# Unintended and accidental medical radiation exposures in radiology: guidelines on investigation and prevention

To cite this article before publication: Colin J Martin *et al* 2017 *J. Radiol. Prot.* in press https://doi.org/10.1088/1361-6498/aa881e

# Unintended and accidental medical radiation exposures in radiology: guidelines on investigation and prevention

**C J Martin[1], J Vassileva[2], E Vano[3], M Mahesh[4], S Ebdon-Jackson[5], K H Ng[6], D P Frush[7], R Loose[8], J Damilakis[9].**

[1] University of Glasgow, 27 Garngaber Avenue, Lenzie, G66 4LL, UK.

[2] International Atomic Energy Agency, Vienna International Centre, 1400 Vienna, Austria

[3] Radiology Department, Complutense University, 28040 Madrid, Spain

[4] Johns Hopkins University, N. Caroline Street, Baltimore 21287-0856, USA

[5] Directorate, CRCE, Public Health England, Chilton, Didcot, Oxfordshire, OX11 0RQ, UK

[6] Department of Biomedical Imaging; University of Malaya, 50603 Kuala Lumpur, Malaysia

[7] Department of Radiology, Duke University School of Medicine, Durham, NC 27710, USA

[8] Hospital Nuremberg, Institute for Medical Physics, D-90340, Nuremberg, Germany

[9] Department of Medical Physics, Faculty of Medicine, University of Crete, Iraklion, Crete

Short title: Prevention of medical radiation accidents

Key words: radiation incidents, interventional radiology, interventional cardiology, computed tomography, digital radiography, foetal exposure, effective dose

## Abstract

This paper sets out guidelines for managing radiation exposure incidents involving patients in diagnostic and interventional radiology. The work is based on collation of experiences from representatives of international and national organizations for radiologists, medical physicists, radiographers, regulators, and equipment manufacturers, derived from an International Atomic Energy Agency Technical Meeting. More serious overexposures can result in skin doses high enough to produce tissue reactions, in interventional procedures and computed tomography, most notably from perfusion studies. A major factor involved has been deficiencies in training of staff in operation of equipment and optimization techniques. The use of checklists and time outs before procedures commence, and dose alerts when critical levels are reached during procedures can provide safeguards to reduce risks of these effects occurring. However, unintended and accidental overexposures resulting in relatively small additional doses can take place in any diagnostic or interventional X-ray procedure and it is important to learn from errors that occur, as these may lead to increased risks of stochastic effects. Such events may involve the wrong examinations, procedural errors, or equipment faults. Guidance is given on prevention, investigation and dose calculation for radiology exposure incidents within healthcare facilities. Responsibilities should be clearly set out in formal policies, and procedures should be in place to ensure that root causes are identified and deficiencies addressed. When an overexposure of a patient or an unintended exposure of a foetus occurs, the foetal, organ, skin and/or effective dose may be estimated from exposure data. When doses are very low, generic values for the examination may be sufficient, but a full assessment of doses to all exposed organs and tissues may sometimes be required. The use of general terminology to describe risks from stochastic effects is recommended rather than calculation of numerical values, as these are misleading when applied to individuals.

## 1. Introduction

The need for improving prevention of incidents and accidents in medical uses of ionizing radiation was highlighted by the International Atomic Energy Agency (IAEA) and World Health Organisation (WHO) in the Bonn Call-for-Action (IAEA/WHO 2012). This summarised the conclusions of an International Conference on Radiation Protection in Medicine: "Setting the Scene for the Next Decade" held in Bonn, Germany, in December 2012. The aim of the conference was to identify issues arising in radiation protection in medicine that needed to be addressed. The Bonn Call-for-Action highlighted 10 actions for the strengthening of medical radiation protection. Action 7 entitled "Improve prevention of medical radiation incidents and accidents" encourages stakeholders to "implement and support voluntary educational safety reporting systems for the purpose of learning from the return of experience of safety related events in medical uses of radiation". Other recommendations were to harmonize taxonomy in relation to medical radiation incidents and accidents; to implement prospective risk analysis methods to enhance safety in clinical practice; and to prioritize independent verification of safety at critical steps in procedures using ionizing radiation. Although the first priority for action was therapeutic applications, the statement specifically mentioned interventional radiology and called for organizations to work towards inclusion of all modalities of medical usage of ionizing radiation in voluntary safety reporting. These recommendations were closely allied with Action 8 "Strengthen radiation safety culture in health care". In addition, the International Basic Safety Standards (GSR Part 3) (BSS) set out requirements for minimizing the likelihood of unintended and accidental medical exposures and investigating when such exposures occur in order to learn from such events (IAEA 2014).

The European Directive 3012/59 (EC 2014) defines an "unintended exposure" as a medical exposure that is significantly different from the exposure intended for a given purpose. The Directive requires the implementation of an appropriate system for record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice. It also requires reporting and timely dissemination of information regarding lessons learned from significant events.

Radiation-related errors in medicine can be considered as medical errors. Medical errors have been recognized increasingly as a contributor to patient morbidity and mortality. Errors in medicine are likely underreported and when they are reported the information recorded is often limited. However, not all errors cause harm and the health effects from the majority of radiation exposures that are greater than intended due to errors in X-ray imaging will be

negligible. The U.S. Institute of Medicine reports that 90% of medical errors result from systemic problems, rather than purely random events. Individuals that err are not intrinsically substandard performers (Kohn et al 2000). Therefore, it is helpful to understand the larger context of error definition and strategies to mitigate these errors through a culture of safety. Moreover, an exposure error implies the existence of established standards, and these may or may not exist across diagnostic imaging departments and other practices. A safety culture requires procedures and standards that include features such as acknowledgment of the high-risk nature of what is done, commitment to achieving consistently safe operations, a blame-free environment, encouragement of collaboration and teamwork, recognition of expertise, organizational commitment (from all levels), and resilience.

Bearing in mind the context, this paper aims to bring together advice based on expertise and experience from professional groups to provide guidelines for implementing systems within healthcare facilities to assist in preventing unintended and accidental exposures in diagnostic and interventional radiology. It draws on methodologies that are being applied in other areas of safety management for accident prevention such as removal of authority gradients (minimization of hierarchy), use of checklists, audits, improved communication, and briefing/debriefing. Guidance is given on preparation of procedures for investigations into causes of incidents, dissemination of information on lessons learned, methodologies for evaluation of doses from overexposures, and approaches to conveying the level of risk from such exposures to staff, patients and the public. Only exposures that are greater than intended are considered in this paper. Although exposures less than intended can also give rise to clinical issues such as missed diagnoses, these may be regarded as a failure in optimization of radiological imaging, and are not within the scope of the present guidance. The paper does not discuss the reporting of exposures that are substantially greater than intended to external bodies, as this will be the subject of a separate paper.

## 2. Methods

### *2.1 Collation of data and experiences*

A meeting was held at the IAEA Headquarters in Vienna, Austria, from 6 to 8 March 2017 which gave member states, and international, regional and national organizations an opportunity to exchange information on methods for identification and prevention of radiation incidents, and the investigation and reporting of unintended and accidental exposure in diagnostic radiology and interventional procedures when they occur. The Governments of all IAEA Member States and relevant international and professional societies were invited to nominate their representatives. The meeting was attended by 52 participants from 25 countries - radiologists, medical physicists, radiographers or radiologic technologists,

regulators, and equipment manufacturers. The following organizations were represented: the Conference of Radiation Control Program Directors (CRCPD), the European Federation of Organisations for Medical Physics (EFOMP), the European Federation of Radiographer Societies (EFRS), the European Society of Radiology (ESR), the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association, the Heads of European Radiological protection Competent Authorities (HERCA), the International Commission on Radiological Protection (ICRP), the IAEA, the International Organization for Medical Physics (IOMP), the International Society of Radiographers and Radiological Technologists (ISRRT), the International Society of Radiology (ISR), the Image Gently Alliance and Image Wisely Campaign, the UK Society for Radiological Protection, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the WHO, and the WHO Patients for Patients Safety Network. Information and data were presented on incidents that had occurred and experiences shared in reporting of such events. Information included advice on reporting within healthcare facilities, methods for investigating to determine root causes, and discussion of factors that contribute to errors, as well as implementation of changes to avoid the recurrence of similar events in the future. Methods of good practice that can help to identify issues that might lead to exposures greater than intended were also discussed. In the latter part of the meeting, participants divided into working groups to discuss issues and prepare recommendations relating to different aspects of the topic. Information from the meeting has been collated in the form of guidance.

### *2.2 Definitions*

It is important at the start to define terminology to avoid confusion. What is considered an accident (versus an incident), the types of errors that might lead to such events which may be a consequence of human factors (e.g. negligence) versus a flawed system, and understanding what is a detriment (remembering that the physical harm is not the only detriment; other detriments include psychological stress from concern about potential cancer risks from overexposure and public or regulatory attention to practices which may be outside of standard exposures). Medical errors can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (Kohn et al 2000). If a medical error relates to the use of radiation, it can be treated as an “event” or as an “incident”. The BSS defines an accident as: “Any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety”. The BSS definition of an incident is similar, except that it also includes “initiating events, accident precursors and near misses, or unauthorized acts, malicious or non-malicious” (IAEA et al 2014). Thus the definition of “incident” overlaps with “accident”, but includes events, the consequences of

which are less severe, ones with the potential to cause harm, and events caused intentionally. However, there can sometimes be little distinction in routine usage of the words accidents and incidents. The BSS uses the more general term “event” described as “any occurrence unintended by the operator, including operating error, equipment failure or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of protection and safety”. In order to avoid overuse of the phrase “accidental or unintended medical exposure” which is the official descriptor of events with which this paper is concerned, the shorter term “incident” will be used in the text to encompass all accidents and events.

Tissue reactions resulting from relatively high exposures involving poor optimization of radiation protection in interventional radiology or in diagnostic use of computed tomography (CT) or CT-guided procedures would be regarded as accidents. However, even here the dividing line is not clear cut, as in some circumstances the complexity of an interventional procedure coupled with the size of the patient, may result in skin damage, despite efforts to optimize the procedure (Bryk et al 2006, Suzuki et al 2008). In this case the exposure may be unintended, in that the operator did not set out to give an exposure of that magnitude, but was unavoidable if the procedure was to be completed. The risk of tissue effects in such cases should be taken into account in the justification and patient consent before the procedure commences and in the optimization during the procedure (e.g. modifying C-arm angulation) (ICRP 2000a, 2013a).

Medical radiation accidents and the majority of radiation incidents involve overexposure. That is the delivery of a larger amount of radiation to the patient than was intended or required for performing a procedure. The term overexposure is not used in the BSS (IAEA et al 2014) or generally in legislation for individual countries, but is employed here, where the entire paper deals with the subject, in order to avoid repetition of the phrase “exposure greater than intended” that is favoured by several organisations. Overexposures that are clinically significant may involve a risk of tissue reactions (deterministic effects) on the skin, for which additional care of the patient may be required, or a quantifiable increased risk of stochastic effects, primarily cancer induction. Since conditions vary throughout the world, judgements as to whether an overexposure is clinically significant are different, as are requirements for reporting of incidents to the competent authority. The majority of overexposures resulting from errors in diagnostic and interventional radiology will not lead to tissue reactions, and there is no obvious effect on the health of the individual, but there may be a small increase in stochastic risk. In a study of radiation incidents reported through an internal system over a period of ten years, for 50% of the diagnostic radiology incidents the effective dose received by the patient was less than 0.1 mSv, and for 74% it was less than 1 mSv (Martin 2005). For the incidents involving doses over 1 mSv, 60% involved CT. An

exposure giving an effective dose of 0.1 mSv might have an associated excess lifetime risk of cancer incidence of 1 in 200,000 by application of the risk coefficient for a population of all ages (ICRP 2007a), and risks of exposures less than 0.1 mSv are described as negligible (Martin 2007, ICRP 2017). There is not a clear boundary above which the risk suddenly increases. It is difficult to argue that doses below 0.1 mSv constitute a health detriment, and stochastic risks from exposures of even 1 mSv are still minimal. Overexposures from which the risks of stochastic effects are minimal or very low still need to be followed-up, especially if they involve exposure of multiple patients.

## 3. Results and discussion

### *3.1 Requirements for investigation of unintended and accidental medical exposures*

#### *3.1.1 Categories of incident*

Unintended and accidental medical exposures may occur with all types of imaging procedure and although health consequences are minimal in the majority of cases, proper investigation, and implementation of changes can avoid similar errors being made in the future (Martin 2005). The transition to digital radiography over the last few decades, which enables grey scale images to be optimized for viewing independent of the exposure, means that higher exposures will no longer immediately give dark images as with conventional screen film systems. This can result in a greater risk that unnecessarily high exposures will not be recognised and addressed, unless the exposure index displayed on the imaging system or in the DICOM header is monitored (ICRP 2004, IAEA 2011). Radiography with flat panel detectors (DR) provides the potential for a reduction in dose, while exposures required for computed radiography (CR) will be similar to those for film, although adjustments are required to the automatic exposure control (AEC) to take account of differences in sensitivity with photon energy (Doyle and Martin 2006). Overexposures can result from use of incorrect exposure factors or inappropriate settings of the AEC and may not be detected, unless the X-ray equipment is tested regularly within a robust quality assurance (QA) system. Overexposures can also result from poor collimation, particularly in paediatric exposures where substantial proportions of the bodies of infants may be exposed unnecessarily, and this type of error can be identified in meetings to review radiographic images. In fluoroscopy poor positioning of the X-ray tube close to the patient together with inadequate collimation and choice of inappropriate exposure options can result in doses being substantially higher than necessary. Although incorrect settings can result in higher radiation doses, they are unlikely to lead to clinically significant injury such as that seen with more complex and relatively higher dose interventional procedures. There is an immense variety in the types of radiation incident that can occur in healthcare as well as in the causes of incidents. The

IAEA BSS requires an investigation to be carried out for the following categories of unintended or accidental medical exposures (IAEA 2014) (N.B. A different numbering system is used here, as this paper does not include therapeutic overexposures).

1) *Error in procedure*: "Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;"
2) *Diagnostic overexposure*: "Any exposure for diagnostic purposes that is substantially greater than was intended;"
3) *Interventional overexposure*: "Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;"
4) *Embryo/Foetus exposure*: "Any inadvertent exposure of the embryo or foetus in the course of performing a radiological procedure;"
5) *Equipment failure*: "Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended."

Examples of incidents within categories 1-4 are given in Table 1, and for category 5 in Table 2.

*3.1.2 Steps in the investigation process*

The following section discusses steps in the investigation process that are useful to ensure that appropriate actions are taken. When an incident occurs, a record of exposure information and the region of the body irradiated should be made at the time, together with any error codes or unusual signals. The exposure data will depend on the type of equipment. Data that might be recorded are as follows:

- *Radiography or fluoroscopy procedures:* kerma-area product (KAP), set tube voltage, tube current time product delivered and set, and other available information, e.g. time for which radiographic exposure appeared to continue if exposure termination failed
- *Interventional procedures:* cumulative air kerma at the interventional reference point ($K_{r,a}$) (IEC 2010), KAP, fluoroscopy time, number of acquired images.
- *CT scans:* volume averaged CT dose index ($CTDI_{vol}$) and dose-length product (DLP) (required by certain regulations).
- *Mammography:* displayed mean glandular dose, kV, mAs, target / filter combination, compressed breast thickness, and other available information.

More recent X-ray equipment may have DICOM radiation dose structured reports that contain most of this information. The BSS (IAEA 2014) states that the aims of an

investigation of the types of incident listed in section 3.1.1 are as follows, paraphrased to shorten the content:

a) Calculate or estimate the doses received and the dose distribution within the patient;
b) Indicate the corrective actions required to prevent recurrence;
c) Implement all the corrective actions that are under the registrant's responsibility;
d) Produce and keep a written record that states the cause of the incident and includes the information specified in (a)–(c), in addition to records required by the regulatory body for significant exposures;
e) Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure.

The local staff with responsibility for radiation protection should undertake an investigation of the incident as soon as possible and prepare a preliminary report. The service manager with advice from the medical physics expert can then decide whether the nature of the incident calls for a more detailed investigation. It may be helpful to appoint an individual specifically to manage any in-depth investigation, and make them responsible for preparing the detailed report.

### *3.2 Procedures for investigation, follow-up and prevention of incidents*

Grouping incidents into categories can help in setting out the appropriate structure for such investigations in departmental procedures, it can also assist in later collation and analysis. The examples of incidents based on UK experiences in Table 1 are listed under categories proposed in the International BSS, but the types of incident that can be recognised and followed up effectively would need to be adapted for individual countries. The investigation has two purposes as far as the healthcare facility is concerned. The first is to assess the consequences for the patient(s) affected and provide any necessary additional healthcare. The second is to identify what went wrong, and implement changes to address the deficiencies and minimize the likelihood of a recurrence. There is a third purpose in wider dissemination of information about radiation incidents and radiation injuries in order to raise awareness, and alert others about the lessons learned from significant events (EC 2014), but that will be discussed in a separate paper. Within the organization, incident data should be secure and available to the appropriate leadership such as a general manager, as well as disseminated through relevant safety committees or incident review meetings.

*3.2.1 Events resulting from errors made in the medical facility using X-rays*

*3.2.1.1 Incident investigation and follow-up*

If an incident is caused by an error made by staff in the department or practice using the X-rays (Table 1, Nos. 1a, 2, 3 and 4), the person carrying out the investigation should take all necessary measures to obtain detailed information, which in many cases will include face-to-face interviews with the staff involved, to determine causes of the incidents and identify contributory factors. They will need to consult a medical physics expert to obtain radiation dose information. The investigation should be instituted with an open "no blame" approach and aim to identify root causes and contributory factors. Details of what occurred, why it happened, and any deficiencies in procedures or staff training that contributed to the incident should be included in the report. Follow-up should look at remedial actions, to see what improvements should or could be made to minimize the risk of a similar incident occurring in the future. On completion of the investigation, debrief of all staff involved should be carried out to explain causes of the incident, and describe any adjustments that have been made to procedures and other changes.

There may be latent systemic factors within the department, such as too many distractions within the workplace or staff shortages that contribute to active errors categories 1a, 2 and 4 also known as human errors. Examples of such latent factors are listed in Table 2. Active factors may be due to decisions linked to poor staff alertness and awareness. The responsibility for addressing the deficiencies will lie with the manager or lead person for the service, and the requirement to ensure that any changes necessary are implemented to address deficiencies in procedures and training should be included in the procedures. However, all relevant stakeholders should collaborate in the process. There may be modifications to procedures, additional training of staff, introduction of additional checks, or other changes. There may also be adjustments to the organisation of the service, to improve clarity for responsibilities.

*3.2.1.2 Systems to aid in incident prevention*

Steps that should be taken following an incident have been described, but the objective is to avoid the occurrence of such incidents in the first place. A variety of systems can be adopted to help in achieving this and some examples are given in Table 3. Professional organisations such as Image Gently (www.imagegently.org) for children and Image wisely (www.imagewisely.org) for adults promote the use of tools to help in this process, such as checklists and audits to assist in the improvement process. In order to prevent incidents there should be a continuing effort to refine procedures. Before starting a procedure, it is useful to pause for a moment while everyone confirms that the actions highlighted in the

checklist have been performed or are in place. This type of “pause and check” routine has been promoted by professional organisations in radiology (Image Gently 2014, RCR 2017). The checks for paediatric fluoroscopy, for example, include: the correct patient, the possibility of pregnancy, justification of the examination, the anatomical site, radiation safety aspects, optimization of the procedure, use of AEC and grid. If these factors are written down on a card or poster, and the checks followed at the start of every procedure, this can help to avoid obvious errors.

Incidents can sometimes result from a lack of clarity about individual responsibilities for carrying out particular tasks. An example of a situation where there may be some dubiety about responsibilities is when X-ray equipment is being maintained by a company X-ray engineer. Here the use of a formal equipment handover procedure, with appropriate checklists, can help to ensure that the responsibility for the equipment and its correct operation is recognised. Then if access to the room and equipment is required for an emergency clinical procedure, all the checks should be made to ensure the equipment is set-up appropriately for clinical use, according to the predetermined format. Such strategies linked with periodic review and audit of procedures, and proper follow-up of any incidents that do occur, should enable robust procedures to be developed that will avoid most incidents.

*3.2.2 Investigation of errors made by the referrer*

An error in a procedure in which the wrong individual or the wrong tissue or organ of the patient is exposed may not be due to an error made in the radiology department or practice carrying out the exposure. It may be because the wrong patient was referred or the wrong examination requested, but with an appropriate clinical history (Table 1, No. 1b). These errors in patient referral are often more difficult to follow-up and in some countries this may not even be possible, because they involve another department or organization. Where there is a co-ordinated National Health Service, the system might involve the lead clinician sending a formal communication (e, g, letter, email) to the referrer and a copy of the document to the consultant or practice manager under whom they were working. This should explain what happened and request a written statement giving an explanation of why the error occurred, and what action has been taken to minimize the risk of a similar incident occurring in the future. Whatever the arrangement, this will require a different approach from the internal investigation within the department or practice carrying out the X-ray procedure.

*3.2.3 Prevention of skin injury from interventional procedures*

*3.2.3.1 The link between dose levels and skin injury*

There are many reports of tissue reactions resulting from interventional procedures in cardiac catheterization laboratories and interventional radiology suites (Rosenthal et al 1997, Vañó et al 1998, ICRP 2000a, 2013a, Koenig et al 2001a, Koenig et al 2001b, Vliestra et al., 2004, Bogeart et al 2009, Balter et al 2010, UNSCEAR 2010, IAEA 2010, Vañó et al 2013). When effects occur or when dose levels are such as to give a high risk of them occurring, a review of procedures may be appropriate, as required for other incidents. However, doses are not measured and even dose estimates are unfamiliar so in many institutions and radiology practices staff is unaware of dose levels and whether there might be a clinically significant risk. When dosimetry information is not available, there is no indication of the potential for tissue reactions, and the link between cases of erythema and radiation exposure may not be recognised. Even when dose information is displayed, the quantities may not be familiar to or understood by the operators, so education in dosimetry and the link to radiation effects is important. If the threshold dose to cause injury is exceeded, the tissue damage will become progressively more severe with increasing dose, but the extent of a tissue reaction injury may not become apparent until weeks or months later. As a result any association between reported erythema and a radiation exposure may be harder to establish, particularly if the possibility is not mentioned at the time an interventional procedure is carried out. Moreover, staff may not believe that radiation injuries could have resulted from the interventional procedures carried out, if they have not previously been alerted to the possibility. Some cases requiring skin grafting have only been recognised almost a year after exposures occurred (Rehani and Srimahachota 2011, Kostova-Lefterova 2015, IAEA 2017a). Since there is a risk of skin injury from interventional procedures, patient consent must be obtained and the radiation risks including clinical manifestations of radiation injury associated with the procedure discussed with the patient if the expected skin dose may be high.

The potentially high radiation levels from interventional procedures coupled with the need for the operators to be close to the patient to perform the necessary manipulations mean that there is also a higher risk of occupational exposure. Reports of lens opacities among interventional staff resulting from exposure over many years highlight the importance of optimizing not only the radiation levels used, but also the appropriate use of protective methods and devices for staff (ICRP 2000a, ICRP 2012, IAEA 2017d).

*3.2.3.2 Minimising the risk of high skin doses*

It is important to put in place procedures to prevent or at least minimize the risk of skin injury, through awareness of potential dose levels before and during any interventional procedure (Table 3). High skin doses often result from poor technique and lack of optimization and sometimes occur due to equipment malfunction (Rosenthal et al 1997), but others while not intended are difficult to avoid because of the complexity of the procedure (Bryk et al 2006, Suzuki et al 2008, Vano et al 2013). Hospitals should identify procedures that have a high potential to cause radiation injury and ensure that the competencies for operators and the equipment settings used are satisfactory (ICRP 2000a). Approaches to reducing these risks in different parts of the world will need to take into consideration the technology and resources available. There are many factors that can contribute to doses being higher than necessary. If the interventionalist does not have a detailed knowledge of all operation modes of the X-ray unit, he/she may not make full use of the patient dose optimization techniques available. The default settings in terms of radiation dose and image quality may not be appropriate for certain patients and procedures. These settings should be optimized during commissioning of the equipment and operators trained in use of the facilities. Involvement of medical physics experts during the commissioning and when the applications specialist is setting-up program options with the operators will assist in informing decisions on dose and image quality. Ensuring that sufficient training is given to interventionalists and radiographers in techniques to minimize skin doses for interventional procedures, such as keeping the image receptor close to the patient, using the lowest appropriate pulsed fluoroscopic and image acquisition dose rates necessary for each stage of the procedure, rotating the gantry slightly to vary the beam entry point, and collimating the X-ray beam as much as possible are crucial (Mahesh 2001, Miller et al 2002, Stecker et al 2009, ICRP 2013a; NCRP 2010, IAEA 2010, Hill et al 2017). The training must include the unique considerations with paediatric procedures as well as the impact of geometrical factors in the operation of C-arm equipment, such as the influence of iso-centre position, and the potential for the X-ray tube being much closer to the skin surface for oblique projections and so delivering higher skin doses, as well as ensuring the patient's arms do not lie within the primary beam, which has led to injuries in the past (Vañó et al 1998, Viesta et al 2008, ICRP 2013a). Interventionalists must understand the impact of all the dose management features of the equipment and how to use those features properly. Training in techniques and radiation protection for cardiologists, surgeons and other clinicians using C-arm equipment, in addition to radiologists (ICRP 2009, 2010, 2013b), will help to avoid practices that may give radiation doses that have the potential to cause skin injury. Free training material on radiation protection in image guided interventional procedures, available on the IAEA website, provides comprehensive information (IAEA 2017b), together with posters on radiation

protection methodology in many languages (IAEA 2017c). Exposure levels in neuroradiology, especially interventional neuroradiology, can be a particular problem, because fields focussed on the head will often overlap irradiating the same area of the skull and these can result in hair loss (Mooney et al 2000, Imanishi et al 2005).

*3.2.3.3 Monitoring skin dose levels*

The threshold and severity of tissue reaction is linked to peak skin dose and the area of skin irradiated. The skin dose will depend on the complexity of the procedure as well as the size of the patient, so procedures where there is a potential risk of exceeding a peak skin dose of 3 Gy should be identified. Repeated procedures with dose levels over about 1 Gy on the same patient within a few months will also increase the risk of injury. In all these cases there is a need to be aware of high doses from previous procedures and to look for strategies to reduce peak skin doses (ICRP 2000a).

Software for mapping skin dose distributions from interventional procedures is becoming available (Johnson et al 2011, Khodadadegan et al 2013) and some modern interventional systems can provide real-time estimates of peak skin dose and maps of dose distribution calculated from exposure parameters (Bordier et al 2015). As these systems become more accessible they should provide operators with the possibility of monitoring peak skin dose throughout a procedure. Although these options are not available on the majority of interventional fluoroscopy units at the present time, there are dose quantities that can be used as indicators such as cumulative air kerma at the interventional reference point, KAP, fluoroscopy time, and number of image acquisition runs/frames. The accuracy of the dosimetry data displayed should be validated by a medical physicist. Protocols should be available which take into account patient size, and contain alert and trigger levels set in terms of the displayed quantities. The levels should be based on recommendations of professional societies, and the values included in operator training (cardiologist, radiologist, radiographer, and other medical specialists using fluoroscopically guided procedures). Values that might be used, based on international guidelines are included in Table 4 (Stecker et al 2009). The more appropriate quantity is the cumulative air kerma at the interventional reference point, however, it should be recognized that this is not an accurate measure of skin dose, as it is based on the assumptions that the skin surface is 15 cm in front of the iso-centre and the X-ray tube is stationary. Moreover it does not include backscatter which can increase skin dose by 30% to 40% or attenuation of the X-ray table. It may therefore be higher or lower than the peak skin dose, so ideally calibration and assessment by a medical physics expert is required. Older equipment may not provide dosimetry information and here fluoroscopy time should be used as a guide, although this is a poor indicator of radiation dose.

Radiation dose estimates should be monitored throughout a procedure for all patients, especially those who are considered to be at risk of skin injury, and the responsibility for this may be delegated to a radiographer, medical physicist or nurse. The interventionalist should be alerted during the procedure when the dose reaches the alert values (Stecker et al 2009). The clinical outcome must be the priority, even if an alert level is reached, so clear recommendations should be made about action to be taken. These may include modifying the procedure or consulting a colleague for advice. Higher trigger levels should be set above which the patient would be informed and followed-up, and for external reporting of the exposure. If any of the dose alerts are exceeded during a procedure, the dose information should be recorded in the patient's medical record (JACR 2008, NCRP 2014). The patient should also be monitored closely if any further procedures are performed during the next two months, and the dose from the first procedure taken into account. If the dosimetry parameter exceeds the trigger level for follow-up, then the patient should be informed of the risk. A patient information sheet should be issued on discharge recommending that a family member or other caregiver inspect the area of skin irradiated for signs of redness or rash two weeks later and including resources for the patient to contact if any effects are observed (Stecker et al 2009). The high skin dose should be entered into the patient's medical record and the patient's condition followed-up on their return to the hospital or they may be contacted after approximately three weeks to check whether they have had any skin reaction. The patient's general practitioner, referring doctor, and other professionals involved in the service should all be informed of the procedural exposure.

The IAEA has established an international web-based database SAFRAD (Safety in Radiological Procedures) to collect radiation exposure data for procedures reaching defined trigger levels in interventional radiology and cardiology (IAEA 2017e). The purpose is to identify patients at high risk of developing tissue reactions from interventional procedures, encourage follow-up examinations for adverse side effects and educate healthcare personnel. The IAEA request that events are reported to SAFRAD if one of the following levels is exceeded: fluoroscopy time > 60 min., KAP > 500 Gy $cm^2$, cumulative air kerma at the interventional reference point > 5 Gy, measured peak skin dose > 3 Gy, number of series or cine runs > 20 or observed radiation injury.

### *3.2.4 Skin injury from CT procedures*

#### *3.2.4.1 CT procedures with a high risk of skin injury*

Events that lead to tissue reactions from CT scans are rare, but if they occur can affect multiple patients, as they are likely to result from use of inappropriate exposure settings (New York Times 2010, 2011). Procedures with higher risks of skin injury are CT fluoroscopy and CT perfusion (ICRP 2000b, ICRP 2007b). Dynamic CT perfusion involves a series of

continuous or intermittent CT acquisitions from which functional hemodynamic parameters such as blood flow, blood volume, mean transit time and time to peak enhancement can be derived (Hoeffner et al 2004). Brain CT perfusion is used for assessment of stroke. The technique may be employed for the body primarily in oncology applications for lesion characterization and assessment of tumour response to medication and radiation treatment, and also in evaluating cardiac function (Sahani 2009). There is a risk of high skin doses in CT fluoroscopy, because scans performed during guidance of a needle, catheter or probe may be repeated in approximately the same location (Teeuwisse et al 2001, Tsalafoutas et al 2007). Examples of skin injury and hair loss from CT perfusion cases in the USA have been publicised (ICRP 2007b, New York Times 2010, 2011). These have involved errors due to use of incorrect settings by operators who did not understand the potential impact of CT parameter changes on dose. Examples include selecting a "Noise Index" for controlling the tube current modulation mode that was too low, yielding doses many times higher than necessary; scanning a patient multiple times because of lack of awareness that multiple image reconstructions could be obtained from the same raw data (Mettler 2017); and a missing beam filter that was dislodged during shipping (Mahesh 2017). Lessons that have been learned from these accidental overexposures are to ensure that acceptance testing is carried out, including comparisons of performance with manufacturer specifications, as well as regular quality control, and to act immediately when an event occurs to assess the radiation dos levels; communicate the findings to everyone involved; and modify procedures in an attempt to avoid future incidents (Mayo-Smith et al 2014, FDA 2017). As a result of these incidents new regulations have been introduced in the State of California requiring accreditation of all CT scanners, annual evaluation by suitably qualified medical physicists, and recording of CT dose descriptors in patient reports for every CT examination (California Law SB 1237). Annual verification of the accuracy of CT dose displays is particularly important.

*3.2.4.2 Prevention of skin injury from CT procedures*

Methods for prevention of incidents should first identify procedures that have a high potential to cause injury and ensure the settings are satisfactory, but also review of all CT protocols including evaluation of dose especially those for more common examinations. CT skin dose is not measured directly on patients, but the volume averaged CT dose index ($CTDI_{vol}$) displayed on the scanner console provides useful information. The $CTDI_{vol}$ is an average of the dose at the surface and at the centre of a phantom. For head CT scans, the dose is similar throughout the phantom and so the $CTDI_{vol}$ is similar to the surface skin dose. However, for body CT scans, the $CTDI_{vol}$ underestimates surface skin dose and the relationship to compute skin dose ~ 1.3 × $CTDI_{vol}$ should be used (Mahesh 2017).

Recently, a “CT Dose Alert” standard (NEMA XR 29, 2013) has been introduced, which will provide an alert to CT machine operators if the scan parameters that have been set will give doses that exceed levels predetermined by the users. The purpose of the CT dose alert is to avoid excessive dose delivery due to incorrect settings or repeat scans. The US Food and Drug Administration has suggested a CT alert value for $CTDI_{vol}$ of 1 Gy, which should allow the user to adjust the scan settings to avoid any potential skin injuries (FDA 2009, 2010). In addition, the user also has the option to set “CT Dose Notification” levels (AAPM 2011) for $CTDI_{vol}$ and DLP that can be chosen for each scan series and when these levels would be exceeded, programs will alert the operator prior to the examination. If the operator wishes to continue with the parameters that have been set, then reasons have to be documented. The CT Dose Notification option can be a useful tool for quality management and users can monitor their respective CT practice by routinely auditing the CT dose reports (Mahesh 2016).

*3.2.5 Investigation of events resulting from equipment faults*

When some aspect of the X-ray imaging equipment fails, this can give rise to an overexposure either because more radiation is delivered than is appropriate or a patient is exposed without any usable images being generated, and some examples are given at the end of Table 2. If there is an unintended overexposure due to an equipment fault, the unit should be taken out of clinical service until the fault has been addressed. The investigation will require the supplier of the equipment to be notified and arrangements made for an investigation into the circumstances and causes of the incident. This will require input from the equipment manufacturer’s representative and the hospital medical physics expert, as well as the imaging staff involved. Technical reports should be obtained from the equipment suppliers and any further actions considered necessary taken to minimize the risk of a similar incident occurring in the future. There should be procedures in place to ensure that any necessary tests are carried out to verify that equipment performance is satisfactory, before the equipment is returned to service. For this type of incident it will in some circumstances be appropriate to submit a report to the National Incident Reporting and Investigation Centre to allow dissemination of relevant information to other users.

Systems that can aid in reducing risks of an incident resulting from an equipment fault are listed in Table 3. Equipment faults are more likely to occur in equipment that is older or has not been maintained properly. Equipment that is between six and ten years old and maintained should still be suitable for practice, although this will depend on the workload for which it is being used. However, radiology departments and practices should develop strategies for replacement of equipment at appropriate intervals to minimize risks and replace equipment that is over ten years old (COCIR 2013). Keeping equipment fault logs is

helpful for informing decisions on equipment replacement. Facilities should have comprehensive QA programmes to assess equipment performance, including evaluation of image quality, and retake analysis (IAEA 2007, 2014). This should include comprehensive tests by a medical physics expert, which may be performed annually depending on the type of equipment, and more regular constancy checks by radiographers to ensure any change in performance is identified at an early stage. QA programmes should involve the active participation of medical physicists, radiographers, and radiologists. There should also be regular surveys to ensure that patient doses are at acceptable levels (Martin 2008).

### *3.3 Assessment of doses to patients from overexposure and risks of stochastic effects*

Reporting of radiation doses following unintended and accidental exposures may be based on organ, skin or effective doses. Organ dose estimations should be used when exposure is predominantly of one organ, but the effective dose for a reference person provides an assessment that can be used when several organs are irradiated and provides a valuable method for giving an indication of detriment for small exposures. The limitations of effective dose, especially when only a limited portion of the body is irradiated, should be borne in mind. Effective dose is a general dose quantity derived from risks averaged over a whole population, and relative risks linked to effective dose, as well as varying with sex for some organs, are known to be substantially higher for adolescents and lower for older groups. The majority of overexposures from incidents will be low, so methods for dose estimation should be fairly simple. If the dose is less than a few mSv, and the additional dose from the overexposure is similar to that of the procedure, as is frequently the case (Martin 2005), then generic values from published data can be used. At low radiation levels the effective dose can be derived from exposure data (e.g. DLP coefficients to derive effective dose in CT, or KAP values for interventional) and coefficients that might be used for this purpose are given in Table 5. When the excess effective dose is much greater than 10 mSv a full evaluation using doses for individual radiosensitive organs and tissues may be appropriate. Local/regional agreement will be required on the level at which determination of organ doses is necessary. General terminology can be used to describe risks of cancer incidence, linked to the dose level. Recommended risk terms that are appropriate for use in explanations to service providers, patients, the public, and administrators when effective doses lie within different ranges are given in Table 6 (Martin 2007). Quantitative risks derived from organ doses using age and sex related coefficients provided by international organizations (e.g. BEIR VII 2006, ICRP 2007, HPA 2011) might be used where an in-depth assessment of risk is required performed by a medical physics expert with a knowledge of radiation effects.

However it must be borne in mind that there are large uncertainties when applying these risks to individuals, even when the sex and age related values of risk are used.

### *3.4 Communicating radiation risk to patients*

Procedures about informing patients of any unintended exposures and related risks will vary, and individual decisions will depend on the staff, patients, and caregivers involved. The operator with responsibility for making the exposure could inform the patient of any unintended exposure at the time of the examination, if he/she judged that was appropriate, or alternatively, the responsible radiologist or other imaging professional might do so before the patient left the department. An indication of risk should be given in general terms (Table 6), together with information on the effective dose, and how this compares with doses from other sources such as natural background radiation can be included. Considerable care should be taken in the explanation, since the perception of radiation risk among the public at large is poor and the stress resulting from knowledge that a patient has received an unintended exposure may be more harmful than the exposure itself. If the patient is not informed of the unintended exposure during his/her visit to the department, then the radiologist should provide information about the exposure to the referring clinician, to allow him/her to inform the patient and explain the level of risk. A record should be made to confirm whether the patient was informed about the incident.

### *3.5 Unintended exposures of the embryo/foetus*

#### *3.5.1 Exposure of pregnant females*

An unintended exposure of an embryo or foetus may occur because a female is unaware that there is a possibility that she might be pregnant. Departments should minimize the risk through making checks on the reproductive status of female patients of child-bearing age (Table 3), which might include the date of their last menstrual period, immediately prior to the examination. Departments should establish procedures for dealing with pregnant patients that set out clearly when checks should be made for different examinations and the actions appropriate for dealing with possible responses from the patient. Other steps such as putting up notices in patient waiting areas requesting anyone who is pregnant to inform a staff member provide an avenue through which patients are alerted of the need for pregnancy to be considered prior to the examination being undertaken. However, if there is a failure in the verbal or written pregnancy screening procedure, and a pregnant female is exposed unintentionally, an internal investigation should be undertaken and an assessment made of the foetal dose. If a female is known to be pregnant, but a decision is made to justify the examination, based on a clinical decision, then the exposure is intended, but special attention must be given to dose optimization taking into consideration both the pregnant

female and the unborn child. If the uterine dose is over a few mGy there may still be a need to make an assessment of the dose to be recorded in the patient's record.

If the exposure occurs during the first two weeks of pregnancy, then the embryo will probably either be aborted or it will recover completely. From the 3rd to the 8th week post conception, the possible forms of damage are organ malformation or mental retardation, but these effects only occur at dose levels over 100 mGy, which is much higher than doses expected from diagnostic imaging (ICRP 2000c). Some radiological examinations involving the abdomen or pelvis are capable of delivering radiation doses of tens of mGy to the unborn child, but situations that may lead to radiation doses of 100 mGy are unlikely to occur from diagnostic exposures. Therefore, medical abortion due to a diagnostic X-ray examination should almost never be justified. However, at dose levels from diagnostic radiology there is a small increased risk of childhood cancer from foetal exposure, and although the risk in almost all cases will be <0.1%, an estimation of embryo/foetal dose is often needed.

*3.5.2 Assessment of foetal dose*

When the uterus is remote from the anatomical area that is exposed to the primary beam, the dose to the embryo/foetus from scattered radiation is usually very small, and any risk is minimal or negligible (Table 6). Therefore, estimates of the foetal dose will be needed only if the foetus is in or near the primary beam. Various studies using Monte Carlo simulation have been undertaken to provide coefficients that link foetal dose to measurable dose quantities. These show that during the first trimester, the dose depends on the depth of the embryo, which can vary from 4 to 10 cm. The depth is affected by the status of the bladder and the mother's body mass index. For radiographic examinations coefficients giving the embryo/foetal dose normalised with respect to the incident air kerma ($K_{a,i}$) for the first, second, and third trimesters of gestation as a function of kVp, and depth for the embryo during the first trimester, are available for different projections (Damilakis et al 2002). A selection of factors giving foetal dose as a fraction of air kerma incident on the skin surface of the mother for radiographic examinations of the abdomen are given in Table 7. The ratios were calculated using on-line software CODE (COnceptus Dose Estimation), a free tool developed by the University of Crete (2015) that allows calculation of embryo/foetal doses and risks from a wide range of exposure parameters for X-ray examinations performed on expectant mothers.

Patient-specific Monte Carlo simulations have been used to derive estimates of embryo/foetal radiation doses from abdominal CT examinations, which are the procedures more likely to lead to doses of tens of mGy. Angel et al 2008 have estimated embryo/foetal doses from typical abdominal and pelvic CT examinations for a range of gestational ages (5 to 36 weeks). While Damilakis et al 2010a have developed a method for the accurate

determination of embryo/foetal dose from abdominal/pelvic multi-detector CT (MDCT) examinations performed on pregnant females during the first seven weeks post conception. These methods provide dose data for typical protocols with a fixed scan length. However, modified low-dose imaging protocols are frequently used in CT and a procedure has been developed for the estimation of embryo/foetal dose from any MDCT examination of the trunk performed during all stages of gestation using dosimetry data from the CT scanner and either the depth of the embryo for the first trimester or the abdominal circumference of the mother for foetal exposures (Damilakis et al 2010b). The CODE software tool (University of Crete 2015) has facilities for calculation of embryo/foetal doses from radiography, fluoroscopy, and CT examinations, from exposure and dosimetry data. The embryo/foetus is more sensitive to radiation exposure than an adult, and recommended terminology for describing risk linked to dose level should be modified accordingly (Table 6).

## 4. Conclusions

The aim of this paper is to provide advice on strategies for identification and prevention of unintended and accidental overexposures. Guidance is given on methods for investigating and reporting diagnostic radiology incidents within healthcare facilities, and implementing changes to reduce the likelihood of similar incidents occurring in the future. Particular attention is given to interventional and CT exposures that could result in skin doses high enough to produce tissue reactions. Some of the more important actions required for preventing incidents are summarised in Table 3. The main factor in reducing risks of tissue reactions is ensuring that staff operating interventional equipment or CT scanners has been given in-depth training in use of the equipment and all the facilities through which doses can be reduced. The use of checks on dose parameters before commencing procedures and setting of dose alert values provide additional safeguards. Such effects cannot always be avoided in interventional procedures, even when techniques are optimized, but if proper procedures are followed, the risks can be kept to a minimum.

The effects of unintended and accidental medical exposures in other types of imaging procedure are less obvious, but nevertheless result in some health detriment in terms of small increases in the risks of cancer. It is important to learn from any errors that occur, so proper investigation procedures should be in place and staff educated in their use. Responsibilities for investigation and reporting should be clearly set out in written policies and procedures in order to ensure that any changes or additional training required are carried out. Systems that can assist in improving arrangements within radiology departments and things that should be in place to help reduce the likelihood of equipment faults are listed in Table 3. If health facilities review and audit their procedures and consider whether they

might adapt and develop robust systems along the lines suggested, then this should go some way to helping to prevent as many exposure incidents as possible, although it will never be possible to eliminate errors entirely.

When an overexposure of a patient occurs, there is a requirement for an evaluation of the dose in order to gain some assessment of the potential risk. When the doses are less than a few mSv, an approximate value for either the organ irradiated or the effective dose, if a number of organs are involved, is likely to be sufficient. This can be based on exposure data, but if the dose is very small a generic value for the examination may be sufficient. For assessment of foetal doses there are various methods described in referenced publications, and software available via the internet that might be used. The use of terminology that gives an approximate indication of the risk of any stochastic effects for adults, children or foetuses from any exposures is recommended. However, if the exposure represents tens of mSv effective dose, then an in-depth assessment involving estimation of doses for individual organs and tissues may be appropriate, and then age and sex related coefficients can be used to derive an estimate of stochastic risk, but it should be remembered that even these risk calculations have large uncertainties.

## References

American Association of Physicists in Medicine (AAPM) 2011 AAPM recommendations regarding notification and alert values for CT scanners: guidelines for use of the NEMA XR 25 CT Dose Check standard. Available at: http://www.aapm.org/pubs/CTProtocols/documents/NotificationLevelsStatement.pdf. (accessed June 2017).

Angel, E, Wellnitz, C V, Goodsitt, M M, Yaghmai, N, DeMarco, J J, Cagnon, C H, Sayre, J W, Cody, D D, Stevens, D M, Primak, A N, McCollough, C H, and McNitt-Gray, M F. 2008 Radiation Dose to the Fetus for Pregnant Patients Undergoing Multidetector CT Imaging: Monte Carlo Simulations Estimating Fetal Dose for a Range of Gestational Age and Patient Size. Radiology 249(1), 220-227.

Balter, S, Hopwell, J JW, Miller, D L, Wagner, L K, and Zelefsky, M J. 2010 Fluoroscopically guided interventional procedures: A review of radiation effects on patients' skin and hair. Radiology 254, 326–-341.

Biological Effects of Ionising Radiation (BEIR) 2006 Health risks from exposure to low levels of ionizing radiation. BEIR VII, Phase 2. Washington, DC: The National Academies Press, National Research Council.

Bogeart, E, Bacher, K, Lemmens, K, Carlier, M, et al. 2009 A large-scale multicentre study of patient skin doses in interventional cardiology: dose-area product action levels and dose reference levels. Brit. J. Radiol. 82, 303–-312.

Bordier C, Klausz R, and Desponds L. 2015 Patient dose map indications on interventional X-ray systems and validation with Gafchromic XR-RV3 film. Radiat Prot Dosimetry 163(3) 306-18.

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

COCIR 2013 Good Maintenance Services Practice Guide. European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry. http://www.cocir.org/fileadmin/Publications_2013/13004.COC.Good_Maintenance_WEB.pdf (accessed June 2017).

Damilakis, J, Tzedakis, A, Sideri, L, Perisinakis, K, Stamatelatos, I E and Gourtsoyiannis, N. 2002 Normalized conceptus doses for abdominal radiographic examinations calculated using a Monte Carlo technique. Medical Physics, 29:2641-2648.

Damilakis, J, Perisinakis, K, Tzedakis, A, Papadakis, A E, and Karantanas, A 2010a Radiation Dose to the Conceptus from Multidetector CT during Early Gestation: A Method That Allows for Variations in Maternal Body Size and Conceptus Position. Radiology 257(2), 483-489.

Damilakis, J, Tzedakis, A, Sideri, L, Perisinakis, K, Stamatelatos, I E and Gourtsoyiannis, N. 2002 Normalized conceptus doses for abdominal radiographic examinations calculated using a Monte Carlo technique. Medical Physics, 29:2641-2648.

Damilakis, J, Tzedakis, A, Perisinakis, K, and Papadakis, A E, 2010b A method of estimating conceptus doses resulting from multidetector CT examinations during all stages of gestation. Medical Physics 37(12), 6411-6420.

Doyle, P and Martin, C J 2006 Calibrating automatic exposure control devices for digital radiography. Phys. Med. Biol. 51, 5475-5485.

EC 1997 European Council Directive 97/43/Euratom laying down measures on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Official Journal of the European Communities, No.L180.

EC 2104 European Council Directive 2013/59/Euratom on basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. OJ of the EU. L13; 57: 1–73.

Food and Drug Administration (FDA) USA 2009 Safety Investigation of CT Brain Perfusion Scans - Update 12/8/2009. https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm232560.htm. (accessed April 2017).

FDA 2010 Safety investigation of CT brain perfusion scans: Update 11/9/2010. Available at: http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm185898.htm. (accessed April 2017).

FDA 2017 Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. https://www.fda.gov/radiation-emittingproducts/radiationsafety/radiationdosereduction/ucm199994.htm. (accessed April 2017).

Health Protection Agency (HPA) 2011 Radiation risks from medical X-ray examinations as a function of age and sex of patient. Authors Wall, B F, Hatlock, R, Jansen, J T M, Hillier, M C, Hart, D, and Shrimpton, P C. HPA Report HPA-CRCE-028 (HPA, Chilton).

Hill K D, Frush D F, Han B K, Abbott, B G, Armstrong, A K, et al 2017 Radiation safety in children with congenital and acquired heart disease: A scientific position statement on multimodality dose optimization from the Image Gently Alliance. J Am Coll Cardiol Imaging doi:10.1016/j.jcmg.2017.04.003.

Hoeffner, E G, Case, I, Jain, R, Gujar, S K, Shah, G V, MD, Deveikis, J P, Carlos, R C, Thompson, B G, Harrigan, M R, and Mukherji, S K 2004 Radiology 231, 632-644.

IAEA 2007 Dosimetry in diagnostic radiology: An international code of practice. IAEA Tech. Report Series no. 457, (Vienna: IAEA).

IAEA 2010 Patient Dose Optimization in Fluoroscopically Guided Interventional Procedures. IAEA TECDOC 1641, (Vienna: IAEA).

IAEA 2011 Avoidance of Unnecessary Dose to Patients While Transitioning from Analogue to Digital Radiology. IAEA-TECDOC-1667. (Vienna: IAEA). http://www-pub.iaea.org/MTCD/Publications/PDF/te_1667_web.pdf (accessed June 2017).

IAEA/WHO 2012 Radiation Protection in Medicine: Setting the Scene for the Next Decade. Proceedings of an International Conference, 3–7 December 2012, Bonn, Germany https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Bonn_Call_for_Action_Platform/ (accessed April 2017).

IAEA et al 2014 European Commission, Food and Agriculture Organization of the United Nations, IAEA, International Labour Organisation, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environment Programme and WHO. Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. IAEA Safety Dtandards Series No GSR Part 3 (Vienna: IAEA).

IAEA 2017a Skin injuries: Occurrence and Evolution. Radiation protection of patients.https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/5_InterventionalCardiology/skin-injuries.htm. (accessed April 2017).

IAEA 2017b Radiation protection of patients. Diagnostic and interventional radiology. https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/index.htm. (accessed April 2017).

IAEA 2017c Radiation protection of patients. Radiation protection in fluoroscopy. https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Information_material/fluoroscopy-posters.htm. (accessed April 2017).

IAEA 2017d Radiation protection of patients. IAEA Cataract studies published. https://rpop.iaea.org/RPOP/RPoP/Content/ArchivedNews/cataract-studies-published.htm. (accessed April 2017).

IAEA 2017e Radiation protection of patients. SAFRAD (SAFety in RADiological procedures) https://rpop.iaea.org/RPOP/RPoP/Modules/login/safrad.htm. (accessed April 2017)

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

ICRP 2000b Managing Patient Dose in Computed Tomography. Publication 87, Ann ICRP 30(4).

ICRP 2000c Pregnancy and medical radiation. ICRP Publication 84, Ann ICRP 30(1).

ICRP 2003 Biological Effects after Prenatal Irradiation (Embryo and Fetus). ICRP Publication 90, Ann. ICRP 33 (1-2).

ICRP 2004 Managing Patient Dose in Digital Radiology. ICRP Publication 93, Ann. ICRP 34 (1).

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

ICRP 2007b Managing Patient Dose in Multi-Detector Computed Tomography (MDCT). ICRP Publication 102, Ann. ICRP 37 (1).

ICRP 2009 Education and training in radiological protection for diagnostic and interventional procedures. ICRP Publication 113, Ann. ICRP 39(5).

ICRP 2010 Radiological Protection in Fluoroscopically Guided Procedures outside the Imaging Department. ICRP Publication 117, Ann ICRP 40(6).

ICRP 2012 ICRP Statement on Tissue Reactions / Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context. ICRP Publication 118, Ann. ICRP 41(1/2).

ICRP 2013a Radiological Protection in Cardiology, ICRP Publication 120, Ann ICRP 42(1).

ICRP 2013b Radiological Protection in Paediatric Diagnostic and Interventional Radiology ICRP Publication 121, Ann ICRP 42(2).

ICRP 2017 The Use of Effective Dose as a Risk-related Radiological Protection Quantity. Consultation document almost complete.

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

Image Gently 2014 http://www.imagegently.org/Procedures/Digital-Radiography/Quality-Improvement (accessed June 2017)

Imanishi, Y, Fukui, A, Niimi, H, Itoh, D, Nozaki, K, Nakaji, S, Ishizuka, K, Tabata, H, Furuya, Y, Uzura, M, Takahama, H, Hashizume, S, Arima, S and Nakajima, Y. 2005 Radiation-induced temporary hair loss as a radiation damage only occurring in patients who had the combination of MDCT and DSA. European Radiology 15, 41–46.

Johnson P B, Borrego D, Balter S, Johnson K, Siragusa D and Bolch W E 2011 Skin dose mapping for fluoroscopically guided interventions. Med Phys. 38 5490-9.

Kambadakone, A R and Sahani, D V 2009 Body Perfusion CT: Technique, Clinical Applications, and Advances. Radiologic Clinics of North America 47, Pages 161–178.

Khodadadegan, Y, Zhang, M, Pavlicek, W, Paden, R G, Chong, B, Huettl, E A, Schueler, B A, Fetterly, K A, Langer, S G, and Wu, T 2013 Validation and Initial Clinical Use of Automatic Peak Skin Dose Localization with Fluoroscopic and Interventional Procedures. Radiology 266, 246-255.

Koenig TR, Wolff D, Mettler FA, Wagner LK 2001a Skin injuries from fluoroscopically guided procedures. Part 1, Characteristics of radiation injury. Am J Roentgenol 177: 3–11.

Koenig TR, Mettler FA, Wagner LK 2001b Skin injuries from fluoroscopically guided procedures. Part 2, Review of 73 cases and recommendations for minimising dose delivered to the patient. Am J Roentgenol 177 13–20

Kohn, L T, Corrigan, J M and Donaldson, M S. 2000 To Err Is Human: Building a Safer Health System. Institute of Medicine; Committee on Quality of Health Care in America. National Academy Press, Washington, D.C.

Kostova-Lefterova D. 2015 Two cases of radiation induced skin injuries from PCI procedures in Bulgaria, Science Cardiology, 2015, 6, 326-328 (in Bulgarian).

Mahesh M. 2001 Fluoroscopy: Patient Radiation Exposure Issues. RadioGraphics. 21, 1003-1045.

Mahesh M. 2016 What Is the CT Dose Check Standard, and Why Do CT Scanners Need to Be in Compliance? J Am Coll Radiol. 13, 64-66.

Mahesh M 2017 Personal communications.

Martin, C J 2005 A survey of incidents in radiology and nuclear medicine in the West of Scotland. Br. J. Radiol. 78, 913-921.

Martin, C J 2007 Effective dose: How should it be applied to medical exposures. Br. J. Radiol. 80, 639-647.

Martin, C J 2008 Radiation dosimetry for diagnostic medical exposures. Rad. Prot. Dos., 128, 389-412.

Mayo-Smith W W, Hara A K, Mahesh M, Sahani D V and Pavlicek W. 2014 How I Do It: Managing Radiation Dose in CT. Radiology 273 (3): 657-672.

Mettler F A 2017 Personal communication.

Miller DL, Balter S, Noonan PT and Georgia JD. 2002 Minimizing radiation-induced skin injury in interventional radiology procedures. Radiology 225 329 –336.

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

Mooney, R B, McKinstry, C S and Kamel H A. 2000 Absorbed dose and deterministic effects to patients from interventional neuroradiology. Brit. J. Radiol. 73(871), pp. 745–751.

National Council on Radiation Protection and Measurement 2011. Radiation dose management for fluoroscopically guided interventional procedures. NCRP Report No. 168.

National Electrical Manufacturers Association (NEMA) 2013 Standard Attributes on CT Equipment Related to Dose Optimization and Management. XR 29-2013. Available at: https://www.nema.org/Standards/Pages/Standard-Attributes-on-CT-Equipment-Related-to-Dose-Optimization-and-Management.aspx#download. (accessed April 2017).

New York Times 2010 After stroke scans, patients face serious health risks. http://www.nytimes.com/2010/08/01/health/01radiation.html. (accessed April 17, 2016)

New York Times 2011 West Virginia hospital over-radiated brain scan patients, records show. http://www.nytimes.com/2011/03/06/health/06radiation.html?ref=topics. (accessed April 17, 2016)

Rehani MMand Srimahachota S. 2011 Skin injuries in interventional procedures. Radiat Prot Dosim. 147(1-2) 8-12.

Rosenthal LS, Beck TJ, Williams JR, Mahesh M, Herman MG, Dinerman, JL, Calkins H, Lawrence JH. 1997 Acute Radiation Dermatitis following Radiofrequency Catheter Ablation of Atrioventricular Nodal Re-entrant Tachycardia. PACE. 20, 1834-1839.

Royal College of Radiographers 2017 http://www.sor.org/ezines/toptalk/issue-136/free-have-you-paused-and-checked-posters-and-card (accessed March 2017)

Shrimpton PC, Jansen J T M and Harrison J D 2016 Updated estimates of typical effective doses for common C T examinations in the UK following the 2011 national review. Br J Radiol 89: 20150346.

Stecker, M S, Balter, S, Towbin, R B, Miller, D L, Vañó, E, Bartal, G, Angle, J F, Chao, C P, Cohen, A M, Dixon, R G, Gross, K, Hartnell, G G, Schueler, B, Statler, J D, de Baère, T, and Cardella, J F. 2009, Guidelines for patient radiation dose management. J Vasc Interv Radiol. 20, S263–S273.

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

Teeuwisse W M, Geleijns J, Broerse J J, Obermann W R, van Persijn and van Meerten E L. 2001 Patient and staff dose during CT guided biopsy, drainage and coagulation. Br J Radiol 74, 720–726.

Tsalafoutas I A, Tsapaki V, Triantopoulou, C, Gorantonaki A and Papailiou J. 2007 CT-guided interventional procedures without CT fluoroscopy assistance: patient effective dose and absorbed dose considerations. Am J Roentgenol 188, 1479 –1484.

University of Crete 2015 http://embryodose.med.uoc.gr/code/ (accessed July 2017).

UNSCEAR, 2010. Sources of Ionizing Radiation: Volume I. Report to the General Assembly, with Scientific Annexes. United Nations, New York. Available at: http://www.unscear.org/unscear/en/publications/2008_1.html (accessed June 2017).

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

Vano E, Escaned J, Vano-Galvan S, Fernandez JM, and Galvan C 2013 Importance of a patient dosimetry and clinical follow-up program in the detection of radiodermatitis after long percutaneous coronary interventions. Cardiovasc Intervent Radiol.36(2):330-7.

Vliestra, R.E., Wagner, L.K., Koenig, T., and Mettlar, F. 2004. Radiation burns as a severe complication of fluoroscopically guided cardiological interventions. J. Interv. Cardiol. 17, 131–142.

Wall BF, Haylock R, Jansen JTM, Hillier MC, Hart D, Shrimpton PC 2011 Radiation risks from medical x-ray examinations as a function of the age and sex of the patient. Health Protection Agency Report HPA-CRCE-028, 2011. (Chilton, UK: Health Protection Agency).

**Table 1 Examples of incidents of different types resulting from human errors**

| |
|---|
| **1) Error in procedure** |
| *a)* ***Radiology error in procedure*** |
| Wrong patient identified for procedure |
| Wrong limb or wrong side of the body examined |
| Wrong examination performed |
| *b)* ***Error in referral*** |
| Request for wrong patient |
| Inappropriate examination requested and performed |
| Exposure of wrong body part or wrong side of the body requested |
| Repeat exposures from duplicate requests |
| **2) Diagnostic overexposure** |
| AEC chamber not aligned with X-ray tube |
| Digital radiography data deleted in error prior to review of images |
| CT scanner position reset and wrong part of patient scanned |
| CT scan performed without contrast medium when contrast was required |
| **3) Interventional overexposure** |
| Threshold for tissue reactions on the skin exceeded because of poor optimization of the procedure |
| **4) Unintended foetal exposure** |
| Failure to identify pregnant female or unknown early pregnancy |
| Error in equipment set-up resulting in CT scan of pelvis instead of chest of pregnant patient |

**Table 2 Latent (systemic) factors that might contribute to incidents and examples of equipment faults**

| **Procedural failures** |
|---|
| Lack of adequate training of staff or instructions |
| Lack of knowledge of equipment being used and its features and options |
| Poor or inadequate standard operating procedures (mandatory in European union since 1997 (EC1997)) |
| Lack of knowledge about optimization of protection for patient |
| Insufficient supervision of inexperienced staff |
| Flaws in examination protocols or lack of protocols |
| Lack of clarity in responsibilities (e.g. No formal handover of responsibility for equipment safety from radiology personnel to X-ray engineer during maintenance, see section 3.2.1.2) |
| Gaps or ambiguities in functions and lines of authority |
| Staff shortage or high staff turnover and pressure of work |
| Lack of operating documents in a language understandable to users |
| Lack of attention to dose display or display not visible to the operator during interventional procedures |
| Lack of dose alerts when selected factors seem inappropriate |
| Ignoring error messages |
| Misunderstanding of displays or software messages |
| Inconsistent use of different dose quantities and units |
| Inadequate quality control of equipment |
| Inadequate programme for acceptance and commissioning of equipment<br>• Doses and dose rates for interventional equipment set too high<br>• Inappropriate settings for AEC |
| Lack of an equipment maintenance programme |
| Poor reliability due to age of equipment |
| **Equipment faults** |
| Malfunction of AEC in radiographic unit |
| Failure of X-ray exposure timer |
| Digital image data lost before examination reported |
| CT scanner failed part way through examination |
| Software upgrade error affecting protocol and image processing settings |
| Internal parameters set incorrectly following equipment maintenance |

**Table 3 Actions helping to prevent unintended and accidental exposures**

| |
|---|
| **Systems for preventing procedural errors and diagnostic overexposures** |
| Pause and check of critical items on list before commencing procedure (often called "time out") |
| Agreed procedures for investigation and reporting of incidents, and defined responsibilities for taking action to address deficiencies that have contributed to incidents |
| Regular meetings to review incidents, determine causes, share experiences, decide upon changes to be implemented, and disseminate information. |
| Periodic audit and review of procedures and protocols |
| Use of equipment handover form for engineers servicing X-ray equipment |
| **Procedures for reducing risks of deterministic effects from image-guided interventional and CT procedures** |
| Ensuring that all staff are aware of the dose metrics, dose monitoring, and potential doses delivered by the X-ray equipment and the levels at which tissue reactions might occur and training on this is refreshed periodically . |
| Ensuring all staff are trained in use of X-ray equipment they operate, especially techniques for minimizing skin dose and dose saving technology on interventional equipment. |
| Optimization of programme options available on the X-ray equipment during commissioning. |
| Reviewing patient information including estimation of radiation exposure from recent previous procedures to determine potential risk of skin damage prior to commencement of interventional procedures. |
| Monitoring dose parameters during interventional procedures and alerting the operator at agreed level when there could be a risk of skin damage. |
| Use of dose check on CT scanners to confirm $CTDI_{vol}$ equates to a skin dose below 1 Gy. |
| Periodic review of interventional and CT scan protocols and correction of inconsistencies. |
| **Systems to minimize equipment faults and their effects** |
| Comprehensive acceptance testing carried out once equipment has been installed |
| Effective QA programmes (involving radiographers and medical physicists) |
| Adequate maintenance of radiological and associated equipment |
| Equipment replacement programme in place |
| Engagement between manufacturers and users – e.g. add/make effective fail-safe systems and warning messages |
| Recording equipment related issues in fault logbook |
| Use of logbook to record software and protocol changes, with system for checking dose performance after any software upgrades or reloads |
| **Systems for preventing unintended foetal exposures** |
| Notices in waiting area asking female patients to inform staff if they are or could be pregnant |
| Agreed procedure for screening female patients to identify individuals who might be pregnant |
| Confirming date of last menstrual period prior to examination of females of child-bearing age. |

**Table 4 Trigger levels for action relating to high skin doses in interventional procedures (Stecker et al 2009)**

| Dose parameter | ICRU symbol | Alert during procedure | Increment between alerts | Trigger level for potential follow-up |
|---|---|---|---|---|
| Peak skin dose | | 2 Gy | 0.5 Gy | 3 Gy |
| Cumulative air kerma at the intervantional reference pt. | $K_{a,r}$ | 3 Gy | 1 Gy | 5 Gy |
| Kerma area product | $P_{K,A}$ | 300 Gy cm$^2$ | 100 Gy cm$^2$ | 500 Gy cm$^2$ |
| Fluoroscopy time | | 30 min | 15 min | 60 min |

**Table 5 Values of coefficients giving effective dose (E) per unit exposure; KAP for radiography and fluoroscopy (Wall et al 2011) and DLP for CT (Shrimpton et al 2016).**

| Radiology examination | E per KAP (mSv / Gy cm$^2$) | CT examination | E per DLP (mSv / mGy cm) |
|---|---|---|---|
| Head AP/PA | 0.058/0.034 | Head (acute stroke) | 0.0020 |
| Head lateral | 0.037 | Cervical spine | 0.0057 |
| Cervical spine AP | 0.19 | Chest | 0.027 |
| Cervical spine lateral | 0.12 | CTA (abdominal aorta) | 0.014 |
| Chest PA | 0.16 | CTPA (pulmonary embolism) | 0.027 |
| Chest lateral | 0.13 | Abdomen | 0.024 |
| Thoracic spine AP | 0.24 | Abdomen and pelvis | 0.020 |
| Thoracic spine lateral | 0.091 | Virtual colonoscopy | 0.020 |
| Lumbar spine AP | 0.22 | Enteroclysis -Crohn's disease | 0.020 |
| Lumbar spine lateral | 0.092 | Kidney-ureter-bladder | 0.018 |
| Abdomen | 0.18 | Urogram | 0.018 |
| Pelvis | 0.14 | Chest abdomen pelvis | 0.021 |
| Coronary Angiography | 0.16 | Whole body | 0.0093 |

PA – postero-anterior, AP – anteroposterior, CTA - CT angiography, CTPA - CT pulmonary angiography

**Table 6 Terms used for describing health detriment from radiological exposures**

| Effective doses (mSv) | Term to describe risk to patients | Examples of radiological procedures within different dose categories |
|---|---|---|
| < 0.1 | Negligible | Radiographs of chest, shoulder, limbs, and teeth. |
| 0.1–1 | Minimal | Radiographs of spine, abdomen, pelvis and head. |
| 1–10 | Very low | CT scans of the head, barium meals and enemas, cardiac angiography, interventional radiology. |
| 10–100* | Low | CT scans of chest, abdomen and / or pelvis, PET-CT, interventional radiology and cardiology. |
| >100 | Moderate (at the minimum) | Multiple interventional or CT procedures |
| **Foetal dose (mGy)** | **Term to describe risk to foetus** | **Examples of radiological procedures performed on pregnant female within different dose categories** |
| <0.01 | Negligible | Radiographs of chest, limbs, neck, thoracic spine, teeth, and mammography. |
| 0.01-0.1 | Minimal | Pulmonary angiogram. |
| 0.1–1 | Very low | Radiographs of abdomen, pelvis, hip; Barium meals; CT pelvimetry, CT chest. |
| 1–10 | Low | Radiograph of lumbar spine; barium enema; CT scans of lumbar spine or abdomen. |
| 10–100 | Moderate | CT scans of abdomen and/or pelvis |

*Note that routine CT body scans in adults rarely exceed the 20 mSv range

**Table 7 Ratios of embryo or foetal dose over air kerma incident on the skin from radiographic examinations of the abdomen for an X-ray unit with 3 mm Al filtration (mGy/mGy).**

Factors were derived using CODE (Damilakis et al 2002, University of Crete 2015)

| | | 1st trimester | | | 2nd trimester | 3rd trimester |
|---|---|---|---|---|---|---|
| | Embryo depth | 6 cm | 8 cm | 10 cm | | |
| kVp | Projection | | | | | |
| 70 | AP | 0.53 | 0.36 | 0.24 | 0.35 | 0.33 |
| 80 | AP | 0.61 | 0.42 | 0.30 | 0.42 | 0.39 |
| 80 | PA | 0.20 | 0.29 | 0.42 | 0.28 | 0.27 |
| 90 | AP | 0.68 | 0.49 | 0.35 | 0.48 | 0.45 |