionuclides with different decay schemes are developed, they may result in different dose profiles near the patients, in some cases there is the expectation of higher doses in PET/CT-guided procedures than in fluoroscopy procedures.
- However, thanks to radiological protection and optimisation efforts to ensure lowered staff doses, first publications on occupational exposure from PET/CT-guided procedures show that the operator effective dose was kept within the range of typical doses from fluoroscopically guided procedures.

2.2. Interventional procedures

2.2.1. Interventional fluoroscopy procedures

(12) There is a large increase in the number of interventional procedures performed annually throughout the world. In the United States, interventional fluoroscopy procedures were the third largest source of medical exposure of patients

in 2006, accounting for 14% (0.43 mSv y^{-1}) of medical radiation exposure (NCRP, 2009) in terms of collective effective dose. Cardiac fluoroscopy procedures, including diagnostic cardiac catheterisation, were 28% of the total interventional fluoroscopy procedures, but accounted for 53% of the interventional fluoroscopy exposure. In 36 European countries the frequency of all medical interventions guided by fluoroscopy ranges from 0.03% to 2.74% with an average of 0.6% of all x-ray procedures. In terms of collective doses, interventional radiology contributes from 0.001 to 0.34 mSv y^{-1}, corresponding to 0.4% to 28.7% of total radiation collective doses (EC, 2015). Seven of 11 developing countries surveyed as part of an IAEA project demonstrated a 50% or greater increase in the number of interventional procedures performed between 2004 and 2007 (Tsapaki et al., 2009).

2.2.2. Interventional CT-guided procedures

(13) Interventions can also be performed with CT guidance. Although relatively few data are available on the number of CT-guided interventions that are performed or on temporal trends, it is clear that the numbers and types of procedures are increasing. For example, the percentage of image-guided percutaneous lung biopsies performed with CT guidance at the Mayo Clinic in the U.S. increased from 66% in 1996–1998 to 98% in 2003–2005 (Minot et al., 2012). The remainder was performed with fluoroscopy guidance. CT is used primarily to guide biopsy of small or deep lesions in the chest, abdomen and pelvis that are not seen well with ultrasound or fluoroscopy.

(14) CT-guided interventions can be performed by using intermittent CT scans performed while the physician steps behind a mobile shield or out of the scanner room, or by using CT fluoroscopy, with physician-controlled intermittent or continuous CT exposure during needle or device manipulation. CT fluoroscopy facilitates CT-guided biopsy procedures by allowing visualisation of the needle trajectory from skin entry to the target point. CT fluoroscopy is applicable to a wide variety of non-vascular interventions (Daly and Templeton, 1999). It is used for needle guidance during drainage of fluid collections and abscesses, spinal pain management, tumour ablation and percutaneous needle biopsy in the neck, chest, spine, abdomen and pelvis (Buls et al., 2003; Hoang et al., 2011; Joemai et al., 2009; Trumm et al., 2012). The principal advantage of CT fluoroscopy over standard CT is the ability to use real-time monitoring to access lesions that move within the body as a result of patient breathing or other motion. Its use allows interventions to be performed more rapidly and efficiently (Gianfelice et al., 2000b), and it is therefore popular. On the other hand, CT fluoroscopy also results in relatively higher radiation doses to both the patient and the physician operator (Gianfelice et al., 2000a; Kim et al., 2011; Saidatul et al., 2010). As CT fluoroscopy images are noisier than conventional CT this technique is predominantly used in cases of moving objects of high contrast such as in lung biopsies.

2.2.3. Interventions for selective internal radiation therapy

(15) Fewer than 20% of patients with primary or metastatic liver cancers are curable at presentation. Therefore, palliative therapies such as radioembolisation with ^{90}Y-labeled microspheres (SIRT) and other loco-regional therapies have become alternative methods to treat patients with unresectable liver tumors (Camacho et al., 2015).

(16) After catheterisation of the hepatic arteries, Yttrium-90 microspheres (^{90}Y, maximal ß-energy 2.27 MeV, $T_{1/2}$ 64.1 h) are delivered under fluoroscopic control. Two types of ^{90}Y-microspheres are used: Resin microspheres [SIR-Spheres; SIRTEX, Lane Cove, Australia], diameter 20 to 60 µm (SIRTEX) and glass microspheres [TheraSphere; Nordion, Ottawa, Ontario, Canada], 22 µm diameter (Nordion). The rationale for SIRT is the dominant hepatic arterial supply of malignant lesions. SIRT has demonstrated a significant increase in patient survival time (Bester, 2012).

(17) SIRT therapy is usually performed in two steps: in the first step, an initial delivery of ^{90}Y microspheres is carried out and embolisation of arteries is achieved. Adverse events such as temporary balloon occlusion of non-target arteries and antireflux cathetersion (Hagspiel, 2013; Fischman, 2014) might occur. Then, shunting into the lung is estimated by means of a SPECT scan of the lung and upper abdomen with ^{99m}Tc-MAA particles into the hepatic artery particle. Lung shunting < 10% allows full ^{90}Y activity delivery. A reduced delivery of ^{90}Y activity (20–40%) is recommended when shunting amounts to 10–20% (SIRTEX). When shunting is > 20%, SIRT is contraindicated.

(18) The second step includes dose calculation, preparation of the ^{90}Y-spheres and delivery via a catheter into the hepatic artery. Typical activities for resin spheres are 2–3 GBq (Jakobs, 2007) and 3–7 GBq for glass spheres (Andrews, 1994). Target dose is typically 120 Gy (range, 80–150 Gy). Nuclide distribution may be examined either by planar or SPECT Bremsstrahlung imaging or PET/CT. PET/CT has higher spatial resolution and quantification of delivered activity may be more accurate (Camacho, 2015).

2.2.4. Use of positron emission tomography in interventional procedures

(19) PET is increasingly playing a role in image-guided interventions as it provides an image guidance technique for metabolically active targets that are inconspicuous, difficult to visualise, or not detected by CT or Magnetic Resonance Imaging (MRI) (Ryan et al., 2013a). Several hospitals are exploring, as part of their research programme, the use of real-time PET-CT-guidance during interventional procedures, such as for biopsies and/or radiofrequency ablations (Purandara et al., 2011; Venkatesan et al., 2011; Ryan et al., 2013a; Aparici et al., 2014b; McLoney et al., 2014), and there is current development of real-time fusion imaging using x-ray CTand PETimaging (Beijst et al., 2016; Purandare et al., 2011). The use of PET and multimodality fusion imaging within the suite also can assist in identifying the location for effective embolisation or biopsies as well as to provide immediate assessment of treatment effectiveness. Occupational exposures from interventional procedures.

2.3. Type of radiation and energy in interventional procedures

(20) Most interventional procedures are performed with a combination of fluoroscopy and image acquisition series. Beam spectra vary with tube voltage and filtration, ranging from 50 to 125 kVp and added filtration of up to 1mm copper (NCRP, 2010). The beam quality and operating parameters, such as tube voltage and current, pulse duration and often beam filtration, are driven by the system´s

automatic exposure control (NCRP, 2010). Higher beam penetration, i.e. higher kVp and filtration, is associated to fluoroscopy in low dose rate modes, e.g. 88–114 kVp; and a half-value layer of 8.0- to 10-mm Al, while tube voltage for image acquisition mode is lower, e.g. 68–84 kVp; half-value-layer 3.5- to 4.0-mm Al (Principi et al., 2014). In some equipment, spectral shaping for image acquisition is achieved by combining low tube voltage, for better visualization of iodine-containing contrast media, with increased filtration for limiting the higher patient dose associated to the lower tube voltage (NCRP, 2010). The distribution of scattered radiation around the patient, which is most relevant to occupational exposure, is discussed in Section 5.

(21) In CT fluoroscopy the tube voltage ranges from 80 to 140 kVp. In PET CT examination using ^{18}F-FDG, the photon energy of 511 keV is much higher than the energy of scattered photons in conventional interventional procedures (NCRP, 2010). The maximal ß-energy from ^{90}Y used in SIRT procedures is 2.27 MeV. As the vast majority of interventional procedures relates to those guided by x-ray imaging, the text of this document refers to them unless otherwise stated.

2.4. Occupational exposure

2.4.1. Effective doses

(22) Summaries and compilations of data on occupational exposure are available (Kim et al., 2008, 2012; NCRP, 2010; ICRP, 2010a). While it is certainly possible for active interventionalists to keep their annual occupational effective dose below 10 mSv, and typically within an effective dose range of 2–4 mSv or less (Miller et al., 2010), surveys have shown that individual occupational doses may exceed these values (Padovani et al., 2011).

(23) Annual effective doses received by the professionals depend on their function and role in the team (primary interventionalist, technologists, nurses, anaesthesiologists), the number of interventions, the medical specifics and complexity of the cases, the patient population (e.g. pediatric patients, obese patients) and other factors such as the skill of the interventionalists, equipment and relative use of fluoroscopic and cine times. Martin (2009) in a review of the literature estimated that a case load of 500 cardiology procedures a year would result in an annual effective dose of about 2 mSv for the first interventionalist. A maximum annual effective dose of 1.2 mSv [$H_p(10)$ measured under lead aprons] was observed for cardiologists at a Glasgow hospital (Martin, 2009). Other types of procedures resulting in an effective dose per procedure greater than 10 µSv might lead to annual effective doses as high as 10 mSv depending on whether thyroid shields were used. Lie et al. (2008) reported a maximum annual effective dose derived from combining the readings of two dosimeters, one under and one above the lead apron, of 11 mSv with a mean of 5 mSv. A review of monthly effective doses (E) obtained during 2011 and 2012 by a dosimetry service provider in the United States, for the workers monitored with two dosimeters (one over and one under the apron, for a total of 102,199 observations) and the workers monitored with a single dosimeter located above the apron at the collar (total of 196,526 observations), revealed mean values of E of 0.13 and 0.31 mSv and median of 0.04 and 0.13 mSv respectively (Yoder and Salasky, 2016).

(24) Sánchez et al. (2012) found monthly median under apron doses of 0.11 mSv for cardiologists and < 0.01 mSv for nurses in a study of 43 workers who

conducted 1,467 procedures in a national survey. The over apron doses were 0.4 mSv per month for both cardiologists and nurses. The authors noted that perhaps as many as 50% of the cardiologists did not use their dosimeters correctly, usually failing to wear the over apron dosimeter (Sánchez et al., 2012).

(25) Not only the main interventionalist, but also other staff may be subject to significant exposure, such as anaesthetists. Kong et al. (2015) showed that anaesthetists´ radiation exposure not only depends on their workload, but largely varies with their positions and beam projections during interventional procedures. Beam projection accounts for a factor of 10 in effective dose and 200 in the eye dose. A position close to the patient combined with the left lateral projection causes the higher exposure. Optimal arrangement of the anaesthesia device was found to be useful to reduce exposure.

(26) Data on occupational exposure from CT fluoroscopy guided interventions are limited. The highest doses are received by the physician's hands, eyes and thyroid (Saidatul et al., 2010). Use of thyroid shields provides substantial protection for the thyroid (Saidatul et al., 2010), which is especially important for younger professionals. Since average patient dose varies according to the type of procedure (Leng et al., 2011), average physician effective dose per case also varies according to the type of procedure, as would be expected; reported values measured outside the apron ranged from 2–25 μSv for $H_p(10)$, with maximum values as high as 0.4 mSv per procedure (Joemai et al., 2009; Paulson et al., 2001; Teeuwisse et al., 2001). A variety of technical refinements and protection methods have been developed that can reduce occupational dose (Carlson et al., 2005; Daly and Templeton, 1999; Hoang et al., 2011; Paulson et al., 2001). Training in proper technique is essential; poor technique can result in the physician's hands being placed in the direct beam (Buls et al., 2003) reaching the annual dose limit of 500 mSv in a few minutes.

(27) The occupational radiation exposure from transcatheter aortic valve replacement (TAVR) or implantation (TAVI) depends on the approach (transfemoral or transapical). Values of $H_p(10)$ up to 0.23 mSv in a single procedure were obtained by Shatila from the over-apron dosimeter of the primary operator (median value 0.11mSv), as well as significant exposures to eight of ten other workers (Shatila, 2015).

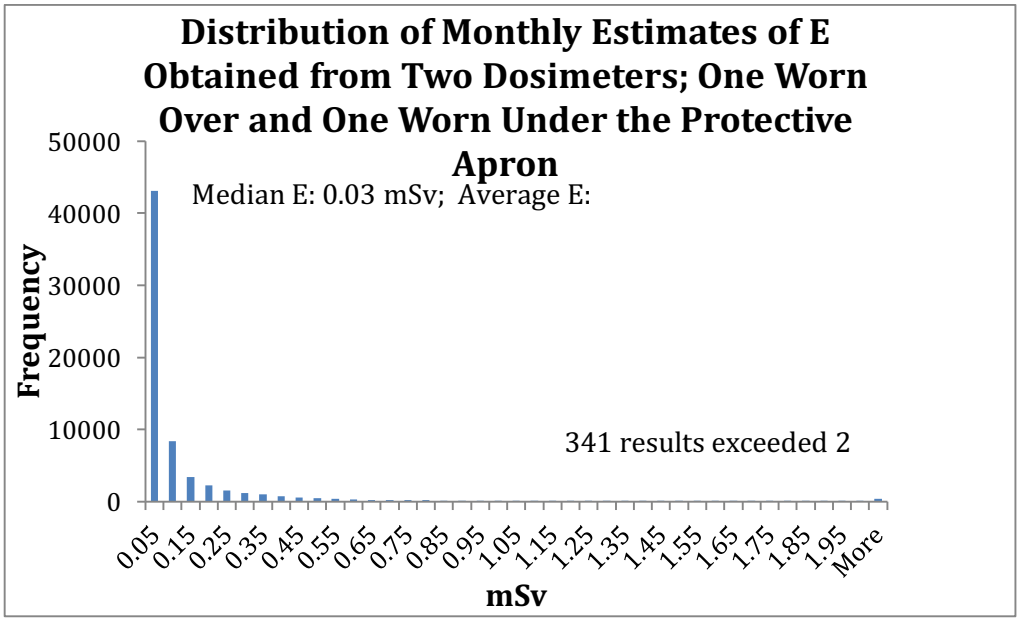
2.4.2. Equivalent dose to the eye lenses

(28) ICRP issued a Statement in 2011 published as part of *Publication 118* (ICRP, 2012) after reviewing epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are or might be lower than previously considered. For the lens of the eye, the threshold in absorbed dose is now considered to be 0.5 Gy. For occupational exposure in planned exposure situations the Commission now recommends an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv. Without protective eyewear, the lens dose may become the operationally restrictive dose (Lie et al., 2008; Korir et al., 2012) and the revised dose limit may be exceeded.

(29) Most data on eye exposures are derived either from static experiments with phantoms or from individual monitors placed on the neck. A few studies have placed dosimeters closer to the eye on the forehead. Lie et al. (2008) compared TLD's placed near the left eye and between the eyes for 144 procedures, mainly

cardiac. The median dose to the lens of the eye was observed to be 23 μSv per procedure and the P_{KA} towards the patient was 0.4 μSv Gy^{-1} cm^{-2}. The left eye dose tended to be higher than that between the eyes due to the left eye being closer to the x-ray generator. Kicken et al. assessed the absorbed dose at the forehead for under couch and over couch x-ray systems (Kicken et al., 1999). They found an average dose for the operator and assistant of 8 and 6 μGy per procedure, respectively at one hospital, 16 and 14 μGy, respectively at a second hospital and 43 and 28 μGy at a third. The first two hospitals used an under couch system and the third hospital employed an over couch x-ray tube that puts the head closer to the beam entrance to the patient irradiated volume. Comparison of urologist´s eye lens doses for per nephrolithotomy procedure, derived from doses measured over the apron, with those received by interventional cardiologists and radiologists has been reported by Vañó et al. (2016). Due to the lack of protective shields in urology, doses to urologists were found to be 18.7 times higher than those received by interventional cardiologists who used ceiling-suspended shields.

(30) Within the European study on Optimisation of radiation protection of medical personnel, TLD measurements and Monte Carlo simulation campaigns were performed for three cardiac and five interventional radiology procedures (Vanhavere et al., 2012). The selection was based on their potential impact on annual worker exposure, i.e. procedures with high frequency or high values of kerma-area product, or both. Operators were substantially exposed from embolisation procedures as well as from percutaneous transluminal angioplasties (PTA) of the lower limbs and the renal arteries. During cerebral and carotid procedures the doses to the operators were relatively low since femoral access is usually chosen and, therefore, the operator stands at a larger distance from the irradiated part of the patient compared to other procedures performed in the thoracic or abdominal region. Eye lenses doses from angiography (DSA) and PTA were around 40 μSv and for embolisations the doses were up to 120 μSv. Among the cardiac procedures included in the measurement campaign, higher operator doses were delivered from the implantation of pacemakers and of cardiac defibrillators), despite their relative low P_{KA} values; this is due to the fact that in these interventions only fluoroscopy is used. The reason for the higher occupational doses from these procedures was that operators work very close to the irradiation field and most of the time without any protective shielding. Average eye doses lie within the range of 40 to 60 μSv.



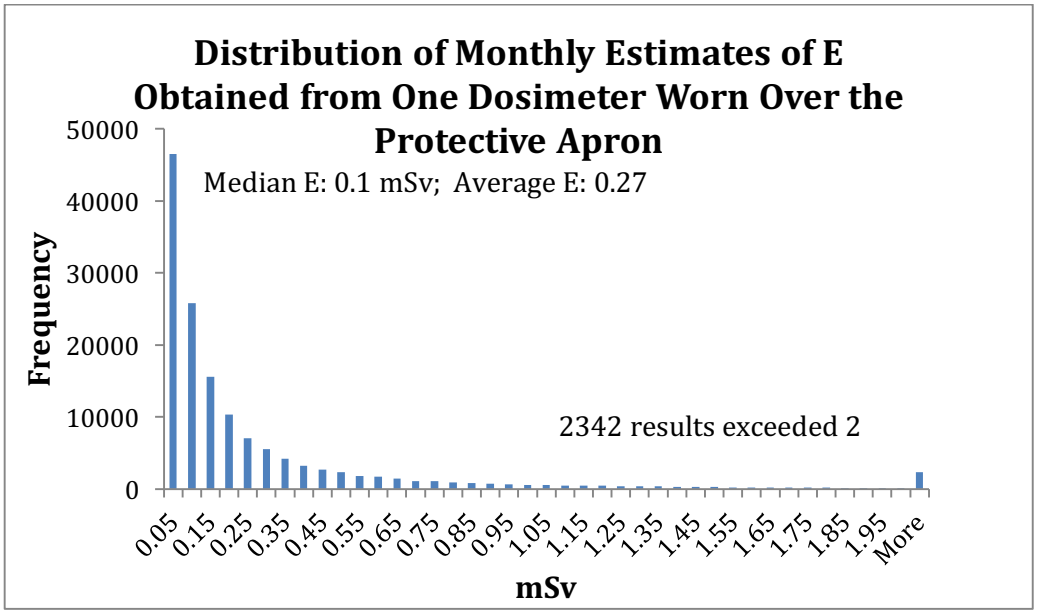


Fig. 2.1. Distribution of effective dose (E) assessd by two and one dosimeter respectively (Yoder and Salasky, 2016).

2.4.3. Equivalent doses to the hands

(31) Dose to the extremities, particularly the hand of the physician or assistant nearest the x-ray generator or x-ray beam path, can be substantially higher than that assessed on the torso thereby creating a need to specifically monitor the hands, and in some less common situations, the feet, should protective shields not extend much below the ray tube and to the level of the feet. Felmlee et al. (1991) compared hand doses for 30 cases at Mayo Clinic, including transhepatic cholangiograms and biliary and nephrostomy procedures, with results from three other studies. The largest hand

dose measured was 5.5 mGy with a median procedure dose of about 1 mGy. The other studies cited reported hand doses per procedure ranging from 0.01 mGy for neurological interventions to 0.4 mGy for peripheral vascular angiography. Whitby and Martin (2005) reviewed 18 studies that reported hand doses per procedure from less than 10 μGy to nearly 2000 μGy. Important factors influencing the dose to the hand were the type of procedure, the x-ray equipment used, he experience of the operator, and particularly the access route (antegrade access to the femoral artery can be difficult in obese patients, which may result in higher doses),. Sauren et al. (2011) reported doses to the hands around 2 mSv per procedure of transcatheter aortic valve implantation (TAVI) or replacement (TAVR) in transapical approach.

(32) In the ORAMED study, an average dose to the left hand for the DSA/PTA of the lower limbs was obtained of around 240 μSv, for the embolisations around 320 μSv and for the cerebral DSA/PTA procedures around 60 μSv. Average doses of 410 μSv have been recorded for the left finger for cardioverter defibrillator implantation (PM/ICD), while for the cardiac angiography and angioplasty (CA/PTCA) and radiofrequency ablations (RFA) the respective values were 180 μSv and 60 μSv (Vanhavere et al., 2012).

(33) Felmlee et al. (1991) made scatter measurements at various distances from a 12cmx15cm field with a phantom entrance dose rate of about 65 mGy min^{-1} and exit dose rate of 0.7 mGy min^{-1}. The scatter dose rates in the lateral direction ranged from 0.7 mGy min^{-1} at a distance of 0 cm, 0.35 mGy min^{-1} at 5 cm distance and 0.13 mGy min^{-1} at 15 cm (Femlee, 1991). The variation in reported hand doses is explained by the large dose gradients near the x-ray beam, movement and placement of the hands and whether the interventional procedure involves femoral, percutaneous and internal jugular vein catheter insertion that place the physician in different positions relative to the patient and x-ray tube (Whitby and Martin 2005; Martin, 2009). Hand doses also tend to be much larger for over table x-ray units due to the greater potential to have the hands enter the primary beam.

2.4.4. Equivalent doses to lower extremities

(34) Artschan et al. (2014) determined occupational effective doses from phantom irradiations, replicating exposure factors used for abdominal procedures, and from radiologists performing actual interventions on patients. They found values for annual lower extremity doses up to 110 mSv, despite the use of a protective curtain hanging on the side of the treatment couch. This exposure is attributed to the presence of a gap between the protective curtain and the floor, the size of which being dependent on the height of the treatment couch. Consequently, for procedures requiring a higher couch height, such as biliary stent procedures, and for taller interventionalists, an increased lower extremity radiation dose may be received.

(35) The group found that, without protection, the lower limb dose was frequently greater than the hand dose, with a mean leg dose between 0.19 and 2.61 mSv per procedure without any protection and between 0.02 and 0.5 mSv per procedure with a protective curtain (Artschan et al., 2014). The ORAMED study showed leg doses of 160 to 250 μSv (Vanhavere et al., 2012).

2.4.5. Specific issues of occupational exposure from selective internal radiation therapy

(36) Three scenarios of occupational exposure are relevant for SIRT:

1. Preparation and calibration of ^{90}Y-microspheres before application by a nuclear medicine technician or radio-pharmacist
2. Trans-catheter delivery into the hepatic artery by a interventional radiologist or other qualified physician
3. Exposure of the nurses after the procedure until patient discharge

(37) Only a few papers on occupational doses from SIRT have been published. Occupational exposure from SIRT procedures is caused by x-rays with relatively low dose rate, and direct ß-radiation especially to the hands and fingers with high dose ratesif precautions are inadequate. In addition to the dose to the hands of workers preparing the individual patient dose and the physician implanting the microspheres, there is potential for significant contamination hazard. Specific advice to reduce this hazard is given in Section 5. Exposure data are 43.5 mSv MBq^{-1} h^{-1} skin equivalent dose due to contact with a 5-ml syringe and 1.35 mSv kBq^{-1} h^{-1} due to contamination with 50 µl on 1 cm^2 (Kemerink et al., 2012).

2.4.6. Specific issues of occupational exposure from PET-guided interventions

(38) ^{18}F-FDG has a photon energy of 511 keV, much greater than the typical scattered photon energies interventional radiologists are exposed to while performing CT and fluoroscopically guided procedures (NCRP, 2010). Several studies have evaluated the radiation doses from patients receiving PET administrations (Chiesa, 1997; Benatar et al., 2000; White et al., 2000; Seierstad et al., 2006; Heckathorne and Dahlbom, 2008; Hippelainen et al., 2008; Nye et al., 2009; Demir et al., 2010; Quinn et al., 2012). These have generally shown that immediately following injection of ^{18}F-FDG a reasonable representation of the dose rate anterior to the chest of patients is ~0.09 µSv MBq^{-1} h^{-1} at 1 m and ~0.37 µSv MBq^{-1} h^{-1} at 30 cm. These values can be reliably scaled to the desired time and distance for planning and prospective worker dose evaluation purposes.Lower values have been measured depending on the specific location of the measurement (Quinn et al., 2012).

(39) PET/CT-guided biopsies are not common. They are performed when CT alone is not sufficient to identify the area of possible cancer (Aparici et al., 2014a; Werner et al., 2011). PET/CT-guided interventional procedures typically use ^{18}F-FDG. Ryan et al. (2013b) specifically quantified radiation exposure to the primary interventionalist. The median effective dose per procedure was 0.02 (0–0.13) mSv for the primary operator, 0.01 (0–0.05) mSv for the nurse anaesthetist, and 0.02 (0–0.5) mSv to the technologist. The median extremity equivalent dose for the operator was 0.05 (0–0.62) mSv per procedure. Radiation exposure of the worker correlated with procedure duration and with the use of in-room image guidance. The authors concluded that operator effective dose from PET/CT-guided procedures was not significantly different than typical doses from fluoroscopically guided procedures. The major determinant of radiation exposure to the operator from PET/CT-guided interventional procedures is time spent in close proximity to the patient. As novel PET isotopes are developed, they may result in different dose profiles near the patients (Holland et al., 2010; Williamson and Dauer, 2014).

(40) With regard to fingertip doses from ^{18}F-FDG, Sánchez et al. measured dose reductions from using a full automatic system for preparing and infusing the FDG. The results show a reduction of the technologists' fingertips average skin

doses of 223 to 83 μSv GBq^{-1} (63%) from preparing the radiopharmaceutical and the nurses´ average fingertips dose was reduced from 83 to 11 μSv GBq^{-1} (87%) from infusion to the patient (Sánchez et al., 2015). The accuracy of the delivered activity was 2%.

2.5. Reported radiation injuries on professionals involved in the interventions

2.5.1. Eye lens injuries

(41) Ocular ionising radiation exposure results in characteristic lens changes leading to opacification. While initial stages of such opacification may not cause visual disability, the severity of such changes increases progressively with dose towards a vision- impairing lesion. The latency of such changes is inversely related to radiation dose (ICRP, 2012). During typical fluoroscopy working conditions, and if radiological protection tools are not regularly used, x-ray exposure to the eyes of interventionalists, other physicians and/or paramedical personnel working close to the patient can be high.

(42) One of the first cases reported on radiation induced opacities in interventional radiologists was in 1998, and the reason for the radiation injuries was the use of a non-optimised interventional radiology laboratory and the lack of a radiological protection programme (Vañó et al., 1998). In 2004. Haskal presented the results of a pilot study of x-ray-associated lens changes in 59 practicing interventional radiologists; 37% of those screened had detectable posterior lens changes consistent with radiation exposure (Haskal, 2004; Junk at al., 2004). Although lens doses were not reported, the authors noted that the frequency and severity of posterior subcapsular lens opacities increased as a function of age and years of practice, thus suggesting a posible dose-effect relationship.

(43) Following these findings, the IAEA promoted in 2008 a project called Retrospective Evaluation of Lens Injuries and Dose, RELID, for interventional cardiology (IAEA, 2013), with the objectives of estimating occupational lens doses and evaluating possible lens opacities.

(44) Since no personal dosimetry data was available, occupational lens doses were estimated in most of the cases by combining published typical scatter dose values (Vano et al., 2008a,b) with information on the declared numbers of working years, workload, fluoroscopy and cine exposure conditions, the radiological equipment used, the location of the worker in the room and the use of radiological protection tools. Availability of some personal monitoring badge data helped in assessing the correlation.

(45) For the ophthalmological examination of posterior subcapsular opacities, the Merriam-Focht scores were used (Ciraj et al., 2010; Rehani et al., 2011; Ciraj et al., 2012; Vano et al., 2010, 2013a). The scoring, i.e. 0.5, 1.0, 1.5, etc. is done separately for each eye. A total of eight surveys were carried out under the RELID programme (IAEA, Web Site Radiation protection of patients: Bogotá 2008, Kuala Lumpur 2009, Montevideo 2009, Varna 2009, Sofia 2009, Bangkok 2009, Buenos Aires 2010 and Kuala Lumpur 2011).

(46) The RELID study concluded that workers in cardiac catheterisation laboratories had shown increased prevalence of eye lens opacities when professionals have been working several years without the proper use of radiological

protection tools. About 40–50% of interventionists, an incidence rate which was 4–5 times higher than that of the unexposed individuals of control group, and 20–40% of technicians or nurses, attending voluntarily the lens injury exam (during the cardiology congresses), were found to have posterior subcapsular opacities compatible with injuries derived from exposure to ionising radiation. The control group had only this kind of opacities in around a 10% of the cases. Estimated lens doses reached up to several Gy in some cases during the full professional life. However, it is still not clear if lens opacities will progress to visually disabling cataracts.

(47) Although a radiation-induced decrease in contrast sensitivity has not been reported in any of the study populations, in the last RELID study (Vañó et al., 2013a) a restricted contrast sensitivity test was made for about 20% of the participants with observable lens changes upon slit lamp examination. The contrast sensitivity curve for these participants resulted in a significant loss of contrast in comparison to the standardised normal data. Retrospective dose estimations are necessary to look for correlations between the radiation dose and the lens opacities (Vañó et al., 2013). Comprehensive reviews of radiation effects on the lens of the eye are provided in ICRP and NCRP publications (ICRP, 2012; NCRP, 2017).

(48) In many of these studies there was an irregular use of personal dosimeters and protective tools. These results point to the need for improving radiological protection, following the recommendations given in Section 5.

2.5.2. Reported incidents in selective internal radiation therapy

(49) Tosi (2003) reported an incident in a department where radioimmunotherapy with monoclonal antibodies and/or peptides was performed. ^{90}Y was used with a concentration up to 150 GBq ml^{-1}. The operator held the vial not with the special pliers, but directly with his hand, protected only with a very thin glove in lead rubber (0.1 mm Pb equivalent) covered by a disposable glove. After a few days finger erythema was observed. Film badges, TLD finger ring dosimeter and urine activity were normal. The estimated dose to parts of the fingers was 12 Gy (based on the energy of the ß-particles, the attenuation by the glass of the vial and gloves and the referred total time of manipulation).

2.5.3. Reported hair loss in lower extremities

(50) Hair loss in the portions of the legs not shielded by a protective device (Balter, 2001) have been observed and Wiper et al. (2005) reported that several senior interventional cardiologists noticed the onset of hair loss affecting both lower limbs and that dermatologist advice suggested that the appearances are consistent with chronic occupational radiodermatitis.

2.6. Challenges in monitoring exposure

(51) There are three major challenges:

1. Designing a simple, easily implemented and consistent approach for occupational exposure monitoring that does not lead to unduly frequent investigations.

2. Estimating effective dose and equivalent dose for specific tissues from one or more dosimeter readings.
3. Ensuring compliance by the worker with monitoring procedures.

(52) Technologically, most dosimeters worn on the thorax or waist allow estimation of effective dose received by workers. Monitoring the extremities poses practical challenges related to wearing comfort and infqection control of hand dosimeters. Evaluation of the radiation dose to the eye, especially when goggles are worn, is not a straightforward issue; current measurement techniques are not sufficiently developed and are not available for routine use.

Incorrect and irregular use of individual dosimeters

(53) Surveys have revealed incorrect and inconsistent use of personal dosimeters. The IAEA ISEMIR (IAEA, 2014b) survey showed that only 76% of interventional cardiologists always used their dosimeters and 45% used the two dosimeters. Sánchez et al. (2012) have indicated that perhaps as many as 50% of the physicians either do not wear their dosimeters, wear them infrequently, or wear them in the wrong place on the body. In the Sánchez report, only 33% of monthly dosimeter readings were judged to be reliable. Physicians were less likely than nurses to use the dosimeters correctly. The data of US fluoroscopic dosimeter results given by a dosimetry service provider in the US revealed similar lack of reliability in many of the readings. Without reliable monitoring data, radiological protection professionals may not have the information needed to offer tools and suggestions to reduce exposure or optimise protection.

(54) Similarly, an important finding in ophthalmological studies (RELID) is the irregular use of personal dosimeters and the poor adherence to the ICRP recommendation to use double dosimetry, with one of them located at collar level over the apron, from which lens doses could be inferred. Only about 50% of the interventionalists in a recent study (Vañó et al., 2013) reported that they use personal dosimeters, and only 30% report their use on a regular basis. Around 90% of nurses and technicians report the use of personal dosimeters, but regular use is reported by only around 40%. Even when used, dosimeters were worn under the lead apron in most cases, making any retrospective evaluation of ocular radiation dose using these devices likely to be inaccurate. In a previous study Niklason had shown that half of the workers did not use their personal dosimeters regularly (Niklason, 1993).

(55) A retrospective study of 15 years follow-up in a cardiology department observed that between 20% and 30% of cardiologists were not using their dosimeters routinely (Vañó et al., 2006). In surveys conducted by the IAEA during various radiological protection training courses, in which cardiologists from over 56 countries participated, responses indicated that 33–77% of interventional cardiologists used radiation badges routinely (IAEA, 2014b).

(56) Sometimes two dosimeters meant for under and over apron position may show similar readings, thus indicating that they were randomly reversed. Another disparity can arise when protective glasses are used only for some procedures. Therefore, during a monitoring period, a consistent deployment of monitors needs to be stressed. Workers need one set of instructions on how many dosimeters to use and where to place them, that would be specific to their most restrictive duty or risk of exposure. The Commission (ICRP, 2000b) and others (NCRP, 2010) recommend that interventional radiology departments develop a policy and good habits for workers to wear the two dosimeters.

Possible reasons for non compliance with monitoring procedures

(57) Reluctance to use dosimeters may be the result of their impression that their accumulated effective doses may approach dose limits thereby potentially constraining them from practicing their profession and treat their patients, or that time-consuming investigations may be triggered by dose readings that are high, but still within occupational dose limits.

Assessment of effective dose

(58) There are multiple approaches for assessing effective dose from one or more dosimeters. In situations in which the dose spatial distribution varies as much as it does in fluoroscopy, dose assessment is subject to large uncertainty. Successive conservative assumptions can lead to dose estimates that are many times the true value. The personal dose equivalent, $H_p(10)$ is recommended as a conservative estimate of the effective dose under a variety of simple exposure assumptions, anterior-posterior, lateral, rotational, isotropic and posterior-anterior incidences on mathematical representations of the human body. When the personal dose equivalent is used to account for non-uniform exposure conditions, further conservatism is introduced. Locating a dosimeter in the area of highest photon fluence may add to the over-estimation. Other sources of conservatism in the effective dose algorithms are the use of high peak kilovoltage x-rays and high copper filtration that are less attenuated by lead aprons and collimator settings that create large fields and levels of scatter radiation. Recommended strategies for exposure monitoring are given in Section 4 and on the assessment of doses to the conceptus in Section 4.4.4.

Challenges in monitoring eye lenses

(59) Without protective glasses, the reading of a dosimeter over the apron at the collar level is a reasonable indicator of the eye lens dose but when protective glasses are used, the collar dosimeter may grossly overestimate the eye lenses dose. In addition, given the significant uncertainties involved and the fact that eye dose levels are of the same order as the dose limit and, assessing compliance with the dose limit represents an important challenge.

3. APPLICATION OF THE SYSTEM OF OCCUPATIONAL PROTECTION TO INTERVENTIONS GUIDED BY RADIOLOGICAL IMAGING

3.1. Main points

- The aim of radiological protection, in general, is to manage and control exposures to ionising radiation so that deterministic effects or tissue reactions are prevented, and the risks of stochastic effects are reduced to the extent reasonably achievable, societal and economic factors considered. Specifically, the most relevant deterministic effects among professionals involved in interventions guided by radiological image include eye lens injuries and possible hair loss in extremities.
- To achieve these objectives, the Commission recommends three fundamental principles of radiological protection: justification of practices, optimisation of protection, and dose limitation for individuals, in the case of this report, for professionals involved in the interventions.
- In addition, the management of occupational protection requires indicators (investigation levels) to alert that protection may not be optimised and investigations of exposure and working conditions should be undertaken. Suitable indicators for interventional procedures are investigation levels.
- Investigation levels can also be selected as mínimum dose values of over apron dosimeters, to alert that dosimeters may not have been properly worn.
- After a worker has declared her pregnancy, her working conditions should ensure that the additional dose to the conceptus does not exceed 1 mSv during the remainder of the pregnancy.
- The restriction on dose to the conceptus does not mean that it is necessary for pregnant workers to avoid work with radiation. It does imply, however, that the employer, with the advice of the medical physicist or radiological protection expert, should carefully review the exposure conditions of pregnant workers. Currently available data do not justify automatically precluding pregnant physicians or other workers from performing procedures in the interventional room.

3.2. The principles of radiological protection

3.2.1. General

(60) The Commission's system of radiological protection aims primarily to protect human health and its objectives are to manage and control exposures to ionising radiation so that deterministic effects or tissue reactions are prevented, and the risks of stochastic effects are reduced to the extent reasonably achievable, societal and economic factors considered (ICRP, 2007). To achieve these objectives, the Commission recommends three fundamental principles of radiological protection: justification, optimisation of protection, and limitation of individual dose (ICRP, 2007). The principles of justification and optimisation apply to all types of exposure; occupational, public and medical exposure, while the principle of dose

limitation only applies to workers and the public, but does not apply to medical exposures of patients, carers or comforters and subjects participating in biomedical research.

3.2.2. Justification of practices and procedures

(61) The principle of justification is that any decision that alters the radiation exposure situations should do more good than harm. This means that when introducing a new radiation source, or working to reduce an existing exposure, or to reduce the risk of potential exposure, sufficient individual or societal benefit to offset the detriment it causes should be achieved (ICRP, 2007b,c). In the context of medical exposure, the aim of justification is to do more good than harm to the patient, subsidiary account being taken of the radiation detriment from the exposure of the radiological workers and other individuals (ICRP, 2007b).

3.2.3. Optimisation of protection

(62) The principle of optimisation of protection 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). More specifically, this means 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. In the context of medical exposure from interventions guided by radiological imaging, optimisation of protection implies keeping patient and workers' radiation dose as low as possible, consistent with achieving the clinical objective of the interventions. It should be applied to the design of facilities that use ionising radiation; to the selection, set-up, and use of equipment; and to day-to-day working procedures.

3.2.4. Dose limitation

(63) The principle of dose limitation 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 applies to the exposure of medical workers.

(64) For occupationally exposed workers in medical interventional procedures, the dose limits for workers specified by ICRP apply. In planned exposure situations, recommended dose limits for workers were established in *Publication 103* (ICRP, 2007), with an updated limit for the lens of the eye in the ICRP statement on tissue reactions (ICRP, 2012).

(65) The following limits apply:

- Whole body: an effective dose of 20 mSv per year, averaged over defined periods of 5 years, provided that the effective dose does not exceed 50 mSv in any single year.
- Extremities: hands and feet, an equivalent dose of 500 mSv per year.
- Skin: an equivalent dose of 500 mSv per year, averaged over 1 cm^2 area of skin regardless of the area exposed.

- Lens of the eye: an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv.

(66) The objective of the recommended limits is to ensure that the occurrence of stochastic health effects is kept below unacceptable levels and that tissue reactions (deterministic effects) are avoided.

3.2.5. Dose constraints

(67) Optimisation is aided by setting a boundary on the predicted dose in the optimisation of protection (ICRP, 2007). Such a boundary is called a dose constraint in planned exposure situations, and is selected for planning purposes so that it effectively assists in the optimisation process taking into account the current distribution of exposures. If later it is found to have been exceeded, an investigation should be conducted to understand the circumstances, and it is unlikely that protection is optimised. Dose constraints are therefore lower than the pertinent annual dose limit. Dose constraints are established prospectively in the process of optimisation and are source related. When an interventionalist works in more than one facility, the dose limits and constraints should apply to the sum of all the individual doses incurred at the facilities. Dose constraints have been suggested by the International Radiation Protection Association (IRPA) (IRPA, 2017).

3.3. Investigations of abnormal doses

(68) There is no need to wait until an annual dose limit or constraint has been exceeded to become aware that protection was not optimised. Non optimised protection can be detected by establishing an investigation level in terms of effective or equivalent dose received in one month, or the value of a related parameter, such as the reading of the over-apron collar dosimeter.

(69) Exceeding a monthly investigation level provides an alert that protection was less than optimal in that period of time and a review of existing radiological protection is needed. The increase in the dosimeter reading may be due to a substantial increase in the number of interventions, or in the dose per procedure, which may be due to an increased complexity or to a degradation of compliance with protection measures.

(70) In the year 2000, the World Health Organization (WHO) recommended that an investigation be carried out when monthly exposure reaches 0.5 mSv for effective dose, 5 mSv for dose to the lens of the eye, or 15 mSv to the hands or extremities (WHO, 2000). Following the new annual limit of equivalent dose to the lens of the eye, the investigation levels should be lowered accordingly. An investigation level of 2 mSv in a month, using the reading from the collar dosimeter, is appropriate for interventional cardiologists (Durán et al., 2013, endorsed by Pacific Society of Interventional Cardiology, the European Association of Percutaneous Cardiovascular Interventions, the Latin American Society of Interventional Cardiology, and the Society for Cardiovascular Angiography and Interventions).

(71) An investigation level in terms of a monthly dose should be such that when extrapolated to a year, it would not exceed the relevant dose limit or dose constraint. In addition, as described in Section 2, personal dosimeters were not

always worn or were worn improperly (Sánchez et al., 2012; Padovani et al., 2011). Investigation levels can be helpful in this situation, by establishing minimum dose values for the over apron and hand dosimeters, thus providing an alert for possible poor compliance with procedures on wearing the dosimeters.

3.4. Classification of areas and workplaces

(72) *Publication 57* (ICRP, 1990) discusses in paragraph 129 the possible classification of workers in categories with regard to the need for individual monitoring and states that interventional radiologists and cardiologists are likely to fall in category A. Classification of workers, however, was not supported in *Publication 60* (ICRP, 1991) and paragraph 184 of *Publication 103* (ICRP, 2007), states that "The Commission continues to recommend the classification of areas of work rather than the classification of workers". The assignment of individual monitoring devices should, therefore, be analysed on grounds of workplace and duties of the workers, their location and time of exposure within the radiation field, and the shielding of the protection devices used.

3.5. Protection of pregnant workers and the conceptus

(73) The Commission provided advice on the management of pregnant physicians and other workers in *Publication 84* (ICRP, 2000a). For women who may be pregnant, the Commission recommends that the standard of protection for the conceptus should be broadly comparable to that provided for members of the general public (ICRP, 2000a, 2007).

(74) The early part of pregnancy (before the pregnancy has been declared) is covered by the normal protection of workers, which is essentially the same for males and females. Once the pregnancy has been declared, and the employer notified, additional protection of the fetus should be considered. The working conditions of a pregnant worker, after the declaration of pregnancy, should be such that the additional dose to the conceptus will not exceed 1 mSv during the remainder of pregnancy (ICRP, 2000a).

(75) Unnecessary discrimination against pregnant women needs to be avoided. The restriction on dose to the conceptus does not mean that it is necessary for pregnant workers to avoid work with radiation completely, or that they must be prevented from entering or working in designated radiation areas (ICRP, 2000a). It does imply, however, that their employer should carefully review the exposure conditions of pregnant workers. In particular, their work should be of such a type that the probability of high accidental radiation exposure is insignificant (ICRP, 2000a). Assessment of anticipated conceptus doses are to be performed on the basis of current practice in the interventional room.

(76) In some countries, regulations prohibit work with unsealed radioactive sources, effectively restricting the worker from working in a nuclear medicine department (Buls et al., 2009). In other countries, the right of pregnant workers to continue working in occupations requiring exposure to radiation if they so wish is protected by law (Uzoigwe and Middleton, 2012). There are responsibilities on both the pregnant worker and the employer. The Commission also states that “the first responsibility for the protection of the conceptus lies with the woman herself to

declare her pregnancy to the management as soon as the pregnancy is confirmed." (ICRP, 2000a).

(77) Although some pregnant workers involved in fluoroscopic procedures, especially interventional fluoroscopy procedures, may receive an annual personal dose >1 mSv (Buls et al., 2009), very few individuals will accumulate such dose beneath a radiation protective apron (NCRP, 2010). The shielding provided by a standard protective lead apron is sufficient to protect the embryo and fetus for typical exposure to staff involved in interventional procedures (Wagner and Hayman, 1982). In addition, as discussed in Section 4.4.5, the fetal dose is lower than the personal dose equivalent under the apron due to the attenuation in the abdomen of the pregnant woman. Therefore, when two dosimeters are used, if the dosimeter under the protective apron shows a value for personal dose equivalent, $H_p(10)$ of < 0.2 mSv per month, the equivalent dose to the conceptus would be below the limit.

(78) Therefore, pregnant women involved in fluoroscopically guided interventions generally do not need to limit their time in the procedure room to remain below the dose limit for the embryo and fetus (NCRP, 2010). A consensus statement by the Society for Cardiovascular Angiography and Interventions and standard of practice for the occupational radiological protection of pregnant or potentially pregnant workers in interventional radiology has been developed as a joint guideline of the Society for Interventional Radiology and the Cardiovascular and Interventional Radiology Society of Europe. It is concluded that excluding pregnant workers from fluoroscopic procedures solely on the basis of radiation risks to the conceptus cannot be justified on scientific grounds (Dauer et al., 2015; Best et al., 2011; Blake et al., 2006).

4. INDIVIDUAL MONITORING AND DOSE ASSESSMENT

4.1. Main Points

- The need for individual monitoring devices should be analysed on grounds of workplace and duties of the workers, their location and time of exposure within the radiation field, and the shielding of the protection devices used.
- It is essential that professionals wear dosimeters correctly. No dose to an individual can be reasonably estimated in a highly variable radiation fields without having some type of individual monitoring during all times of exposure.
- Two dosimeters, one shielded by the apron and one unshielded at collar level, provide the best estimate of effective dose. The under-apron dosimeter also provides confirmation that the apron has been actually worn and that its shielding is sufficient to keep the dose low under the apron.
- Not only high dose readings but also very low dose readings may indicate misuse or failure to wear dosimeters.
- Individual dosimeters should have a means to let the users identify their own dosimeters and their expected position. Consistency analysis of the two readings also allows for an indication of the proper use of the monitoring system, making the monitoring system more robust.
- Active, electronic personal dosimeters have proven useful for optimisation monitoring, for educational purposes and for special studies of dose by procedure or for specific aspects of a procedure. Type-test procedures and calibration of active personal dosimeters (APDs) and area monitors should be carried out using radiation fields representative of the interventional procedures, including tests in pulsed mode with high dose rates.
- Ambient monitors (such as at the C-arm) are useful to continually assess the scatter radiation fields and provide backup to personal dosimetry, to discover non-compliance when wearing individual dosimeters and to help estimate occupational doses when personal dosimeters have not been used.
- While there is considerable work on Monte Carlo calculations combined with measurements in the frame of research studies, improved methodologies to assess eye lens doses received in daily interventions need to be developed, including when lead glasses are worn. Industry should pursue the development of computational technologies (not requiring dosimeters), with personnel position sensing, to assess personnel doses, including eye doses.

4.2. Individual exposure monitoring

4.2.1. Exposure monitoring and verification of compliance with dose limits

(79) Exposure monitoring is required for demonstrating compliance with annual dose limits as well as for optimization of protection. Monitoring compliance with dose limits requires assessment of effective dose and equivalent doses to the skin, lens of the eye, hands and feet. Equivalent dose and effective dose cannot be measured directly in body tissues and cannot be used directly as quantities in exposure monitoring. The protection system therefore includes operational quantities that can be measured and from which equivalent doses and effective dose can be assessed (ICRP, 2007). Operational quantities for area and individual monitoring of external exposures have been defined by ICRU and those relevant for interventions guided by radiological imaging are summarised in Annex B.

(80) Occupational exposure rests on a series of assumptions regarding the relationship between what is measured by a dosimeter and the dose received by an individual. Standards include accuracy requirements and uncertainties of the dosimetry system so that these assumptions hold for the relationship between operational and protection quantities. Ensuring that workers correctly wear the dosimeters during all working time is the most important part in this series of assumptions and relationships. No dose to an individual can be reasonably estimated in highly variable radiation fields without having some type of individual monitoring present on the workers during all times of exposure. Auditing compliance with procedures is important to verify that the workers wear the dosimeters regularly and correctly.

4.2.2. Exposure monitoring and optimisation of protection

(81) Verification of compliance is not typically performed by checking doses from individual interventional procedures but by integrating the doses over many interventions carried out during a prescribed monitoring period. The period is established by the regulator and is usually one month. While this period is adequate for checking compliance with annual dose limits, it is not sufficient for optimisation of protection in specific procedures. Monthly analysis of doses from a variety of procedures is less informative than collecting information on the same type of procedures over multiple monitoring periods, for example. Therefore, verification of compliance is occasionally accompanied by monitoring designed for evaluating optimisation of protection in order to more quickly evaluate the effectiveness of radiological protection efforts.

(82) Often a reduction of occupational exposure is accomplished by reducing patient doses. Actions taken to reduce patient doses will frequently translate into reduced scattered radiation levels or the times during which elevated levels exist, thus reducing worker exposure. Separate actions may be taken that are directed specifically at the worker (see Section 5). The proper use of protective shielding and locating the staff in the lower dose rate areas around the x-ray system are examples of optimisation actions, the outcome of which can be verified by individual exposure monitoring. Over time, the impacts of optimisation will appear through lower occupational doses for comparable workloads and case mix.

4.3. Characteristics of individual dosimeters and their use

4.3.1. Types of dosimeters: passive and active dosimeters

(83) The dosimeters need to have adequate accuracy under a variety of exposure conditions, to be of a size that makes them convenient to use and does not interfere with the staff's ability to execute their tasks. Passive dosimeters are typically small, lightweight and do not require power. This makes them easy to incorporate into packages that do not interfere with the staff's actions and comfort, thus being the most widely used option, particularly for demonstrating compliance with dose limits. However, the absence of an instant reading capability is a disadvantage of all passive dosimeters for optimisation monitoring, especially for education of the workers involved in interventions.

(84) For monitoring of the hands, small ring shaped dosimeters are used due to their relative ease of fit under surgical gloves. Rings can be sized for different finger diameters; expandable plastic rings have been known to become tight on larger fingers that may swell during long procedures. Fingertip sachets that fit over a finger have been used as an alternative to ring dosimeters and are placed with the radiation sensor at the most proximal part of the hand where the largest doses may occur. The disadvantages of fingertip dosimeters are sterilisation problems and the interference of tactile feeling in the operator's hand thus affecting the ability to manoeuvre catheters and instruments precisely. An alternative solution that reduces interference with tactile feeling consists of wearing a TLD-type dosimeter on a finger nearest the patient.

(85) The physical construction of the dosimeter has to be compatible with the intended wearing location. Infection control is a particular concern for ring dosimeters because many ring dosimeters do not withstand a sterilisation process, and they are typically worn during procedures where infection control is essential.

(86) Dosimeters worn on the body should not induce sharp pressure points that cause discomfort when placed between the heavy leaded apron and the user's clothing. If whole body dosimeters are placed near the neck atop the leaded apron or over a protective thyroid shield to assess doses to unshielded areas, they should not have any edges that could irritate the neck or chin area. All methods of attachment should be strong enough to prevent dislodging during strenuous use but not cause dislocation of protective aprons or damage to clothing in the event the dosimeter catches on a foreign object.

(87) APDs or electronic dosimeters are used for optimisation monitoring or for special studies that require analysis of dose by procedure or discern aspects of a procedure, for example the relative dose received during fluoroscopy compared to image acquisition series. Active dosimeters are able to provide immediate information about dose rate so that rapid feedback is available to staff against which they can assess changes to their behaviour that result in lower dose rates and subsequently lower accumulated doses. Dose rate information is preferred over accumulated dose if actions are desired during a procedure as it can directly lead to procedural change. In addition, active dosimeters provide information on the time of each exposure, which facilitates correlation of occupational with patient doses and auditing of the wearing of the personal dosimeter during the interventions.

(88) Electronic dosimeters are useful for educating the staff. For example, the large dose rate reduction when a ceiling-suspended shield is brought into place is very illustrative and encourages clinicians to use them diligently.

(89) Until recently, electronic dosimeters were of sizes that were not convenient to use under leaded aprons. Power requirements of older units added to the operational overhead of assuring the use of charged batteries so that the units would not power off during a lengthy procedure.

(90) Advances in power management and wireless transmission of signals from an electronic dosimeter to a base station have overcome some of the disadvantages of using electronic dosimeters. Some manufacturers of interventional systems have included electronic monitors with wireless data transmission so that dose rates and doses can be viewed adjacent to or as part of the image video screens that the operators use.

(91) Optimisation monitoring does not need to conform to the strict dose quantities required for compliance monitoring. Optimisation seeks to compare relative changes in conditions to evaluate effectiveness of actions to reduce dose. Electronic dosimeters are usually calibrated to assess the operational quantities not taking into account the non-uniform irradiation of the body during interventional radiography. That is, electronic dosimeters indicate the dose at a single point and make no inferences regarding effective doses or doses at some distance from the dosimeter. Conceptually, there is no technical reason why multiple electronic dosimeters could not be worn and the data combined to yield compliance type dose information but practical issues have tended to limit the use of electronic dosimeters to investigatory and optimisation monitoring.

(92) Electronic dosimeters have not been developed for routine use on the fingers or near the eyes. An attempt was made to place small electronic sensors on the fingers but the electrical cable leads back to the power source and electronics were not convenient or found practical for routine use.

4.3.2. Dosimeter specificity

(93) To generate confidence in using a measurement made externally to the body for estimating doses occurring in the body, dosimetry systems have to meet standard requirements for accuracy, precision and reproducibility for the operational quantity of concern, and for the range of photon energies between 20 and 150 keV such as those spectra prescribed for whole body dosimeters in IEC standard 62387 (IEC, 2012) or similar standards, as well as internationally accepted guidance (ICRP, 2010b; IAEA, 2014a) and by national regulatory bodies.

4.3.3. Dosimeter reliability and simplicity

(94) The dosimetry system must be reliable and fail-safe, that is, possess a continued ability for measuring the radiation field. In addition, actions required from the user should be simple and efficient to execute. For electronic dosimeters that require the user to energise the dosimeter an item needs to be included in the procedures for staff to remember in the process of putting on dosimeters. The fewer the actions and decisions required from the staff, the greater the likelihood of compliance with monitoring. Integrating passive dosimeters such as those containing film, thermoluminescence crystals (TLD), optically stimulated luminescence crystals (OSL), and radiophotoluminescent glass (RPL) are generally used in the fluoroscopic theatre for compliance monitoring.

4.3.4. Dosimeter exchange periods

(95) Passive dosimeters provide total dose accumulated over the period of use and at the end of the use period must be exchanged for new dosimeters. The exchange period should be on a predetermined schedule to instill a habitual routine among staff. Generally, fluoroscopic staff should be monitored for monthly periods to provide dose data with sufficient frequency that unusual events can be detected and appropriate responses implemented. Therefore, the radiation sensing material, be it TLD, OSL or film, should have the sensitivity to detect the minimally relevant dose over the shortest period of expected use and should retain the dose information for the longest expected use period.

4.3.5. Examples of problems of wearing the dosimeter incorrectly in interventional procedures

(96) Problems with wearing dosimeters may include not only high doses but also very low doses that may suggest misuse of or failure to wear dosimeters. Examples of incorrect use include wearing a dosimeter over an apron that was intended for use under an apron, wearing a ring dosimeter on the incorrect hand, wearing a dosimeter issued to another person or a lost dosimeter. Indirect approaches may be useful in identifying the lack of compliance in wearing personal dosimeters and in estimating occupational doses when personal dosimeters have not been used. These approaches include making use of area dosimetry of the scatter radiation near the patient (e.g. at the C-arm), together with conversion coefficients from patient-related quantities such as kerma-area product for different kinds of procedure and geometries to worker´s eye lens dose. Wearing the over-apron dosimeter on a lanyard that can move in front of the body would introduce an additional difference from the radiation incident on the apron.

4.3.6. Different scatter conditions between type- testing, and calibration and real interventions

(97) Monitoring to assess the effective dose has been attempted using a single or two dosimeters. A discussion of the algorithms that adjust the dosimeter readings is presented later in this Section; however, a few points should be made here. Whole body dosimeters are calibrated and assessed without any consideration of the effects of shielding materials. Type test standards tend to define performance evaluations under simple conditions with dosimeters being placed on a flat surface of a tissue equivalent phantom. In the interventional theatre, whole body dosimeters will either be placed under or over an apron containing high atomic number shielding elements. The close proximity to the shielding materials places the dosimeter in a much different scatter environment from that typically assumed during type testing. Assurances should be requested from the supplier to verify that the measurement of the operational quantities is within expected dosimeter performance requirements and similar conditions to that of normal use.

4.3.7. Dosimeter for eye lens

(98) Monitoring of the lens of the eye presents special challenges due to the absence of objects near the eyes on which to attach the dosimeter. With the reduction of the dose limit for the lens of the eye, the use of protective eyewear has become

more prevalent. This provides greater opportunities for locating dosimeters near the eye and under the protective lenses. Until eyewear has been designed for inserting a dosimeter, eye doses can be assessed from a dosimeter placed above the leaded apron at the collar or level of the neck, or another dosimeter on a strip of plastic attached to a headband such that the sensor is adjacent to the temple closest to the x-ray tube. Some attempts at eye monitoring have used a TLD chip wrapped in an elastic band that is fitted on the side arm of the glasses. In any case, dosimeters placed near the eyes must not interfere with the vision of the wearer. A dosimeter placed behind the glasses means the use of three dosimeters: one under, one over the apron and the eye dosimeter. An arrangement based on three dosimeters poses a challenge with regard to reliable and consistent use. It could, however, be used for comparison purposes during a short period of time. If leaded glasses are actually worn and the primary interventionalist uses a ceiling suspended shield, the need for an eye dosimeter is not as critical, but quality control is necessary to ensure that the screen and the leaded glasses are actually used. The issue of when the glasses should and can be worn becomes the key issue.

4.3.8. Identification of the dosimeter and the worker

(99) Individual dosimeters should have a means to let the users identify their own dosimeters. A one to one relationship between a dosimeter and the user is indispensable if the dosimeter results are to be applied to a specific person. Means of identification, such as labels need to have their content easily readable to prevent someone from using another's dosimeter. A suitable approach consists of racks on which dosimeters are stored when not needed and visual identification.

4.3.9. Wearing location

(100) Visual means should designate the intended wearing location, particularly when the shape of the dosimeter does not convey the proper placement. When two dosimeters, one over and one under the apron, are used to assess the effective dose, operators may frequently reverse the location of the over and under apron dosimeters so that the doses reported approximate an average of the two values. This inconsistency results in higher reported effective doses, which may frustrate the operators and discourage them from using both or one dosimeter. Visual elements should also help locate each dosimeter in its correct place. Moreover, for better response reproducibility, the dosimeters should be worn in precise positions over and under the apron, and the compliance with the correct location can be assured by using specific pockets on the personal apron. Icons or images of where the dosimeter is to be located combined with colours and labels have been tried to improve proper practice. A similar situation arises if both hands are to be independently monitored. The left and right rings can be reversed if distinctive features are not used. Labelling of hand or finger dosimeters is difficult given the limited space available to print all of the needed information on the ring. Different colours are an effective method to distinguish right from left. As a result of the potential for extremity dosimeters to be mixed up, the use of a single dosimeter has become common with placement on the hand closest to the x-ray beam. This typically means the left little finger (Martin, 2009).

4.3.10. Calibration of active personal dosimeters

(101) In the course of the European project ORAMED, Clairand et al. (2011) and Sánchez et al. (2014) tested the influence of dose rate as well as pulse frequency and duration on the APDs responses. With the exception of Geiger-Müller equipped APDs, which did not give any signal in pulsed mode, the APDs provided a response affected by the personal dose equivalent rate, which means that they could be used in routine monitoring provided that correction factors are introduced. Type-test procedures and calibration of APDs and area monitors should include radiation fields representative of the interventional procedures, including tests in pulsed mode with high dose rates (Clairand et al., 2011; Sánchez et al., 2014; Chiriotti et. al., 2011).

4.4. Assessment of the occupational exposure

4.4.1. Assessment of effective dose

(102) In general, effective dose is assessed from the reading of a personal dosimeter calibrated in terms of personal dose equivalent, $H_p(10)$. This assessment of effective dose is sufficiently precise for radiological protection purposes provided that the dosimeter is worn on a position of the body representative of its exposure, under the assumption of a uniform whole-body exposure (ICRP, 2007). However, in interventions guided by radiological imaging, part of the body is protected while other parts are unprotected. Therefore, the reading of a single dosimeter placed over the protective apron overestimates effective dose beause the reading does not reflect to the dose to organs of the trunk protected by the apron, while the single dosimeter placed under the apron underestimates effective dose because the reading does not reflect the higher exposure of unprotected body parts, such as the head, neck, and part of the lungs and other organs in the thorax that are exposed via the arm holes (Franken, 2002; Siiskonen et al., 2007). Thus, in order to estimate effective dose from a single dosimeter reading, a correction should be applied to the $H_p(10)$ values. The correction factor is lower than 1 if the dose meter is placed over the apron and higher than 1 if placed under the apron.

4.4.1.1. Considerations of the two-dosimeter approach

(103) *Publication 85* (ICRP, 2000b) recommended that two-dosimeters, one over the apron and one under the apron, should be used to obtain a better estimate of the effective dose. The readings of the two dosimeters, in terms of $H_p(10)$, are usually combined by means of simple algorithms of the form:

$$E = \alpha H_u + \beta H_o,$$

where H_u and H_o are the personal dose equivalents $H_p(10)$, where H_u is measured under the apron either on the chest or the waist, and H_o is generally measured on the collar, outside the apron, and α and β are pairs of weighting factors to be applied to the dosimeter readings.

(104) A number of pairs of α and β values have been proposed over the years, but due to the fact that no single α and β pair adequately represents occupational exposure for all types of procedures, there has been no worldwide consensus about which should be used. Without an international consensus supported by a standard

and means to facilitate the mistake-free placement of the two dosimeters, the estimated values of effective dose will not be reliable nor comparable.

(105) Within the European Coordinated Network for Radiation Dosimetry (CONRAD) project, dosimetry methods used in 13 European countries were compared. In five countries, a single dosimeter was worn over the apron, in seven, a single dosimeter under the apron was recommended, and in one country two dosimeters, above and below the apron, (Järvinen et al., 2008) were recommended. In some countries, there are no recommendations from the regulatory bodies and hospitals adopt different methods (IAEA, 2014b).

(106) Also within the CONRAD study, Järvinen et al. made a comprehensive comparison of 11 different pairs of α and β values proposed by different authors for double dosimetry and four values for the single dosimeter approach (Järvinen et al., 2008). The study consisted of both Monte Carlo simulations and some measurements on a Rando-Alderson phantom taken for H_o correction purposes. The phantom was provided with a wrap-around 0.35 mm lead apron and a separate collar for both the experiment and the Monte Carlo calculation. The criteria for determining the best estimate from the pairs of α and β were that there should not be underestimation of the effective dose obtained from Monte Carlo simulations for typical irradiation geometries, and that overestimation should be minimal.

(107) The CONRAD study concluded that there is no optimal algorithm for all possible geometries and that, therefore, compromises have to be made when making a choice. From all the double-dosimeter algorithms tested, two of them were found closer to the specified criteria, namely the sets of values α and β given in the Swiss Ordinance (1999) and by McEwan (2000). These values of α and β are presented in Table 4.1. More recently, algorithms based on *Publication 103* weighting factors for effective dose have been developed (von Boetticher et al., 2010) and the values are also presented in Table 4.1.

Table 4.1. Values of α and β [adapted from Järvinen et al. (2008)] of the algorithms, that best meet the criteria: no underestimation, minimum overestimation for the typical geometries and an algorithm based on *Publication 103*.

Algorithm	With thyroid shielding		Without thyroid shielding	
	α	β	α	β
Swiss Ordinance [2008]	1	0.05	1	0.1
McEwan [2000]			0.71	0.05
Von Boetticher et al. [2010]	0.79	0.051	0.84	0.100

(108) However, when the estimated effective dose is close to the annual dose limit (e.g. > 15 mSv), more accurate assessment considering the specific geometry and irradiation parameters should be investigated, because of possible over or underestimation of effective dose using any of the values above, as concluded by Järvinen et al. (2008).

(109) The National Council on Radiation Protection and Measurements (NCRP, 2010) recommends the two-dosimeter method as it provides the best estimate of E for comparison with the dose limit for stochastic effects, a better indication (from the dosimeter worn under the protective apron at the waist or on the chest) of the shielding provided by the protective apron, and an estimate of the dose to the lens of the eye from the dosimeter worn outside and above the apron at the neck.

4.4.1.2. Considerations of the single-dosimeter approach

(110) Studies have been performed on the usefulness of a single dosimeter worn outside the protective apron for assessments of dose to interventional radiologists (Stranden et al., 2008). Some authors have formulated objections to the generalised use of two dosimeters (Kuipers et al., 2008; Martin, 2012). Several studies have concluded that there is no significant difference in the accuracy of double and single (over apron) dosimetry algorithms (Schultz and Zoetelief, 2006; Kuipers et al., 2008; Järvinen et al., 2008; Kuipers and Velders, 2009). Although the two-dosimeter approach gives a better accuracy in principle, the authors argue that the two-dosimeter approach has several drawbacks: 1) the lack of international consensus on a combination algorithm renders comparison of effective doses difficult to interpret; 2) the reliability of clinicians wearing two dosimeters correctly and consistently is questionable; 3) the cost of two dosimeters is higher. In practice, interventional clinicians sometimes accidentally reverse the positions of the two dosimeters and since the exposure received by the unshielded dosimeter may be ten times that of the under-apron one, this leads to a substantial overestimate of effective dose. Clinicians also often forget to wear the second and even the first dosimeter.

(111) In addition, exposure geometry is variable, radiation is distributed non-uniformly, and parts of the body are shielded. Thus, achieving a high degree of accuracy in assessment of effective dose is not feasible anyway. When doses are well below the respective dose limits, a pragmatic dosimetry system that is simple to implement and serves the purpose of providing a reasonable indication of dose levels is sufficient.

(112) A single dosimeter worn under the apron provides an indication of the dose received by the radiosensitive organs in the trunk, shielded by the apron. However, monthly readings of under-apron dosimeters are often below detection level, so the accuracy of the technique is poor and the value in providing information is limited.

(113) Martin (2012) suggests a pragmatic approach of using a single dosimeter placed at the collar outside the apron, and only when readings of the collar dosimeter exceed an established dose level in a single year, or a shorter period to be established, wearing a second dosimeter would be warranted. The reading of the collar dosimeter, corrected by a factor to take account of the organs that are protected, could provide an indication of effective dose and could also be used as an indicator of the dose to the lenses of the eyes.

(114) Studies of the relationship between the $H_p(10)$ from the collar outside the apron and values for effective dose derived either from Monte Carlo simulations or TLD measurements in anthropomorphic phantoms suggest correction factors between 0.011 and 0.18 for situations where an apron is worn but no thyroid collar is worn, and 0.02 and 0.083 when both an apron and a thyroid collar are worn (Martin and Magee, 2013). Martin and Magee (2013) have proposed that a reasonable indication of effective dose (E) for staff involved in radiology procedures who are wearing protective aprons can be obtained from the simple relationship:

$$E = 0.1\ H_o$$

(115) This proposal of a factor of 0.1, would represent a conservative assessment of effective dose, appropriate for the majority of staff working in radiology departments, including those involved in interventional radiology and cardiology. If the H_o reading exceeded 20 mSv (effective dose ≈ 2 mSv), then

wearing of a second dosimeter under the lead apron and the use of specific algorithm should be considered. NCRP (2010) also concluded that, if a single dosimeter is used, this should be worn outside the lead apron, and a single dosimeter worn under the radiation protective garments is unacceptable.

4.4.1.3. Recommended option

(116) A single over-apron dosimeter at collar level provides a reasonable estimate of effective dose. The single dosimeter method is simpler and less likely to cause errors due to the wearer's confusing the correct location for the two dosimeters. However, the expression E = 0.1 $H_{o,}$ relies on the assumption that the apron is worn during all interventions and that all aprons are alike in their attenuation. Different lead-equivalent thicknesses are available, as are lighter-weight aprons that contain no lead. The lead-equivalent thickness of the apron may also differ from the stated lead-equivalence thickness on the apron label (Lichliter et al, 2017). Since it cannot necessarily be assumed to be true for all countries and institutions that all staff wear aprons, nor that the aprons have similar and sufficient attenuation, the Commission maintains the principal recommendation to use the two-dosimeter approach with a simple algorithm, such as one of those found to meet the criteria and proposed in the CONRAD study (see Table 4.1).

(117) If for a given institution it can be reliably assumed that all professionals wear lead aprons with sufficient attenuation during all interventions, the under-apron dosimeter could be omitted for the majority of staff members of the intervention team because the over apron dosimeter will be sufficient for the assessment of their exposure. However, the two dosimeters are recommended for the interventionalist performing the procedures, since interventionalists typically receive the highest occupational doses, and the actual attenuation of the interventionalist's apron is rarely known.

4.4.2. Assessment of equivalent dose to the eye lens

4.4.2.1. Use of operational quantities for monitoring eye lens doses

(118) ICRP (2010b: Annex F) has considered the calculation of absorbed doses to the eye and lens of the eye using two dosimetric approaches: first, using the ICRP (2009) Reference Computational Phantoms and second using the stylised model of the eye developed by Behrens et al. (2009). This stylised eye model was used to supplement eye lens dose conversion coefficients derived from *Publication* 110 phantoms at low incident particle energies to capture the rapidly changing dose gradiants for external ocular irradiations. ICRP (2010b) also compared doses averaged over the lens with doses to the anterior epithelial cell layer, noting that this layer gives rise to the underlying anuclear lens fibre cells. Comparisons showed that for all but the lowest energy photons and electrons, similar doses were calculated for the two geometries. Bolch et al. (2015) provides details of the dosimetric models of the eye and lens of the eye and their use to calculate dose coefficients for ocular exposures.

(119) ICRU (1992) recommended the use of the operational quantity, personal dose equivalent Hp(3) for eye lens dosimetry. However, while Hp(3) is well suited to assess eye lens doses, calibration of dosimeters in Hp(3) is not available in many countries. In both *Publications* 103 (ICRP, 2007, Annex B) and 116 (ICRP, 2010b),

it is recommended that the operational quantity Hp(0.07) is adequate for monitoring the eye lens for photon exposures. Behrens and Dietze (2010, 2011) and Behrens (2012b) compared equivalent dose to the eye lens and the corresponding value of the operational quantities at the three recommended depths, 0.07, 3 and 10 mm, using realistic photon and beta radiation fields. The authors concluded that both *H*p(0.07) and *H*p(3) are adequate for x-rays fields calibrated on a slab phantom to simulate backscatter. Similar results were reported by Vanhavere et al. (2012) and Sánchez et al. (2014).

(120) With regard to the suitability of $H_p(10)$ for eye lens dosimetry, measurements by Sánchez et al. (2014) have shown that differences between $H_p(10)$ and $H_p(0.07)$ measured with OSL dosimeters are lower than 10% for four different spectra with mean energies higher than 44 keV, as typically used in fluoroscopy and CT guided procedures, but increases to about 17% when the photon spectrum has a mean energy of 36 keV. IAEA (2013) and International Organization for Standardization (ISO) (2015) have suggested that $H_p(0.07)$ can be used as an approximation to $H_p(3)$ for photon radiation in general and that $H_p(10)$, can also be used, but only if the photon spectrum reaching the dosimeter has a mean energy above 40 keV and photons are incident mainly from the front. Monitoring procedures for the eye lens have been provided by ISO, IAEA and IRPA (ISO, 2015; IAEA, 2013, 2014b; IRPA, 2017).

4.4.2.2. Assessment of the eye-lens doses when leaded glasses are not worn

(121) State of the art studies of methods for assessment of eye lens dose through experimental and computational modelling are reported in the literature (Vanhavere et al., 2012). An extensive review of these studies has been made by Carinou et al. (2015). For a given tube potential and current the resulting doses to the lens are influenced by several factors, mainly: patient size, projection angle, distance from the x-ray focus to the patient and from the patient to the interventionalist, beam collimation and operator technique (Vañó et al., 2015a).

(122) A number of studies have investigated the position where an eye dosimeter should be worn when no eye protection is used. A dosimeter worn on the head at the left eyebrow ridge or the middle of the forehead will generally provide the best assessment of eye dose. Some studies report that TLDs positioned on the eyebrow ridge on the side adjacent to the x-ray source measured doses 3 to 5 times higher than dosimeters placed between both eyes, whereas in other studies the latter has tended to record a higher dose (Efstathopoulos et al., 2011; Vanhavere et al., 2012; Principi et al., 2014). Thus the optimum position appears to vary with the type of procedure and the practice of the operator.

(123) If a collar dosimeter is worn outside the lead apron on the side adjacent to the x-ray tube, then this should give a good indication of the level of radiation to which the eye is exposed, if no eye protection is used. It is likely to overestimate the dose to the lens of the eye, although results in the literature vary (Martin and Magee, 2013). A reasonable approximation (Clerinx et al., 2008; Martin, 2009) is given by $H_{eye} = 0.75\ H_o$where H_o is the personal dose equivalent $H_p(3)$ or $H_p(0.07)$ from a dosimeter worn at the collar outside the lead apron.

(124) However, the collar dosimeter is only an indicator of eye dose, rather than an accurate measurement. When the collar dosimeter reading exceeds a certain value (e.g. 10 mSv) and no protective eyewear is worn, it may be advisable to wear an eye dosimeter adjacent to the most exposed eye.

(125) There are situations in which an interventionalist has not used a dosimeter regularly during interventions, and there is a need to make a moderately conservative dose estimate for this period. In exploring ways of obtaining a reasonable estimation of eye doses in these circumstances, Vañó et al. (2013b) investigated the ratio between the kerma-area product, KAP (or P_{KA}) from interventional cardiology and the reading of an active dosimeter placed on the C-arm, 95 cm from the isocentre, as a surrogate for eye lens doses. The study, based on 1969 interventional procedures, resulted in a ratio of the scatter dose at the C-arm to the kerma-area product, within 10.3 and 11.3 μSv Gy^{-1} cm^{-2}. This ratio is just an example valid for the type of procedure investigated and the particular conditions of this facility. In the absence of any other information, radiological protection officers could use such indirect approaches for estimations, provided that the type and the approximate number of procedures are known. If the dose approaches the limit, a more detailed investigation may be required.

4.4.2.3. Assessment of the eye-lens doses when glasses are worn

(126) At the present time, there are no dosimetry systems that take into account the protection provided by lead glasses or other protective eyewear. Moreover, it is likely that even when such dosimeters become available, many staff will be monitored by standard dosimeters at the collar above the apron. Therefore, the question arises as to how and when protection provided by eyewear should be taken into account.

(127) Magee et al. (2014) reported measurements on 30 sets of protective eyewear made using Rando phantoms to determine DRFs equal to the ratio of the dose with no eyewear, divided by that when lead glasses are worn.

(128) The protection provided by lead glasses depends on the angle at which scatter from the patient is incident on the head (McVey et al., 2013; Van Rooijen et al., 2014; Magee et al., 2014). For the majority of times that an interventional radiologist or cardiologist is carrying out a procedure, he/she will not be looking towards the patient when x-rays are being emitted, but will be viewing the resulting images on the monitor. Therefore, the dose reduction factor, DRF, should take account of x-ray beams incident from the side and below the level of the head.

(129) Studies of lead glasses have concluded that the dose to the eyes when protective eyewear is worn results primarily from radiation scattered from surrounding tissues of the interventionalist (Moore et al., 1980; Day and Forster, 1981; Cousin et al., 1987; McVey et al., 2013; Magee et al., 2014). The size of the lenses, the use of side shields for glasses with flat lenses, and the closeness of the fit to the facial contours are all important in determining the extent of protection provided. Since the scattered radiation is incident from a level below the head and to the side of the operator, then the closeness of the fit and the extent of the lenses protecting regions beneath the eye and to the side of the face are crucial factors determining the DRF.

(130) Magee et al. (2014) have concluded that for most situations, the majority of lead glasses with a lead equivalence of 0.75 mm provide a DRF between 3 and 6 for exposures occurring in clinical practice. Based on these results, division by a DRF of 2 would be both a reasonable and conservative approach that could be applied routinely to account for the protection offered by lead glasses with a lead equivalence of 0.75 mm.This factor should be applied to the reading of the collar dosimeter, provided that the eyewear is of appropriate design, either with side

shields or of a wraparound design, and includes protection in the frames (Martin, 2016) and is consistently worn. In addition, for the DRF to be applied there must be a quality assurance programme in place, with regular documented checks to confirm that the interventional clinician concerned always wears the protective eyewear.

(131) A study using Monte Carlo simulations and measurements and considering the effect of the eye equivalence and the size of the glasses was performed by Hu et al. (2016). According to the study, eye lens doses were reduced by a factor from 3 to 9 when wearing a 20 cm^2-sized lead ranging from 0.1 to 1.0mm Pb. While the increase of dose reduction factor (DRF) was not significant when increasing the lead equivalence above 0.35 mm, the DRF was proportional to the size of glass lens from 6 to 30 cm^2 with the same lead equivalence. They also concluded that reasonable and effective protection is achieved by 0.5 mm Pb and large-sized glasses (at least 27 cm^2 per glass lens).

(132) In institutions where a higher DRF value is considered appropriate, comprehensive measurements should be made, taking into account the direction of the primary and the scattered x-rays in clinical practice including angulation in both the horizontal and vertical planes, and these measurement be fully documented. ISEMIR has recommended that improved methodologies to assess eye lens dose need to be developed, including when lead glasses are worn (IAEA, 2014b).

4.4.3. Assessment of equivalent dose to extremities

(133) The dose limit for the skin is applied as an average over an area of 1 cm^2 in the most exposed area and therefore applies to the most exposed part of the hand. The hands of interventional clinicians can be close to the x-ray beam, and the operator's position, which is determined by the type of procedure and access route, is an important factor for estimating doses.

(134) The outer or ulnar aspect of the hand, which is side-on to the x-ray beam and closer to the irradiated volume of the patient, receives a higher dose, so dosimeters should be worn either on the little finger or the side of the wrist closest to the x-ray tube (Whitby and Martin, 2005; Vanhavere et al., 2012).

(135) When the x-ray tube is positioned below the couch, the primary beam is also scattered downwards from the patient and the base of the couch, so doses received by the legs can be substantial. Where no table shield is used, doses to the legs can be greater than those to the hands (Whitby and Martin, 2003). Dose monitoring of the lower extremities may be necessary to determine whether protective leg shields are adequate. Consideration should be given to assess the parts of the leg that are not shielded either by the lead apron or lead/rubber drapes.

(136) Proper dosimetry to evaluate doses to the hands and fingers is not easy in clinical practice. The most common method to estimate hand doses in interventional radiology is a wrist dosimeter but, due to the inhomogeneity of the radiation field near the patient and the possibility to introduce part of the hands in the direct beam, doses measured by the wrist dosimeters could be much lower than the actual finger doses.

4.4.4. Assessment of exposure in SIRT

(137) An open problem in therapy with ß-emitters is the finger dosimetry of the staff. TLD finger dosimeters should be worn on the index finger of the hand, which is closer to the radiation source. Due to the very small distances between the

ß-source and skin and the concomitantly high dose gradient the dose can be underestimated. At some workplaces, Rimpler and Barth (2007) measured local skin doses $H_p(0,07)$ at the fingertips due to direct ß-radiation of more than 100 mSv up to about 700 mSv per working day.

4.4.5. Assessment of exposure to the embryo and fetus

(138) For pregnant workers who perform or assist in fluoroscopic procedures, dose to the conceptus is usually estimated using a dosimeter placed on the mother's abdomen at waist level, under her radiation protective garments (Miller et al., 2010; NCRP, 2010). This dosimeter overestimates actual conceptus dose because radiation attenuation by the mother's tissues is not considered. The dosimeter should be evaluated monthly. Electronic dosimeters can be used to provide rapid access to data (Balter and Lamont, 2002).

(139) In facilities where a two-dosimeter system is used, workers who may become pregnant should place the dosimeter that is worn under the apron at waist level. After the conception is confirmed, the dosimeter should be worn in the middle of the abdomen as a dosimeter at the waist in the lateral position will underestimate the dose to angular dependence. The foetal dose is about half of the dosimeter reading for the relevant x-ray scatter radiation, due to attenuation by the mother's abdominal wall and anterior uterine wall (NCRP 2010; Faulkner and Marshall, 1993; Trout, 1977), which is a conservative estimate (Osei and Kotre, 2001). Therefore, when the dosimeter under the protective apron shows a value for personal dose equivalent, $H_p(10) < 0.2$ mSv per month, the equivalent dose to the conceptus would be below the limit.

4.4.6. Computational methods for real time monitoring

(140) Badal et al. (2013) described a dose monitoring system that uses an accelerated Monte Carlo code, detailed anatomical phantoms and physical sensors in the imaging room. The system has the future potential to provide accurate real-time dose estimations for both patients and staff during interventional fluoroscopy with higher accuracy than current dosimetry systems. Research efforts should pursue the development of computational technologies (not requiring dosimeters), with personnel position sensing, to assess personnel doses, including eye doses (IAEA, 2014b; NCRP, 2016).

5. RADIOLOGICAL PROTECTION METHODS AND PROGRAMME

5.1. Main Points

- Occupational exposure in interventional procedures is closely related to patient exposure and occupational protection should be managed in an integrated approach with patient protection. Moreover, occupational protection is achieved by optimising patient protection and by use of protective devices. Measures to protect staff should not impair the clinical outcome, and should not increase patient exposure.
- All professionals in the room should wear protective aprons; the interventionalist should be protected by ceiling suspended screens, table suspended curtains and shielding drapes when feasible. Staff such as nurses and anesthesia personnel who need to remain near the patient, can benefit from protection by movable screens and the rest of the personnel can be benefit from protection by distance.
- Ceiling suspended lead acrylic shields should always be included for interventional installations as they can reduce doses to the whole head and neck by factors of 2–10. If no protective measures for the eyes are used, personnel with a typical workload will receive doses to the lens of the eye that would exceed the dose limit, and over time could result in lens opacities. Dose reduction achieved by ceiling-suspended shields depends on their positioning and use.
- Leaded glasses should fit closely to the wearer's facial contours.
- Leaded drapes attached to the bottom edge of the ceiling-suspended shield as well as drapes and pads applied on the patient can be effective in protecting the operator's hands for some procedures.
- The operator's feet are exposed even when lead curtains suspended from the table top are in place.
- All vials containing ^{90}Y-activity, all instruments and disposable items used for preparing the dose and implanting the device should be handled with forceps and appropriate shielding to reduce finger doses. Due to the high-energy beta emission, shielding is best provided with a low atomic number material such as acrylic.
- When protective eyewear is worn, the eye exposure results primarily from radiation scattered from surrounding tissues of the interventionalist. The size of the lenses, the use of side shields, and the closeness of the fit to the facial contours are all important in determining the extent of protection provided.
- Hospital staff in charge of occupational protection should be familiar with the interventional procedure.

5.2. Relationship between protection of the patient and that of the staff

5.2.1. Actions that reduce patient and staff exposuse

(141) The following actions protect the patient and also the workers, because the reduction of patient dose reduces scattered radiation in a similar proportion. These actions are: reduction of fluoroscopy time, number of acquisition runs and number of images per run, use of lower-dose mode fluoroscopy and acquisition, lower pulse frequency, last image hold and image loops, image receptors close to the patient, collimation to the required field of view (FOV), cautious use of steep oblique projections and wedge attenuators where appropriate, removal of the anti-scatter grid for procedures on small children.

5.2.2. Additional measures to reduce only staff exposure

(142) The following devices and actions protect the staff but do not affect the patient: protective apron and collar, ceiling-suspended shield, protective eye glasses, table-top suspended lead curtains, shielding drapes on the patient, stepping back to increase distance from the patient and staying on the image receptor side rather than on the side of the x-ray tube.

5.2.3. Other issues of relationship between patient and staff exposure

(143) Electronic magnification in image intensifiers increases the patient skin dose and dose to tissues in the FOV, but reduces irradiated volume; with regard to the amount of scattered radiation the increase in dose to the tissues in the FOV may be compensated by the reduced irradiated volume (and mass), thus the scattered radiation and staff dose may stay similar, depending on the automatic brightness control sensor design and the algorithm used. The increase in dose to tissues in the FOV in the case of electronic magnification with flat panel is generally lower than with image intensifiers and so the scatter radiation to the staff is reduced (Srinivas and Wilson, 2002).

(144) Changing beam projection angle to avoid exposing the same skin area all the time may avoid patient skin injuries in complex and long interventions, but the way it affects the staff exposure depends on the extent of gantry angulation and the position of the x-ray tube with respect to the position of the interventionalist. Staff dose from scatter radiation increases when the x-ray tube is on the same side as the interventionalist with respect to the irradiated volume of the patient.

5.3. Distribution of scattered radiation

(145) In previous Sections it is mentioned that medical staff working in interventional radiology and interventional cardiology can receive relatively high doses of radiation compared to other occupational groups involved with x-ray imaging (Kim et al., 2008; Martin, 2009; Koukorava et al., 2011a; Vanhavere et al., 2012; Kim et al., 2012; Jacob et al., 2013; ICRP, 2013a,b; Vañó et al., 2015b). In addition, procedures often require the interventionalist to remain close to the patient in order to manipulate catheters. Other staff that provides assistance may also need to be in close proximity to the patient.

(146) The higher dose rates around the patient in a fluoroscopic x-ray room result from radiation scattered back from the surface of the patient. If the tube is positioned below the couch doses to the head, upper body, and hands of the interventionalist will be substantially lower, as they are then exposed predominantly to scattered radiation that has been transmitted through the patient´s body (Fig. 5.1). Thus, this is the arrangement recommended for the majority of procedures (ICRP, 2013a,b).

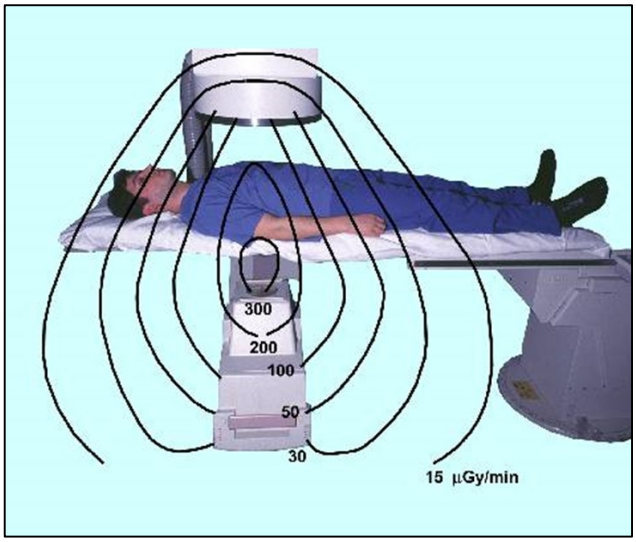


Fig. 5.1. Air kerma rate distribution from an undercouch X-ray tube. [Whitby and Martin, 2003] (*Permission given from British Journal of Radiology*)

(147) When the C-arm angulation departs from the vertical, staff standing on the same side of the couch as the x-ray tube will be exposed to higher levels of radiation from x-rays scattered from the side of the patient, while the radiation to which staff on the far side are exposed is again attenuated by passage through the patient (Fig. 5.2) (Balter, 1999; Whitby and Martin, 2003; Schueler et al., 2006; Morrish and Goldstone, 2008). The ratio of dose rates on the two sides of the couch will change as the angle of the tube is increased. When the x-ray beam is directed at 10° to the vertical, the dose rate on the side adjacent to the tube will be double that on the far side, and when the angle is increased to 30°, the dose rate may be five times that on the far side. Therefore, staff who stands near to the couch while performing or assisting interventional procedures should avoid the region adjacent to the x-ray tube for oblique and lateral projections.

(148) As the x-ray tube angle is increased towards the lateral for examinations of the trunk, the x-rays will also be passing through a greater depth of tissue. This will require a higher x-ray intensity to form an adequate image and so further increase the dose to both patient and staff. Thus although it is important to move the x-ray field to ensure that an area of the patient's skin does not receive too high a dose, larger gantry angulation should be used sparingly.

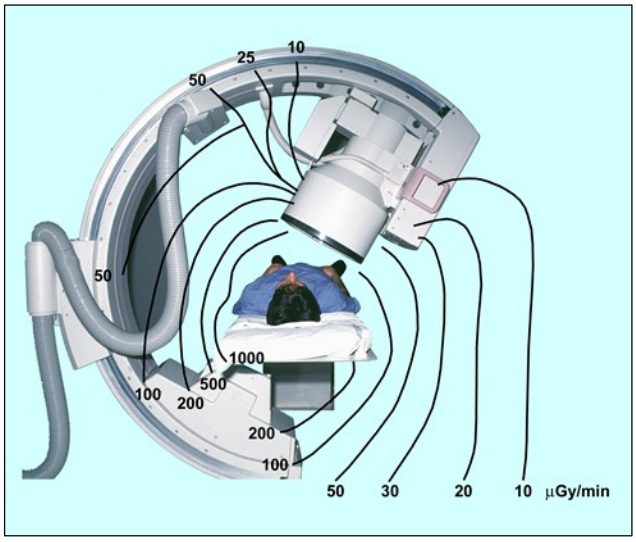


Fig. 5.2. Air kerma rate distribution around interventional X-ray unit with angled tube [Whitby and Martin, 2003] (Permission given from British Journal of Radiology).

(149) Knowledge by the staff of the distribution of scattered radiation levels around a patient and understanding of how different factors influence it, well as the effective use of protective devices is indispensable. These issues should be included in the training of all interventional physicians in relevant radiological protection techniques (ICRP, 2009). Occupational exposures are determined by the complexity of the procedures, the size of the patient, the modes of operation available on the x-ray equipment, and the skills of the operator (Vañó et al., 2015b).

(150) A number of professional societies, radiological protection organisations and others have issued guidelines on practices to be followed and made recommendations on the use of protective devices (Miller et al., 2010; NCRP, 2010; Sauren et al., 2011; Durán et al., 2013; ICRP, 2013a,b; Chambers et al., 2011; Hiles et al., 2016).

5.4. Protection of the body

5.4.1. Protective aprons

(151) Personal protective equipment, such as aprons, is worn by all interventional staff working in fluoroscopy inside the x-ray room. The aprons usually contain the equivalent of 0.25 mm, 0.35 mm, or 0.5 mm of lead and some designs have an overlap at the front to provide protection of 0.5 mm lead equivalence with 0.25 mm lead equivalence elsewhere. Transmission is typically between 0.5% and 5% in the range 70 kV to 100 kV (Marx et al., 1992). Although they shield the trunk against scattered radiation, part of the body, including the head, arms, hands and legs are not protected by the apron and need to be considered in the radiological protection programme.

5.4.2. Lighter weight aprons

(152) The weight of lead aprons often causes discomfort to the staff; fatigue and musculoskeletal problems, including those of the spine, and needs specific consideration (Papadopoulos et al., 2009; NCRP, 2010; Klein et al., 2015). Different designs of lead apron are available, some of which aim to reduce the ergonomic hazards in order to minimise risks of back injury. Two-piece aprons consisting of a waistcoat and skirt allow some of the weight to be supported at the hips to reduce strain on the back (Klein et al., 2009).

(153) There are lighter-weight aprons containing composite layers of high atomic number elements such as tin or bismuth, as well as or instead of lead. Similar levels of attenuation can be achieved with lighter aprons because the alternative metals are more efficient per unit mass than lead for absorbing x-ray photons with energies between 40 keV and 88 keV. These aprons may be more effective for attenuating scattered x rays from tube voltages of 70–80 kV, but less effective for tube voltages above 100 kV (Christodoulou et al., 2003). They provide a reasonable alternative where weight reduction is required to alleviate back or neck problems. Lightweight or “lead-free” aprons have different x-ray transmission from ones containing lead for different x-ray spectra. A study concluded that these aprons provide less lead equivalent thickness than what is stated on the lead aprons and their manufacturing certificates. (Papadopoulos et al., 2009). Users and patients wearing lead-free x-ray protective clothing might unknowingly be exposed to a greater dose than generally assumed.

(154) Manufacturers often specify the attenuation properties in terms of lead equivalence (e.g. 0.5 mm lead equivalent); these data without further qualification can be misleading (Finnerty and Brennan, 2005; Schlattl et al., 2007; Eder et al., 2010) since attenuation varies significantly over the photon energy spectrum, with the largest variations occurring in the diagnostic imaging range.

(155) The indication of the protective value of garments should be accompanied with specification of the characteristics of the radiation beams (IEC, 2014) used to measure the attenuation and the combination of measurements made at different beam qualities to reflect the conditions under which the garment is used. Johns et al. suggested the diagnostic radiation index for protection (DRIP) to specify the protective value of the device, but recognised that work remains to be done to mature the DRIP into a user-friendly method for specifying protective value (Wagner and Mulhem, 1996).

5.4.3. Independent support of the apron weight

(156) Reduction of the ergonomic hazards associated with leaded aprons can be also achieved by an independent support of the apron, but in a manner such that it can be moved easily by the operator (Klein et al., 2009). This might be through an independent floor mounted frame (Pelz, 2000) or through suspension from the ceiling (Savage et al., 2009). The latest versions extend from the head to the lower extremities and travel on rails suspended from the ceiling.

(157) The fit of the protective apron is often more important in determining the effective dose to the body than the thickness of lead (Detorie et al., 2007). Thoracic organs, including the lungs and oesophagus may receive higher levels of exposure when the operator is irradiated from the side through the armholes of the apron (Franken, 2002). This is particularly important for protection of the axillary portion

of the female breast. Some facilities favour aprons with shoulder protection to reduce this exposure (Guersen et al., 2013).

5.5. Protection of the thyroid

(158) Aprons do not incorporate protection for the neck. If no thyroid protection collar is worn, the dose to the unprotected thyroid, which is known to be sensitive to radiation in young persons, may double the effective dose (Niklason et al., 1993; Mateya and Claycamp, 1997; Theocharopoulos et al., 2006; Siskonen et al., 2007; Siiskonen et al., 2008; Martin, 2009). However, the risk of cancer incidence is strongly dependent on age-at-exposure and the risk for males above 30 years of age for males and females above 40 years is small (NA/NRC, 2006; NCRP, 2010). NCRP (2010) suggested the use of thyroid collars (or protective aprons with thyroid coverage) for younger workers and for all personnel whose personal dosimeter readings at the collar level (unshielded) exceed 4 mSv ($H_p(10)$) in a month (Wagner and Archer, 2004).

Fig 5.3. Risk of exposure induced incidence of thyroid cancer per sievert of thyroid equivalent dose based on data for the ICRP composite population defined in *Publication 103* (ICRP, 2007).

(159) Monte Carlo simulations (Marshall et al., 1992) have shown that a collar with protection of 0.5 mm lead reduces the equivalent dose to the thyroid by a factor of 12, while a collar containing 0.35 mm of lead will reduce it by a factor of 7. However, thyroid collars can be uncomfortable when fitted tightly around the neck, so they are often worn more loosely for comfort. If the collar is at a lower level around the larynx, about 10 mm of upper thyroid may be unprotected. This will reduce the protection factors to 6 and 5 for the two lead thicknesses respectively. These calculations agree broadly with measurements made on an anthropomorphic phantom during simulated patient exposures, which suggest a factor of 6 (Marx and Balter, 1995). Thus the overall reduction in the equivalent dose to the thyroid in clinical practice resulting from wearing a collar is by a factor between 5 and 10.

(160) In addition to interventional radiologists and cardiologists, surgeons and other groups of clinicians also undertake diagnostic or therapeutic procedures in standard operating theatres with guidance from mobile C-arm fluoroscopy units

(ICRP, 2010a). Doses to the head and thyroid might be significant in some cases, but the availability of protective devices in the operating theatre is often limited. Risk evaluations are needed to assess the techniques used and determine whether staff should wear thyroid collars as well as protective aprons (Vañó et al., 2016).

(161) Radiation doses from the majority of orthopaedic procedures are low, but surgeons may be working close to the x-ray beam and for some procedures may need to use the x-ray tube in an over-couch configuration, for which scatter dose to the head and upper body will be greater. Table-suspended lead curtains and ceiling-suspended shields are rarely available. However, for procedures involving the patient extremities, the dose levels should be relatively low compared to procedures where the patient's body is in the beam. A few orthopaedic procedures such as vertebroplasty and kyphoplasty (also performed by interventional radiologists), in which cement is injected into vertebrae to stabilise the spine, have the potential to deliver high doses to the eyes and hands of the operator (Struelens et al., 2013).

(162) Freestanding adjustable over-table shields cut away to allow a closer fit to the body contour can provide good protection to the body, but interventional staff often find them intrusive. Anything which interferes with the manipulations, thereby lengthening the procedure and increasing the dose to the patient and staff should be avoided.

5.5.1.1. Disposable drapes

(163) Lightweight disposable lead-free drapes or pads containing tungsten/antimony or bismuth can be placed outside the field of the primary beam to reduce scattered radiation levels (King et al., 2002; Dromi et al., 2006; Thornton et al., 2010; Politi et al., 2012; Martin, 2016; Ordiales et al, 2015). Such drapes may have an aperture through which catheters can be inserted into the skin, and the shielded surround cuts down the radiation scattered within the patient. They are placed in position after the operation site has been prepared, outside the field of the x-ray beam. This type of protection should be considered for procedures where the operator needs to be very close to the irradiated volume of the patient. These drapes protect the head, hands and upper body and have been shown to reduce doses to the eyes by a factor of 5–25 (Thornton et al., 2010). Evaluation of sterile disposable lead-free drapes used for percutaneous nephrostomy procedures, as reported by King et al. concluded that the small amount of time and the relatively little added cost required to use the drapeswere well worth (King et al., 2002). Reusable drapes can be fabricated from scrapped lead apron or shielding (Miller et al., 1985).

5.6. Protection of the head and eyes

5.6.1. Ceiling suspended shields

(164) Studies have shown that annual doses to the eyes of some interventional clinicians may be in the region of 50 mSv to 100 mSv (Vañó et al., 2008a; Ciraj-Bjelac et al., 2010; Thornton et al., 2010; Koukorava et al., 2011; Jacob et al., 2013; Martin and Magee, 2013; IAEA, 2014b; Principi et al., 2015). Thus radiation doses to the lens of the eye for interventional clinicians with high workloads can readily exceed the revised 20 mSv dose limit for the lens of the eye (ICRP, 2012), unless appropriate radiological protection measures are put in place.

(165) Eye doses are influenced by tube angulation, operator position, and beam collimation as discussed in Section 1.1. Perhaps the most important factor in protection of the head is the proper use of shields (Vañó et al., 1998; ICRP, 2013a; Vañó, 2015a). Ceiling suspended lead acrylic shields should always be specified for interventional installations as they can reduce doses to the whole head and neck by factors of 2–10 (Martin, 2016).

(166) The protection to the eyes provided by ceiling suspended shields or lead glasses can be quantified in terms of DRFs equal to the ratio of the dose with no protection, divided by that when protection is used. Reports on dose reductions to the eyes achieved through use of ceiling suspended shields give varying DRFs. A large-scale report of clinical measurements for interventional procedures gave DRFs between 1.3 and 7 (Vanhavere et al., 2012). A review comparing doses from groups at different centres performing similar procedures gave DRFs between 0.7 and 2.5 (Jacob et al., 2013), and a study comparing dose rates for periods when radiologists were using and not using shields gave a DRF of 5 when the shield was in use (Magee et al., 2014). However, DRFs derived from phantom simulations with precise positioning of shield yield higher values. In a phantom study, Galster reported DRFs values between 8.5 and 17.6 for transjugular portosystemic shunt (TIPS) creation, abdominal bleedings and pelvic embolisations. Ceiling suspended screens demonstrated a significant higher dose reduction than lead glasses and protect the whole head and neck and not only the eyes (Galster et al., 2013). One clinical study with careful placement of a shield for percutaneous coronary interventions observed a DRF of 19 (Maeder et al., 2006).

(167) When use of a ceiling suspended shield is possible, the level of dose reduction achieved depends on the use of the shield and how effectively it is positioned. The shield should be placed just above the patient, with the operator viewing the irradiated area of the patient through the shield, and this is an important element of radiological protection training for interventionalists (Vanhavere et al., 2012). However it is often more difficult to use these shields effectively with the tube in lateral or oblique projections. Effective use of shields requires continual repositioning as the x-ray tube and couch are moved. Thus, although the shields give good protection in principle, difficulties in their effective deployment for the range of projections throughout clinical procedures may limit the overall level of protection in routine use. Nonetheless with diligence DRFs of 2 to 5 should be achievable. This reduction should allow interventional operators to keep eye dose levels below the limit, and avoid eye lens opacities which may otherwise occur through the accumulation of dose over a professional working life.

(168) Vañó et al. (2015) estimated that more than 800 procedures per year and per operator would be needed to reach the new eye lens dose limits for three interventional specialties (cardiology, neurology and radiology) using the conservative approach of estimating eye lens doses from the over-apron chest dosimeter and assuming proper use of ceiling-suspended protective shields (Vañó et al., 2015c).

5.6.2. Other movable shields

(169) Staff such as nurses and anesthesia personnel who need to remain near the patient, may benefit from the additional protection provided by movable (rolling) shields that can be positioned between them and the x-ray source.

5.6.3. Protective eyewear

(170) Lead glasses are an important component of the protection for the eyes against scattered radiation. A variety of lead glasses are available, but care should be taken in the selection. A close fit to the facial contours, particularly around the underside, can be more important than the lead equivalence, as the glasses should also provide protection against exposures from below and to the side.

(171) For the majority of the time that interventionalists carry out a procedure when x-rays are being emitted, they will be viewing the resulting images from the monitor rather than looking towards the patient. The interventionalist usually stands adjacent to the patient couch, often to the right of the x-ray tube/image receptor gantry, and his/her eyes will be irradiated from below, at an angle between 20° and 90° with the horizontal plane.

(172) The majority of the lead glasses have a protection equivalent to 0.75 mm or 0.5 mm of lead and many have protection in side-shields of 0.5 mm or 0.3 mm lead equivalence. The designs can be divided into a number of categories which are listed below.

1. Purpose-designed lead glasses with large flat lenses and protective side shields
2. Wraparound lead glasses with front lenses angled to provide more protection for radiation incident from the side
3. Lead glasses adapted from conventional spectacles with lead glass side shields added
4. “Fit-over” glasses, similar in design to (1), but arranged to fit over conventional spectacles
5. Face masks of lower lead equivalence, held in place by a headband

(173) Values for DRFs between 5 and 10 have been reported from experimental measurements for a variety of lead glasses when protecting against x-rays incident from the front in the same horizontal plane as the eyes (Moore et al., 1980; Marshall et al., 1992; Thornton et al., 2010; McVey et al., 2013; Van Rooijen et al., 2014) and Monte Carlo simulations (Carinou et al., 2011; Koukorava et al., 2014). However, the DRF in practice needs to take account of x-ray beams incident from the side and below the level of the head similar to those encountered in clinical practice. For head positions behind a ceiling suspended screen Galster reported additional DRFs for lead glasses between 1.8 and 5.8 (Galster et al., 2013).

(174) The protection provided by leaded glasses in practice depends on the angle at which scatter from the patient is incident on the head (McVey et al., 2013; Van Rooijen et al., 2014; Magee et al., 2014). When the head is at an angle to the direction of irradiation, the DRF may be lower.

(175) Custom-designed lead glasses of categories (1) and (2) having a lead equivalence of 0.75 mm, provide protection for the eyes with DRFs between 3.5 and 6 (Cousin et al., 1987; Vanhavere et al., 2012; Koukorava et al., 2014; Magee et al., 2014; Principi et al., 2015; Martin, 2016), and 0.50 mm lead equivalence pairs might provide DRFs of 3 to 4. Wraparound lead glasses provide better protection for radiation incident from the side and below because the gaps between the frames and head tend to be smaller. Glasses based on adaptations of standard spectacles of 0.75 mm lead with added side shields have DRFs between 3 and 4, as gaps between the glasses and the head tend to be larger (Magee et al., 2014).

(176) “Fit-over” glasses designed to be worn over prescription spectacles are bulky, and have larger gaps underneath to allow wearing of conventional spectacles.

DRF values tend to be lower for irradiation from the side due to the larger spaces left between the glasses and the head for the prescription spectacles (Magee et al., 2014). If the operator's head is angled towards the monitor, which is likely to be the case for the majority of the time, then scattered radiation is able to pass through gaps behind the lenses and through parts of the frame that are not protected to irradiate the eyes directly.

(177) Verification that critical parts of the frames are protected is important, as some models, particularly the heavier "fit-over" glasses, do not use protection in the frames in order to keep the weight down.

(178) Facemasks or visors of lower lead equivalence such as 0.1 mm cover the whole of the face and so also reduce the exposure of regions of the head surrounding the eyes that would make a significant contribution to the eye dose from backscatter (Martin, 2016). Despite the lower lead equivalence, they provide a viable alternative to lead glasses, but are sometimes not favoured by clinicians due to their size and the tendency to fog.

(179) Unattenuated x-rays incident on tissues that are close to the eyes are a major source of exposure to the eye lens when protective eyewear is worn (Marshall et al., 1992; Moore et al., 1980; Cousin et al., 1987; McVey et al., 2013; Koukorava et al., 2014; Magee et al., 2014). For exposures from the front, differences between various categories of glasses relate to the sizes of the lenses, and so the proximity of unprotected and therefore irradiated tissue. While for exposures from the side, the eye dose depends on the closeness of the fit to the facial contours and the extent of the protection from the side. When the radiation scattered by the patient is incident toward the eye from below, it may enter directly through the gaps underneath the glass lenses, without an additional scattering.

(180) Measurements of the protection offered by lead glasses can provide useful data based on which adjustments to dosimeter reading values recorded by unshielded eye dosimeters can be based to derive a dose representing that to the lens of the eye for any interventional clinicians for whom it could be guaranteed that they wore the protective eyewear consistently.

(181) However, any calculations assume that lead glasses are worn for every procedure. Therefore, for an attenuation factor to be applied, quality controls should be in place with regular documented checks to confirm that the interventionalist concerned always wears the protective eyewear.

(182) The factor applied could be one based on measurements with the glasses concerned, but should take account of exposure from x rays at angles encountered in clinical practice. The measurement technique and the results should be documented, and the DRF applied should not be greater than 4.

(183) Where no measurements are available to confirm the DRF, but the glasses are of designs (1) or (2) and incorporate the equivalent of at least 0.5 mm of lead, division by a DRF of 2 represents a conservative approach to account for the protection offered by the glasses (Magee et al., 2014).

(184) The use of leaded glasses has proved to significantly reduce the dose to the lens of the eye. Lead glasses are commercially available with an equivalent lead thickness of 0.75 mm that can reduce doses above 85% (Sandblom et al., 2012; Magee et al., 2014; Martin, 2016) for all tube potentials. Care is recommended in the fit of the eye pieces to the face in order to avoid open spaces through which radiation may reach the eye without attenuation.

5.6.4. Combined used of protective means

(185) In the framework of the ORAMED programme, Monte Carlo simulations of clinical conditions and geometries and measurements were performed to find out the effect of different protecting devices on radiation doses to eye lenses and extremities. The results include the following: the ceiling suspended shield can reduce the eye dose 2–7 times; protective glasses can reduce eye doses 10 times (90%); shielding curtains from the table can reduce the dose to the legs 2–5 times; the x-ray tube under table can reduce dose to the eye 2–27 times and to the hands 2–50 times as compared with the x-ray tube over the table; femoral access of the catheter reduces doses 2–7 times as compared with radial access, when proper shielding is used; stepping back or leaving the room for image acquisition can reduce doses 4–7 times (Vanhavere et al., 2012; Martin, 2016).

(186) Thornton et al. (2010) evaluated the impact of common radiation-shielding strategies, used alone and in combination, on scattered dose to the fluoroscopy operator's eye. Operator phantom lens radiation dose rate was recorded with and without a leaded table skirt, non-leaded and leaded (0.75 mm lead equivalent) eyeglasses, disposable tungsten-antimony drapes (0.25 mm lead equivalent), and suspended (0.5 mm lead equivalent) transparent leaded shields. Lens dose measurements were also obtained in right and left 15° anterior obliquities with the operator at the upper abdomen and during digital subtraction angiography (two images per second) with the operator at the patient's groin. Each strategy's shielding efficacy was expressed as a reduction factor of the lens dose rate compared with the unshielded condition. Use of leaded glasses alone reduced the lens dose rate by a factor of five to 10; scatter-shielding drapes alone reduced the dose rate by a factor of five to 25. Use of both implemented together always provided more protective than either used alone, reducing dose rate by a factor of 25 or more (Thornton et al., 2010).

5.7. Protection of the extremities

5.7.1. The hands

(187) The hands of interventional clinicians can be close to the primary x-ray beam. If the operators' hands stray into the beam transmitted through the patient, the dose rate above the patient would be typically 2 to 5 $\mu Gy\ s^{-1}$, so a one-minute exposure would give a dose to 100 to 300 µGy. Doses from primary x-rays scattered from the surface of the patient on the tube side of the couch will be higher, and direct exposure to the incident primary beam could be 50 times greater.

(188) The positions of the operator´s hands during procedures employing different access routes have a substantial effect on the dose level (Fig. 5.3). For cardiologists, introduction of catheters via the radial rather than the femoral artery route has advantages in achieving patient mobility more quickly, but the cardiologists' hands are closer to the x-ray beam and so the doses they receive, particularly to the side of the hand, are higher (Mann et al., 1996).

(189) In interventional radiology, femoral access is used much of the time, but percutaneous procedures such as percutaneous biliary drainage, nephrostomy tube placement, and gastrostomy placement require the operator to manipulate catheters

inserted close to the area being imaged and thus can give relatively high doses to the finger tips (Whitby and Martin, 2005).

(190) In procedures such as TIPS, in which the radiologist gains access via the internal jugular vein (IJV), the hands are located further from the area being imaged, but TIPS procedures can be technically challenging, fluoroscopy times are long and doses relatively high (Fig. 5.3).

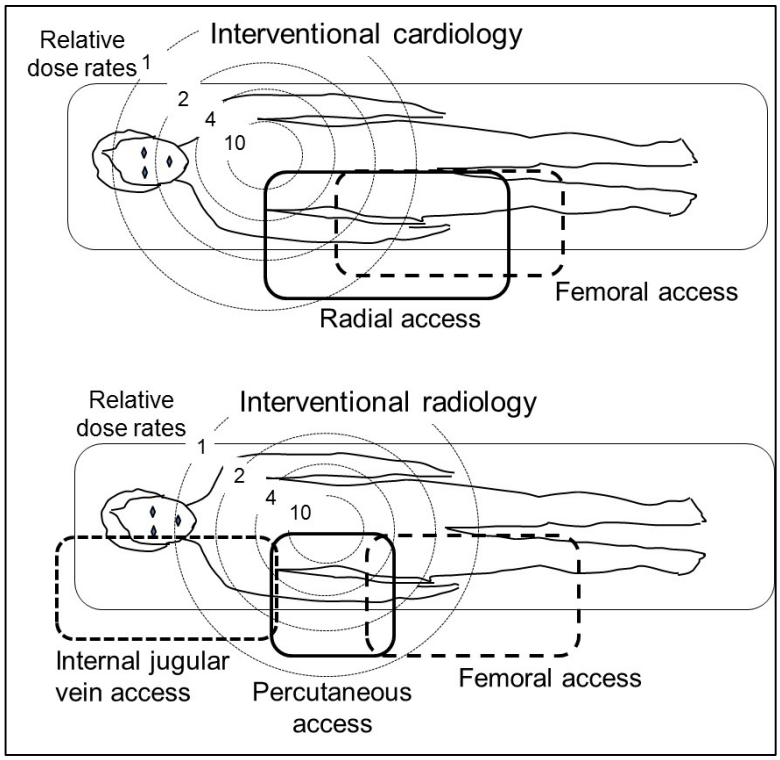


Fig. 5.3. Positions where the hands of operators will be manipulating catheters during a) interventional cardiology using radial and femoral access routes, and b) interventional radiology procedures by internal jugular vein (IJV), percutaneous, and femoral access [Figure from Martin and Sutton (2014), from Fig. 16.3, p 308, Practical Radiation Protection in Healthcare. 2nd edition, Ed. C J Martin and D G Sutton (: Oxford). 2014. Reproduced with permission of Oxford University Press. https://global.oup.com/academic/product/practical-radiation-protection-in-healthcare-9780199655212?cc=gb&lang=en&]

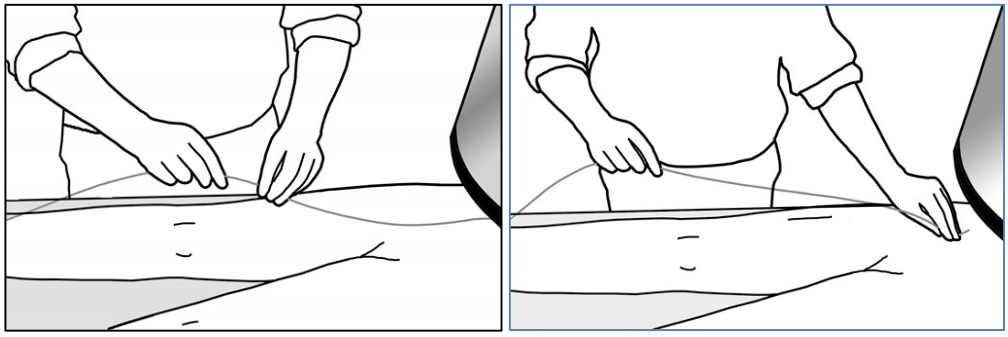


Fig. 5.4. Position of the hands for manipulation of catheters for procedures undertaken with a femoral access. [Whitby and Martin, 2005] (Permission given by British Journal of Radiology)

(191) The hand that holds the catheter is usually closer to the edge of the x-ray beam and receives the higher dose, while the other hand performs the manipulations (Figs. 5.4 and 5.5).

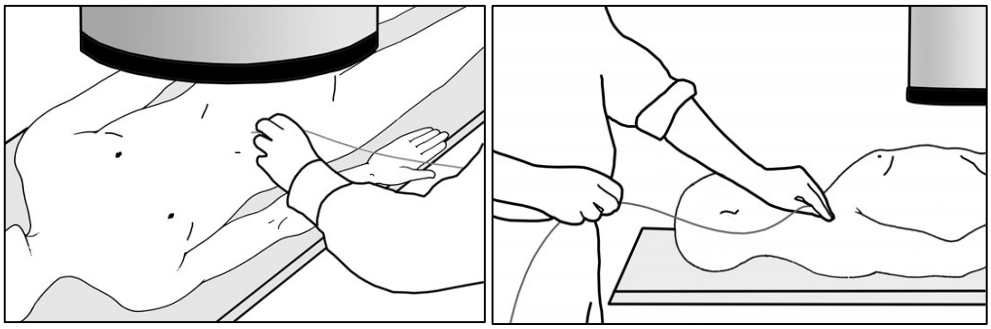


Fig. 5.5. Examples of the positions of the hands for percutaneous and IJV access routes. (Whitby and Martin, 2005) (Permission given by British Journal of Radiology)

(192) Ceiling suspended shields provide good protection for the head and upper body, but the hands are generally positioned below the shield and so receive less protection. However, some reduction can be achieved with careful practices (Maeder et al., 2006). Lead/rubber drapes attached to the bottom edge of the shield can be effective in protecting the hands for some procedures (Vanhavere et al., 2012).

(193) Freestanding adjustable over-table shields can shield the operator's hands, but the hands may stretch underneath the shield and so receive less protection. Protective drapes and pads can also offer good protection for the hands and have been shown to achieve a 29–fold reduction in the dose to the hands in one study (King et al., 2002).

(194) Thin protective gloves are available, but reports of the protection offered are varied (15–60%). If a hand protected by a glove strays into the x-ray field, the dose rate will be increased automatically to compensate for the attenuation, thus increasing patient exposure without achieving any protection of the hand of the physician (Wagner and Mulhern, 1996). New shielding materials (e.g. bismuth) have been proposed also as a hand cream for hand protection, subsequently to be covered with a surgical glove to provide containment of the cream material (McCaffrey et al., 2012). This cream has the same potential to increase dose if the hand is placed in the x-ray field. On the other hand, the reduction in tactile feedback from radiation-attenuating material may lead to an increase in fluoroscopy time or CT exposure time for delicate procedures (NCRP, 2010).

5.7.2. The legs and feet

(195) When the x-ray tube is positioned below the couch, radiation from the primary beam is scattered downwards from the base of the couch, so the legs can receive a substantial dose. Where no shield is available, the doses to the legs can be greater than those to the hands. The dose to the feet of radiologists is closely related to the kerma-area product P_{KA} when no protection is used, with procedures having a kerma-area product, P_{KA} of 100 Gy cm^2 giving an absorbed dose to the legs of about 1 mGy (Whitby and Martin, 2003).

(196) Lead curtains attached to the side of the couch that usually have a lead equivalence of 0.5 mm provide the operator with the best protection (Whitby and Martin, 2003; Shortt et al., 2007). These drapes can reduce doses to the legs by factors of 10 to 20 if correctly positioned throughout a procedure (Martin, 2009), but factors between 2 and 7 are typical in practice (Vanhavere et al., 2012). Such drapes should be specified for all interventional facilities.

(197) A lead curtain that is attached to the table and hangs down from it has the advantage of being as close as possible to the source and is always in place so that no conscious decision is needed to use it. For the majority of procedures, where the interventionalist stands at the side of the table, a lead drape attached to the table provides a good option. However, it rarely fully protects the feet.

(198) Usually the leaded curtain attached to the table does not extend for the full length of the table, so positioning is important for protection of both the operator and assistants. Operators standing at the side of the table will be adequately protected, but when a radiologist stands at or near the head of the table, as in the case of TIPS procedures, the drape will only provide protection for the operator if it can be moved to the head of the table. These shields may be less effective for procedures where the operator is positioned near the head or foot of the table.

(199) For such procedures other staff may need to stand to the side of the table and they will require leg protection.

(200) Mobile freestanding shields are available for protecting the legs. A conscious decision needs to be made to put them in place before the start of the procedure, to preserve a sterile environment. There is a risk of collision with the couch, when it is moved up and down or tilted. Such shields may also be used for protecting other staff who are assisting with procedures. The types of shield that are appropriate for use in an interventional facility require careful consideration when a unit is being purchased.

(201) Stepping back from the couch during radiography is an effective method of reducing occupational dose; this is rarely possible during fluoroscopy, as the operator must be close enough to the patient to perform the procedure.

5.8. Protection in PET CT interventional procedures

(202) Personal protective equipment, such as lead aprons and glasses for conventional fluoroscopically guided interventions are ineffective against the PET photons' 511 keV annihilation energy (Ahmed et al., 2007). Once the patient has been injected with the radiopharmaceutical, the interventionalist has minimal control over the radiation emitted from the patient, in contrast to fluoroscopically or CT-guided procedures, where the amount and quality of x-rays is directly controlled by the operator. Therefore, PET/CT-guided procedures require careful design of the PET/CT suite to optimise staff and adjacent room shielding (Madsen et al., 2006; Cruzate and Discacciatti, 2008; IAEA, 2008; Elschot et al., 2010) to ensure protection. As shown in Section 2, the major determinant of radiation exposure to the operator from PET/CT-guided interventional procedures is time spent in close proximity to the patient, and reducing the time is an important occupational radiological protection factor. The same considerations apply to PET/fluoroscopy guided interventions.

5.9. Protection in selective internal radiation therapy

(203) All vials containing ^{90}Y activity, all instruments and disposable items used for preparing the dose and implanting the device should be handled with forceps and appropriate shielding to reduce finger doses. Due to the high-energy beta emission, shielding is best provided with a low atomic number material such as poly (methyl methacrylate) (PMMA). Vendors of SIRT spheres provide advice and training material to minimise a contamination risk of staff, patients and the room (SIRTEX, 2016). This includes the use of special shielding boxes for preparation and injection. Furthermore, double gloves are recommended to allow removal of a contaminated outer glove with a gloved hand. All available actions should be taken to reduce the hazard of direct exposure and contamination as recommended by the manufacturer.

(204) For implantation of the microspheres the vendor provides an acrylic delivery box and delivery set. This prevents direct contact with the ^{90}Y vial and all stopcocks or tubes. It is essential to flush all tubes and catheters with water or saline for injection before manual manipulation. Table 5.1 gives a representative overview on typical exposure of the different staff members for a single SIRT procedure.

Table 5.1. Representative exposures for the technician or pharmacist preparing a typical patient dose, and for the physician implanting that prepared dose (SIRTEX, 2016).

		Trunk (mSv)	Lens of the eye(mSv)	Hands(mSv)
Pharmacist	$H_p(0.07)$	0.027	0.026	0.35
	$H_p(10)$	0.003	0.004	
Physician	$H_p(0.07)$	0.038	0.12	0.32
	$H_p(10)$	0.004	0.054	
Radiation safety officer	$H_p(0.07)$	<0.02	0.04	0.2
	$H_p(10)$	0.01	0.017	

(205) In addition to all technical measures of radiological protection, training to speed up all steps of the procedure leads to a significant reduction of occupational exposure. Aubert et al. (2003) demonstrated the extremity dose reduction by optimising the ^{90}Y injection technique. They found an extremity dose reduction from 14–23 mSv/injection to 1.6–2.8 mSv/injection after optimisation of the procedure.

(206) After the SIRT, the patient requires observation, general nursing care, and accommodation. In many facilities patients are transferred to single rooms in a nuclear medicine department, although the radiation exposure to staff, visitors and other patients is relatively low. McCann et al. (2012) determined in 143 SIRT procedures (124 with resin spheres and 19 with glass spheres) mean equivalent dose rates of 1.1 μSv h^{-1} at 1 m for resin spheres and 2.4 μSv h^{-1} at 1 m for glass spheres. Typical dose equivalent rates 6 hours after implant of 2 GBq ^{90}Y activity for different distances (SIRTEX, 2016) are shown in Table 5.2.

Table 5.2. Typical ambient dose equivalent rates 6 hours after implant of 2 GBq ^{90}Y activity for different distances.

Distance from the sources	Ambient Dose equivalent rate
0.25 m	18.8 µSv/h
0.5 m	9.2 µSv/h
1 m	1.5 µSv/h
2 m	0.4 µSv/h
4 m	<0.1 µSv/h

5.10. Handling, storage and testing of protective garments

(207) Lead aprons should never be folded as cracks in the lead lining can develop at the fold. Protective aprons should be inspected visually prior to each use for damage and defects, kinks and irregularities.

(208) They should be inspected with x-rays for any defects in the protective material, upon receipt and thereafter annually for any deterioration. Clements et al. (2015) developed a new evaluation method using CT for quicker evaluation time, staff exposure, and to provide evidence of that testing occurred by storing the images. Archived images are also used for future comparisons. Standardised methods for acceptance testing of protective aprons are needed, due to the wide variation in actual attenuation values of aprons (Christodoulou, 2003; Finnerty, 2005; CRCPD, 2001). With regard to lead-free protective aprons, transmission measurements should use broad x-ray beams and involve x-ray spectra that used for interventions in the facility where the aprons will be worn, including scattered x-ray spectra as proposed Pasciak et al. (2015).

(209) Instructions and procedures to clean protective equipment while avoiding damage of the item should be included in the quality assurance programme (Vañó, 2015c).

5.11. Education and training

(210) Professionals participating in interventional procedures guided by radiological imaging, in addition to general knowledge on radiological protection, should be aware of the distribution of scattered radiation levels around a patient, understand how different factors influence the distribution, and the effective use of protective devices, such as ceiling suspended shields, leaded eyewear and the shielding curtains and drapes.

(211) Given the close relationship between protection of the patients and the staff, the audience of this document, which is composed of hospital staff in charge of occupational protection, dosimetry services staff, clinical applications specialists from suppliers and regulators, need not only knowledge of general radiological protection but also of the clinical practice and the x-ray equipmen used in interventions guided by radiological imaging. They should have also knowledge of

the strategaies for exposure monitoring and dose assessment, the protection methods and protective garments for interventions guided by radiological imaging.

(212) Medical physicists and radiological protection specialist providing support to the interventional facilities should have the highest level of training in radiological protection as they have additional responsibilities as trainers for interventionalists and other health professionals involved in the interventions (ICRP, 2009). Dosimetry services staff need the background knowledge of the clinical practice for calibrating dosimeters (e.g. radiation qualities, scatter radiation fields, pulsed radiation) and for investigating abnormal dose values.

5.12. Records related to occupational protection

(213) The records to be kept are established as requirements in standards and regulations. Records of occupational exposure include information on the nature of the work in which the worker is subject to occupational exposure monitoring; including, for interventional staff, of information on work for other employers that involves radiation exposure; outcomes of health surveillance; education and training on radiological protection, including refresher courses; results of exposure monitoring and dose assessments, including results of investigation of abnormal exposure values. Employers have to provide the staff with access to records of their own occupational exposure.

(214) Information on workload in terms of procedures per year is useful for optimization of protection and for comparing and investigating unusual exposure.

5.13. Need for a quality assurance system

(215) A comprehensive quality assurance programme should be established by the organisation. The programme should aim at maintaining best radiological protection practice to ensure appropriate occupational exposure control (ICRP, 2007; IAEA, 2014a). Active participation of the staff involved in the use of radiation is advisable, taking into account ICRP recommendations for planned exposure situations. The programme should be part of the management system implemented at institutional level, including regular and independent audits, internal and external.

(216) Procedures should be in place for employment of new staff expected to be involved in interventions guided by radiation imaging to ensure the following: their education and training in radiological protection, arrangements for obtaining and evaluating the previous dosimetric history, for performing pre-employment health surveillance, and arrangements for sharing information with other employers in case that the staff works in more than one place.

(217) Procedures should be in place for the selection of the appropriate radiation detectors and dosimetry equipment. These procedures should be developed following the international recommendations and be in compliance with recognised quality standards. Arrangements for staff radiological protection and health surveillance should be in place, with monitoring of body, eye and hand exposure as well as workplace monitoring, as set forth in the radiological protection programme. Personal protective devices, such as aprons, thyroid shields and leaded eyewear, as well as ceiling-suspended shields and table-mounted curtain should be in place and their features should be regularly controlled.

(218) Results of personal exposure monitoring and workplace monitoring should be recorded, as well as the necessary corrective measures to be taken in response to unusual results. Personal dosimetry suppliers should document the accreditation and performance in dose assessment from the supplied personal dosimeters and the information be recorded and kept safe for regulatory recommended time.

(219) Procedures should include investigation, reporting and recording results and audits of occupational doses as well as corrective actions in case of incidents or accident.

(220) Procedures should address the obligation and instructions for wearing protective devices to the extent possible and compatible with the success of the interventions, including the use of ceiling suspended shields and protective eyewear. Procedures should also include audits and recording of the wearing of protective eyewear, especially if a dose reduction factor is applied to dosimeter readings to account for the attenuation.

(221) Radiological protection training and certification of interventional staff should be documented and subject to reviews at established periods or whenever there is a significant change. Induction training in the operation of the quality assurance system should be part of the strategy of the organisation. Administrative procedures including the assignment of responsibility for quality assurance actions and for reviewing and assessing the overall effectiveness of radiological protection measures need to be established and be part of the quality assurance manual.

(222) Since occupational protection is closely related to patient protection, the overall quality assurance programme should include the quality control of the radiological equipment, acceptance test and commissioning, full characterisation of the radiological equipment, the calibration of the air kerma area product (P_{KA}) meters, as well as the quality control of the personal protective devices.

6. SUMMARY OF RECOMMENDATIONS

6.1. General

1. The recommendations summarised in this Section are a consolidation of the advice already provided in Sections 3 to 5. Occupational exposure in interventional procedures is closely related to patient exposure, as most actions to reduce patient exposure contribute to protect also workers; in addition, occupational protection requires proper use of shielding garments. Actions to protect staff should not impair the clinical outcome of the intervention and should not increase patient exposure. Therefore, occupational protection should be managed in an integrated approach with patient protection and hospital staff responsible for radiological protection in interventional procedures should be familiar with these procedures.

6.2. Individual exposure monitoring

2. Occupational exposure monitoring in interventional procedures has two major objectives: to verify compliance with dose limits and to optimise occupational protection.
3. Compliance monitoring should not only include the assessment of effective doses, but also of doses that could be received by non apron-protected organs, such as the lenses of the eyes, extremities and the cerebrovascular system. Recent studies have shown that there is high incidence of radiation-related eye lens opacities in interventionalists, which emphasises the need for eye-lens exposure assessment.
4. The use of two dosimeters, one shielded by the apron and one unshielded above the apron, at the collar, has been recommended by ICRP for interventional procedures as it provides not only the best available estimate of effective dose, but also a reasonable indication of the dose to the eye lenses, the head dose and a confirmation that the protective apron has been actually worn.
5. Visual elements should be in place to help users place their own dosimeters in the correct position. Consistency analysis of the two readings allows an indication of the proper use of the dosimeters, making the monitoring system more robust.
6. Optimisation monitoring evaluates the effect of protective action to reduce staff doses without impairment of the success of the procedures. Over time, the impacts of optimisation will appear through lower occupational doses. APDs have proven to be useful for optimisation purposes, for studies of radiation exposure by type of procedure or for specific aspects of a procedure and for educational purposes.
7. Type-test procedures and calibration of APDs and area monitors should include radiation fields representative of the interventional procedures, including tests in pulsed mode with high dose rates.

8. Improved technology and methodology is needed to assess eye-lens doses when lead glasses are worn.

9. The Commission recommends that proper dosimeters should be adequately worn and that audits of compliance with procedures should be performed. In addition, ambient dosimeters are useful to continually assess the scatter radiation fields and provide backup to personal dosimetry. Comparing individual dosimeter readings with that of an ambient dosimeter near the patient (such as on the C-arm) may be helpful in discovering non- compliance with procedures for wearing individual dosimeters, as the ambient dosimeter can provide a reasonable estimate of occupational exposure, especially doses to the unshielded eye lens. For managing optimisation of protection, investigation levels are required to alert when radiation exposure is higher than normal and a review of the working conditions is, therefore, needed. In addition, a low-dose investigation level for the reading of over-apron and hand dosimeters can also be used, to trigger a review of whether dosimeters are worn consistently and properly when the reading of these dosimeters are lower than expected.

10. The operational quantity $H_p(0.07)$ can be used as an approximation to $H_p(3)$ for photon radiation of all energies used in radiology in general; $H_p(10)$, can be also used for the same purpose, but only if the photon spectrum has a mean energy above 40 keV.

11. Wrist dosimeters, as used in many centers, may not be able to reflect real finger doses, if part of the hands is very close or even introduced into the direct x-ray beam.

12. Consideration should be given to assess doses to the parts of the leg that are not shielded either by the lead apron or lead/rubber drapes.

13. Research efforts should pursue the development of computational technologies (not requiring dosimeters), with personnel position sensing, to assess personnel doses, including eye doses.

14. The radiological protection programme should include audits of occupational doses, investigation of abnormal exposure, reporting and recording results as well as corrective actions if appropriate.

6.3. Occupational radiological protection methods and devices

15. Actions for patient protection generally protect the personnel in a similar proportion. In addition, the following means and actions are applicable specifically for occupational protection: protective apron and collar, ceiling-suspended shield and leaded eye glasses, table top suspended leaded curtains, stepping back to increase distance from the

patient and staying on the image receptor side rather than on the side of the x-ray tube.

16. There are lighter-weight aprons containing composite layers of high atomic number elements such as tin or bismuth, instead of lead. Characterising attenuation properties in terms of "lead equivalence" can be misleading, since photon attenuation varies significantly over the photon energy spectrum, with the largest variations occurring in the imaging range. Attenuation factors should be specified with information on the radiation beam qualities used to measure the attenuation and the weighting of measurements made at different beam qualities, in order to reflect the conditions under which the garment is used.

17. If no protective measures for the eyes are used, personnel with a typical workload will receive doses to the lens of the eye that would exceed the dose limit, and over time could result in lens opacities. Interventionalists should, therefore, make use of ceiling-suspended shields whenever possible during the intervention. The effectiveness of these shields depends on their positioning and proper use.

18. When protective leaded eye glasses are worn the eye doses result primarily from radiation backscattered from surrounding tissues of the head of the interventionalist. In addition, most of the time, the interventionalist looks at the image monitor, and so the eye lenses are exposed by the radiation coming from the side and from below the level of the head. Leaded glasses should, therefore, fit closely to the wearer's facial contours. Doses can be reduced by a factor of 2–7 by the use of leaded glasses.

19. The hand of the interventionalist that is closer to the x-ray beam and to the irradiated volume of the patient receives the higher dose. Leaded curtains attached to the bottom edge of the ceiling-suspended shield as well as drapes and pads applied on the patient can be effective in protecting the operator's hands for a number of procedures. Such drapes may have an aperture through which catheters can be inserted.

20. The operator's feet may be exposed even when lead curtains suspended from the table top are in place, due to the presence of a gap between the curtains and the floor. This is especially true when the couch is in higher position. Interventionalists should step back from the couch during cine or DSA acquisition and whenever possible.

21. The specification of the protective value of garments should be accompanied with indication of the characteristics of the radiation beams used to measure the attenuation and the combination of

measurements made at different beam qualities that should reflect the conditions under which the garment is used.

6.4. Protection of pregnant workers

22. The early part of pregnancy (before the pregnancy has been declared) is covered by the normal protection of workers, which is essentially the same for males and females. Once the pregnancy has been declared and notified to the employer, additional protection of the fetus should be considered. The working conditions of a pregnant worker, after the declaration of pregnancy, should be such as to make it unlikely that the additional dose to the conceptus will exceed about 1 mGy during the remainder of pregnancy.

23. Unnecessary discrimination against pregnant women should be avoided. Currently available data do not justify automatically precluding pregnant physicians or other workers from performing procedures in the interventional room.

24. When two individual dosimeters are used, the under-apron dosimeter should be worn on the abdomen for the monitoring of the dose to conceptus. If this dosimeter shows a value for personal dose equivalent [$H_p(10)$] of < 0.2 mSv per month, the equivalent dose to the conceptus would be below the dose limit.

6.5. Storage and quality control for protective garments

25. Lead aprons should never be folded as cracks in the lead lining can develop at the fold. Protective aprons should be inspected visually prior to each use for damage and defects, kinks and irregularities. They should also be inspected with x-rays for any defects in the protective material, upon receipt and thereafter annually for any deterioration.

26. Written procedures to clean protective equipment while avoiding damage of the item should be included in the quality assurance programme, and carefully followed.

6.6. Quality assurance programme

27. A comprehensive quality assurance programme should be established by the organisation. The programme should aim at maintaining best radiological protection practice to ensure appropriate occupational exposure control. The programme should include appropriate audits to ensure that personnel adhere to procedures, especially related to

wearing the dosimeters, protective devices and methods to optimise occupational protection.

6.7. Education and training

28. Given the close relationship between protection of the patients and the staff, the audience of this document, which is composed of hospital staff in charge of occupational protection, dosimetry services staff, clinical applications specialists from suppliers and regulators, need not only knowledge of general radiological protection but also of the clinical practice in interventional procedures and the x-ray equipment used. They need also knowledge of the strategies for exposure monitoring and dose assessment, and the protection methods and garments.

29. Medical physicists and radiological protection specialist providing support to the interventional facilities should have the highest level of training in radiological protection as they have additional responsibilities as trainers for interventionalists and other health professionals involved in the interventions (ICRP, 2009). Dosimetry services staff need the background knowledge of the clinical practice for calibrating dosimeters (e.g. radiation qualities, scatter radiation fields, pulsed radiation) and for investigating abnormal dose values.

6.8. Records

30. The records on occupational exposure should include information on the nature of the work,; exposure from work for other employers; outcomes of health surveillance; education and training on radiological protection, including refresher courses; results of exposure monitoring and dose assessments, including results of investigation of abnormal exposure values. Employers must provide the staff with access to records of their own occupational exposure**.**

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ANNEX A. BRIEF SUMMARY OF BIOLOGICAL BASIS FOR RADIOLOGICAL PROTECTION

Text taken from *Publication 105*.

(A1) The biological effects of radiation can be grouped into two types: tissue reactions (deterministic effects) and stochastic effects (cancer and heritable effects). These effects are noted briefly here; the biological basis for radiological protection is covered in depth in the 2007 Recommendations (ICRP, 2007) and other Commission's documents.

Deterministic effects (harmful tissue reactions)

(A2) If the effect only results when many cells in an organ or tissue are killed, the effect will only be clinically observable if the radiation dose is above some threshold. The magnitude of this threshold will depend on the dose rate (i.e. dose per unit time) and linear energy transfer of the radiation, the organ or tissue irradiated, the volume of the irradiated part of the organ or tissue, and the clinical effect of interest. With increasing doses above the threshold, the probability of occurrence will rise steeply to l00% (i.e. every exposed person will show the effect), and the severity of the effect will increase with dose. The Commission calls these effects 'deterministic' (tissue reactions), and a detailed discussion and information on deterministic effects (tissue reactions) is found in *Publication 103* (ICRP, 2007). Such effects can occur in the application of ionising radiation in radiation therapy, and in interventional procedures, particularly when fluoroscopically guided interventional procedures are complex and require longer fluoroscopy times or acquisition of numerous images.

Stochatisic effects (cancer and heritable effects)

(A3) There is good evidence from cellular and molecular biology that radiation damage to the DNA in a single cell can lead to a transformed cell that is still capable of reproduction. Despite the cellular repair mechanisms, which are normally very effective, there is a small probability that this type of damage, promoted by the influence of other agents not necessarily associated with radiation, can lead to a malignant condition (somatic effect). As the probability is low, this will only occur in a few of those exposed. If the initial damage is to the germ cells in the gonads, heritable effects may occur.

(A4) For stochastic effects, a simple linear non-threshold dose-response relationship is assumed for radiological protection purposes and is considered a reasonable interpretation of current knowledge. At higher doses and dose rates, the probability may increase with dose more markedly than simple proportion. At even higher doses, close to the thresholds of deterministic effects (tissue reactions), the probability increases more slowly, and may begin to decrease, because of the competing effect of cell killing. These effects, both somatic and heritable, are called 'stochastic'. The probability of such effects is increased when ionising radiation is used in medical procedures.

(A5) A detailed discussion and information on somatic and heritable effects is found in *Publication 103* (ICRP, 2007), and the Commission's view on cancer risk at low doses is presented in *Publication 99* (ICRP, 2005c). It is not feasible

to determine on epidemiological grounds alone that there is, or is not, an increased risk of cancer for members of the public associated with absorbed doses of the order of 100 mGy or below. The linear non-threshold model remains a prudent basis for the practical purposes of radiological protection at low doses and low dose rates.

(A6) The Commission has also reviewed the topic of individuals with genetic susceptibility to cancer, and expressed its preliminary view in *Publication 79* (ICRP, 1999a) that the information available is insufficient to provide a meaningful quantitative judgement on this issue. The Commission will continue to monitor this subject with regard to its implications for radiological protection.

Effects of in-utero irradiation

(A7) There are radiation-related risks to the embryo/fetus during pregnancy that are related to the stage of pregnancy and the absorbed dose to the embryo/fetus. These are noted below briefly under the topics of lethal effects, malformations, central nervous system effects, and leukaemia and childhood cancer. The Commission has evaluated the effects of prenatal irradiation in detail in *Publication 90* (ICRP, 2003b).

Lethal effects

(A8) There is embryonic sensitivity to the lethal effects of irradiation in the preimplantation period of embryonic development. At doses below 100 mGy, such lethal effects will be very infrequent and there is no reason to believe that significant risks to health will express after birth.

Malformations

(A9) During the period of major organogenesis, conventionally taken to be from the third to the eighth week after conception, malformations may be caused, particularly in the organs under development at the time of exposure. These effects have a threshold of approximately 100 mGy.

Central nervous system

(A10) From *Publication 84*. From 8 to 25 weeks after conception, the central nervous system is particularly sensitive to radiation. A reduction in intelligence quotient cannot be identified clinically at fetal doses below 100 mGy. During the same time period, fetal doses in the range of 1 Gy result in a high probability of severe mental retardation. The sensitivity is highest from 8 to 15 weeks after conception, and lower from 16 to 25 weeks of gestational age.

Leukaemia and childhood cancer

(A11) Radiation has been shown to increase the probability of leukaemia and many types of cancer in both adults and children. Throughout most of pregnancy, the embryo/fetus is assumed to be at approximately the same risk for potential carcinogenic effects as children (i.e. about three times that of the population as a whole).

(A12) Consideration of the effects listed above is important when pregnant patients undergo diagnostic examinations, interventional procedures, and radiation therapy using ionising radiation. A balance must be attained between the health

3643 care of the patient and the potential for detrimental health effects to the
3644 embryo/fetus that accompanies the specific radiological procedure.
3645

ANNEX B. QUANTITIES AND UNITS

(B.1) Implementing the system of radiological protection requires the assessment of doses from radiation exposures of individuals. The protection quantities are used to specify exposure limits to ensure that the occurrence of stochastic health effects is kept below unacceptable levels and that tissue reactions are avoided.

Absorbed dose, D.

(B.2) Absorbed dose is defined as the quotient of the mean energy, imparted to an element of matter by ionising radiation and the mass of the element.Absorbed dose is the basic physical dose quantity and is applicable to all types of ionising radiation and to any material. Absorbed dose is a measurable quantity for which primary standards exist.

(B.3) In the International System of Units, SI, the unit for absorbed dose is the ratio joule per kilogram (J kg^{-1}) to which the special name of gray (Gy) is given.

Averaging of dose: the organ dose

(B.4) When using the quantity absorbed dose in practical protection applications, doses are averaged over tissue volumes. It is assumed that, for low doses, the mean value of absorbed dose averaged over a specific organ or tissue can be correlated with radiation detriment for stochastic effects in that tissue with an accuracy sufficient for the purposes of radiological protection.

(B.5) For external radiation the extent to which mean absorbed dose is representative of the distribution of dose over organs and tissues depends on the homogenity of the exposure and its penetrability. For low penetrating radiation, such as scatter radiation from x-rays and for widely distributed tissues, such as the skin, the absorbed dose distribution can be very inhomogeneous. This requires specific consideration in assessing the mean dose in organs and tissues for occupational exposure of individual members of the staff engaged in interventional tasks. In cases of extreme partial body exposure, such as the exposure of the fingers in interventional procedures, the dose to part of the tissue may exceed thresholds for tissue reactions, while the mean skin dose remains low. According to *Publication 103* (ICRP, 2007), for the assessment of tissue reactions the quantity to be applied is absorbed dose and its distribution, rather than equivalent dose and effective dose.

Equivalent dose and radiation weighting factors

(B.6) The definition of protection quantities is based on the average absorbed dose $D_{T,R}$ over a specified organ or tissue T, due to radiation type R. The protection quantity equivalent dose in an organ or tissue, H_T, is defined by the weighted sum over all types of radiations R involved, of the mean absorbed dose $D_{T,R}$ in the specified organ or tissue T, i.e. $H_T = \sum w_R D_{T,R}$.

(B.7) The unit for dose equivalent, equivalent dose and effective dose is J kg^{-1} to which the special name of Sievert (Sv) is given.

(B.8) Radiation weighting factors for the type and energy of radiation, w_R, are based mainly on experimental results from the relative biological effectiveness for the different types of radiation at low doses, and their values are assigned by the Commission. For photon and beta radiation w_R takes the value of one. *For* heavier ionising particles, protons, alpha, heavy ions, neutrons, the factor may take values up to 20.

Effective dose and tissue weighting factors

(B.9) The effective dose, E, is defined by a weighted average of tissue equivalent doses as:

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

where w_T is the tissue weighting factor for tissue T. The sum is performed over all organs and tissues of the human body considered to be sensitive to the induction of stochastic effects. The tissue weighting factors are age- and sex-averaged, and intended to apply as rounded values to a population of both sexes and all ages.

(B.10) The unit of effective dose is J $kg^{-1}$with the special name Sievert (Sv). The unit is the same for equivalent dose and effective dose as well as for some operational dose quantities. Care must be taken to ensure that the quantity being used is always clearly stated.

Detriment and detriment adjusted nominal risk coefficients

(B.11) Radiation detriment is a concept used to quantify total harm to health experienced by an exposed group and its descendants as a result of the group's exposure to a radiation source, taking into account the probability of attributable fatal cancer, weighted probability of attributable non-fatal cancer, weighted probability of severe heritable effects, and length of life lost if the harm occurs.

(B.12) The detriment is determined using nominal risk coefficients. Total detriment is the sum of the detriment for each tissue or organ of the body.

(B.13) From information on radiation induced cancer risk and hereditable effects the Commission in *Publication 103* (ICRP, 2007) has proposed for adults (workers) revised nominal probability coefficients for detriment adjusted cancer risk of 4.1 10^{-2} Sv^{-1}. For heritable risk the coefficient is 0.1 10^{-2} Sv^{-1} with a significant 8 fold reduction in the coefficient value for adults from previous recommendations in *Publication 60* (ICRP, 1991).

(B.14) For simplicity and robustness of the system of protection, the Commission adheres to the policy that nominal risk coefficient should be applied to whole population (of adult workers in this case) and not to individuals recognising that there are significant differences between males and females and in respect of age

of exposure. Still the Commission considers that the difference in the nominal risk since 1990 is of no significance therefore the overall fatal risk coefficient of 5% per Sv, is appropriate for the purpose of radiological protection.

Operational quantities

(B.15) Equivalent dose and effective dose cannot be measured directly in body tissues. The protection system therefore includes operational quantities that can be measured and from which the equivalent dose and the effective dose can be assessed (ICRP, 2007). Dosimeters and instruments for radiation monitoring are calibrated in terms of operational quantities. Below are summarised the operational quantities relevant to interventional procedures. More details are given in Annex B of *Publication 103* (ICRP, 2007).

Dose equivalent and quality factors

(B.16) The product of D and Q at a point in soft tissue, where D is the absorbed dose and Q is the quality factor for the type and energy of the radiation at this point, thus $H = Q\ D$. For the range of energies of the scattered photons in fluoroscopically guided interventions the value of Q is taken to one.

Operational quantity for area monitoring

(B.17) The operational quantities for area monitoring are the ambient dose equivalent $H^*(10)$ and the directional dose equivalent $H'(0.07,\Omega)$ in the direction Ω. Ambient dose equivalent is the dose equivalent at a point in a radiation field that would be produced by the corresponding expanded and aligned field in the ICRU sphere at a depth of 10 mm on the radius vector opposing the direction of the aligned field. The unit of ambient dose equivalent is joule per kilogram (J kg^{-1}) and its special name is also the Sievert (Sv).

Operational quantities for individual monitoring

(B.18) The operational quantity for individual monitoring is the personal dose equivalent $H_p(d)$ which is the dose equivalent in ICRU soft tissue at an appropriate depth, d, below a specific point on the human body. The specified point is normally taken to be where the individual dosimeter is worn.

(B.19) For monitoring the effective dose the operational quantity $H_p(d)$, and for the assessment of the dose to the skin and to the hands and feet the personal dose equivalent, $H_p(0.07)$ is used.

(B.20) A depth d=3 mm is adequate for monitoring the dose to the lens of the eye. In practice, however, in many countries, calibration of dosimeters in terms $H_p(3)$ has not been implemented, but $H_p(0.07)$ can be used for the same monitoring purpose for photon radiation, which is the case in interventions guided by radiological imaging.