Safety Reports Series

No. 59

Establishing Guidance Levels in X Ray Guided Medical Interventional Procedures: A Pilot Study

IAEA
International Atomic Energy Agency

ESTABLISHING GUIDANCE LEVELS IN X RAY GUIDED MEDICAL INTERVENTIONAL PROCEDURES: A PILOT STUDY

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SAFETY REPORTS SERIES No. 59

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2009

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1400 Vienna, Austria
fax: +43 1 2600 29302
tel.: +43 1 2600 22417
email: sales.publications@iaea.org
http://www.iaea.org/books

Printed by the IAEA in Austria
June 2009
STI/PUB/1346

IAEA Library Cataloguing in Publication Data

Establishing guidance levels in X ray guided medical interventional procedures : a pilot study. — Vienna : International Atomic Energy Agency, 2008.
p. ; 24 cm. — (Safety reports series, ISSN 1020–6450 ; no. 59)
STI/PUB/1346
ISBN 978–92–0–107308–2
Includes bibliographical references.

1. Radiation — Safety measures. 2. Diagnosis, Radioscopic — Safety measures. 3. Radiation dosimetry. I. International Atomic Energy Agency. II. Series.

IAEAL 08–00546

FOREWORD

Large differences in exposure for the same medical examinations indicate that there is a large potential for dose reduction. The concept of guidance or reference levels was developed as a tool for optimization of protection in the exposure of patients for common diagnostic purposes. In those countries that have implemented guidance levels, radiologists and radiographers have been provided with a straightforward tool for comparing the radiation doses that they deliver to patients with those delivered by their colleagues. This has produced an increased awareness among professionals of the radiation doses associated with their practices and stimulated corrective action by facilities at the high end of the dose distribution. In countries where successive surveys have been performed, significant reductions in patient radiation doses have been observed. Guidance levels are therefore well established and uncontroversial for common, simple and standardized procedures, and are even required by international safety standards.

However, the application of guidance levels in interventional radiology and interventional cardiology has remained the subject of scientific debate. To answer the question "Can the concept of diagnostic guidance (or reference) levels be extended to the development of appropriate interventional guidance levels?", research in the form of a pilot study was deemed necessary, in order to obtain scientific information and practical experience. The results of the pilot project are given in this report

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CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [1] require that medical practitioners who prescribe or conduct diagnostic radiological examinations "ensure that the exposure of patients be the minimum necessary to achieve the required diagnostic objective, taking into account norms of acceptable image quality established by appropriate professional bodies and relevant guidance levels for medical exposure;…". The BSS further establishes that "Corrective actions be taken as necessary if doses… fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;…" and "reviews be considered if doses or activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice;…".

Guidance levels are therefore required in the BSS as an important tool for optimization. They are an indication of "what is achievable with current good practice…", but are "to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement;…". Concerning the sources of guidance levels, the BSS establishes that they should be "derived from… wide scale quality surveys which include entrance surface doses and cross-sectional dimensions of the beams delivered by individual facilities… for the most frequent examinations in diagnostic radiology…".

The ICRP [2, 3] and the European Union in its Medical Exposure Directive [4] use the term 'diagnostic reference levels' for the same concept. Both of these organizations also recognize that guidance or reference levels should be established by the appropriate professional bodies involved in medical imaging, should be specific to a country or region, and should be reviewed at intervals that represent a compromise between the need for stability and long term changes in observed patient dose distributions.

The United States Nationwide Evaluation of X-ray Trends (NEXT) programme has periodically sampled patient doses from common diagnostic procedures since 1963. The surveys were periodically repeated to track trends as technology and clinical practices change. Surveys have been conducted on examinations related to adult chest radiography, abdominal radiography, lumbosacral spine radiography, upper gastrointestinal fluoroscopy, mammography, computed tomography (CT) of the head, dental radiography and paediatric chest radiography. This programme was originally administered

by the Federal Bureau of Radiological Health (now the Center for Devices and Radiological Health (CDRH)), and is now a project of the Conference of Radiation Control Program Directors (CRCPD). Information and data are available at www.crcpd.org/free_docs.asp.

In those countries that have implemented guidance levels, radiologists and radiographers have been provided with a straightforward tool for comparing the radiation doses that they deliver to patients with those delivered by their colleagues. This has created awareness among professionals of the radiation doses associated with their practices and stimulated corrective action by facilities at the high end of the dose distribution. Where successive surveys of patient doses have been performed, significant reductions in patient doses have been observed [5]. The use of diagnostic reference levels in the United Kingdom and appropriate optimization resulted in a 50% reduction in average patient radiation doses from their first publication in the mid-1980s until 2000 [5].

Image quality may decrease as dose decreases. Thus, overzealous reduction in radiation exposure may result in clinically unusable images. Any actions taken to reduce patient exposure based on the application of guidance levels should never result in a loss of confidence in the outcome of the procedure. This can be avoided by verifying that image information is clinically acceptable whenever an exercise on establishing or using a guidance level is carried out.

1.1.1. Possible extension of diagnostic guidance levels to interventional guidance levels for X ray guided interventional procedures

The question to be asked is whether the concept of diagnostic guidance (reference) levels (DRLs) can be extended to the development of appropriate interventional guidance reference levels. Initial information relevant to this question has been supplied by the ICRP [3].

> "Note on Fluoroscopically-guided Interventional Procedures WEB MODULE 3
>
> (19) For fluoroscopically-guided interventional procedures, diagnostic reference levels, in principle, could be used to promote the management of patient doses with regard to avoiding unnecessary stochastic radiation risks. However, the observed distribution of patient doses is very wide, even for a specified protocol, because the duration and complexity of the fluoroscopic exposure for each conduct of a procedure is strongly dependent on the individual clinical circumstances. A potential approach is to take into consideration not only the usual clinical and technical factors, but also the relative "complexity" of the procedure. More than

one quantity (i.e. multiple diagnostic reference levels) may be needed to evaluate patient dose and stochastic risk adequately.

(20) Diagnostic reference levels are not applicable to the management of deterministic radiation risks (i.e., radiation-induced skin injuries) from fluoroscopically-guided interventional procedures. In this case, the objective is to avoid, [where clinically appropriate[1]], deterministic effects in individual patients undergoing justified, but long and complex procedures. The need here is to monitor in real time whether the threshold doses for deterministic effects are being approached or [have been] exceeded for the actual procedure as conducted on a particular patient. The relevant risk quantity is absorbed dose in the skin at the site of maximum cumulative skin dose. A helpful approach is to select values for maximum cumulative absorbed dose in the skin at which various clinical actions regarding the patient's record or care (related to potential radiation-induced skin injuries) are taken (ICRP, 2000). Then, during actual procedures, appropriate quantities that can help indicate the maximum cumulative absorbed dose in the skin is monitored."

1.1.2. Major factors that influence the patient radiation dose delivered during an interventional procedure

1.1.2.1. Equipment and equipment configuration

Equipment parameters are amenable to optimization of protection in interventional procedures using techniques similar to those used to optimize diagnostic examinations. Dose rates are determined for each of the clinical modes of operation over a range of phantom thicknesses. The evaluation range extends from those typical of the smallest patients examined or treated with the equipment to those of the maximum patient thickness and highest deliverable

[1] In very rare circumstances, physicians may need to exceed the thresholds for deterministic effects when this is in the patient's best interest. Surgical alternatives have their own risks, including the certainty of skin injuries (from the incision). However, experience has shown that the frequency and severity of most major radiation injuries could have been reduced with proper optimization of protection without losing any of the benefits of the procedure.

dose rate[2]. Imaging performance of the system needs to be validated at the same time and over the same working range to support the choice of a desired level of image information at an acceptable dose rate. Measured dose rate values and other data need to be compared with published values. Available guidance levels and protocols for performance testing provide well known procedures for these evaluations.

1.1.2.2. Physician training and experience

Operators performing procedures for which they have limited clinical experience will consume more resources and deliver higher radiation doses than may be needed by a more experienced operator. Adequate training, credentialling and backup policies provide well known methods for managing issues of training and experience.

In addition to medical competence, there are requirements for specific technical knowledge of radiation biology, imaging physics and equipment functionality. The medical education system, licensing authorities, professional society statements and credentials mandated by regulatory authorities provide a pathway towards providing and documenting this competence.

In this regard, the BSS establish the following requirements:

> "Medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure"; "medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training adequately to discharge assigned tasks…" and that "for diagnostic uses of radiation the imaging and quality assurance requirements of the Standards be fulfilled with the advice of a qualified expert in … radiodiagnostic physics …". It further requires that "training criteria [in radiation protection] be specified or be subject to approval, as appropriate, by the Regulatory Authority in consultation with relevant professional bodies".

[2] Recent publications, notably the IAEA Code of Practice on Dosimetry in Diagnostic Radiology (Technical Reports Series No. 457), point out the experimental difficulty in determining the absorbed dose to air, especially in the vicinity of an interface, and that, in reality, the instrument calibration is done in terms of air kerma. Thus, these publications, when referring to air, recommend the use of air kerma rather than absorbed dose to air.

1.1.2.3. Patient size and disease

Patients do not come in a uniform height or weight; rather, patients vary from one to another in all aspects. Factors entering the decision to treat using angioplasty include the patient's size, lesion location, anticipated complexity of the intervention, radiation history and co-morbidity. All of these factors influence the amount of radiation needed to complete the procedure.

The radiation output of an X ray system is driven by the beam's path length in tissue. Path lengths are influenced by patient size and beam projection angles. Clinically necessary beam orientations (complex angulations) can result in tissue path lengths exceeding 30 cm, even for a small patient. Beam angles are selected to provide an appropriate view of the lesion under treatment. Operators are taught to vary beam angles where clinically feasible so as to avoid exposing the same area of the skin all of the time. However, in some circumstances, most of the treatment can only be controlled at one beam angle. Operators are expected to exercise additional dose vigilance of patient exposure under these circumstances.

The complexity of a treatment is affected by the number of vessels requiring treatment, the tortuosity of the vessel, the presence of calcium in or near the lesion and other factors. The treatment of a complex lesion usually requires more resources and more patient radiation exposure than the treatment of a simple lesion.

1.1.3. Other radiation exposure considerations

All procedures need to be justified in terms of a risk–benefit assessment prior to starting. A procedure is justified when its expected benefits exceed the anticipated risks of the procedure. This justification includes consideration of the risks of alternative therapies or of simply doing nothing. Significant amounts of radiation are required for some patients, which may have been anticipated prior to the procedure or may be a consequence of unexpected clinical factors. Documentation of radiation usage, a discussion with the patient and specific follow-up on possible radiation effects are appropriate in such cases.

Deviations from the anticipated procedure are commonly due to anatomical and pathological complexity and the need to manage emergent events. The operator needs to be sufficiently aware of radiation usage to use this information as part of an ongoing risk–benefit assessment.

The patient consent process includes appropriate consent for the anticipated radiation risk, if use of substantial amounts of radiation is a possibility.

1.1.4. Potential benefits of extending guidance levels to interventional procedures

The annual number of fluoroscopically guided interventional procedures has grown by about an order of magnitude in the past decade. This has been facilitated by increased clinical skills of the operators, the availability of new medical devices (e.g. stents) and the development of purpose designed interventional fluoroscopic systems. Thus many procedures that previously would have required open surgery or that would not have been possible can be performed using interventional techniques. In recent years, drug eluting stents (DES) have brought a substantial improvement in both immediate and long term results, which become similar to those obtained with surgery. In addition, hospital stay time is also reduced. Consequently, both patients and hospitals seek increasing access to these less invasive procedures. This increase has been observed in both developing and developed countries.

This growth poses a number of radiation protection problems. It is vital that public confidence in these techniques is not undermined by the adverse consequences of high radiation exposures. Some interventional fluoroscopy procedures are very complex and involve extended fluoroscopy times or sometimes require the operation of fluoroscopy equipment in a high dose rate mode. Procedures are repeated on the same patient due to the need for staged interventions or disease recurrence. New clinical indications for interventional cardiology lead to increasingly complex procedures, which require imaging with even more radiation. The range of patient radiation exposures reflects in part variations in the complexity of these procedures, the use of a variety of clinical protocols, or the use of poorly adjusted or inappropriate equipment.

Deterministic radiation injuries following angioplasty have been reported since the early 1990s. Figure 1 [6] shows an example, in which the patient underwent two long coronary angioplasty procedures in a 24 h period; square or rectangular areas of skin injury appearing days to weeks after a procedure are typical (Fig. 1(a)). In this case, necrotic tissue remained below the apparently healed skin (Fig. 1(b)). The tissue eventually broke down and required grafting (Fig. 1(c)).

As stated in Section 1.1, guidance (reference) levels are a tool to optimize protection of patients in radiology. They are intended to apply to common, high volume procedures, and were introduced as an evolving value that would act to continually optimize the radiation protection of patients. For state of the art equipment, technological improvements have reduced dose rates by a factor of approximately two in the past decade. However, there is little evidence to indicate that total exposure levels are on the decrease in interventional radiology or interventional cardiology. Rather, exposure levels are increasing,

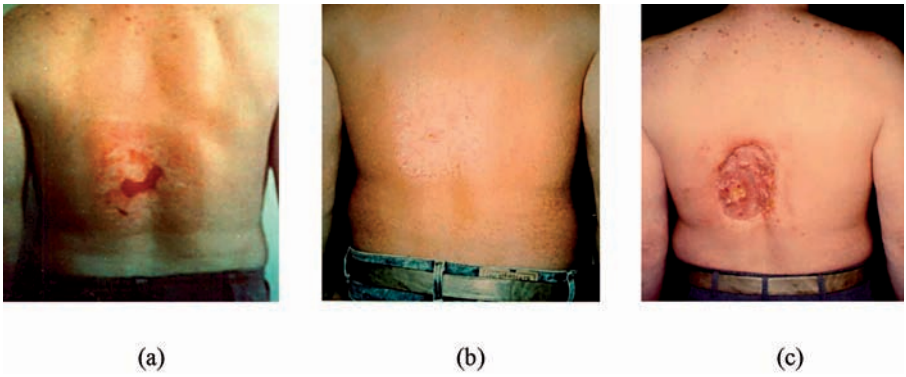

FIG. 1. Time course of a deterministic radiation injury following high dose coronary angioplasty. (a) Two months post-procedure; (b) four to five months post-procedure; (c) 18–21 months post-procedure. Source: US Food and Drug Administration (FDA), Center for Devices and Radiological Health.

due to the increased complexity of fluoroscopically guided procedures. Owing to the substantial influence of complexity on radiation exposure, the application of guidance levels in this area needs to be accompanied by a consideration of methods of comparing the complexity of procedures. This influence was also explored in the pilot study.

Patient radiation exposure surveys results can be compared to identify centres that have average patient exposures higher than expected (e.g. in the upper quartile of a patient dose distribution) and then determine the underlying cause of these high exposures. These high exposures could be due to suboptimal equipment, inappropriate use of equipment or unavoidable patient related factors. Concentrating exposure reduction efforts on the upper quartile of the patient dose distribution is an efficient method for optimizing protection.

Guidance levels can be applied to practices both between and within hospitals. They may be used to identify practices in a hospital in which patient exposures are higher than the norm and hence where there is the greatest potential for dose reduction. Within a hospital, patient exposures may be monitored and guidance levels developed for specific interventions. This approach may be used to identify rooms where high exposure procedures are mostly performed. Optimization studies would then be concentrated on details regarding fluoroscopic equipment and practice (e.g. too high a fluoroscopic frame rate). This pilot project has produced an adaptable optimization tool, which can be applied to practices among a wide range of centres and within hospitals.

Results of patient exposure surveys in interventional radiology and interventional cardiology, in common with general radiology, also exhibit a wide range of exposures for what is nominally the same procedure. In interventional radiology and interventional cardiology this is in part due to the variation in the complexity of the procedure. However, even when allowance is made for differences in complexity, a wide range of exposure levels exist, thus indicating that protection in these procedures may not be optimized. The extension of the concept of guidance levels to these procedures is therefore logical. Since the contribution to population exposure for this group of procedures is so large, the potential impact of the use of guidance levels in this area is also large.

In summary, guidance (reference) levels for standard diagnostic procedures are well established and uncontroversial. However, their application in interventional radiology and interventional cardiology remains the subject of scientific debate. These procedures can be diagnostic, therapeutic or a combination of both. Individual procedures can have a wide range of complexity, accompanied by a wide range of exposure levels. There are also philosophical and ethical questions relating to the establishment and application of guidance levels to therapeutic procedures. It is both dangerous and unethical to curtail an uncompleted procedure, midway through it, on the basis of radiation exposure. It is therefore important to properly understand the concept of guidance levels as required by the BSS; that is, guidance levels are "to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement". In any case, guidance levels can help to detect and improve non-optimized protection in the procedures.

To find out whether guidance levels can be derived from and applied to interventional procedures, a pilot study was organized, in order to obtain scientific information and practical experience to enable these questions to be answered. The pilot study focused on two common invasive, fluoroscopically guided cardiac procedures in different countries: diagnostic coronary angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA). These were initially selected because they are among the most commonly performed fluoroscopically guided vascular procedures in all countries. In addition, the basic clinical and technical procedures are also relatively standardized around the world. These are clinically important procedures, because a high fraction of all reported fluoroscopically induced deterministic injuries are attributable to PTCA. As the study progressed, procedure data collection was confounded by a variable decline in pure PTCA procedures (balloon angioplasty without any other form of intervention or diagnostic component.) Therefore, the data will be also analysed in terms of CA (the pure diagnostic procedure) and percutaneous cardiovascular intervention (PCI). For the purposes of this study, PCI includes all forms of

coronary artery interventions and may also include a partial or complete diagnostic study.

1.2. SCOPE

This report contains a description of the methods and results of a pilot study in which patient exposure and image quality in the most common interventional cardiac procedures using X rays was surveyed, as well as an evaluation of the results, recommendations and proposals for further research.

1.3. OBJECTIVE

The purpose of this report is to disseminate the information gathered during the research and to provide answers to the scientific debate as to whether guidance levels can be derived from and applied to complex X ray procedures such as interventional procedures using X rays.

1.4. STRUCTURE

A bibliography review is presented in Section 2, followed in Section 3 by a description of the methodology used in the pilot study, including the participating hospitals and countries, the X ray systems, the procedures, the characterization of X ray equipment, the image quality criteria and the influence of procedure complexity. Section 4 deals with results and discussions, and Sections 5–7 contain conclusions, topics for future research and recommendations. The ten appendices contain more detailed information on the methods, and discussions of the results and annotated references with abstracts of publications related to the topic. The annexes contain the relevant BSS requirements and other related scientific information.

2. REVIEW OF THE LITERATURE

Radiation injuries to both patients and operators caused by fluoroscopy were reported within months of Roentgen's discovery of X rays. Even though

the physical and biological root causes were poorly understood, pragmatic and effective protective measures were soon introduced.

Radiation injuries associated with diagnostic procedures seldom occurred between the 1920s and the 1980s, since radiation doses were not high enough to exceed the threshold for deterministic effects. Those few that did occur were usually traced to defective or malfunctioning equipment. Thus the focus of radiation protection was directed towards minimizing the risk of cancer induction while obtaining the necessary clinical information.

Radiotherapy skin reactions caused by low energy beams, which deliver their maximum absorbed dose at the skin, persisted and still occur. Delivering an adequate tumour dose, even with multiple beam treatment plans, often resulted in deterministic skin effects. When a cure was possible, it was not uncommon to treat the patient to 'skin tolerance'. This meant that the treatments would continue until either the entire prescription was fulfilled or the skin damage (typically wet erythema) was so severe that the patient refused further treatment.

Modern fluoroscopically guided diagnostic procedures such as CA are clinically justified, and protection needs to be optimized to minimize stochastic radiation risks as well as other types of risks associated with the procedures. Guidance levels could, in principle, be developed and applied whenever these procedures are sufficiently standardized.

Fluoroscopically guided interventional procedures are therapeutic procedures performed with the aid of diagnostic imaging. Unlike the majority of diagnostic procedures, interventional fluoroscopically guided procedures may require absorbed radiation doses to the skin high enough to produce deterministic effects. Another distinct difference is that there is no unique end point. Procedures continue until the clinical task is complete or is abandoned as impractical. Clinical complications arising during the intervention require further work on the patient, and therefore more radiation, for their resolution.

Fluoroscopically guided interventions became common in the late 1980s with the introduction of balloon angioplasty by Grunzig. The clinical successes of this technique lead to secondary treatments such as stenting. Associated radiation skin injuries were reported in the early 1990s. The American College of Radiology and the FDA organized a workshop on interventional fluoroscopy in 1992 [7]. Since then, the literature has contained a steady flow of case reports and technologies for dose management [6–46].

The quantities and units and their notations for dosimetry in X rays used in medical imaging have been recently revised by the International Commission on Radiological Units (ICRU) [47] and the IAEA [48]. This report uses the new notation found in these two reports, except in quotations or

excerpts from other papers in the appendices to this publication, where the original notation has been retained.

3. METHODS AND MATERIALS

3.1. PILOT PROJECT

A wide variety of fluoroscopically guided procedures are performed, using a wide variety of equipment and clinical techniques, in different institutions and in different countries. A comprehensive survey of the entire field is time and resource consuming, and therefore a pilot study with the aim of preparing the way to more comprehensive surveys was initiated. Guidance levels were originally established for standardized high volume examinations (e.g. chest radiography). The most frequent interventional procedures in most countries include those performed on coronary arteries. Therefore, two representative procedures were selected: CA, a diagnostic procedure, and PCI, a therapeutic procedure. The pilot project explored the topic by examining a limited number of hospitals. The results include evaluation of the process itself and identification of the difficulties encountered in performing such a study. The lessons learned from this process could be applied to wider scale activities.

3.2. SELECTION OF SITES AND HOSPITALS

The selection of sites was centred on research teams that had previously investigated guidance levels for interventional procedures (Spain and Italy) and two additional teams from countries in which no research had been done on the subject (Chile and Uruguay). Other countries (Austria, the UK and the USA) provided support in the evaluation of the results. The teams from Chile, Italy, Spain and Uruguay selected one or more hospitals for clinical investigation. Data from one major US hospital were added to the pool in 2005.

Knowledge of the X ray systems and the level of training of the involved staff are quite different among the participating centres. Some of the centres are involved in the training of a significant number of fellows, which has a direct effect on some dosimetric parameters such as fluoroscopy time (FT) (typically higher in these centres). The presence of a dedicated physicist for the catheterization laboratories also had an important influence on the dosimetric

parameters of the X ray systems and in the optimization of protection in the procedures. In some of the selected centres, the physicists conducted seminars and other training activities contributing to physician awareness in the use of radiation, and there was a statistically significant reduction in patient exposure after these dedicated training activities. Another important training consideration is the existence of a national or local requirement for interventional cardiologists to be accredited in radiological protection; this requirement is mandatory in Italy and Spain.

3.2.1. Chile

The Cardiac Laboratory of the Hospital Clínico (Chile University) has one interventional cardiology room. The staff of this facility consist of five senior cardiologists, two nurses, two medical technicians and five auxiliary technical assistants. Each year, 1300 diagnostic coronary arteriograms and 350 PTCAs (96% with stent) are performed. Some percutaneous valvuloplasty is also performed for mitral stenosis and pulmonary artery stenosis. Other interventional procedures are also performed in this laboratory, such as treatment of subclavian artery stenosis, and disease in the iliac arteries, renal arteries, abdominal aorta and peripheral arteries.

3.2.2. Italy

Santa Maria della Misericordia hospital in Italy is a 900 bed regional and teaching hospital for a population of 500 000 inhabitants. The cardiology and cardiac surgery departments perform general cardiology, general cardiac surgery and heart transplantation. Interventional cardiac procedures (haemodynamic and electrophysiology) are performed in two interventional rooms by five experienced interventional cardiologists plus, on average, two cardiologists in training.

3.2.3. Spain

Two Spanish centres were involved in the patient exposure survey. One is a large university hospital (San Carlos) with 1000 beds serving a population of approximately 550 000 people. The cardiovascular institute of this hospital, which performs approximately 4500 procedures per year, has four catheterization rooms (one dedicated to electrophysiology procedures), ten senior staff cardiologists and 12 fellows. The staff also use a new catheterization room in another public hospital in Madrid (Severo Ochoa Hospital). The other centre is a private hospital (Clínica Ruber) with a single catheterization

laboratory (used also for general angiography and vascular and visceral interventional procedures) used by several cardiologists that performs 200–300 procedures per year, with 30% of these being therapeutic procedures.

3.2.4. United States of America

The adult interventional cardiology laboratory of Columbia University Medical Center in New York was added to the study in 2005. This facility has six major interventional rooms. Staffing is approximately 20 senior staff cardiologists and eight fellows. It provides services for the hospital's own local patient population as well as serving as a major regional and national referral centre. The laboratory performs approximately 6000 coronary artery procedures per year (50% therapeutic).

3.2.5. Uruguay

Two hospitals in Uruguay were involved in the survey. Hospital de Clínicas Dr. Manuel Quintela is a university hospital with 500 beds. Two staff cardiologists and seven fellows use the single existing catheterization laboratory. At present, they perform 230 procedures per year, approximately 50% of which are therapeutic. The other institution is a private hospital, Instituto de Cardiología Infantil, Hospital Italiano de Montevideo, with one catheterization laboratory. Two senior cardiologists and one fellow perform approximately 450 procedures per year, of which 50% are therapeutic procedures.

3.3. X RAY SYSTEMS INVESTIGATED

Tables 1 and 2 show the X ray systems investigated in the pilot project.

3.4. PROCEDURES SELECTED

Three procedures were selected for this pilot study: diagnostic CA, PTCA and combined CA + PTCA procedures. However, based on a review of the collected data, the results of this project are reported in two classes: CA and PCI. This latter category includes all interventional procedures with or without a diagnostic component. These are the most prevalent categories of fluoroscopically guided invasive procedures around the world. Their estimated current worldwide frequencies are each of the order of a few million

TABLE 1. X RAY SYSTEMS USED FOR PATIENT RADIATION EXPOSURE STUDIES

Facility ID[a]	System ID	Manufacturer	Model	Imaging technology	Copper filters	Typical cine frame rate (fps)[b]	Installation year	Country
1 ICI	PIA10	Picker	CV-PRO	Image intensifier	No	12.5	1997	Uruguay
2 HDC	PH309	Philips	Integris 3000	Image intensifier	No	25	1995	Uruguay
3	SIA08	Siemens	Axiom Artis	Image intensifier	Yes	15	2001	Chile
4	PH306	Philips	Integris 3000	Image intensifier	Yes	12.5	1994	Italy
4	GEF07	GE	Innova 2000	Flat panel detector	Yes	12.5	2002	Italy
5	PHF04	Philips	Allura	Flat panel detector	Yes	12.5	2003	Spain
6	GEA05	GE	Advantx	Image intensifier	No	25	1994	Spain
6	PH301	Philips	Integris 3000	Image intensifier	Yes	12.5	1994	Spain
6	PH502	Philips	Integris 5000	Image intensifier	Yes	12.5	2000	Spain
6	PH503	Philips	Integris 5000	Image intensifier	Yes	12.5	2000	Spain
7	GEF11	GE	Innova 2000	Flat panel detector	Yes	15	2001	USA
7	SIAL12	Siemens	Axiom Artis	40 cm Image Intensifier	Yes	15	2001	USA
7	PHF13	Philips	Allura	Flat panel detector	Yes	15	2005	USA
7	SIA14	Siemens	Axiom Artis	Image intensifier	Yes	15	2001	USA
7	SIF15	Siemens	Axiom Artis	Flat panel detector	Yes	15	2005	USA
7	SIF16	Siemens	Axiom Artis	Flat panel detector	Yes	15	2005	USA

[a] ID: identification.
[b] fps: frames/s.

TABLE 2. OTHER X RAY SYSTEMS EVALUATED

Facility ID[a]	System ID	Manu-facturer	Model	Imaging technology	Copper filters	Typical cine frame rate (fps)	Installa-tion year	Country
11	SIF11	Siemens	Axiom Artis	Flat panel detector	Yes	15	2002	Luxembourg
12	SIF12	Siemens	Axiom Artis	Flat panel detector	Yes	15	2004	Spain

[a] ID: identification.

procedures per year. Other fluoro guided invasive diagnostic and interventional procedures are performed at lower frequencies. For comparison, chest radiography is estimated to be of the order of a few hundred million examinations per year.

The diagnostic coronary angiogram is relatively standardized in uncomplicated patients. It usually includes several cinefluorographic views of the right and left coronary artery systems and one or two views of the left ventricle. Fluoroscopy is used to place the catheters and to monitor the procedure. There are regional, institutional and individual variations on the definition of what views comprise a standard study. Additional views are often required if the standard study provides insufficient information to reach a clinical decision. Diagnostic studies of patients with coronary artery bypass grafts are often more complicated than standard studies. Thus there is a range of variability in the images collected during the performance of this procedure.

PCI procedures are highly tailored to the clinical condition of the individual patient. Within this category one finds procedures ranging from the simple treatment of a single discrete lesion to a complete endovascular reconstruction of the entire coronary artery system. The range is too large to be encompassed within a single ‘standard’ category. Patient and procedural complexity scores were expected to permit scaling of PCI guidance levels in a logical manner.

An increasing fraction of patients are referred for CA with possible PTCA in the same session. This referral is based on the patient’s medical history and prior non-invasive studies (e.g. treadmill, nuclear medicine, CT). If the diagnostic angiogram is positive, the PTCA is usually performed immediately. Such combined procedures require more exposure than a simple diagnostic study or a separate simple PTCA, but usually require less radiation than that needed to perform two independent simple procedures.

An interesting pattern was observed at two major referral centres. Patients scheduled for PTCA only tended to need relatively complex procedures. These patients typically were either referred after the diagnostic CA procedure was done in an outside laboratory, or represent continuing stages of a very complex procedure. The effects of this pattern are discussed below.

Further information can be found in Appendix I.

3.5. CALIBRATION AND COMPARISON OF PRODUCT KERMA–AREA (P_{KA}) METERS

The quantity for guidance levels in the procedures under investigation here will be the air kerma–area product of the X rays of the beam entering the patient after attenuation and scattering by the patient's couch and mattress.

Since these conditions depend on each radiological unit, calibration of the P_{KA} (KAP) meter needed to be done in situ for each unit. Calibrations were made against reference ionization chambers (mainly RADCAL and PTW) with low energy dependence or with energy correction factors supplied by the manufacturer or calibration laboratory for some radiation qualities.

In addition, as a centralized quality control of the whole process followed in every facility, a comparison using thermoluminescent dosimeters (TLDs) was performed. Reference chamber and TLDs were then irradiated in a common exposure and all TLDs were read with the same TLD reader and protocol. To take care of the energy dependence of the TLDs, individual calibrations were made according to the radiation qualities used with each unit. All measurements were made for typical radiation qualities used in the procedures. The procedure used for this project is documented in Appendix VI. A calibration protocol, which may be used to set up a monitoring programme, is also found in the same appendix.

3.6. FILM DOSIMETRY FOR SKIN DOSE MEASUREMENTS

Additionally to P_{KA} measurements, films were used on a sample of patients submitted to cardiac procedures to determine the skin absorbed dose distribution. Film has the advantage that the readout is directly related to the radiation that enters locally on the skin, includes backscatter and is practically independent of the beam projection angle.

Radiochromic film was selected as a dosimeter because it can be handled in normal lighting conditions, is self-developing and responds nearly

immediately to exposure to radiation. It is used to measure absorbed dose and to map radiation fields produced by X ray beams. As such, radiochromic film has the advantage of locally specific dose monitoring without error resulting from beam reorientation or backscatter. It can be examined during a procedure by removing it from under the patient, if there is a need to obtain an estimate of skin dose. Exposure to ionizing radiation causes radiochromic film to change colour and darken. The degree of darkening is proportional to the incident air kerma and can be quantitatively measured with a reflectance densitometer. This film gradually darkens with time, and darkening is usually maximized within 24 h. However, the amount of additional darkening within the period immediately following the initial exposure is not large. This phenomenon does not interfere with the ability to use radiochromic film for skin dose guidance during a procedure, as long as it is understood and taken into account.

The film is positioned on the patient table under the patient's back, in a position to intercept all the X ray beams entering the patient with posteroanterior (PA) and oblique projections. The contribution of lateral projections will be lost, but this projection is rarely used in cardiac procedures.

When used in this manner, film darkening includes backscatter. Beam orientation and field non-uniformities are recorded. The only correction factor necessary is the conversion from entrance surface air kerma (K_e) to absorbed dose in the skin. As an approximation, multiplying the recorded entrance surface air kerma (K_e) by 1.06 renders the estimated absorbed skin dose.

3.7. ROLE OF CHARACTERIZATION OF EQUIPMENT AND CONSTANCY TESTS

3.7.1. Rationale

The variability of patient exposure and clinical image quality is due to a combination of performance of the imaging equipment, its use including the selection of its modes of operation, and the complexity of the procedure. Knowledge of equipment performance under test conditions for different modes of operation is therefore crucial. This process includes the performance of acceptance tests and commissioning on new equipment to verify radiation doses under various operational modes and image parameters. The process continues with periodic constancy checks intended to confirm continued compliance with the initial performance. Service actions are required if equipment performance deviates significantly. This process helps interventionalists to perform their procedures with clinically acceptable images obtained at appropriately low dose rates. Thus comprehensive characterization

of the X ray system during commissioning and after major changes is indispensable. If, in some installations, this task has never been performed, this is the first step to take in an optimization process.

3.7.2. Description

In the context of this report, the characterization of the system is obtained by measurements obtained over a range of polymethylmethacrylat (PMMA) thicknesses (PMMA is used to simulate tissue). The ranges used are from 4 to 20 cm for paediatric applications and from 6 to 28 cm for adult studies. The key dosimetric parameter is phantom (or patient) entrance surface air kerma (K_e); related image quality parameters are high contrast detectability, spatial resolution and low contrast detectability.

The initial characterization of a fluoroscopic system requires a qualified physicist to spend between four and eight hours on direct measurements as well as the substantial amount of time needed to evaluate the results.

The characterization of a system includes full documentation of its major hardware components (e.g. X ray tube, generator and image receptor). The performance of a modern system is as much a function of its overall software version and of its operational programming as it is of its hardware. Systems often have operational settings that have been customized to meet the requirements of different procedures, institutions and individual operators. The configuration files describing the exact status of this software should also be documented.

The appropriate use of specialized programming should be verified. Examples of questionable use are the application of adult studies to small children or the routine use of special high image quality (with associated high dose) modes.

Automatic dose rate control systems are designed to image tissue and materials such as stents and iodinated contrast media in specific clinical contexts. The use of physical test objects such as copper attenuators and resolution plates influences different systems in different ways. Air kerma rates are best measured by placing only the air kerma meter and an appropriate thickness of PMMA in the beam. It can be useful to observe the influence of a test object by repeating the measurement with the relevant test object in the beam.

System characterization should include calibration of all available dosimetric displays (e.g. IEC cumulative dose $(CD)^3$, P_{KA}) and the accuracy of operational displays (e.g. kV, mA).

In the case of interventional procedures, beam collimation systems are complex mechanical systems also managed by software. Manufacturers

frequently overframe the imaging chain. Checks should include determination of the actual image field size at the image receptor (overframed systems will have a measured field size smaller than the nominal receptor size). Collimation is expected to change to conform with changes in the active field of view (FOV) of the image receptor as well as with the source–image distance (SID).

The objective of a consistency check is to detect significant changes in patient exposure or image quality factors using a relatively short experimental time (1–2 h) with materials easily transported from one laboratory to another (for the purpose of this report, 2 mm and 4 mm of copper). The first constancy check is performed as part of the commissioning process. Baseline constancy check values are therefore determined when the system is known to be in an acceptable state as determined by the more extensive acceptance test process.

3.7.3. Results to be obtained

The detailed characterization protocol is described in Appendix V. In brief, this protocol uses patient size thicknesses of PMMA with test objects placed at the isocentre and the image receptor placed at 5 cm from the exit surface of the PMMA.

The following information is expected:

(a) Phantom (patient) entrance surface air kerma rates ($\dot{K}_e$) and air kerma per frame for different fluoroscopic and image acquisition modes as a function of PMMA thickness (16–28 cm in steps of 4 cm) and image receptor FOV.
(b) The associated added filter for each measurement. These may be fixed for a given imaging mode or vary with patient size. In the latter case, small changes in phantom (patient) thickness may drive changes in filter thickness, with a resulting major change in air kerma rate.
(c) Image quality parameters for these combinations of imaging mode, PMMA thickness and FOV.
(d) A description of the output of the X ray tube as a function of operating mode (fluoroscopy, cine, fluorography) and patient thickness. These data may be used to estimate the patient entrance surface air kerma (K_e). Systems with automatic filter settings exhibit output step functions when the filters change; however, using a simple air kerma table for such

[3] As indicated in footnote 2, the calibration is done in terms of air kerma. Consequently, quantities such as cumulative dose, when referred to air, are expected to be replaced in future by cumulative air kerma.

systems can be problematic. Fortunately, systems with automatic filter settings usually comply with IEC 60601-2-43 and include a measurement of the cumulative air kerma at the interventional reference point (IRP).

Image quality can be subjectively or objectively evaluated. Subjective evaluation requires an observer to report on the number of visible high contrast resolution groups and low contrast targets. Repeated subjective evaluations of the same image are subject to inter- and intra-observer variability. Objective (numerical) evaluation can be performed if appropriate DICOM (Digital Imaging and Communications in Medicine) images are available. Typical evaluations could include modulation transfer function (MTF), noise, contrast and signal to noise ratio (SNR). At present, numerical evaluations are more time consuming than subjective evaluations. Repeated numerical evaluations of the same image are very consistent.

Numerical evaluation of different parts of an image or of different images in a series introduces additional uncertainty. Inhomogeneities in an image (particularly one produced using an image intensifier) can be significant.

The irradiation time used to produce a single image (pulse width) is of considerable importance when clinically important structures are moving; for example, the right coronary artery can reach velocities of 200 mm/s during systole. The accurate measurement of X ray pulse width requires the use of instruments that may not always be available in a hospital. Approximate values are typically indicated by the X ray systems themselves. Preferable short pulse widths often result in an increase in kV. However, contrast may be reduced to an unacceptable level if the kV increase is too large; thus there is a need to balance pulse width and image contrast.

Constancy checks should be performed at least one to two times per year, and should allow the investigator to determine:

(a) Phantom (patient) $\dot{K}_e$ and air kerma per frame for different fluoroscopic and image acquisition modes and image receptor FOV for 2 mm and 4 mm of copper;
(b) Image quality parameters associated with these settings;
(c) Verification of proper collimator performance as a function of FOV and SID;
(d) Calibration of the displays of air kerma K and/or P_{KA}.

3.7.4. Use and importance of the results

The quantitative characterization of the radiological system provides interventionalists with information on how their system performs as a function

of mode of operation, effective patient size and FOV. This is expected to provide inputs to the clinical task of optimizing the system configuration for a particular patient and procedure. The expected result is the production of acceptable image quality with a minimum amount of unnecessary radiation.

Consistency checks provide a facility with the means of detecting significant changes in the X ray system (caused by drift or modification) and thereby triggering necessary corrective actions. Sources of inconsistency include real changes in the system, configuration reprogramming or defects in the consistency test process itself.

3.8. ROLE OF IMAGE QUALITY CRITERIA

Following the recommendations of the ICRP and the BSS, dose limits are not applicable to medical exposure. However, attention is drawn to the use of reference (guidance) levels as an aid to optimizing radiation protection in the medical setting. The imaging process needs to be optimized for clinically justified examinations and interventions. The optimal use of ionizing radiation involves the interplay of three important aspects of the imaging process:

(a) The diagnostic information of the radiological images;
(b) The radiation dose to the patient;
(c) The choice of radiological technique to keep the exposure of patients to the minimum necessary to achieve the required image information.

Objective and subjective methods have been developed to assess image quality. Objective methods include mathematical models and quantitative assessment of test object images; some of their parameters are discussed in Section 3.7.3, in the context of characterizing equipment performance. Subjective methods include the visual assessment of test object images and the visual evaluation of clinical images.

Quality criteria for adult and paediatric radiographic images can be found in European guidelines [49, 50]. These criteria are based on the visibility of examination specific anatomical markers.

3.8.1. Quality criteria in cardiology

The DIMOND project (a European research group on Measures for Optimising Radiological Information and Dose in Digital Imaging and Interventional Radiology) has used these guidelines as the basis of a set of

quality criteria for CA examinations. These quality criteria specify anatomical image criteria and important image details [51, 52].

Quality criteria have been developed for left and right coronary arteries and for left ventriculography (LV). These are the most common fluoroscopically guided diagnostic procedures performed in cardiac laboratories. The quality criterion evaluation process directly involves clinicians in the evaluation of image quality.

These quality criteria are not intended to prescribe day to day cardiology practice. They are an attempt to assess basic factors that have proved necessary for high quality diagnostic information. The method can be used by a facility to assess the quality of studies that it performs in the context of a comprehensive quality assurance programme or as a means of comparing itself with other institutions.

Clinical quality evaluation can be matched with imaging performance observed using physical phantoms during characterization and consistency checks of the equipment.

Quality criteria can be divided into two main parts:

(a) A set of 'clinical criteria' based on the level of visualization (reproduction, visualization and sharp visualization) of anatomical markers in the CA images; for the complete visualization of some features, more than one projection is required.
(b) A set of 'technical criteria' dealing with operational aspects that can influence both image quality and patient exposure. Technical elements of an optimized procedure (e.g. frame rates, number of imaging sequences and images per sequence) are described. This material helps clinicians select an appropriate operational configuration.

Fulfilment of the 'clinical criteria' provides assurance about the information content of the study, while non-fulfilment of some of the technical criteria is an indication of the need for the clinician to undertake appropriate corrective action.

3.8.2. Scoring system

A scoring system has been added to the quality criteria to provide means for documenting the quality of cinefluorographic sequences in a semi-quantitative manner. Reviewing recorded sequences off-line allows the scoring. Some newer imaging systems provide the means for archiving fluoroscopic sequences, which allow recording and scoring of representative fluoroscopic

sequences to monitor the fluoroscopic mode. A description of the quality criteria and the associated scoring system is given in Appendix IX.

3.9. USE OF QUALITY CRITERIA IN THIS PROJECT

At each centre, a sample of five to ten CA examinations was locally assessed using the protocols described above. In addition, an outside cardiologist assessed three studies per centre. This re-evaluation provided an estimation of the inter-centre assessment variability.

3.10. ROLE OF THE COMPLEXITY INDEX

3.10.1. Need for a complexity index for interventional procedures

Interventional radiology and interventional cardiology procedures can result in high patient exposures. In some cases, the patient skin dose crossed the threshold for significant deterministic effects. Consequently, there is a need for exposure assessment during the intervention and for documentation [53].

The concept of guidance (reference) levels refers to 'common examinations' performed on large numbers of patients in a relatively standardized manner, as recommended by the ICRP [3], as required by the BSS [1] and as recommended in an IAEA Safety Guide [54] and a European Council Directive [55]. As indicated above, this pilot project addressed the need to explore the possibility of establishing guidance (reference) levels for interventional procedures, as an extension of diagnostic guidance (reference) levels.

Extending the concept of guidance levels to X ray guided interventions raises several problems. In addition to technical variables (patient size, equipment performance and operational technique), procedures are often non-standard for clinical reasons. The complexity of a procedure is affected by factors related to the patient's anatomy and to the severity of the treated pathology. Since the complexity of the procedure strongly influences patient exposure, it may not be appropriate to develop a guidance level without taking complexity into account.

An index related to patient specific clinical factors affecting an individual procedure could reflect the complexity of the procedure. Appropriate scaling of guidance levels provides an additional tool for optimization processes in a facility.

3.10.2. Use of the complexity index in this project

The results of a previous European project [56] were adapted to develop a complexity index (CI) for PCI procedures. The index is related to aspects of cardiac anatomy and pathology that influence the complexity of an interventional procedure and therefore might influence patient exposure.

The CI substudy is designed to evaluate the relationships among clinical factors; anatomical factors as a function of FT and the number of acquired images; and kerma–area product (P_{KA}). The intent is to develop a CI capable of predicting the level of the patient's exposure.

The derived CI has several potential applications:

(a) As a means of expressing the average complexity of the mix of procedures performed by an individual physician or centre;
(b) As a means of normalizing dosimetric data to account for the complexity of procedures performed by an individual physician or centre;
(c) As a means of relating a hospital's performance against national or local guidance levels for the purposes of quality assurance and optimization of clinical practice.

Each participating facility was asked to collect relevant data from a sample of 200 PTCA procedures. These data included patient demographics (height, weight, age), severity of pathology (location of the lesion, size, tortuosity) and procedural variables (FT, number of acquired images, total P_{KA}, fluoroscopic P_{KA} and cinefluorographic P_{KA}).

The data were analysed using multiple linear regression. This analysis supplies the regression coefficient for each variable, including its standard error and statistical significance. Both forward and backward stepwise regressions were run to identify P_{KA} predictors.

Variables are sequentially entered into the forward stepwise regression model. The variable with the highest simple correlation with P_{KA} is entered as the first step. The partial correlation of all of the other variables is then computed. The variable with the largest statistically significant partial correlation is then entered into the model. The process iterates by sequentially adding the additional variable that yields the greatest multiple correlation (R^2) increase.

Backward stepwise regression starts with a full model (all variables included) and eliminates the variables that do not significantly enter the regression equation. The order of exit is now determined by the variable that causes the minimum squared multiple correlation (R^2) decrease.

When there is high correlation among the independent variables, the estimates of regression coefficients can become unstable. Tolerance is a measure of this condition. It is calculated as $1 - R^2$ for an independent variable when it is predicted by the other independent variables already included in the analysis. (Note that the dependent variable is not used.) By setting a minimum tolerance value, variables highly correlated with others already in the model are not allowed to enter. A value of 0.01 was chosen.

Basic imaging physics predicts higher entrance surface air kerma and P_{KA} in larger patients. It is possible to use the collected data to test whether there is a better correlation with size corrected P_{KA} than with measured P_{KA}. Previous work [57] indicated the appropriateness of an exponential relationship between P_{KA} and the patient's equivalent diameter (D_e):

$$\ln(P_{KA}) = kD_e + c$$

This can be used to adjust the measured values ($P_{KA,\,meas}$) to equivalent values ($P_{KA,\,ref}$) for D_{ref}. The ICRP reference man has a weight of 70 kg and an equivalent diameter (D_{ref}) of 22.9 cm. Thus:

$$P_{KA,\,ref} = P_{KA,\,meas} \exp(k(D_{ref} - D_e))$$

4. RESULTS AND DISCUSSION

This section of the report contains summary data and graphics. More detailed information is found in the relevant appendices.

4.1. PILOT STUDY

4.1.1. Data collection

Patient dosimetry and demographic data were obtained for each patient included in the study using a standardized approach. Data were recorded in computer spreadsheets at each centre and then forwarded to the IAEA. These spreadsheets were then forwarded to the centres where the patient dosimetry and CI analyses were undertaken. Data sets were checked for accuracy and

completeness before being collated into spreadsheets for subsequent statistical analysis.

Patient dose data were collected into an Excel workbook and analysed using both Excel functions and standard statistical packages (MINITB and SYSTAT). The overall data set and several pertinent subsets were evaluated. Summary tables are found in Appendix VII.

A total of 12 596 clinical procedures were collected from the seven hospitals (Table 3). Since two of these hospitals contributed very large data sets, those were randomly sampled to reduce each of them to approximately 1000 procedures. The relative proportions of CA, PTCA and CA + PTCA found in the submitted sets were preserved in the sampled sets used for the following analysis. The analysed set consists of 4109 procedures.

4.1.2. Overall kerma–area product (P_{KA})

Figures 2 and 3 present the histograms of all CA and PCI procedures included in this study. These data distribution histograms approximate a log-normal shape. This dose distribution represents the effects of a range of anatomic and complexity differences among patients. This report presents data in terms of medians and key percentiles (10th, 25th, 50th (median), 75th and 90th). Procedures with patient doses greater than the 90th percentile or less than the 10th percentile usually represent uncommon or unique clinical situations. The 10th and 90th percentiles are better representations of a facility's overall range of patient doses than the observed minimum or maximum values.

TABLE 3. COLLECTED CLINICAL PROCEDURES

Hospital code	CA	PTCA	CA + PTCA
1	111	95	32
2	149	100	0
3	131	316	79
4	305	178	0
5	377	28	155
6	Used 739 of 6166	Used 138 of 1301	Used 150 of 1318
7	Used 453 of 814	Used 172 of 290	Used 401 of 651
Evaluated data set	2265	1027	817

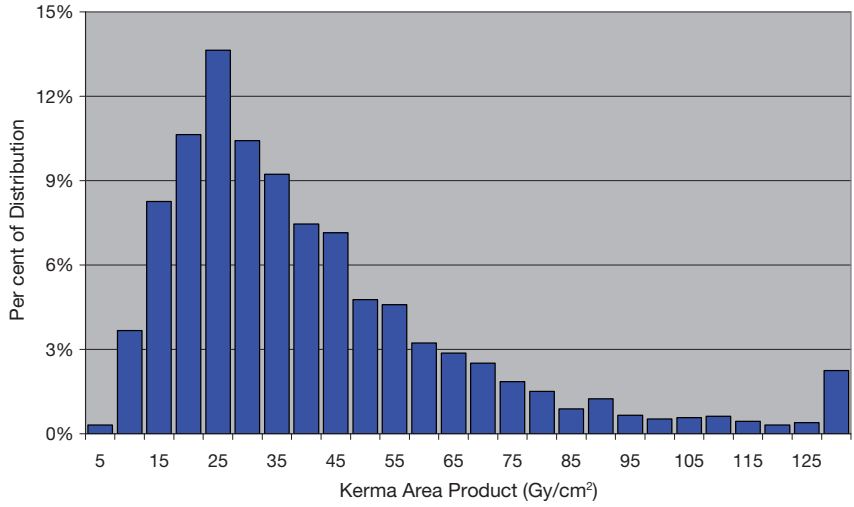

FIG. 2. Histogram of P_{KA} values for the 2265 CA procedures included in this study.

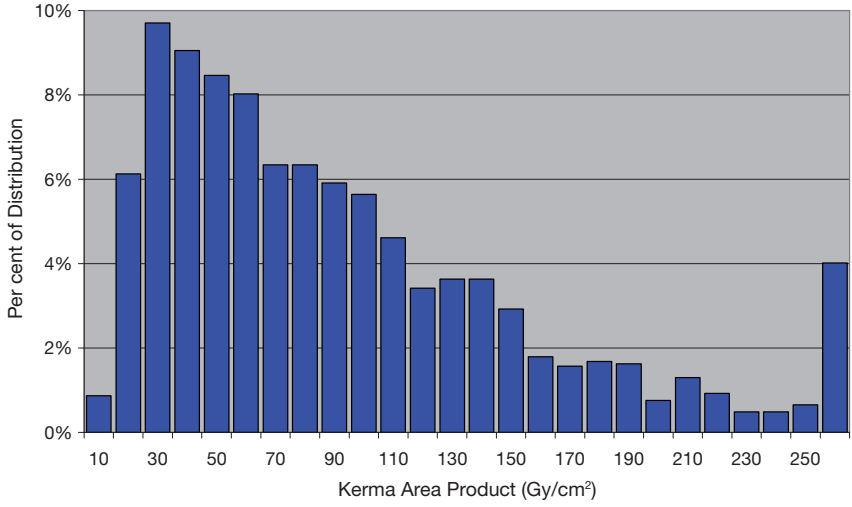

FIG. 3. Histogram of P_{KA} values for the 1844 PCI procedures included in this study.

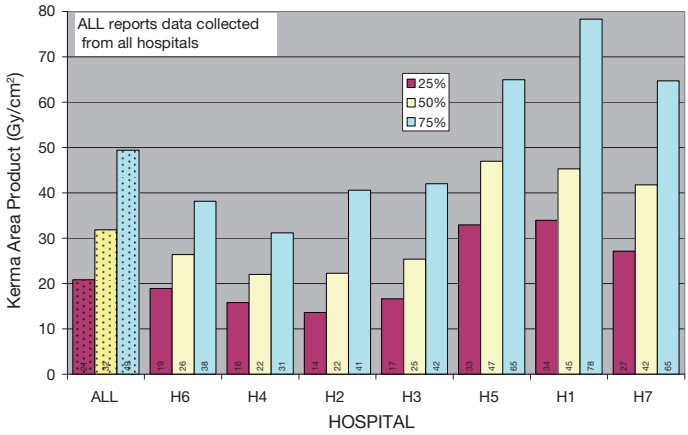

FIG. 4. P_{KA} kerma–area product percentiles for CA. The 25th, 50th and 75th percentiles are shown. Data are clustered by institution. The results from all procedures included in the study are grouped in the first cluster (ALL). The remaining clusters are arranged in order of increasing median P_{KA} of PCI for the same institution.

Figure 4 presents the overall results for the 2265 CA procedures analysed in this study. Each institution is represented by a data cluster. One additional data cluster for all institutions (ALL) is included, which represents the entire set of CA procedures. The clusters are ordered by increasing median P_{KA} of the PCI studies at the corresponding institution. The 75th percentile bar in the ALL cluster is highlighted. The CA guidance level will be derived from its value. The causes for this variability include differences in the details of how the procedures are performed in different institutions (e.g. fraction of procedures including a ventrilogram), different patient populations (e.g. fraction of procedures involving evaluation of bypass grafts), intrinsic differences in equipment and lack of optimization.

Figure 5 presents the overall results for the 1844 PCI procedures observed in this study. A data cluster represents each institution. One additional data cluster for all hospitals (ALL) represents the entire set of PCI procedures. The clusters are ordered by increasing the median P_{KA}. It can be seen that the ordering of the PCI mean values does not match the ordering of the CA values. This may represent differences in complexity in addition to the factors discussed above.

Figure 6 presents the interquartile ranges of P_{KA} for all of the hospitals included in the study. The studies have been grouped into four clusters: CA, PTCA, PCI and combined CA + PTCA procedures. Note that PCI represents the sum of the PTCA and CA + PTCA procedures. The rounded 75th

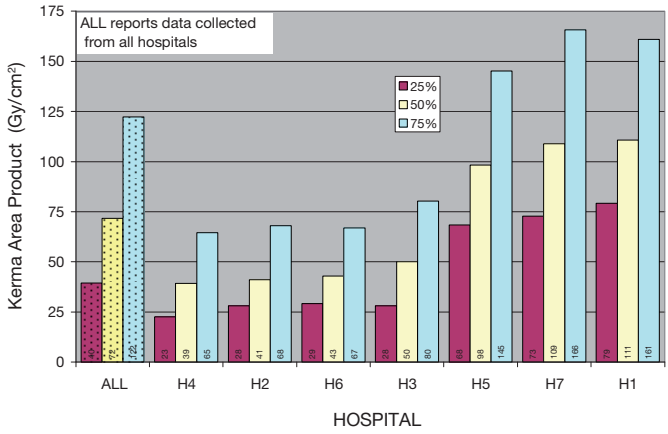

FIG. 5. P_{KA} kerma–area product percentiles for PCI of the coronary arteries. The 25th, 50th and 75th percentiles are shown. Data are clustered by institution. The results from all PCI procedures included in the study are grouped in the first cluster (ALL). The remaining clusters are arranged in order of increasing median P_{KA}.

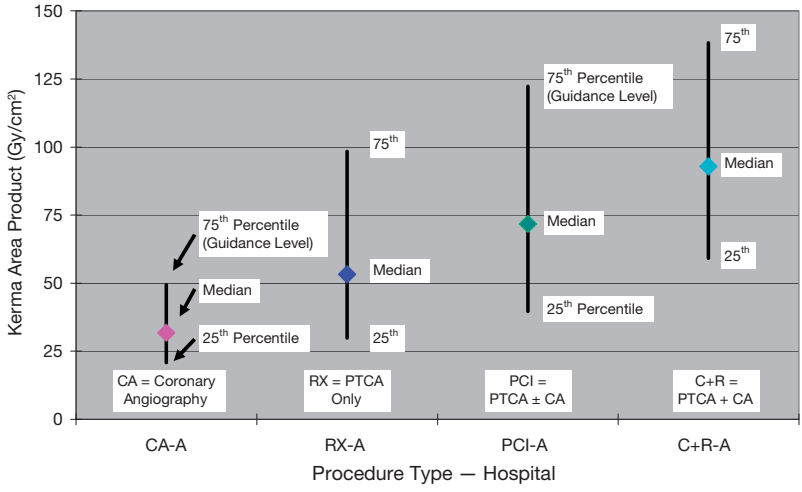

FIG. 6. P_{KA} kerma–area product: interquartile ranges for CA(CA), PTCA(RX), PCI(PCI) and CA + PTC(C + R). Data are for all hospitals in the project. The upper end of each vertical line is the 75th percentile of the corresponding data set; the lower end is the 25th percentile. The 75th percentiles of the CA and PCI data pool were used to derive the guidance levels.

percentiles for CA and PCI were used to obtain the guidance levels reported in this publication.

Figure 7 presents the interquartile ranges of P_{KA} and Fig. 8 presents the interquartile ranges of FT for each individual hospital included in the study. The studies have been grouped into the same four clusters shown in Fig. 6. The rounded 75th percentiles for CA and PCI were used to obtain the FT guidance levels reported in this report.

4.1.3. Effect of patient weight on the results

Entrance surface air kerma, K_e, depends on the patient or phantom thickness. This is particularly true when automatic exposure control (AEC) is used to keep the dose to the image receptor constant, which requires compensation for the larger attenuation of heavier patients.

Fluoroscopic and cinefluorographic patient entrance air kerma rates are driven by automatic control devices, which manage beam parameters such as kVp, mA, pulse width and added beam filtration. Figures 8 and 9(a, b) illustrate measured fluoroscopic data on a typical interventional fluoroscope on a

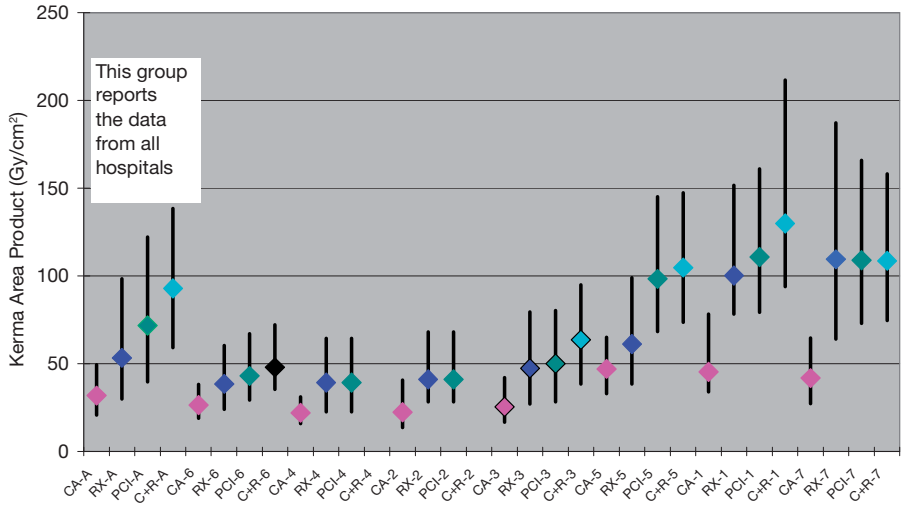

FIG. 7. P_{KA} kerma–area product: interquartile ranges for CA(CA), PTCA(RX), PC(PCI)I, and CA + PTC(C + R). Data are shown for each individual hospital participating in the project. Hospital numbers (1–7) are shown in the abscissa. See Fig. 6 for further legend information.

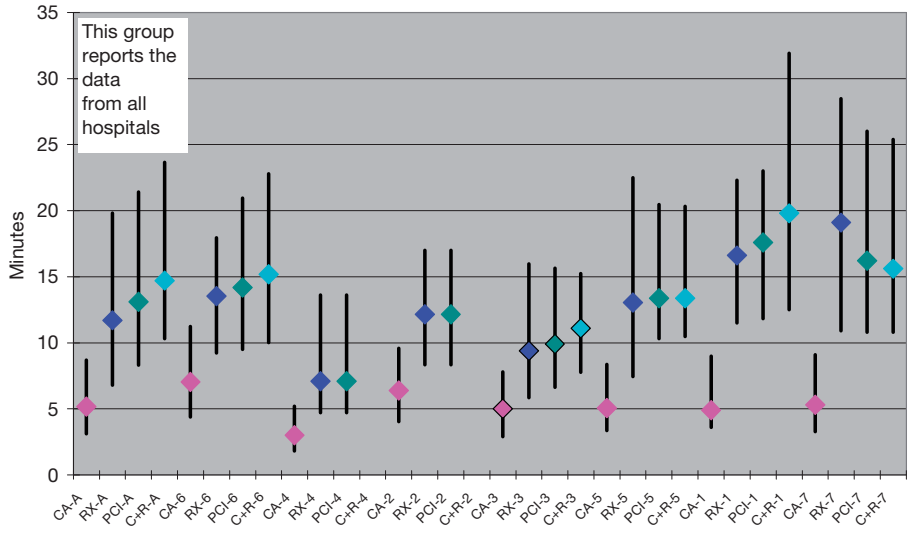

FIG. 8. P_{KA} kerma–area product: interquartile ranges for CA(CA), PTCA(RX), PC(PCI)I, and CA + PTC(C + R). Data are shown for each individual hospital participating in the project. Hospital numbers are shown in the abscissa. See Fig. 6 for further legend information.

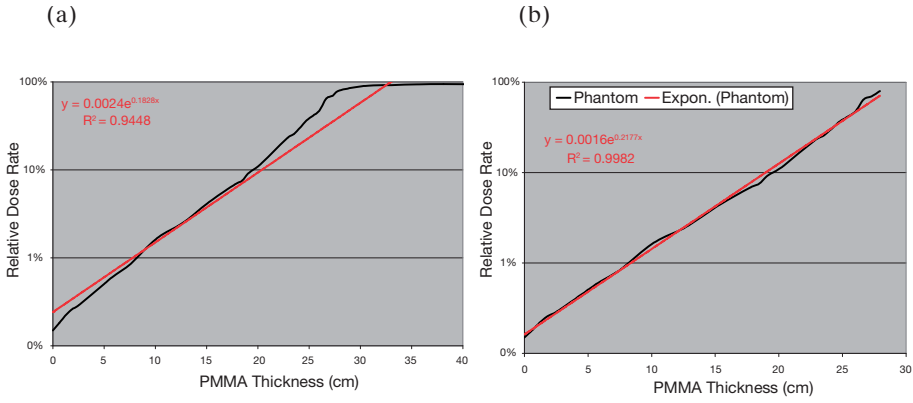

FIG. 9. (a) Relative phantom entrance air kerma rate as a function of PMMA thickness over an extended range of thicknesses. The shoulder represents output limitation for conformance with FDA regulations. (b) Relative phantom entrance dose rate as a function of PMMA thickness over the controllable range of thicknesses for this system and test geometry (0–28 cm PMMA).

phantom of variable thickness of PMMA. Other manufacturers' systems display similar behaviour. The figures show an exponential-like behaviour.

In interventional procedures, there are many factors influencing K_e and P_{KA}, thus masking the weight dependence, as illustrated in Figs 10–12, which show scatter plots of P_{KA} for all the interventional procedures included in this report. The analysis in Appendix VIII has shown an increase in air kerma–area product (P_{KA}) as a function of procedural complexity. As a result, procedural complexity and variability cause large variations in P_{KA} values for the same patient weight, thus causing a poor correlation between P_{KA} and patient.

The 'masking' effect can be removed or reduced to reveal the dependence of P_{KA} on patient weight, by just averaging out the "confounding" factors. To do so, patients can be grouped into several weight groups and P_{KA} data can be averaged for each weight group into a single value. Patients with available weight data were clustered into five weight groups (<50 kg, 50–65 kg, 65–85 kg, 85–100 kg, >100 kg) and three procedure groups (CA, PCI and all procedures). The results are shown in Table 4 and Figs 13–15, from which the weight dependence becomes evident and the R^2 for fits to exponential functions are strikingly good.

Guidance (reference) levels for simple examinations are usually determined by evaluating K_e from 'standard size' (65–85 kg) patients. This pilot project evaluated the feasibility of using data from interventional procedures obtained from all patients in place of those with a restricted weight range. The results are shown in Table 5.

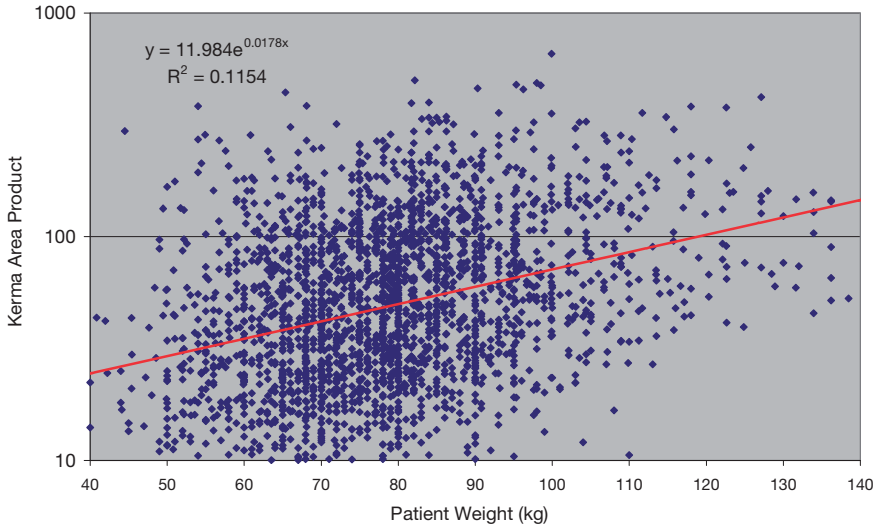

FIG. 10. Kerma area product versus patient weight (ALL).

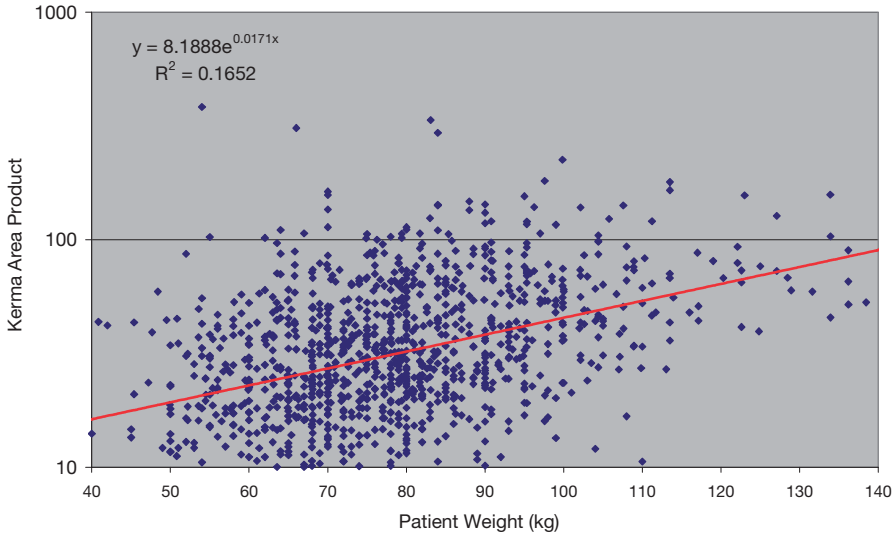

FIG. 11. Kerma area product versus patient weight (CA).

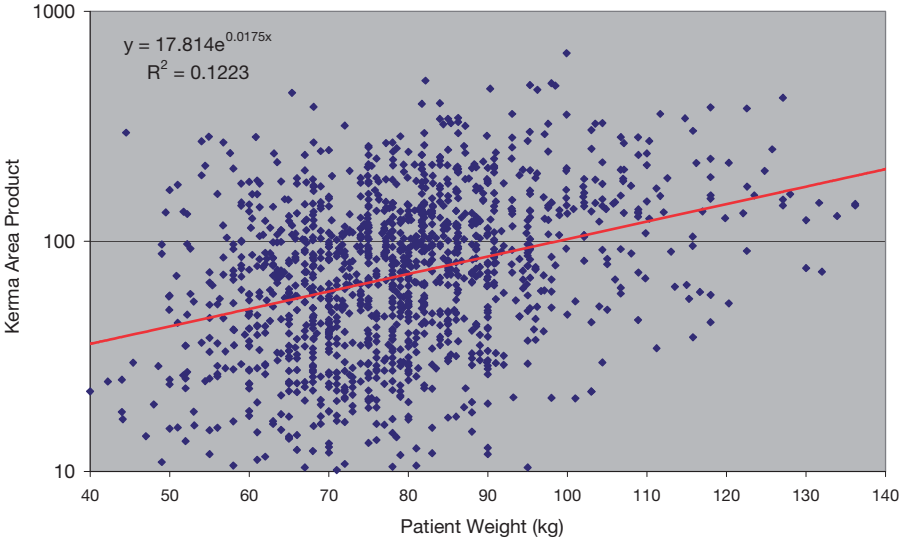

FIG. 12. Kerma area product versus patient weight (PCI).

TABLE 4. KERMA–AREA PRODUCT (P_{KA}) VALUES FOR THE 90% PERCENTILE IN Gy·cm^2 FOR EACH WEIGHT GROUP

Patient weight group (kg)				
<50	50–65	65–85	85–100	>100
All procedures				
86	111	134	187	226
CA (diagnostic) procedures				
45	50	68	90	127
PCI (interventional) procedures				
149	161	173	216	284

It is noted that the percentiles obtained from the 2488 procedures for which weight data are available are slightly different than those obtained from all of the 4109 procedures used to derive the final guidance levels.

Table 5 reports key statistical measures of patient weight for the set of 2488 procedures used above. It is seen that all three groups have essentially the same weight distribution. It can also be seen that more than half of the patients (55% (1366/2488) by a more detailed analysis) are within the 65–85 kg weight group.

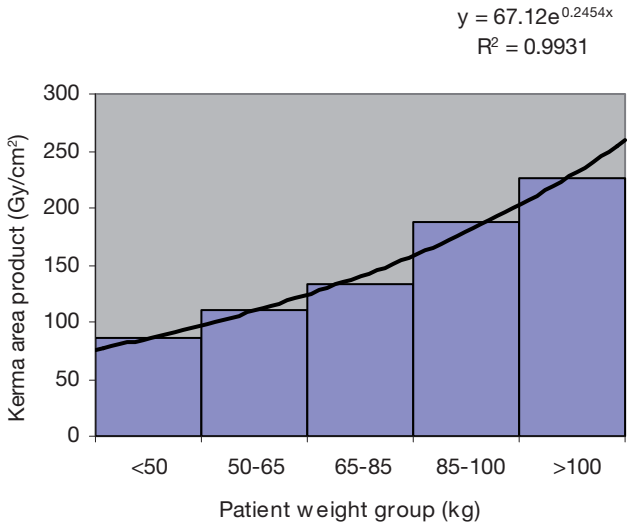

FIG. 13. P_{KA} values clustered by patient weight groups. All procedures.

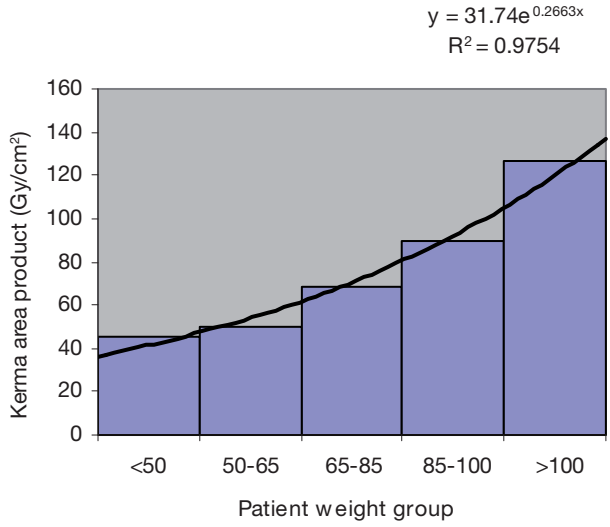

FIG. 14. P_{KA} values clustered by patient weight groups. CA procedures.

Given the weight distribution of the included patients, it is not surprising to find that there are only small differences to be found in an analysis based on patients of all weights in comparison to an analysis made using patients weighing between 65 and 85 kg.

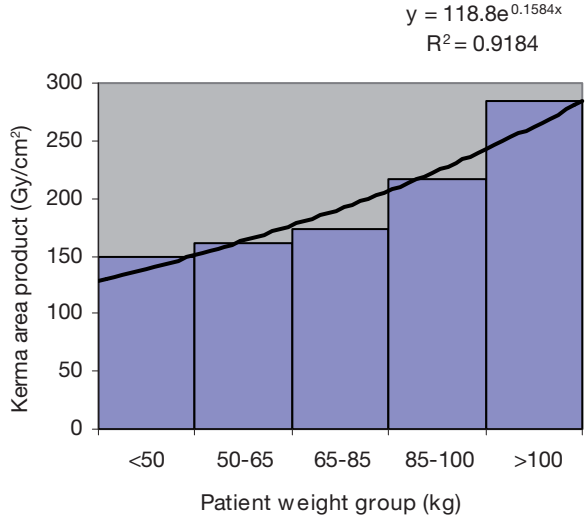

FIG. 15. P_{KA} values clustered by patient weight groups. PCI procedures.

TABLE 5. KERMA–AREA PRODUCT (P_{KA}) VALUES IN Gy·cm^2 PERCENTILES FOR EACH WEIGHT/PROCEDURE GROUP

	Patient weight group (kg)					
Percentile	All	<50	50–65	65–85	85–100	>100
			All procedures			
10%	16	6	13	16	22	34
25%	26	12	18	25	35	52
50%	48	20	33	44	66	89
75%	92	43	62	84	115	153
90%	151	86	111	134	187	226
			CA (diagnostic) procedures			
10%	13	6	11	13	17	28
25%	20	7	15	20	25	42
50%	31	14	23	29	40	59
75%	51	40	37	45	63	82
90%	76	45	50	68	90	127
			PCI (interventional) procedures			
10%	24	15	17	23	33	54
25%	41	18	29	38	61	90
50%	77	25	57	68	93	143
75%	128	83	97	111	151	188
90%	193	149	161	173	216	284

This conclusion will not be valid if the patient weight distribution is markedly different to that observed during the pilot project. Where this occurs, local guidance levels should be based on the local distribution of patient weights. They would be expected to increase for 'heavy weight' regions of the world and decrease for 'light weight' regions of the world. It is speculated that an all weight patient data collection could be appropriate. The lighter and heavier weight groups observed in this study might supply useful guidance for appropriate populations.

Figure 16 illustrates the relationship between P_{KA} and weight class for all 2488 procedures with weight data. The R^2 for fits to exponential functions at

each P_{KA} percentile level are also strikingly good. Similar results are seen in Figures 17(a, b) for the CA and PCI subgroups.

The finding of an exponential growth of P_{KA} with weight class is an indicator that other factors, such as procedural complexity and variability, account for most of the variance in P_{KA} within the entire data set. The change

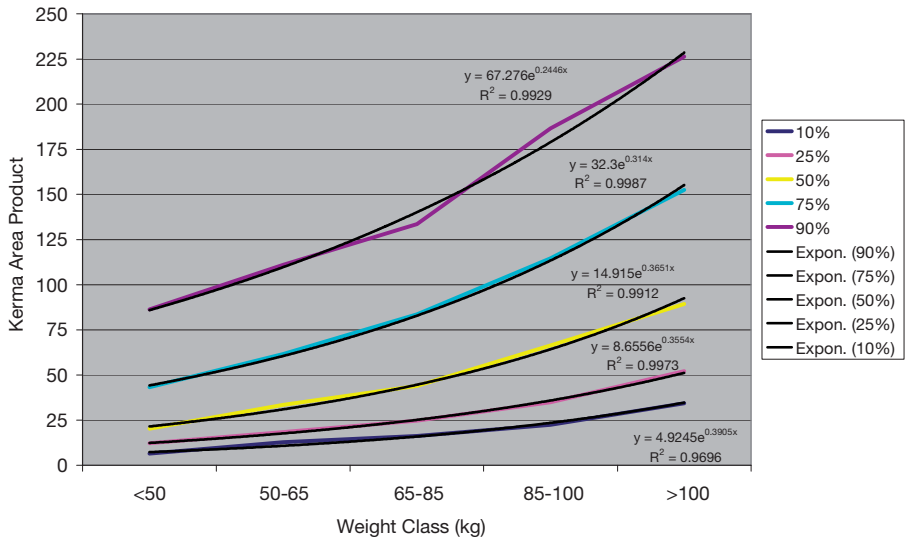

FIG. 16. Effect of weight class on kerma–area product (P_{KA}) for all procedures using subgroup P_{KA} percentile as a classifier.

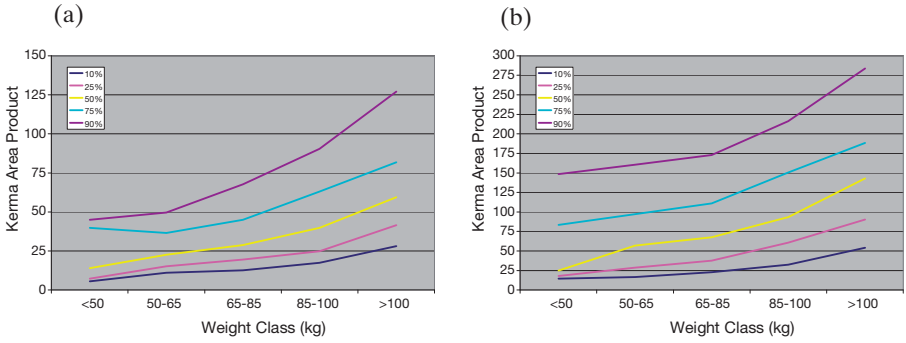

FIG. 17. (a) Effect of weight class on kerma–area product (P_{KA}) for CA using subgroup P_{KA} percentile as a classifier. (b) Effect of weight class on kerma–area product (P_{KA}) for PCI using subgroup P_{KA} percentile as a classifier.

in the exponent recovered from the curve fits at different percentiles represents a correlation between procedure type and complexity. CA is a relatively simple and standardized procedure that contributes more cases to low P_{KA} percentiles. PCI contributes more cases to high percentiles.

The data suggest that the dose percentiles obtained from the type of procedure weight clusters used for this analysis are an effective way of removing procedural and complexity factors. The resultant closely follows the physically expected growth in phantom entrance dose with phantom thickness (patient weight).

4.1.4. Effective dose (*E*)

The risk of inducing malignancies in a population by a practice can be estimated if the effective dose (E) delivered by that practice is known[4]. There is a reasonable amount of literature describing the conversion from P_{KA} to E for fluoroscopically guided cardiac procedures (Appendix III). Based on a review of the literature, this team established a consensus conversion factor (for adult patients) for this pilot study:

1 Gy·cm^2 (P_{KA}) yields 0.18 mSv (E)

This factor is based in the weighting factors found in ICRP Report 60 [59]. It should be re-evaluated whenever the weighting factors are adjusted. Table 6 presents the typical mean effective dose produced by the procedures in our study.

4.2. FILM DOSIMETRY FOR SKIN DOSE MEASUREMENTS

Peak (local skin) dose (PSD) was evaluated in a sample of PTCA procedures in four cardiac centres. A sample of dose distribution is shown in

[4] Caution must be exercised when using effective dose for patient populations. The UNSCEAR 2000 report [58] emphasizes that effective dose should not be used directly for estimating detriment from medical exposure by application, for example, of the nominal fatality probability coefficient given by the ICRP. The reason is that there are large uncertainties derived from demographic differences, in terms of health status, age and sex, between the population of patients and that general population for whom the ICRP derived the risk coefficients. Notwithstanding this caveat, UNSCEAR uses, for comparative purposes in diagnostic radiology and interventional procedures, the quantities ‘effective dose’ for individuals and ‘collective dose’ for populations.

TABLE 6. TYPICAL MEDIAN EFFECTIVE DOSE FOR CORONARY ANGIOGRAPHY AND PERCUTANEOUS CARDIOVASCULAR INTERVENTION

Procedure	Median P_{KA} (Gy·cm^2)	Effective dose (E) (mSv)
CA	32	5.6
PCI	72	13.0

Note: Based on mean values found in this study and a consensus conversion factor of 0.18 mSv/Gy·cm^2.

Fig. 18. Large variability among centres is expressed by the median values reported in Table 7 that summarize the results.

The distribution of PSD for all centres is reported in Fig. 18. Doses higher that 3 Gy were measured in eight PTCAs, demonstrating the need for monitoring patient exposure and for identifying high patient skin dose and the factors causing it.

Figure 19 shows that there is not a very good correlation between the PSD and P_{KA}; this indicates P_{KA} is not sufficient to predict some high skin dose measured. Other technical factors can influence the PSD, mainly: the focus to skin distance and the degree of superimposition of X ray beams of different projections, which depends on change in projection and collimator opening. However, P_{KA} can be used to prospectively identify patients at risk of skin injury. An example of a working policy is shown in Appendix X.

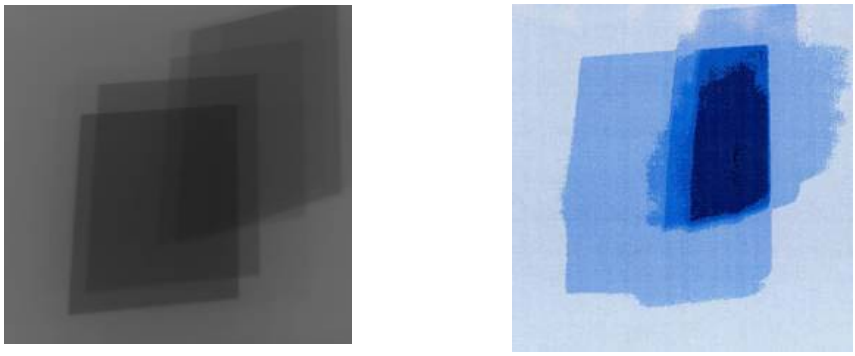

FIG. 18. Example of a Gafchromic image (red component of the film colour) and dose distribution image.

TABLE 7. MEAN AND MEDIAN MAXIMUM LOCAL SKIN DOSE EVALUATED IN A SAMPLE OF PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY PROCEDURES WITH GAFCHROMIC FILMS

	Number of PTCA procedures	Maximum local skin dose (mGy)	
		Mean	Median
Uruguay	14	1070	870
Chile	14	630	250
Spain	9	2840	2090
Italy	31	1090	920

4.3. IMAGE QUALITY EVALUATION

External experienced cardiologists evaluated the clinical aspects of image quality and medical physicists evaluated the technical aspects of 14 CA procedures. These procedures were collected from centres in Chile, Italy, Spain and Uruguay on CDs in DICOM format. Evaluations were performed using the image quality criteria and scoring system described in Appendix IX. Information provided by the equipment in DICOM format and accompanying data permitted the analysis of technical parameters such as projection angles, P_{KA}, FT, number of cine series and the number of images for each series. Based on the total score, all examinations except those indicated by 'NRR' had adequate image quality.

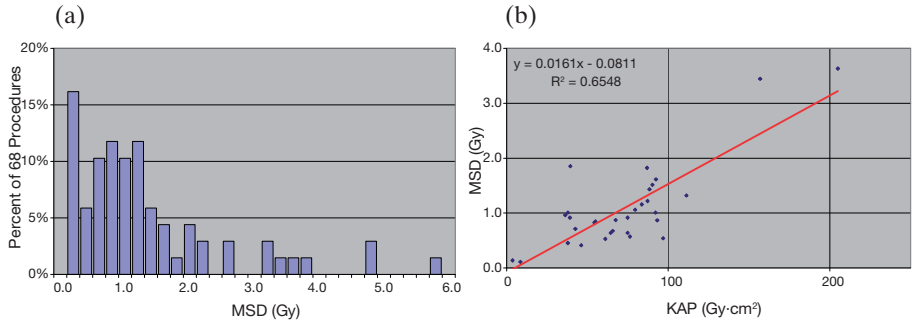

FIG. 19. Distribution of PSD derived from the sample of measurements performed in four centres on 68 patients and relationship between PSD and P_{KA}.

Local image quality evaluations of the submitted procedures were also provided by the centres in Chile and Uruguay. These were compared with the external evaluations. Technical, clinical and overall scores are reported in Fig. 20. The patient numbers are consistent for all of these plots. Additional anatomical evaluations are shown in Appendix VII. Significant variability is seen between the vascular scores and the LV score.

The technical criteria account for factors such as placement of the patient's arms outside the beam, apnea, full opacification of vessels, appropriate panning and redundancy of information. The technical scores have high variability, which indicates that the examinations were performed differently in the different centres. The normalized technical scores were less than 0.6 for 4/13 studies (31%) and over 0.95 for 2/13 studies (15%).

Evaluation of the DICOM header information demonstrated significant differences between the clinical protocols used by the different centres. These included differences in cine frame rates (25 versus 12.5 frames/s), number of series and number of frames per series. The DICOM header did not provide information on FT or mode (continuous versus pulsed). Further analysis of the projection angles can provide additional protocol information.

Significant differences were also found in perceived image quality (noise, contrast and spatial resolution) between the different angiographic systems used in this project. This is generally attributable to known differences in technical characteristics of the different systems.

4.4. PROPOSED GUIDANCE AND ACTION LEVELS

The results of the pilot project supplied useful statistical data for CA, PTCA, CA + PTCA and PCI. However, the boundary between pure interventions and interventions involving some diagnostic runs is not easy to define in clinical practice. We therefore recommend segmenting procedures into two classes:

(a) CA: Diagnostic studies of the coronary arteries with or without imaging of the left ventricle and/or grafts.
(b) PCI: Therapeutic procedures performed on the coronary arteries and/or vein grafts. These procedures may or may not include a diagnostic component.

The 75th percentile of the dose distributions reported here provides a reasonable set of initial values. Table 8 presents suggested guidance levels.

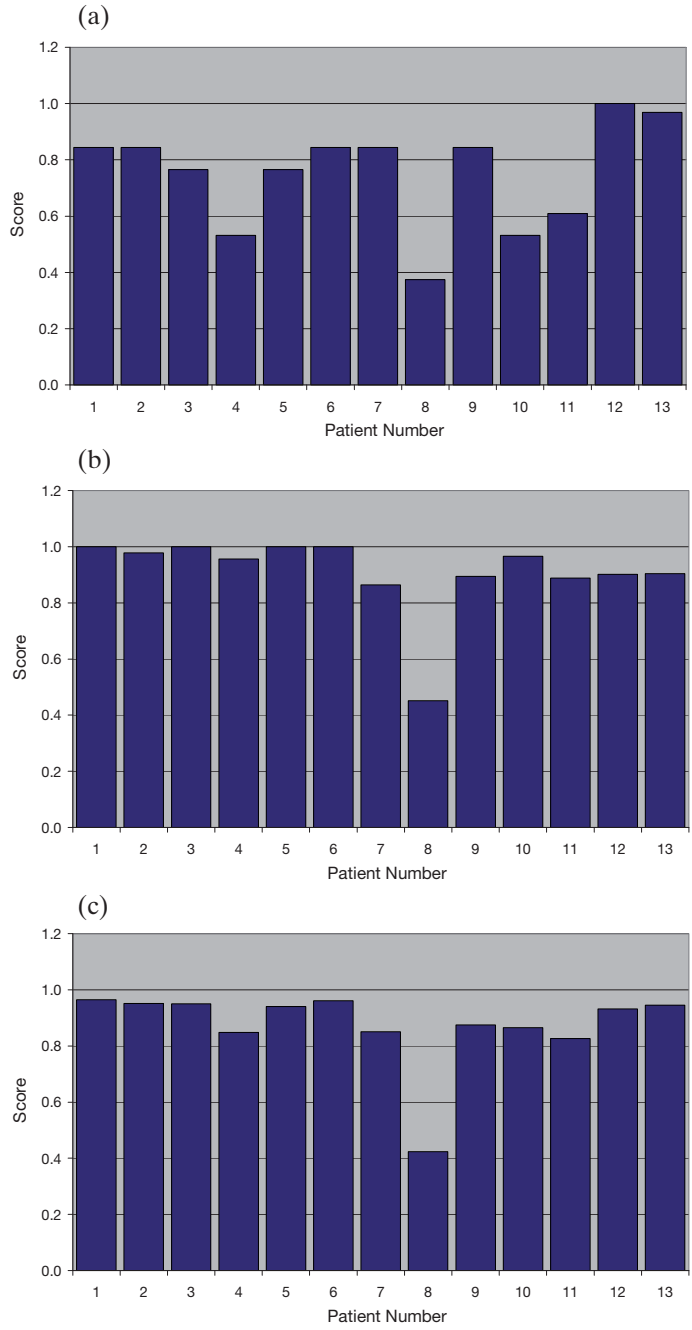

FIG. 20. (a) Normalized technical quality score; (b) normalized clinical quality score; (c) normalized total quality score.

Each individual facility should compare their complexity adjusted mean values against these guidance levels. An appropriate investigation is needed if the facility's values are too high.

Guidance levels are expected to change over time. They may decrease if equipment becomes more dose rate efficient or if clinical devices and techniques become more proficient. However, guidance levels may increase if the average clinical complexity of procedures increases.

Preliminary data were discussed at a project meeting at IAEA Headquarters in Vienna. Based on the data presented, an interim PTCA guidance level of 100 Gy·cm^2 was established. Note that this value is for PTCA procedures without any diagnostic component; not the PCI procedures (intervention with or without a diagnostic component) mentioned in this report.

Figure 21 examines PTCA P_{KA} values for six of the hospitals included in the study; only two hospitals were found to exceed 100 Gy·cm^2. The reasons were apparent: one hospital was routinely using cine at 25 frames/s (others ranged from 7 to 15). Reducing the cine rate reduced the high total P_{KA} in this hospital. The other hospital had not been performing physics quality assurance on the tested cardiac laboratory, thus both the cine and fluoro P_{KA} values were high. Appropriate action remediated these conditions.

Very low patient exposure is not desirable if the clinical purpose of the procedure is compromised. For CA and PCI, too low a dose may indicate an incomplete procedure, inadequate image quality, low complexity or excellent technical settings. Action levels are shown in Table 9. Centres with mean values below the action levels should investigate the quality of their procedures.

The guidance levels for PCI should be adjusted for a facility's measured CI or using the following formula (the equivalent formula for PTCA is derived in Appendix VIII):

$$P_{KA}\ (\text{Gy·cm}^2) = 56\text{CI} + 20$$

TABLE 8. SUGGESTED GUIDANCE LEVELS

Procedure	P_{KA} (Gy·cm^2)	Fluoroscopy time (min)	Number of images
Coronary angiography (CA)	50	9	1000
Percutaneous cardiovascular intervention (PCI)	125	22	1700

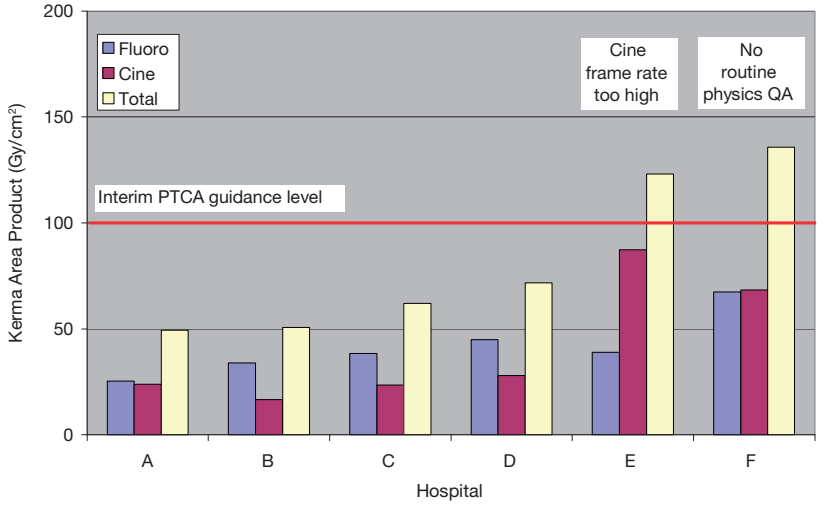

FIG. 21. Corrective action based on preliminary PTCA P_{KA} values. The reasons why two institutions exceeded interim guidance levels are shown.

TABLE 9. SUGGESTED ACTION LEVELS (10th PERCENTILE)

Procedure	P_{KA} (Gy·cm^2)	Fluoroscopy time (min)	Number of images
Coronary angiography (CA)	15	2	500
Percutaneous cardiovascular intervention (PCI)	25	5	400

5. CONCLUSIONS

The pilot study demonstrated that it is possible to establish guidance levels for complex procedures such as CA and that guidance levels are also feasible for therapeutic procedures (PCI) provided that an appropriate adjustment is made for procedural complexity.

For interventional procedures, it is particularly important to emphasize that guidance levels are never meant for individual patients and are to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement.

The pilot study identified hospitals with higher patient exposure and the causes for it, thus allowing straightforward optimization of protection, resulting in a dose reduction, without losing confidence in the image information.

Overzealous dose reduction may lead to poor images, and be detrimental to the clinical outcome. Low dose action levels can help to trigger investigation as to whether too poor images are been used.

There is a relatively good correlation between the values of kerma–area product and the weight of the patients, although there is a reduction of the range below that observable with simple phantoms, which can be attributed to variations in the procedures' complexity, especially for therapeutic interventions.

6. TOPICS FOR FUTURE RESEARCH

The research findings presented here suggest avenues for further research. The following research topics should be considered:

(a) Guidance levels for non-cardiac interventional procedures. This project has shown that guidance levels may be successfully applied to cardiac procedures to identify centres where optimization measures should be targeted. This approach could be applied to other interventional procedures.

(b) Low dose action levels for cardiac and non-cardiac interventional procedures. Cardiac procedures are increasingly performed using digital imaging equipment on which dose is a user selectable variable. Image quality is partially linked to patient dose. The operator, the manufacturer or both can adjust the balance between image quality and dose. Overzealous pursuit of lower doses could result in equipment operating at such low doses that the clinical outcome is prejudiced. It is suggested that action levels be introduced to help prevent this occurrence. A process for the development of action levels for other examinations and procedures should be investigated. This research should include practical examples of approaches to improving clinical outcomes.

(c) Real time displays of skin dose. A real time display of the PSD is desirable but not currently available. Research and development of

methods, techniques and software for the estimation of skin dose in real time are necessary[5].

(d) Uniform worldwide means for reporting and following up patients with deterministic injuries are needed. There is a perceived imbalance in the reporting of deterministic injuries, with most reports originating from North America. Recording at the national and international level would help in investigating the underlying cause of this imbalance. In addition, lessons learned from this information should be used for avoiding radiation injuries in the future.

(e) Investigate the feasibility of establishing cancer risks for intervention patients. Effective doses from interventional procedures can be relatively high. In addition, some patients require multiple procedures. There is scope for epidemiological research on potential cancer induction effects from these procedures. The feasibility of establishing cancer risks from this group of patients will depend on the size of the cohort and control group, required for statistical significance at this level of radiation exposure. The feasibility study may require databases for epidemiological study.

(f) Develop improved complexity indices for all interventional procedures. Exposure in cardiology depends on the complexity of the procedure. The approach of developing a CI for individual cardiology procedures has been successful. The method needs to be extended to account for very complex PTCA procedures. In addition, complexity indices should also be developed by professional societies for non-cardiac interventional procedures.

(g) Periodic review of guidance levels and complexity indices. As interventional fluoroscopy procedures evolve over time, and as new ones are introduced, it is necessary to review the guidance and action levels as well as the complexity indices on a regular basis, at periods depending on the evolution of the practice.

[5] As a matter of standardization and usability, dose information needs to be stored in the DICOM header and DICOM radiation dose structured report in a format that meets an upcoming International Electrotechnical Commission standard.

7. RECOMMENDATIONS

Guidance levels for cardiology procedures can be established using the 75th percentile; the dose–area product is an appropriate quantity to use for this purpose. Based upon the work undertaken in this study, guidance levels of 50 Gy·cm^2 for CA examinations and 125 Gy·cm^2 for PCI procedures are recommended. These guidance levels should be kept under review.

It is recommended that cardiology departments undertake dose surveys as part of a quality assurance programme. The results obtained should be used to compare local practice with that in other centres using the guidance levels indicated above. An investigation into local practice should occur if the dose levels exceed the guidance levels.

The use of an approach using a CI is advisable. This approach enables centres to be compared on an equitable basis. Further research into the use of complexity indices is suggested.

The approach that has successfully been applied to cardiology procedures can be adapted for other interventional procedures. Further research should be undertaken to explore the use of guidance levels for other interventional procedures and to develop appropriate complexity indices suitable for these techniques.

Suppliers of interventional X ray equipment should be encouraged to incorporate an appropriate method of dose monitoring into equipment. Irrespective of the approach to dose monitoring, it should be capable of indicating the dose–area product and the entrance surface air kerma. Dose information should be stored in the DICOM header and DICOM radiation dose structured report in a format that meets the proposed International Electrotechnical Commission (IEC) standard.

Dose information recorded in the DICOM header and DICOM radiation dose structured report should be recorded in the patient's electronic medical record alongside demographic information. The latter information should be recorded as part of a patient dose survey. This will then facilitate a comparison of practice in which patient size and body composition is taken into account.

Appendix I

DETAILS OF THE CLINICAL PROCEDURES

I.1. CORONARY ARTERIOGRAPHY (CA)

CA is an invasive procedure that is carried out by puncturing a peripheral artery. A catheter is advanced through the arterial tree to the heart. It is possible to selectively catheterize each coronary artery. By injecting an iodinated contrast material, it is possible to selectively identify the lumen of each coronary artery. In order to obtain optimal imaging of the arterial segments, different projections are done from the left and right hand sides of the patient, with cranial or caudal angulations as a means to obtain a diagnostic view of the coronary artery. Usually, series of six to eight cinefluorographic runs are acquired for the left coronary artery, and two to four cinefluorographic runs are acquired for the right coronary artery. Any bypass grafts are also imaged. In most cases, the procedure is completed by imaging the left ventricle in the right oblique projection and in the left oblique view when required by the clinical condition of the patient. In certain specific clinical situations, the ascending portion of the aorta is imaged. Also, in specific clinical situations, when it is necessary to evaluate the pressure in the pulmonary circulation or to measure the patient's cardiac output, a haemodynamic measurement catheter can be advanced into the pulmonary arteries from a peripheral vein.

I.2. PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)

In this procedure coronary artery stenoses and occlusions are treated using angioplasty (balloon) catheters. A percutaneous approach is used, with puncture of a peripheral artery. The ostium of the coronary artery of interest is catheterized selectively using a guiding catheter. Through the guiding catheter, a guide wire with a very flexible distal tip, designed to be manipulated easily and safely in diseased vessels, is advanced through the area of stenosis. In some cases is not easy to cross the stenosis or even to achieve a stable position in the coronary ostium as a consequence of anatomical variations among patients. An angioplasty catheter with a balloon diameter proportional to the size of the normal artery is placed in the stenotic segment over the guide wire and through the guiding catheter. The balloon is inflated with a contrast material solution to reach a pressure level at which the stenosis disappears. In the great majority of

cases, and in a proportion that differs from one centre to the other, the procedure is complemented by insertion of a metallic prosthesis (stent), which is introduced to the area of the lesion in a very similar manner to that of the balloon catheter. There are clinical circumstances in which the stent is placed in a stenotic coronary artery without pre-dilation of the lesion. Depending on the particular circumstances, two or more arteries, each with two or more lesions, may be treated in the same session.

I.3. COMBINED CA AND PTCA

Patients may be scheduled for a combined CA and PTCA procedure. This generally occurs when the patient's history and/or symptoms or the results of non-invasive cardiac testing indicate a significant possibility of coronary artery disease or if previous CA images are inadequate. The combined procedure may also be offered as a scheduling convenience. A single combined procedure is planned: the patient is prepared to have an immediate PTCA procedure if indicated by the results of the CA procedure. Nothing further is done if the CA is negative.

I.4. PERCUTANEOUS CARDIOVASCULAR INTERVENTION (PCI)

For the purposes of this project, PCI was defined as any type of interventional procedure performed on the coronary arteries. These procedures may or may not include a partial or complete CA procedure performed in the same setting.

Appendix II

MONITORING EXPOSURE OF PATIENTS

Patient radiation dose may be measured and recorded in different ways. There are four relatively standard methods for measuring dose during interventional fluoroscopic procedures; these methods differ in both usefulness and availability. In many countries, one method is widely available, while the others vary in availability from relatively common to extremely uncommon. Note that none of these methods are applicable to dose measurements for CT fluoroscopy.

The simplest and most widely available measurements are FT and number of fluorographic images. These are analogues of dose; that is, they do not measure dose directly, and by themselves they are insufficient to permit calculation of absorbed dose to the patient. To estimate patient dose from FT and number of fluorographic images, both the fluoroscopic dose rate and the dose per image must be measured or estimated. FT and number of fluorographic images are the least useful measures of patient dose.

The next most commonly available measurement is air kerma–area product (P_{KA}) (formerly the quantity dose–area product (DAP) was used). P_{KA} is a measure of the total radiation energy entering the patient. It is a good indicator of stochastic risk and correlates with operator and staff dose [62, 63]; P_{KA} meters may be integrated into the fluoroscopic unit or installed as add-on devices.

Kerma–area product (P_{KA}) is not an ideal indicator of deterministic risk. The principal deterministic risk to the patient is radiation induced skin injury. The likelihood and severity of radiation injury at any point on the skin are related to the dose delivered to that portion of the skin [6, 64]; P_{KA} is a surrogate measure of skin dose, although it does not correlate well with skin dose [65–69]. A large dose delivered to a small skin area yields the same P_{KA} as a small dose delivered to a large skin area. However, rules of thumb can be developed that improve the correlation for particular procedures such as CA and PCI.

The IEC introduced the concept of CD (air kerma) in 2000 [70]. CD is the air kerma value at a specific point, the IRP, which is defined for fluoroscopic systems with an isocentre as a point along the central ray 15 cm from the system isocentre in the direction of the focal spot. Depending on the patient's size, the table height and the angulation of the beam, the IRP may be outside the patient, may coincide with the skin surface or may be inside the patient.

CD is an approximation of the total radiation dose to the skin, summed over the entire body. It does not include tissue backscatter. CD is usually

measured with a dosimeter integrated into the fluoroscopic unit. Relatively few fluoroscopic units incorporated CD measurement capability as of 2006, but this will change as IEC 60601-2-43 compliant interventional fluoroscopic systems are installed. Additionally, new regulations introduced by the US Food and Drug Administration require CD measurement and display capability in all new fluoroscopes sold in the USA after June 2006. As a result, most manufacturers will be able to include this capability in their new equipment sold anywhere in the world.

During the course of virtually all interventional radiology and interventional cardiology procedures, the X ray beam is moved periodically with respect to the patient, and is directed at different areas of the patient's skin. In general, therefore, estimates of the likelihood of radiation induced skin injury that are based on CD tend to overstate this risk [71].

The likelihood and severity of radiation induced skin injury to the patient as a whole are a function of the highest radiation dose at any point on that patient's skin: the PSD. Typically, no point on the patient's skin is within the irradiated field for the entire procedure. For this reason, the PSD is usually less than the CD [72]. It is desirable to measure the PSD during interventional radiology procedures, but this has proved difficult in practice [73].

The PSD may be determined with a computerized analysis tool integrated into the fluoroscopic unit [27, 32], with real time point measurement devices applied to the patient [62, 71, 74], with TLDs applied to the patient or with dosimetric film interposed between the X ray beam and the patient. (Dosimetric radiochromic film was used for measurement of the PSD in the pilot project.) Data derived from point measurement devices are likely to underestimate the true PSD unless the measurement device is placed at the exact site of the PSD. Exact placement of a point measurement device is unlikely, since the PSD is usually confined to a small area of skin whose precise location is not known prior to the procedure [71, 72, 75].

PSD measurement may be accompanied by a display of a skin dose map. A real time skin dose map is an extremely valuable tool for assisting the operator in minimizing skin dose [27, 32]. Dosimetric film may also be used to obtain a skin dose map, albeit not in real time [69, 76]. The skin dose map may also be added to the medical record at the conclusion of the procedure, thereby indicating not only the magnitude of the skin dose, but its location. This satisfies the most stringent interpretation of the US Food and Drug Administration, American College of Radiology and international recommendations for recording skin dose [77–79]. A real time skin dose map that indicates both the site and magnitude of the PSD is the ideal means for managing and recording patient radiation dose. Unfortunately, as of 2007, this technology is not commercially available. Alternative methods of dose mapping, such as dosimetric film and TLD arrays, are not often used.

Appendix III

SKIN AND EFFECTIVE DOSE DERIVED FROM KERMA–AREA PRODUCT (P_{KA})

Kerma–area product (P_{KA}), the dose metric used in this project, is a convenient quantity to measure. The required instrumentation is found on most modern interventional fluoroscopes. Available accessory P_{KA} meters can be installed on older systems.

P_{KA} does not provide a direct measure of either skin dose or stochastic risk. However, reasonable estimates of both of these can be made using P_{KA} in combination with anatomical and procedural parameters [57]. The reliability of these estimates increases as the range of the parameters decreases.

III.1. SKIN DOSE ESTIMATES

The simplest situation for estimating skin dose from P_{KA} occurs when the X ray beam does not move during the procedure and the area of the entrance beam on the patient's skin is known. Under these conditions, the skin entrance air kerma is simply the measured P_{KA} divided by the known field size. Published backscatter factor tables [80] can then be used to calculate the tissue dose from air kerma as a function of field size and beam energy.

An unrefined estimate of skin dose for CA and PTCA can be made by assuming a typical entrance field size of 70 cm^2 and a representative backscatter factor of 30%. Under these conditions, and without beam motion during the procedure, the skin dose delivered by a P_{KA} of 140 $Gy \cdot cm^2$ can be computed as follows:

$$\text{Skin dose (Gy)} = 1.30 \times 140\ \text{Gy}\cdot\text{cm}^2/70\ \text{cm}^2 \quad (1)$$
$$\text{Skin dose (Gy)} = 2.6\ \text{Gy}$$

There is substantial beam motion associated with most clinical procedures. Motion spreads the X ray energy around the skin and thereby reduces the PSD. A better estimate of the PSD can be obtained by tracking the beam during the procedure. This is at present a tedious procedure that may be suitable only for reconstructing significant total P_{KA} procedures.

Procedural based conversion factors can be derived by comparing observed P_{KA} against skin dose distributions measured using TLD arrays or film or against modelled skin dose distributions [27, 72]. The conversion factors are procedure specific and may be operator specific. Table 10 gives typical

TABLE 10. PUBLISHED CONVERSION FACTORS TO DERIVE PEAK SKIN DOSE FROM P_{KA}

Reference	Peak skin dose/P_{KA} conversion factor (mGy/Gy·cm^2)
Vano [29]	4.5–4.9 (for CA and PCI)
Trianni [45]	14 (for PCI)

values. Caution: the information in this table assumes typical beam motion. Discussions with the operator while reviewing the archived images from the procedure will help decide whether motion in any particular case was more or less than typical. For typical motion in the 140 Gy·cm^2 case described above, the conversion factor is taken as 0.4. Thus with motion:

$$\text{Skin dose (Gy)} = 2.6 \text{ Gy} \times 0.4 = 1.04 \text{ Gy} \quad (2)$$

Without motion, the PSD was shown to be 2.6 Gy. For real world cases, the actual PSD is less than 2.6 Gy and may be less than 1.04 Gy.

For constant P_{KA}, the PSD increases as the field size decreases. The causes of decreased field size include selecting a small FOV, beam collimation within a FOV and the patient's skin being closer to the X ray tube than assumed. The first two factors are usually seen by reviewing the cine. Patient position relative to the X ray tube is harder to reconstruct.

III.2. EFFECTIVE DOSE ESTIMATE

The chance of inducing a radiogenic malignancy from a given X ray examination can be calculated using the dose delivered to each organ in the body combined with the radiosensitivity of those organs. This convolution can be converted into an effective dose (the uniform whole body dose that produces the same radiogenic risk).

Direct calculation of effective dose (E) for a clinical cardiac procedure is virtually impossible, because complete data on organ locations and their doses are not available. However, effective doses from many procedures have been estimated using phantom measurements, Monte Carlo calculations and combinations of both. Several investigations have focused on cardiac

TABLE 11. PUBLISHED CONVERSION FACTORS USED TO OBTAIN EFFECTIVE DOSE FROM P_{KA}

Reference	Effective dose conversion factor (mSv/Gy·cm^2)
McParland [81]	0.18
Ropolo [82]	0.15
Broadhead [83]	0.18–0.21
McFadden [30]	0.14

procedures. These investigations yielded a relatively modest range of conversion factors (C) relating effective dose to kerma–area product.

$$E\ (\text{mSv}) = C \times P_{KA}\ (\text{Gy·cm}^2) \tag{3}$$

The variability in C is produced by variability of both the X ray beam distribution assumed for the procedure and the nature of the model. Additional variability is introduced by changes in the ICRP organ weighting factors over time.

Appendix IV

FILM FOR SKIN DOSE ASSESSMENT

IV.1. METHODOLOGIES

Large area portal films are a practical tool for measuring skin dose distribution and for assessing maximum entrance surface air kerma ($K_{e,max}$) in interventional fluoroscopically guided procedures.

Usually in interventional procedures the X ray beam enters the patient from below the table. The portal film can be conveniently positioned on top of the mattress, under the patient, and centred at the level where the primary X ray beam is expected to enter the patient.

Today, two types of film are commonly used: (a) low sensitivity radiographic films, originally intended for radiotherapy portal verification; and (b) radiochromic films. These films are fairly large, and cover a large area of the skin. This provides a high probability that the dose to the portion of the skin receiving the highest dose will be represented on the film. Film also permits simple and rapid evaluation of the results.

Less frequently, a matrix of TLDs or a single solid state detector is used. The main drawback of a TLD matrix is the long period of time required prior to the procedure for TLD preparation and the long period of time required after the procedure for reading the TLDs. For single solid state detectors the principal drawback is the need to predict, in advance, where on the patient the highest skin dose will be located. This is notoriously difficult to do. Single solid state detectors have the advantage of providing continuous, real time dose information for the site on the skin where the dosimeter is positioned.

IV.2. CALIBRATION AND READING PROCEDURE

For film calibration, an unexposed film is irradiated free in air with a conventional radiographic or angiographic system over a range of 0 Gy–1 Gy air kerma, in steps of 0.05 Gy–0.1Gy, at X ray qualities similar to those used in clinical practice (e.g. 80 kVp, 3 mm HVL (half-value layer)). The source to film distance can be very small, in order to reduce exposure time. Care should be taken to avoid scatter contributions and beam inhomogeneity. Air kerma must be measured with a calibrated dosimeter at the same position as the film.

The calibration film is developed with an automatic film developer that undergoes regular constancy tests (in order to guarantee constant developing conditions when patient dose films are developed).

The optical densities of the portions of the film exposed to different kerma values are read with a calibrated optical densitometer or a film scanner. A calibration curve is obtained, interpolating with a curve such as the following [79]:

$$OD = \frac{A_0}{1 + \left(\frac{\text{Kerma}}{A_1} \right)^{A_2}} \tag{4}$$

IV.3. RADIOCHROMIC FILM

For radiochromic film calibration, an unexposed radiochromic film is cut into pieces of about 3 × 3 cm^2 and individual pieces are irradiated free in air with a conventional radiographic or angiographic system over a range of 0–5 Gy air kerma, in steps of 0.05 Gy–0.1 Gy, at X ray qualities similar to those used in clinical practice (e.g. 80 kVp, 3 mm HVL). The source to film distance can be very small, in order to reduce exposure time. Care should be taken to avoid scatter contributions and beam inhomogeneity. Air kerma must be measured with a calibrated dosimeter at the same position as the film. The exposed portions of radiochromic film, including a non-irradiated portion for the background evaluation, are assembled, in ascending dose value order, into a 'calibration film'.

Density measurements can be performed with: (a) a reflective densitometer with a light wavelength that matches the maximum absorption of the film; or (b) a flatbed digital colour scanner with a minimum 36 bit per pixel depth and possibly with an A3 scanning area. To allow development of maximum density, density measurements should be obtained at least 48 h after irradiation of the film.

When a densitometer is used, a calibration curve is obtained by reading the optical density of each exposed piece of calibration film and interpolating from the data using a polynomial curve. The calibration curve is used to convert the optical density of patient films into entrance surface air kerma, K_e.

When a flatbed scanner is used to create the calibration curve, scanner performance should be verified in advance. This includes evaluation of short and long term stability and area uniformity. To derive the calibration curve, an image of all the exposed calibration pieces is acquired. When only a small part of the scanner surface is covered, and in order to reduce the amount of possible

scattered light, the portion of the scanner surface not covered by the film should be covered with a black sheet of paper or film. In addition, two reference steps, pure black and pure white, should be scanned to obtain values covering all possible densities. The scanner working values (i.e. contrast, brightness) used during creation of the calibration curve must be recorded and used for all subsequent acquisitions of exposed films. Subsequent acquisitions must be acquired in manual acquisition mode in order to maintain scanner calibration.

Although the acquisition is performed in RGB (red, green, blue) mode, only the red component of the film image is analysed, since it shows a higher sensitivity in the relevant dose range than the green and blue components. The resulting optical values on the red channel and the corresponding air kerma calibration values are then interpolated with a square function to give the calibration curve. Commercial or homemade software tools can be used to automate the procedure.

IV.4. INTERPRETATION

Portal films exposed during an interventional procedure are processed and analysed according to the methodology described above for dosimetric calibration. The maximum entrance surface air kerma (K_e) is determined by visually selecting the portion of the film with the greatest density change or with a software routine that selects the most exposed area.

Appendix V

CHARACTERIZATION OF THE EQUIPMENT

V.1. OVERVIEW

Fourteen different systems were analysed; four of these had flat panel fluoroscopic detectors, while the remaining ten systems were equipped with image intensifiers. The systems were located in ten different hospitals and in four different countries.

The description of the size of the flat panel image receptor surface differs between manufacturers. While Philips and Siemens specify a diagonal measurement of the field, GE specifies the side of the field.

The analysis consisted of initial system characterization using PMMA and periodic same system consistency checks using copper. The same consistency test tools were also used across systems.

Patient entrance surface air kerma rates ($\dot{K}_e$) were evaluated during characterization using a 20 cm PMMA phantom. For the same image receptor FOV, the fluoroscopic $\dot{K}_e$ varied by a factor of five and the cinefluorographic $\dot{K}_e$ varied by a factor of nine. These ranges indicate that optimization of X ray system settings should be beneficial.

The effect of changing the FOV (using a 20 cm PMMA phantom) produced fluoroscopic dose rate increases between 12% and 25% for the flat panel systems (25–20 cm) and 40% and 50% for image intensifiers (23–18 cm).

In cine mode, using a 20 cm PMMA phantom, magnification produces a significant increment in K_e per frame. For one flat panel detector and using a 20 cm PMMA phantom with the Leeds test object at the isocentre, the increase in K_e with magnification was 12% from 25 to 20 cm format and 33% from 20 to 16 cm. Magnification from 25 to 16 cm results in a 49% increment in K_e.

The Leeds test object increases dose rates when added to a 20 cm PMMA phantom by 40% for flat panel systems and 30% for image intensifier systems. The test object was placed at the isocentre for all evaluations.

Owing to the presence of copper in the Leeds test object, its influence depends on the total phantom thickness. As an example, for the Philips Allura system, and for 16 cm PMMA, the Leeds test object positioned at the isocentre means 53% more in dose rate than with the test object removed. For 20 cm PMMA, this increment is 40%.

The consistency of three different systems (same make and model) was tested using 4 mm thick copper attenuators in 2003 and 2004. The differences in

fluoroscopic $\dot{K}_e$ ranged from 2% to 23%. The difference in cine K_e per frame ranged from 3% to 10%.

V.2. CONCLUSIONS FROM THE 2003 PROGRESS REPORT

Attenuation of the X ray beam by the table top and mattress can be significant. The table top attenuation factor was between 20% and 23% (using an 80 kVp beam with 3.8 mm aluminium filtration). Mattress attenuation factors ranged between 5% and 13%. Thus these attenuation factors should always be taken into account during calibration of the transmission ionization chambers.

Subjective analysis of image quality was performed using the same imaging monitor. The operator was free to change window, level and magnification during the analysis. The analysis demonstrated that the NEMA XR-21 test object is more sensitive than the Leeds test object. However, neither tool is free from observer variability.

Numerical analysis was performed using OSIRIS software. The SNR typically decreases by a factor of 4 when the PMMA thickness of the phantom is increased from 16 to 28 cm.

The performance of the X ray systems studied in the project was highly dependent on both the system settings provided by the manufacturer and by the operator's selection of operating factors. For a fixed phantom size of 24 cm PMMA, patient K_e ranged from 24 to 240 mGy/min, with different combinations of image receptor FOV (22–17 cm formats) and fluoroscopic modes (low to high). Increasing patient thickness over the range expected in adult cardiac angiography (16–28 cm PMMA) causes the patient K_e to increase by a second order of magnitude.

These findings emphasize the importance that operators understand the sources of this variability and thereby have the necessary knowledge to optimize their procedures. The wide range of K_e values attributable to different default settings in different systems demonstrates a scope for significant $\dot{K}_e$ reduction without impacting upon clinical results.

V.3. DETAILED RESULTS FROM THIS PROJECT

Figures 22 and 23 provide the detailed results from all of the equipment characterization measurements made during this project.

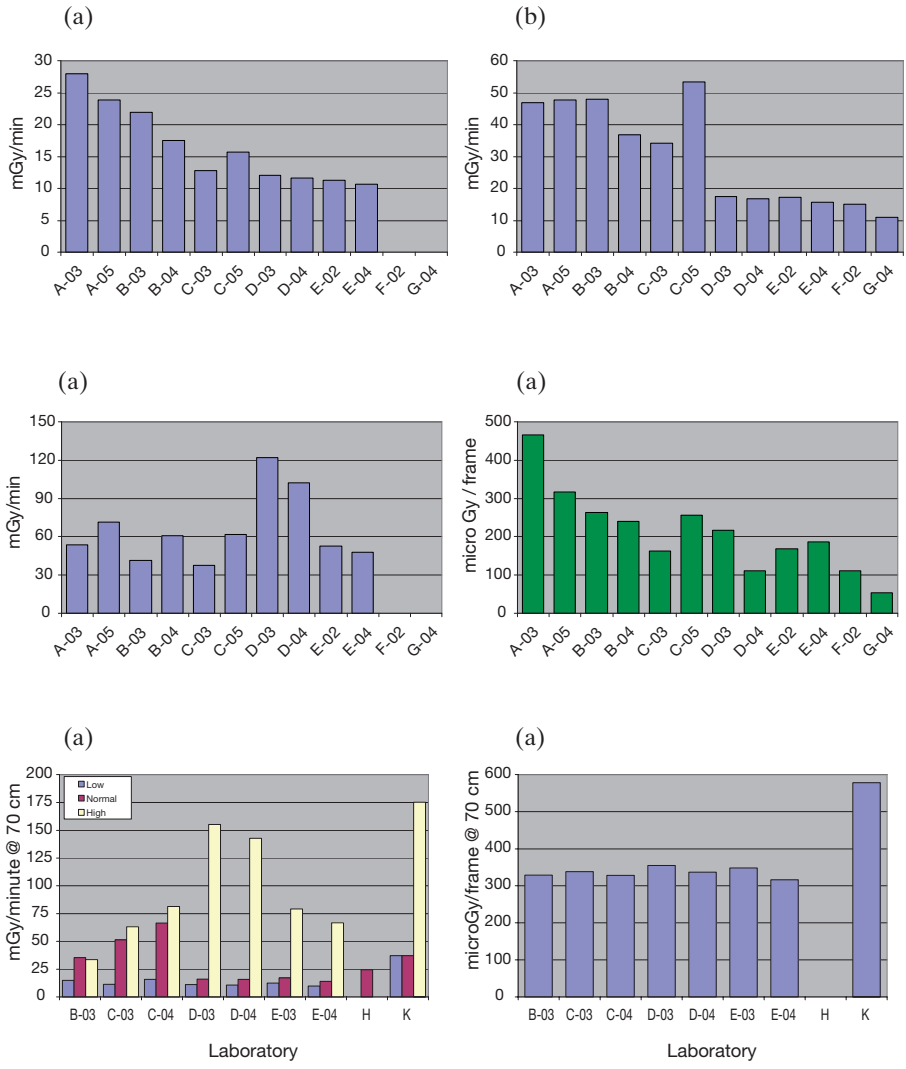

FIG. 22. (a) Low fluoroscopy mode. Results for 20 cm PMMA with Leeds TOR 18FG, at the isocentre. (b) Medium fluoroscopy mode. Results for 20 cm PMMA with Leeds TOR 18FG, at the isocentre. (c) High fluoroscopy mode. Results for 20 cm PMMA with Leeds TOR 18FG, at the isocentre. (d) Cine mode. Results for 20 cm PMMA with Leeds TOR 18FG, at the isocentre. (e) Simple checks (with 4 mm of Cu) for different X ray systems (Spain and Uruguay). Fluoroscopy modes. (f) Simple checks (with 4 mm of Cu) for different X ray systems (Spain and Uruguay). Cine mode. In all parts, the laboratories are indicated by a letter followed by the year of measurement.

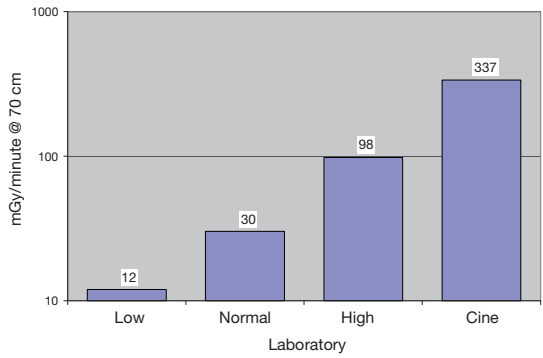

FIG. 23. Mean values for cine and the three fluoroscopy modes using all the available data from the characterization of the X ray systems.

Appendix VI

KERMA–AREA PRODUCT (P_{KA}) METER CALIBRATION

VI.1. PURPOSE

The pilot project was concerned with the possibility of establishing guidance levels for interventional procedures. The quantity for guidance levels in these procedures is the kerma–area product of the radiation impinging upon the patient. This requires determination of the P_{KA} that enters the patient after attenuation and scattering in the patient's couch and mattress. Since these conditions depend on each radiological unit, calibration of the P_{KA} meter needs to be done for each unit.

VI.2. BACKGROUND

The calibration has to account for the differences between the P_{KA} displayed by the transmission chamber placed on the collimator and the P_{KA} of the radiation impinging on the patient. These differences are not only due to the attenuation and scattering in the patient's couch and mattress but include also the following effects:

(a) Energy dependence of the transmission chamber (which usually contains metal electrodes). The energy dependence of the reference chamber is low for the purposes of this research.
(b) Inhomogeneity of the beam throughout the cross-section. This effect can be reduced when the angle is relatively small. The calibration is made for a symmetrical field of 100 cm^2, for which the variation due to this effect is acceptable.
(c) Extra focal radiation and radiation scattered in the collimator and filters, which may cross the P_{KA} meter but not reach the patient.
(d) Recombination effects taking place in the transmission chamber. These have been shown to be negligible by Larsson [84].

In interventional radiology, the only important problem deserving specific attention for P_{KA} calibration is the energy dependence of the transmission chamber, especially when the equipment includes copper filters, which substantially harden the X ray spectrum. This effect, together with the kV variation, can change the calibration factor by as much as 20% or more.

In certain radiological equipment and for some modes of operation, the copper filters are automatically inserted or changed. If a built-in P_{KA} meter is available, the software in certain equipment automatically corrects the values displayed by the built-in P_{KA} meter for the energy dependence every time the filter is inserted or changed. This automatic correction does not affect external P_{KA} meters. Since filters are inserted or changed during the procedure, it is impracticable to keep track of these changes. For this reason, the only solution for external P_{KA} meters is to choose a mid-value for the calibration factor and give the range associated to it; for example, if the range is about 20%, a central value can be chosen and an uncertainty of ±10% can be associated with the P_{KA} measurements on patients. The range can be obtained by measuring without the copper filter and with the maximum copper filter. Once the range is known, the mean value of the two calibration factors can be chosen.

VI.3. CLINICAL CALIBRATION PROCEDURE (FOR USE IN SETTING UP A PROGRAMME)

The following calibration procedure takes account of the energy dependence of the P_{KA} meters. It is suggested to choose two modes of operation (which involve the maximum copper filter and no copper filter) and two different kV values representing the range of kV usually encountered in practice. If the equipment does not have copper filters, the calibration procedure can be simplified accordingly.

The calibration factor is the ratio between the air kerma–area product for the radiation that actually impinges on the patient and the value displayed by the P_{KA} meter. The beam has been attenuated in the couch and mattress and there is some scatter radiation produced in the couch and mattress, but there should not be backscatter radiation from the patient or phantom.

$$k = K_{i,ref} A_{nom}/P_{KA} \quad (5)$$

where

k is the calibration factor to be applied to the transmission chamber to obtain the patient's P_{KA};

$K_{i,ref}$ is the air kerma value measured by the reference chamber on the top of the patient's couch and mattress;

A_{nom} is the area that can be determined by exposing a film placed on the table top (a small correction for difference in distance between the film to the

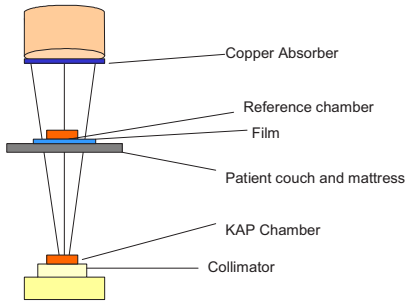

FIG. 24. P_{KA} calibration geometry. Note that for this project the P_{KA} meter calibration accounts for attenuation from the patent support and mattress.

point of reference of the chamber can be made, but this correction is usually negligible for this purpose, approximately 1.6–1.7%).

The set-up is illustrated in Fig. 24. The absorber is needed to protect the image intensifier from direct irradiation and to drive the AEC to the kV values required. The distance from the tube to the table top should be similar to the one used in practice for an average patient. The distance of the image intensifier to the reference chamber should be sufficient to minimize the backscatter radiation from the copper absorber reaching the reference chamber.

The values of the measurements should be recorded in a table. Every measurement should be performed three times and the average taken (see Table 12).

VI.3.1. Determination of the area (A_{nom})

To determine the area, the following steps should be taken:

(a) Place a film cassette with a medium speed film screen combination on the table top (patient's couch and mattress);
(b) Select the collimation to about 100 cm^2, referred to the level of the film;

TABLE 12. P_{KA} CALIBRATION WORKSHEET

Operation mode	X ray tube filtration (mm Al and mm Cu)	Absorber thickness	kV	A_{nom}	D_{ref}	P_{KA}	Calibration factor (k)

(c) Make a low exposure of approximately 50 kV and 5 mAs, to avoid overexposure of the film, which would blur the edges;
(d) Develop the film and evaluate the field size at the optical density of 50%.

It is usually not possible to expose the film at the same time as the measurement of P_{KA} because it would overexpose the film unless a low speed non-screens film was used, for example radiotherapy film.

The area can also be determined from the image intensifier by placing an object of known length for reference, running a series and recording the image. The number of pixels can be used to evaluate length, but it is essential to avoid using the peripheral part of the field, because the distortion of distances would influence the result. This can be achieved by using an image intensifier format, which is substantially larger than the field size to be determined. In our case, for a field size of 10 cm × 10 cm, or 100 cm^2, it would be adequate to use the image intensifier format of greater than 15 cm diameter or preferably 20 cm. In this way, it is almost certain that the periphery is not used to evaluate the area.

VI.3.2. Determination of reference air kerma ($K_{i,ref}$) and P_{KA}

The set-up is indicated in Fig. 24.

(a) Attach a copper absorber of 2 mm thickness to the image intensifier, which would drive the AEC to a relatively low kV value (around 60 kV).
(b) If the equipment has a device for automatic insertion of copper filters for certain operation modes, select an operation mode that does not include any copper filter.
(c) Run a series corresponding to a P_{KA} higher than 1 Gy·cm^2.
(d) Record the $K_{i,ref}$ and P_{KA}.
(e) Calculate the calibration factor, k, for this condition.
(f) Select an operation mode that automatically inserts a copper filter, and repeat procedures (b) to (d).
(g) Attach an additional absorber to the image intensifier, which drives the kV close to 100 kV (this can be achieved by 4 mm copper absorber, but some radiological systems may require up to 6 mm of copper to raise the kV to this level).
(h) Repeat procedures (c) to (d).
(i) If the equipment includes automatic insertion of copper filters, select an operation mode for which the copper filter is inserted in the beam. If there are several filters, choose the mode that inserts the higher value of copper thickness.
(j) Repeat procedures (c) to (d).

(k) Indicate the range of k values obtained and select a central value for the use of the P_{KA} meter to obtain patient data. Record the uncertainties to be associated with the patients' measurements (half of the range, expressed in per cent).

VI.4. ADDITIONAL COMPARISONS USED IN THE RESEARCH

VI.4.1. Comparison of reference chamber with thermoluminescent dosimeters

If possible, 80 kV as a typical tube voltage and a total filtration of 3–4 mm of aluminium were chosen as the exposure parameters. To avoid direct exposure of the image intensifier and to obtain a reasonable air kerma rate, an absorber was attached close to the image intensifier entrance, thus not changing the quality of the X ray beam impinging on the dose meters and the TLDs. A 4 mm copper plate was suggested as the absorber. If the AEC did not allow manually selecting 80 kV, the absorber thickness had to be varied such that the automatic control drives the kV to a value close to 80 kV. Care was taken to restrict the beam size to a field size smaller than the area covered by the copper plate in order to avoid direct exposure of some part of the image intensifier.

The reference chamber was then placed on the patient couch, which included the mattress, and centred in the beam. One badge with TLDs was placed on the top of the reference chamber. This gives a small increase in distance from the tube focus for the TLDs as compared with the reference chamber. Exposure of the reference chamber and the TLDs was then made with a target air kerma value of about 10 mGy. The TLD badge was then removed and the process was repeated to give a total of three irradiated badges. The P_{KA} readings were not used in this measurement. P_{KA} chambers have an equivalent in attenuation of about 0.2 mm Al. To keep the chamber in position is advantageous but not essential.

VI.4.2. Determination of the half-value layer

To have an indication of the radiation quality obtained in the exposures, the HVL was also determined for each X ray unit. HVL determination requires a series of exposures, with increasing aluminium attenuation keeping the radiation quality constant. One way of ensuring identical exposures on an interventional radiology facility is to run a series in acquisition mode and obtain the air kerma per frame and use it to derive the attenuation curve and the HVL.

If the AEC cannot be switched off and a manual selection of the acquisition parameters is not possible, the AEC would adjust exposure settings according to each thickness of the aluminium attenuator, resulting in a varying radiation quality. In this case keeping the full aluminium attenuators in the beam for all measurements but moving the attenuators from the position close to the image intensifier to a position close to the tube exit kept the total attenuation constant during the whole experiment. If this regime was followed the aluminium attenuators were also kept in the beam for the irradiation of the TLDs.

VI.4.3. Calibration of the thermoluminescent dosimeters

The TLDs used were Harshaw TLD-100 chips (Thermo RMP, Solon, USA) made from LiF. The reading of the dosimeters was accomplished with a Harshaw TLD 4000 TLD reader. The reading cycle of a chip starts with a preheat period (125ºC/12 s), followed by reading the air kerma at 5°C/s up to 275°C. Annealing of the dosimeters is performed prior to their usage by a temperature cycle of 400°C/1 h, followed immediately by 100°C for 2 h. In each irradiation and measurement cycle, a group of at least three chips was used to determine the background signal (instrumental and background radiation). The stability of the TLD reader was checked repeatedly after ten readings were taken by the reference light source available in the TLD reader. The variation of reader gain was <0.5%.

Before starting the comparison, the variation in sensitivity of TLD chips was investigated. The chip carriers were irradiated in the ^{60}Co unit at the Klinik für Strahlentherapie, Vienna (distance: 279 cm; build-up layer: 25 mm PMMA; time: ~1.9 min), giving an air kerma value of 100 mGy. For that purpose the chips were stored in PMMA chip carriers, keeping a maximum of 120 TLDs each. Measurement was achieved with an ionization chamber corrected for temperature and pressure with an accuracy of 2%. Calibration factors are traceable to the Austrian Federal Office of Metrology and Surveying.

For each chip, three irradiations and readings were made and the mean for the calibration factor (air kerma to signal ratio) was determined, giving an average error for three measurements with a single TLD of ±0.83%. Individual calibration factors were thus determined for a total number of 307 TLDs. The sensitivity for each chip in relation to the average sensitivity of the whole batch was obtained and used in all further measurements.

Three TLDs were welded into a polythene badge. For the comparison, three badges were sent to each participant for each X ray unit involved in the project for an exposure with an additional badge for the determination of background.

VI.4.4. Calibration of thermoluminescent dosimeters for diagnostic radiation qualities

The dependence of the TLDs on the radiation qualities used in this comparison was determined with a Siemens Polydoros 50S clinical X ray unit (tube: anode angle 16°; nominal inherent filtration: 2.5 mm Al). For the measurement of kerma, an M77334-638 ionization chamber and a UNIDOS 10001-11114 electrometer from PTW were used.

VI.4.5. Fading of thermoluminescent signal

Since the period for sending and retrieving the TLDs covered a few months, the fading of the thermoluminescent signal in this batch was taken into consideration. After exposure with ^{60}Co, the signal losses were monitored for a total of eight weeks. Individual correction factors for signal fading were obtained by interpolation according to the given irradiation and reading times whenever possible. For longer times, the fading correction factor was obtained by extrapolation using an average fading of 0.45% per week.

Appendix VII

DETAILED DATA

VII.1. SUMMARY STATISTICS BY PROCEDURE

Tables 13–18 show statistical data on patients and on the parameters that are most relevant to patient exposure to radiation.

TABLE 13. ABBREVIATIONS AND UNITS

Age	Patient age in years
Height	Patient height in cm
Weight	Patient weight in kg
F_{min}	Total FT for the procedure in minutes
C_{frames}	Total number of cine frames for the procedure (count)
Total P_{KA}	Total kerma–area product for the procedure (Gy·cm^2)
Fluoro P_{KA}	Fluoroscopic component of kerma–area product for the procedure (Gy·cm^2)
Cine P_{KA}	Cinefluorographic component of kerma–area product for the procedure (Gy·cm^2)
Total reference point air kerma	Total air kerma accumulated at the IEC IRP for the procedure (Gy)
Contrast	Quantity of radiographic contrast (dye) used during the procedure (mL)

TABLE 14. SUMMARY STATISTICS FOR ALL HOSPITALS AND PROCEDURES (N = 4109)

	N	Mean	SD[a]	10%	25%	50%	75%	90%
Age	2486	63.7	11.9	48	56	65	72	78
Height	2487	168.4	10.1	155	163	169	175	180
Weight	2488	78.9	16.5	60	68	78	87	99
F_{min}	3470	11.7	11.4	3	4	8	15	25
C_{frames}	3072	1042.7	657.6	470	655	871	1241	1823
Total P_{KA}	4109	62.8	60.0	16.4	24.9	42.8	79.0	135.0
Fluoro P_{KA}	3079	22.3	27.5	3.4	6.4	13.1	27.9	52.1
Cine P_{KA}	3080	29.6	27.7	7.7	13.3	21.7	35.9	59.4
Total RP air kerma	1586	1.5	1.3	0.4	0.6	1.1	1.9	3.0
Contrast	1016	227.7	147.0	84	115	191	306	425

[a] SD: standard deviation.

TABLE 15. SUMMARY STATISTICS FOR CORONARY ANGIOGRAPHY FOR ALL HOSPITALS (N = 2265)

	N	Mean	SD[a]	10%	25%	50%	75%	90%
Age	1133	63.9	12.7	47	56	65	73	79
Height	1135	168.2	10.6	155	162	168	175	180
Weight	1136	78.5	16.9	58	68	77	88	100
F_{min}	1826	7.1	6.9	2	3	5	9	15
C_{frames}	1806	867.7	389.9	510	655	810	1003	1295
Total P_{KA}	2265	39.9	31.4	13.8	20.8	31.8	49.4	73.3
Fluoro P_{KA}	1808	13.4	16.8	2.5	4.4	8.5	15.6	28.7
Cine P_{KA}	1809	23.9	18.1	7.6	13.1	19.8	29.8	43.8
Total air kerma	830	0.8	0.5	0.3	0.5	0.7	1.0	1.3
Contrast	449	130.5	67.1	60	90	115	155	210

[a] SD: standard deviation.

TABLE 16. SUMMARY STATISTICS FOR PERCUTANEOUS CARDIOVASCULAR INTERVENTION FOR ALL HOSPITALS (N = 1844)

	N	Mean	SD[a]	10%	25%	50%	75%	90%
Age	1353	63.6	11.1	49	56	64	72	78
Height	1352	168.5	9.6	155	163	170	175	180
Weight	1352	79.2	16.2	61	68	78	87	98
F_{min}	1644	16.7	13.1	5	8	13	21	31
C_{frames}	1266	1292.3	852.5	407	654	1124	1691	2410
Total P_{KA}	1844	91.1	73.2	23.9	39.6	71.8	122.2	181.8
Fluoro P_{KA}	1271	35.0	34.1	8.7	13.7	24.8	44.5	70.9
Cine P_{KA}	1271	37.6	35.8	7.8	13.8	26.5	49.0	80.0
Total AK	756	2.2	1.4	0.8	1.2	1.9	2.8	4.0
Contrast	567	304.7	147.5	150	200	280	380	497

[a] SD: standard deviation.

TABLE 17. SUMMARY STATISTICS FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY FOR ALL HOSPITALS (N = 1027)

	N	Mean	SD[a]	10%	25%	50%	75%	90%
Age	851	63.2	10.6	49	56	64	71	77
Height	848	168.1	9.1	155	163	169	175	180
Weight	848	77.4	14.7	61	68	76	85	95
F_{min}	916	15.2	13.0	5	7	12	20	30
C_{frames}	852	1100.1	782.2	346	527	881	1465	2173
Total P_{KA}	1027	75.9	68.3	18.8	29.9	53.3	98.4	157.6
Fluoro P_{KA}	855	33.8	33.4	8.5	13.0	23.7	43.9	69.8
Cine P_{KA}	855	29.9	31.1	6.5	11.3	19.6	36.8	65.4
Total AK	200	2.3	1.7	0.6	1.1	1.9	3.0	4.6
Contrast	170	292.9	179.6	100	155	250	390	500

[a] SD: standard deviation.

TABLE 18. SUMMARY STATISTICS FOR COMBINED CORONARY ANGIOGRAPHY AND PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY FOR ALL HOSPITALS (N = 817)

	N	Mean	SD[a]	10%	25%	50%	75%	90%
Age	502	64.2	12.0	49	56	65	73	80
Height	504	169.1	10.4	155	163	170	178	180
Weight	504	82.3	18.0	60	70	82	91	105
F_{min}	728	18.6	13.2	8	10	15	24	33
C_{frames}	414	1687.8	855.8	887	1174	1468	1976	2729
Total P_{KA}	817	110.0	74.8	36.6	59.1	92.9	138.3	208.0
Fluoro P_{KA}	416	37.5	35.4	8.9	15.3	27.9	46.5	74.8
Cine P_{KA}	416	53.5	39.3	17.0	26.5	43.3	70.1	97.2
Total AK	556	2.2	1.3	0.9	1.3	1.9	2.7	3.9
Contrast	397	309.7	131.3	170	219	290	380	494

[a] SD: standard deviation.

VII.2. SUMMARY STATISTICS FOR PATIENT WEIGHT BY HOSPITAL

Table 19 shows summary statistics for patient weight by hospital.

TABLE 19. SUMMARY STATISTICS FOR PATIENT WEIGHT (kg) BY HOSPITAL (N = 2357)

	Hospital							
	All	1	2	3	4	5	6	7
Number of cases	2357	238	249	385	462			1023
Mean	79.2	76.5	73.4	75.7	76.5			83.7
SD[a]	16.7	13.6	13.4	12.8	12.4			19.6
10%	60.0	60.0	56.0	60.0	60.0			61.3
25%	68.1	67.0	65.0	68.0	68.0			70.4
50%	78.0	75.5	71.0	75.0	76.0			81.7
75%	88.0	84.0	82.0	82.0	85.0			94.4
90%	99.9	95.0	90.6	90.0	92.0			108.9

[a] SD: standard deviation.

VII.3. EFFECT OF PATIENT WEIGHT

Table 20 shows statistics of patient weight, FTs and values of air kerma area product.

TABLE 20. SUMMARY STATISTICS FOR PATIENT WEIGHT GROUP BY PROCEDURE TYPE

	Patient weight (kg)			Total fluoroscopic time			Total kerma–area product (P_{KA})		
	All	CA	PCI	All	CA	PCI	All	CA	PCI
				All patient weights					
N	2488	1136	1352	3470	1826	1644	4109	2265	1844
Mean	78.9	78.5	79.2	11.7	7.1	16.7	62.8	39.9	91.1
SD[a]	16.5	16.9	16.2	11.4	6.9	13.1	60.0	31.4	73.2
25%	68.0	68.0	68.1	4.4	3.1	8.3	24.9	20.8	39.6
50%	78.0	77.2	78.0	8.2	5.2	13.1	42.8	31.8	71.8
75%	87.2	88.0	87.2	14.8	8.7	21.4	79.0	49.4	122.2
				Patient weight <50 kg					
N	38	21	17	38	21	17	38	21	17
Mean	43.2	44.3	41.9	11.4	8.1	15.5	38.4	21.1	59.9
SD[a]	7.0	4.3	9.4	10.9	7.1	13.4	53.7	17.1	73.5
25%	40.9	41.7	40.0	4.7	3.9	7.5	12.2	7.3	18.0
50%	45.0	45.4	44.1	7.4	5.8	10.9	20.3	14.0	25.0
75%	48.0	47.7	48.1	15.0	9.8	21.3	43.3	39.8	83.4
				Patient weight >50 kg, <65 kg					
N	371	185	186	371	185	186	371	185	186
Mean	58.3	58.0	58.7	11.5	6.7	16.2	51.5	29.8	73.1
SD[a]	4.2	4.3	4.1	11.6	5.2	14.1	52.3	32.1	59.1
25%	55.0	54.5	56.0	4.5	3.1	8.3	18.4	15.3	28.9
50%	59.0	58.0	60.0	8.5	5.3	12.3	33.4	22.6	57.0
75%	62.0	62.0	62.0	14.2	9.0	20.8	61.6	36.6	97.1

TABLE 20. SUMMARY STATISTICS FOR PATIENT WEIGHT GROUP BY PROCEDURE TYPE (cont.)

	Patient weight (kg)			Total fluoroscopic time			Total kerma–area product (P_{KA})		
	All	CA	PCI	All	CA	PCI	All	CA	PCI
				Patient weight >65 kg, <85 kg					
N	1366	611	755	1366	611	755	1366	611	755
Mean	75.1	75.0	75.2	11.8	6.5	16.2	63.3	36.9	84.7
SD[a]	5.9	5.9	5.9	11.7	7.0	12.8	57.9	31.0	65.4
25%	70.0	70.0	70.0	4.3	2.8	7.4	24.7	19.6	37.6
50%	75.0	75.0	75.0	8.2	4.5	12.6	44.0	28.8	67.7
75%	80.0	80.0	80.0	15.1	8.0	21.0	83.7	45.0	111.0
				Patient weight >85 kg, <100 kg					
N	495	219	276	495	219	276	495	219	276
Mean	91.7	92.3	91.2	13.0	6.4	18.2	88.3	48.9	119.5
SD[a]	4.2	4.2	4.1	13.3	6.1	15.1	80.6	33.3	92.6
25%	88.5	89.2	88.0	4.4	2.6	8.8	34.9	24.9	60.7
50%	90.8	92.0	90.0	9.0	4.6	13.7	66.3	39.9	93.3
75%	95.0	95.3	95.0	16.8	7.5	22.5	114.6	63.1	150.7
				Patient weight >100 kg					
N	218	100	118	218	100	118	218	100	118
Mean	114.1	114.3	114.0	12.3	6.1	17.5	115.1	68.1	155.0
SD[a]	13.2	12.8	13.6	11.2	5.8	12.0	83.9	42.7	89.7
25%	104.4	104.4	102.1	4.4	3.0	6.0	52.1	41.6	54.1
50%	109.4	109.4	104.4	8.4	4.4	8.7	89.2	59.5	90.2
75%	119.0	122.1	109.4	17.5	6.8	13.6	152.6	81.8	142.8

[a] SD: standard deviation.

Appendix VIII

COMPLEXITY INDEX FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY PROCEDURES

This substudy investigated the relationships between the complexity factors of a PTCA procedure and the observed technical factors such as FT, number of cine frames and kerma–area product (P_{KA}). Multiple linear regressions produced a CI capable of predicting the level of patient exposure. This index provides a tool for comparing individual practices and institutions as well as permitting a normalized comparison with guidance levels.

Samples of PTCA procedures were collected from cardiac centres located in Chile, Italy, Spain and Uruguay. The mean patient age at all centres ranged between 64 and 65 years (standard deviations between 8 and 12 years). The dosimetric data are summarized in Table 21. Each centre's sample was initially checked to verify data consistency and to make a subjective evaluation of the complexity mix at that centre. Relevant clinical data are summarized in Table 23.

TABLE 21. RELEVANT DATA USED FOR THE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY COMPLEXITY SUBSTUDY

Hospital	N		Fluoro time (min)	Number of images	P_{KA} (Gy·cm^2)
Chile	401	Mean	13.5	1027	62.6
		Median	9.9	668	50.0
Italy	180	Mean	10.2	584	50.8
		Median	7.1	504	38.9
Spain A	183	Mean	18.7	1307	69.5
		Median	15.2	1144	44.3
Spain B	58	Mean	20.5	1731	130.5
		Median	15.6	1633	101.7
Uruguay A	98	Mean	14.2	1301	50.8
		Median	12.3	1183	41.1
Uruguay B	121	Mean	20.4	2536	128.3
		Median	15.1	2520	119.1

TABLE 22. CHARACTERISTICS OF PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY SAMPLES: NUMBER OF CASES WITH COMPLEXITY OR PATHOLOGY FACTORS IN THE DIFFERENT SAMPLES

Centre	Vessels	Lesion type	Occlusion > 3 months	Severe tortuosity	Ostial stenting	Bifurcation stenting
Chile	36	60	3	13	14	33
Italy	25	54	4	6	15	19
Spain A	28	61	21	12	11	20
Spain B	9	22	2	22	0	11
Uruguay A	32	31	2	7	—	1
Uruguay B	12	5	2	2	1	3

The data were then analysed using multiple linear regression. For each variable, the analysis gives the regression coefficients, their standard errors and the statistical significance *P*(2 tail).

Table 23 lists those factors that correlated significantly with FT. The number of vessels treated, the severity of the lesion (lesion > B2), occlusion of the lesion for more than 3 months, severe tortuosity of the vessel and stenting at a vessel bifurcation are the only complexity factors in the different samples that were identified in the statistical analysis.

TABLE 23. COMPLEXITY FACTORS THAT CORRELATED WITH PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY FLUOROSCOPY TIME FOR EACH OF THE PARTICIPATING SITES

Centre	Vessels	Lesion type	Occlusion > 3 months	Severe tortuosity	Ostial stenting	Bifurcation stenting
Chile	X	X	X	X		X
Italy	X	X		X		X
Spain A	X		X			
Spain B	X	X		X		X
Uruguay A	X	X				
Uruguay B	X					

The results of the statistical analysis demonstrate that each data sample can be described with different factors, different coefficients and different weighting factors giving different complexity indices. This result is in part explained by the differences in case complexity in the samples, as reported in Table 24.

After these analyses, the data were merged. The merged data set is characterized by a large number of cases, with the factors and weights reported in Table 25.

TABLE 24. COEFFICIENTS AND WEIGHTING FACTORS FOR THE DATA SETS FROM EACH SITE

(the fluoroscopy time coefficient is given, with a weighting factor of 1, for 'number of vessels')

Centre	Vessels	Lesion type	Occlusion > 3 months	Severe tortuosity	Ostial stenting	Bifurcation stenting
Chile	1 (10.3)	0.54	1.54	0.91		0.80
Italy	1 (4.6)	0.63		2.06		0.95
Spain A	1 (12.8)		1.20			
Spain B	1 (9.5)	0.75		1.03		1.17
Uruguay A	1 (7.8)	1.00				
Uruguay B	1 (13.1)	0.35				

TABLE 25. FACTORS AND WEIGHTS FOR ALL PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CASES

All PTCA (857 cases)	Multi-vessel	Lesion type	Occlusion > 3 months	Severe tortuosity	Ostial stenting	Bifurcation stenting
Number of cases	117	161	24	25	22	58
Coefficients (min) (p value, 2 tail)	9.75 (0.000)	4.98 (0.000)	7.20 (0.002)	6.77 (0.000)		5.66 (0.000)
Weighting factors for the complexity index	1	0.51	0.73	0.69		0.58

Multivariate analysis applied to the whole sample gave the coefficients and the derived weighting factors reported in Table 25. All factors have a p (2 tail) < 0.001.

The derived weighting factors were applied to each PTCA case to derive the relative CI:

$$CI = No.ves * 1 + No.LesType * 0.51 + No.Occl3m * 0.73 + No.SevTort * 0.69 + No.BifSt * 0.58$$

Table 26 reports the mean and median values of the CI for each of the six centres. On average, more complex cases were reported from Spain B and Uruguay B than from the other centres.

Based on the derived CI, the whole sample was divided into three complexity groups:

(a) 'Simple' PTCA procedures with CI = 1;
(b) 'Medium complex' PTCA procedures with 1 < CI < 2;
(c) 'Complex' PTCA procedures with CI > 2.

Segmentation of the procedures into three complexity groups was validated using t tests. FT, total P_{KA} and fluoroscopic P_{KA} were compared between groups. All two-tail p values were < 0.001.

TABLE 26. COMPLEXITY INDEX (MEAN AND MEDIAN VALUES) CALCULATED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY FOR EACH CENTRE IN THE STUDY

	Complexity index	
	Mean	Median
Chile A	1.3	1.0
Italy A	1.4	1.0
Spain A	1.5	1.5
Spain B	1.8	1.0
Uruguay A	1.5	1.5
Uruguay B	1.7	1.0
All data	1.4	1.0

To confirm that the complexity indices are more relevant than body part thickness for estimating patient exposure, we assumed an exponential relationship between P_{KA} and patient equivalent diameter (as described in the methods) for the group of 'simple' PTCA procedures. Figures 25 and 26 demonstrate the distribution of ln(P_{KA}) and relative equivalent diameter and

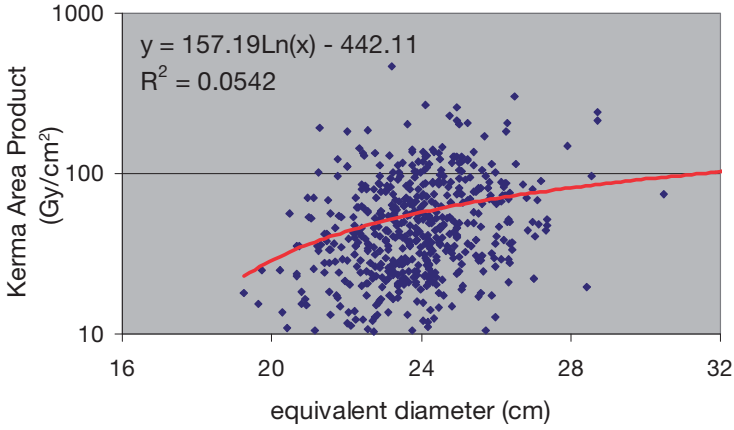

FIG. 25. Ln(P_{KA}) vs. patient equivalent diameter shows poor correlation (r^2 = 0.054) to a log trend line.

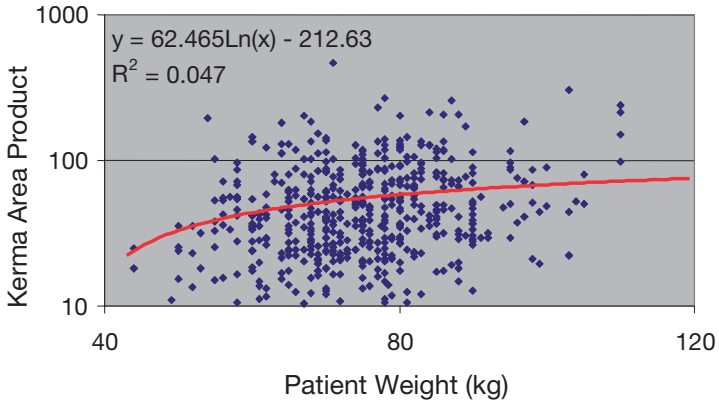

FIG. 26. Ln(KA) versus patient weight also shows poor correlation (r^2 = 0.047) to a log trend line.

TABLE 27. GROUPED COMPLEXITY CHARACTERISTICS

Complexity group	No.		Fluoro (min)	P_{KA} (Gy·cm^2)	P_{KA} f (Gy·cm^2)	Number of images	CI
Low	610	Mean	12.0	60.1	30.4	1123	1.0
		Median	9.7	46.2	21.4	940	1.0
		SD[a]	9.7	49.0	30.2	787	0.0
Medium	286	Mean	16.3	72.3	39.7	1218	1.7
		Median	12.5	54.9	29.6	1012	1.5
		SD	12.7	55.5	37.2	797	0.2
High	146	Mean	25.9	122.8	68.3	1751	2.7
		Median	22.5	114.0	57.3	1582	2.5
		SD	14.7	84.0	64.9	1049	0.6

[a] SD: standard deviation.

patient weight, along with the correlation coefficients. The poor correlations are an indicator that other factors like procedure protocol, operator experience and equipment performance are more important than patient absorption properties (body part thickness) in determining patient exposure as expressed in P_{KA}.

The rounded values for the third quartile of the distributions for the three groups of complexity can be used to propose a set of reference (guidance) levels (Tables 27 and 28 and Figs 27–29).

TABLE 28. REFERENCE (GUIDANCE) LEVELS FOR SIMPLE, MEDIUM AND COMPLEX PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY PROCEDURES EXPRESSED IN TERMS OF FLUOROSCOPY TIME AND P_{KA}

Complexity group	Reference (guidance) levels		
	Fluoroscopy time (min)	Number of images	P_{KA} (%)
Simple CI = 1	15	1500	100
Medium 1 < CI <= 2	20	1650	130
Complex CI > 2	32	2250	200

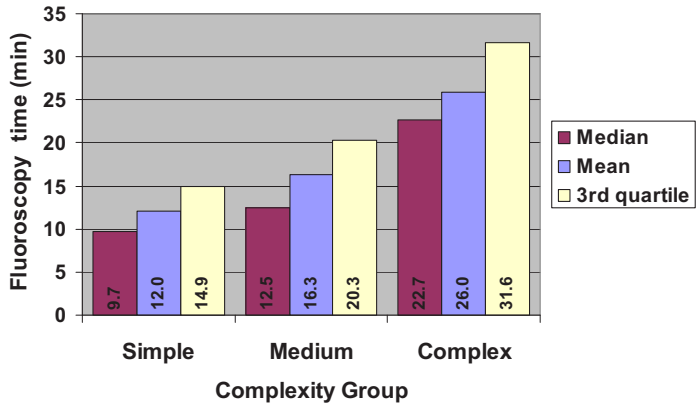

FIG. 27. FT as a function of complexity group for PTCA procedures. The observed mean and median values are shown along with the recommended guidance level.

The following simple linear relationships between $P_{KA,}$ FT and CI are derived from the previous analysis:

$$P_{KA}\ (\text{Gy}\cdot\text{cm}^2) = 35\text{CI} + 23$$

$$\text{FT (min)} = 6.8\text{CI} + 5.5$$

These equations cannot be applied to single cases, but only to large samples of PTCA cases. They may be used when no other local evaluation of complexity factors is available.

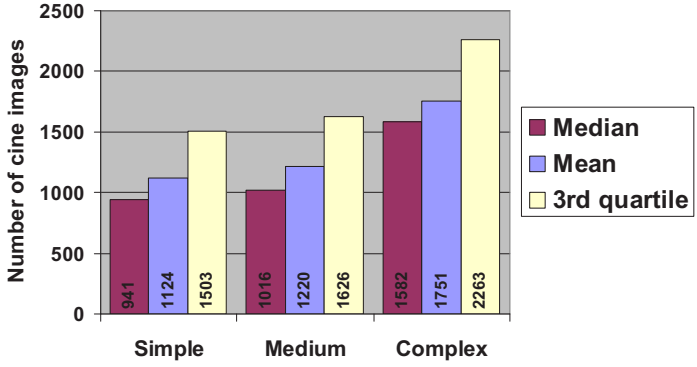

FIG. 28. Number of cinefluorographic images as a function of complexity group for PTCA procedures. The observed mean and median values are shown along with the recommended guidance level.

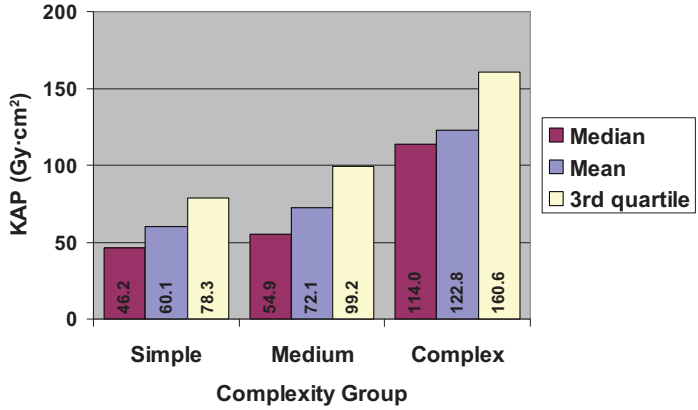

FIG. 29. Kerma–area product (P_{KA}) as a function of complexity group for PTCA procedures. The observed mean and median values are shown along with the recommended guidance level.

Appendix IX

IMAGE QUALITY SCORES OF CORONARY ANGIOGRAPHY PROCEDURES

Fourteen CA procedures from Madrid, Udine, Chile and Uruguay were evaluated by a cardiologist and a medical physicist according to the proposed quality criteria set. A set of procedures from Uruguay were not readable (provided in AVI and not in DICOM format). External evaluations performed in Udine are summarized in Figs 30(a)–(e), where for each examination are reported:

(a) The total score for the complete procedure (Fig. 30(a));
(b) The total technical score for left coronary angiography (LCA) and right coronary angiography (RCA), taking into account only technical factors (Fig. 30(b));
(c) The score for the LCA part of the examination (Fig. 30(c));
(d) The score for the RCA part of the examination (Fig. 30(d));
(e) The score for the LV part of the examination (Fig. 30(e)).

Total scores are derived from the scoring system applied to the quality criteria. All examinations, excluding the examination 'NRR', have sufficient or good image quality, in terms of clinical information content, expressed in terms of total score.

When the 'technical criteria' are considered, the scores show a high variability for the different examinations, which indicate that the examinations are performed differently in the participating centre. The technical score takes into account the following factors: arms outside the beam, apnoea, full opacification of vessels, panning and redundancy of information. The technical score of 4 of 13 studies is less than 60% and only 2 over 95%.

The scores for LCA and RCA are, usually, higher than those evaluated for LV. Important deficiencies are detected in some LCAs and RCAs.

Analysis of the DICOM header on projection used has given important information on the protocol adopted in the different centres. Important differences were: frame rate 25 or 15/12.5 fps in cine mode (continuous or pulsed mode in fluoroscopy is not known because fluoro images are not usually stored), number of series and number of frames per series. Important differences have been also detected in the perceived image quality (noise, contrast and spatial resolution) for the different angiographic system used.

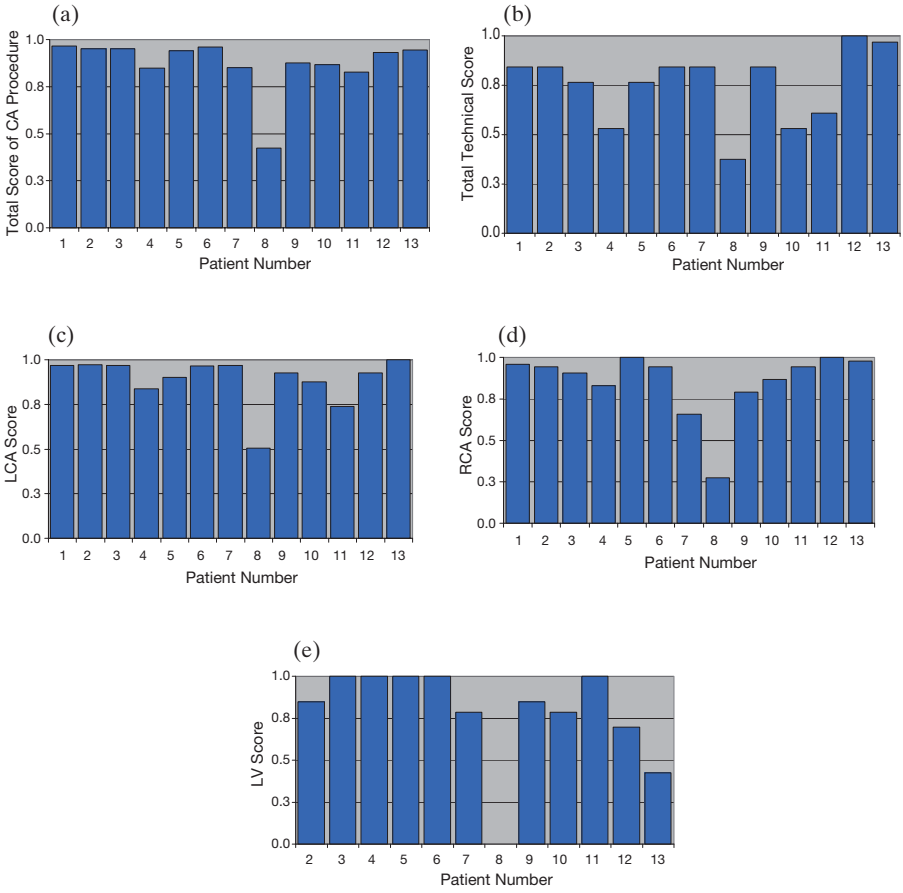

FIG. 30. (a) Total quality scores for a complete CA. (b) Scores representing the fulfilment of technical factors described in the quality criteria for a complete CA. (c) Quality scores for LCA. (d) Quality scores for RCA. (e) Quality scores for LV.

Appendix X

DETAILED ANALYSIS OF ONE INSTITUTION

This appendix presents the methodology used by one major facility to analyse its data and compare results with the proposed guidance levels given in this report.

X.1. COLUMBIA UNIVERSITY MEDICAL CENTER

This section describes a further analysis of the data collected from Columbia University Medical Center in New York City. This analysis uses the entire 1755 procedures submitted to the CRP. A random subset of 1026 of these procedures was included in the overall CRP analysis. Statistics for the full and sample data sets are shown below.

The Columbia workflow differs in many respects from that found in most institutions. Pure CA procedures (with no a priori intention to intervene) are generally performed as angiographic follow-ups to research procedures. Most CA procedures are more typically initially scheduled to be part of a CA + PTCA procedure. If no angiographically treatable disease is found, these procedures are concluded at the end of the CA stage. Patients with angiographically manageable disease are treated in the same session. Pure PTCA procedures are scheduled either as follow on phases of a previous procedure or as potentially high complexity procedures referred from outside hospitals.

Many more complex procedures are performed at Columbia than is usual in most institutions. As examples; many of the diagnostic studies include evaluation of vein grafts, an average of just over two stents are placed during each intervention, and intravascular ultrasound is extensively used for both diagnostic and interventional purposes.

Six procedure rooms form the core of this laboratory. The kerma–area product meters are calibrated semi-annually. The data reported in this appendix reflect calibration factors equivalent to those used in the main body of the report.

X.2. DATA COLLECTION AND PROCEDURAL CLASSIFICATION

All data shown in this appendix were collected from existing clinical and quality assurance records with the approval of the Columbia University Medical Center Institutional Review Board.

A manual procedure log is maintained for clinical workflow and quality assurance purposes in each laboratory. At the conclusion of a procedure, the FT, number of runs (cine plus stored fluoro), total air kerma–area product and total air kerma at the IEC IRP are recorded. These logs are later matched with the laboratory's clinical database to determine the corresponding procedures. Logs from all rooms were used in this analysis.

The clinical database provides a data field describing procedure type. Three of these fields report coronary artery procedures. It is not uncommon to find multiple procedure codes describing portions of a single procedure. Cases reported in this appendix were pure coronary artery procedures and are coded at the highest level found in the database. Non-coronary procedures and procedures with a non-coronary element were excluded from further analysis. Biplane procedures have also been excluded.

All categories generally include more complex subprocedures than most of the procedures reported in the main section of this report. A formal investigation of complexity analysis is in progress. However, specific complexity factors are not included in this appendix.

X.3. RESULTS

A total of 1755 eligible procedures were collected in the period November 2005 to March 2006. There were 814 diagnostic, 290 PTCA, and 651 CA + PTCA procedures in the complete set. Descriptive statistics for the 1026 procedure subset used in the main report and the entire 1755 procedure data set are shown in Figs 31(a)–(d). It was seen that the random sample is an excellent representation of the entire data set. Key data are shown in Figs 31(a)–(d) and 33(a) and (b).

X.4. DISCUSSION

The preliminary guidance levels given in this report were used to benchmark laboratory performance. Before adjustments for complexity: It is seen that the median 45 Gy·cm^2 P_{KA} for the diagnostic (CA) category is below the CA guidance level of 50 Gy·cm^2. This is an indication that exposure management in this facility is appropriate. It is seen that the medians, 108 Gy·cm^2 P_{KA} for all classes of interventional procedures (PCTA, CA + PTCA, and PCI), are below the suggested PCI guidance level of 125 Gy·cm^2. The observed median P_{KA} values fall below the proposed guidance levels;

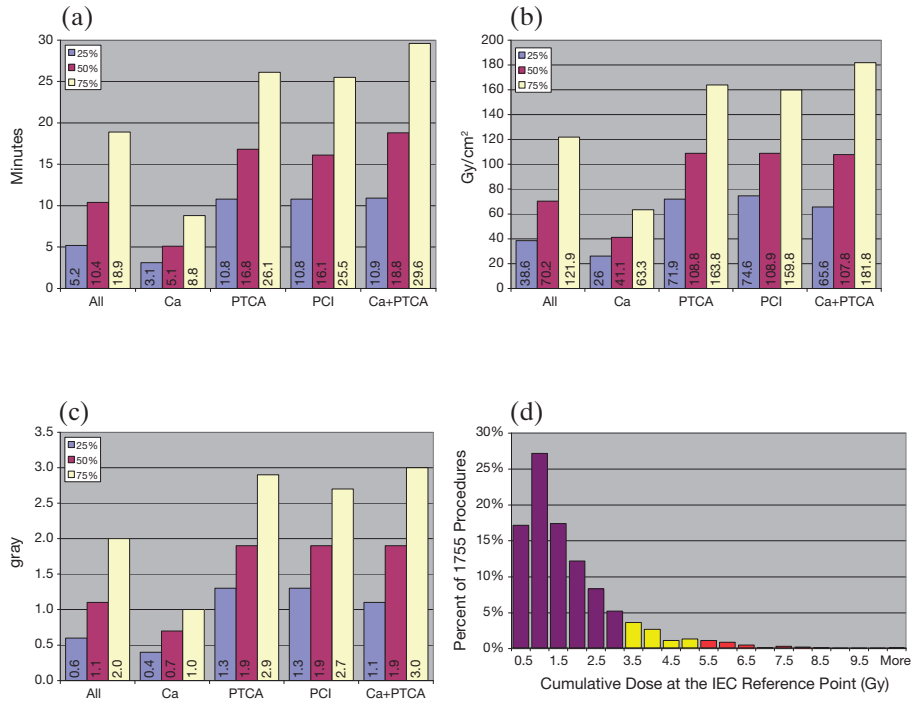

FIG. 31. (a) Fluoro time percentiles for different procedure categories. (b) Kerma–area product percentiles for different procedure categories. (c) Reference point dose (CD) at the IEC reference point. Percentiles for different procedure categories. As indicated in footnote 4, the instrument calibration is done in terms of air kerma. Consequently, quantities like reference point dose and cumulative dose, when referred to air, are expected to be replaced in future by cumulative air kerma. (d) Columbia IEC CD, all patients. The laboratory informs all patients who 'receive' an IEC dose above 5 Gy. These patients are followed for potential radiation injury.

however, they fall above the medians observed in this pilot project. Possible reasons for these deviations are discussed in Section X.4.2.

X.4.1. Special observations

The relative P_{KA} and the IEC dose for PTCA both exceed those for CA + PTCA at high percentiles. The same trend is seen for FT but not for the number of cine runs. This is likely to be a representation that the most complex 'pure'

PTCA procedures are more difficult than the CA + PTCA procedures. This observation is compatible with the patient referral patterns discussed above.

X.4.2. Possible technical causes of P_{KA} variability

All of the equipment in this laboratory has been installed in the past three years. All three manufacturers furnished systems with dose rate reducing technologies such as copper beam filtration and digital image management. For a variety of reasons, the dose rates produced by this equipment are approximately 50% that of early 1990s systems.

Both fluoroscopy and cinefluorography are performed at 15 fps at this institution instead of the 7.0–12.5 fps characteristic of most of the systems included in the main pilot project (Table 1). The effect of this difference can be estimated. We assume 12.5 fps for both modes, the same dose per frame for cine, the same dose rate per second for fluoroscopy, and an average of 50% of P_{KA} attributable to cine. Given these assumptions, the fluoroscopic contribution to P_{KA} is independent of the frame rate. The cine contribution will be increased by 10%. Thus the overall P_{KA} delivered by a procedure is estimated to be 5% higher for a 15 fps system when compared with a 12.5 fps system.

Most Columbia systems used flat panel image receptors with a square input field instead of image intensifiers with overframed round input fields. Part of the P_{KA} difference might simply be due to a difference in field size. This effect is shown in Fig. 32. The middle FOV of the image receptor is represented. This corresponds to the most common FOV used in interventional cardiology. The outer square represents a flat panel detector with a diagonal size of 20 cm. The two broken circles represent collimated fields corresponding to 17 cm and 15 cm image intensifier fields of view. Most clinical systems overframe to an effective field size somewhere in the grey region of the figure.

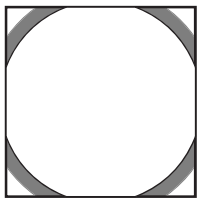

FIG. 32. Overframing influences P_{KA}. The rectangle represents the 20 cm (diagonal) FOV of a flat panel detector. The circular arcs represent 17 and 15 cm overframed image intensifier FOVs. Most image intensifier systems are overframed to levels between these values.

Flat panel systems are typically programmed to require a higher fluoroscopic image receptor dose per frame than corresponding image intensifier systems. Cine dose per frame values are usually similar between the two technologies. Qualitatively this results in a higher output from the X ray tube during fluoroscopy and therefore a higher total P_{KA}. The magnitude of this effect is strongly affected by the manufacturer's clinical programming of the imaging system.

Five of the six systems adjust the thickness of the copper spectral shaping field as a function of patient thickness. Many of the systems use a single copper thickness for a given mode. This difference results in higher patient dose rates for heavy patients in the target system relative to the systems. The influence of this difference on the P_{KA}s included in this report is unknown.

Five of the six laboratories have the ability to retrospectively store fluoroscopic runs. The operators often use this facility to document events (e.g. balloon inflations) that do not require cine image quality. The magnitude of this dose saving is unknown. Retrospective storing of fluoroscopy can lead to confusion in an exposure management programme. A the end of a case, present day systems indicate the number of runs and frames available to send to an archive. These counts include both cine and archived fluoroscopy. The inappropriate use of these numbers could lead to errors in estimating the cine component of patient exposure.

X.4.3. Possible operator influences on P_{KA} and skin dose

Operators can influence P_{KA} in three ways. Optimizing beam on time is the one factor that is obvious to all operators. Two other factors that could reduce P_{KA} are careful collimation of the beam to the region of interest and minimizing SID.

The degree of beam collimation can be estimated by measuring CD at the IEC IRP. The ratio P_{KA}/CD is the X ray beam size at the IEC reference point. CD data were collected for all procedures included in the Columbia University series. The relationship between P_{KA} and reference point dose (CD) is shown in Fig. 33(a). The r^2 of the regression line was 0.98. This, coupled with the small dispersion of the data, indicates minimal use of collimation.

Increasing, SID simultaneously increases CD and P_{KA}. The relative influence of this factor on the Columbia University data in comparison with the main pilot project is unknown.

A low table position coupled with the image receptor near the patient will minimize P_{KA}. However, the patient skin dose rate is increased due to the inverse square law. A low table position coupled with maximum SID will further increase the skin dose rate by a factor of two. A high table position will

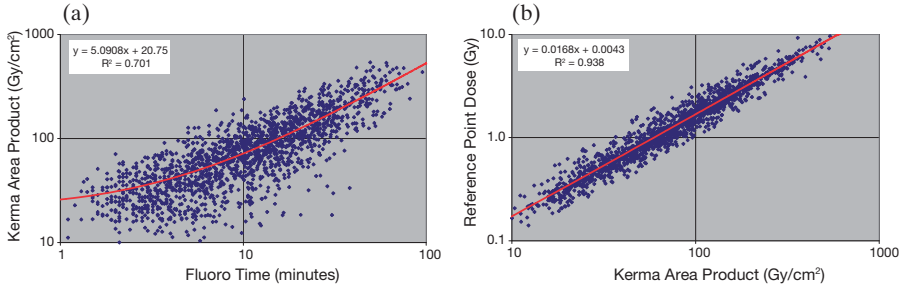

FIG. 33. (a) P_{KA} versus fluoro time. Note the order of magnitude variability in P_{KA} for most FTs. (b) Reference point dose (IEC CD) versus P_{KA}. The high r^2 and small degree of scatter about the regression line results from minimum operator attention to collimation.

increase P_{KA}. However, it will decrease the patient skin dose rate. Increased P_{KA} usually results in increased operator exposure. This combination of factors poses some interesting issues in balancing patient and staff safety.

X.4.4. Procedure mix and procedure complexity

The complexity of the procedures performed at Columbia has not been scored using the criterion described in this report. However, the nature of the clinical practice suggests that the mean procedural complexity is likely to be significantly higher than the average of those reported in the main section of this report. The lower percentiles are likely to match the main study when corrected for complexity. The 90th percentile and above generally reflects extremely complex procedures (e.g. opening a chronic total occlusion) that were very uncommon when procedures reported in the main study were performed.

Diagnostic only (CA) procedures are seldom performed as an independent procedure. A large fraction of the diagnostic procedures were performed on patients who were referred for possible interventions and found not to have significant disease of their coronary arteries or bypass grafts. Many of the remaining patients are seen for follow-up procedures either as part of a research protocol or as part of the management of a major clinical situation (e.g. heart transplant).

Intervention only (PTCA) procedures at Columbia (and other large referral centres) differ significantly from the model initially used to define the research performed by the pilot project. Many of these patients are referred to Columbia by invasive cardiologists who do not feel qualified to safely and

successfully complete a complex intervention. Another significant fraction is composed of patients whose disease is too complex to treat in a single session. These individuals receive an 'intervention only' procedure as the second or third session in their treatment. In general, 'intervention only' procedures consume as much or more resources than a classical combined procedure.

Combined diagnostic and interventional procedure (CA + PTCA) patients fall into two broad categories: patients referred to the laboratory by primary cardiologists who suspect repairable coronary artery disease, and patients referred for interventions who do not have previous adequate diagnostic studies, and therefore CA is required prior to PTCA. In some sense, the primary referrals are simpler than intervention only patients because of a somewhat less complex disease process.

X.4.5. Evaluation of patient exposure management

Comparison of median values with guidance levels serves to manage the overall technical performance of the laboratory. As previously discussed, these comparisons need to include appropriate consideration of the average clinical complexity of the procedure mix in a given laboratory.

Managing the possibility of deterministic injuries involves a focus on the 'extreme values' rather than on mean or median values. These extreme value procedures are not outliers in the traditional sense. Each represents real data describing an individual patient and procedure. These patients deserve appropriate clinical exposure management. Columbia's policy is reproduced in the next section of this appendix.

Many studies, including this one, demonstrate the difficulty in using FT as a dose surrogate for estimating the possibility of deterministic injury. Figure 33(b) is a scatter plot of the relationship between FT and P_{KA} for the Columbia series.

Although $r^2 = 0.7$ for this series, there is an order of magnitude spread of P_{KA} at all fluoro times. Reasons for this include lack of consideration of the effects of cine, patient size and beam angulation. The use of the regression line to predict P_{KA} will underestimate maximum P_{KA} by more than a factor of three. FT is therefore not recommended for use in estimating patient skin dose.

The in-laboratory process is based on the reference point dose (CD as defined by the IEC). The laboratory standard is to notify those patients who 'received' a reference point dose of 5 Gy or more. With normal beam motion, the reference point dose usually corresponds to a PSD between 2.0 and 2.5 Gy. The 5 Gy level was exceeded in approximately 20% of Columbia's interventional patients. All such patients are followed after their procedures. One deterministic injury was reported (reference point dose = 11 Gy). There

was no skin breakdown. This injury healed to a hyper pigmented area within six months with simple supportive therapy.

Significant exposure procedures (even without clinical injury) are routinely discussed as part of the catheterization laboratory's quality assurance process. Actual injuries are reported to, and discussed by, the institution's radiation safety committee.

X.5. OUTLINE OF COLUMBIA UNIVERSITY PATIENT EXPOSURE MANAGEMENT POLICY

X.5.1. Pre-procedure

At risk patients are identified:

(a) Over 150 kg (any procedure);
(b) Complex procedure planned (any patient size);
(c) Previous long PCI procedures (any patient);
(d) Previous or planned radiation therapy to the chest (any patient).

The consent process is tailored to the risk factors identified above.

X.5.2. During the procedure

(a) The operator and monitoring procedure track the reference point dose (IEC CD);
(b) The monitoring person alerts the operator when the reference point dose exceeds 3 Gy;
(c) The operator includes radiation effects while continuously evaluating the benefits and risks.

X.5.3. Post-procedure (reference point dose exceeds 5 Gy)

(a) The operator immediately makes a note in the patient's medical record justifying the use of significant amounts of radiation.
(b) Before discharge, the patient is informed that significant amounts of radiation were required to complete the procedure and warned about their potential effects. The patient is asked to call the catheterization laboratory if any signs of radiation injury are observed.

(c) All PCI patients are called 30 days after their procedures. Signs of potential radiation injury are asked for at this time. Patients with positive or equivocal signs are brought back to the laboratory for evaluation.

X.5.4. Continuous quality assurance (all patients)

(a) Dose and related data are collected and inserted into a dedicated radiation monitoring database.
(b) Weekly reports are generated of patients with a reference point dose exceeding 5 Gy. These are sent to the quality assurance manager and the physician laboratory director.
(c) Significant exposure procedures, including the follow-up results, are discussed in the laboratory's monthly quality assurance meeting.
(d) Observed deterministic events are reported to the institution's radiation safety committee at its next quarterly meeting.

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[78] FOOD AND DRUG ADMINISTRATION, Important Information for Physicians and Other Health Care Professionals: Recording Information in the Patient's Medical Record that Identifies the Potential for Serious X-ray-induced Skin Injuries Following Fluoroscopically Guided Procedures, FDA, Washington, DC (1995), http://www.fda.gov/cdrh/xrayinj.html
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Annex I

BSS REQUIREMENTS ON GUIDANCE (REFERENCE) LEVELS AND ICRP ADVICE

I–1. FROM THE PRINCIPAL REQUIREMENTS OF THE BSS

I–1.1. Guidance levels for medical exposure

From the BSS [I–1]:

"2.27. Guidance levels for medical exposure shall be established for use by medical practitioners. The guidance levels are intended:

(a) to be a reasonable indication of doses for average sized patients;
(b) to be established by relevant professional bodies in consultation with the Regulatory Authority following the detailed requirements of Appendix II and the guidance levels given in Schedule III;
(c) to provide guidance on what is achievable with current good practice rather than on what should be considered optimum performance;
(d) to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement; and
(e) to be revised as technology and techniques improve."

From the detailed requirements of the BSS [I–1]:

"II.16. Registrants and licensees shall ensure for diagnostic radiology that:

(a) the medical practitioners who prescribe or conduct radiological diagnostic examinations:

  (i) ensure that the appropriate equipment be used;
  (ii) ensure that the exposure of patients be the minimum necessary to achieve the required diagnostic objective, taking into account norms of acceptable image quality established by appropriate professional bodies and relevant guidance levels for medical exposure;…"

Guidance levels from the BSS [I–1]:

"II.24. Registrants and licensees should ensure that guidance levels for medical exposure be determined as specified in the Standards, revised as technology improves and used as guidance by medical practitioners, in order that:

(a) corrective actions be taken as necessary if doses or activities fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;
(b) reviews be considered if doses or activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice; and
(c) for diagnostic radiology, including computed tomography examinations, and for nuclear medicine examinations, the guidance levels be derived from the data from wide scale quality surveys which include entrance surface [air kerma (Ke)] and cross-sectional dimensions of the beams delivered by individual facilities and activities of radiopharmaceuticals administered to patients for the most frequent examinations in diagnostic radiology and nuclear medicine respectively.

II.25. In the absence of wide scale surveys, performance of diagnostic radiography and fluoroscopy equipment and of nuclear medicine equipment should be assessed on the basis of comparison with the guidance levels specified in Schedule III, Tables III-I to III-V. These levels should not be regarded as a guide for ensuring optimum performance in all cases, as they are appropriate only for typical adult patients and, therefore, in applying the values in practice, account should be taken of body size and age."

ICRP advice on diagnostic reference levels (from Ref. [I–2]):

"(12) The objective of a diagnostic reference level is to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task. This is accomplished by comparison between the numerical value of the diagnostic reference level (derived from relevant regional, national or local data) and the mean or other appropriate value observed in practice for a suitable reference group of patients or a suitable reference phantom. A reference group of patients is usually defined within a certain range of physical parameters (e.g. height, weight). If an unselected sample of patients were used as a reference group, it would be difficult to interpret whether the observed value for the sample is higher or lower than the diagnostic reference level. A diagnostic reference level is not applied to individual patients.

(14) Appropriate local review and action is taken when the value observed in practice is consistently outside the selected upper or lower level. This process helps avoid unnecessary tissue doses being received by patients in general and, therefore, helps avoid unnecessary risk for the associated radiation health effects."

REFERENCES TO ANNEX I

[I–1] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[I–2] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Diagnostic Reference Levels in Medical Imaging: Review and Additional Advice, ICRP Supporting Guidance 2, Pergamon Press, Oxford and New York (2001) 33–52.

Annex II

NON-CARDIAC PROCEDURES — THE RAD-IR STUDY

In 1997, the United States Food and Drug Administration (FDA) invited the Society of Interventional Radiology (SIR) — a professional organization of interventional radiologists, primarily from the USA — to gather information on dose levels associated with common interventional radiology procedures. In response, SIR formed a task force to develop a method for collecting dose information prospectively from medical centres across the USA. A multicentre protocol was developed to create a radiation dose database for each of 21 different interventional radiology procedures. The study was conducted with the approval of, and under the supervision of, the Institutional Review Board at each participating medical centre. Over a three year period, seven academic medical centres in the USA participated in the SIR Radiation Dose in Interventional Radiology Study (RAD-IR Study) and collected data from 2142 instances of a variety of procedures. These data were reported in three parts [II–1 to II–3].

The RAD-IR Study was designed to provide data on 'real world' doses for a variety of interventional procedures. For this reason, there was no attempt to standardize either the technical factors for each fluoroscopic unit or the way in which each procedure was performed.

All interventional fluoroscopy units in the study contained an integrated dosimeter and performed exposure measurements automatically, including FT, dose–area product (DAP), and CD[6] at the IRP. All of these units were compliant with the dosimetry portion of IEC standard 60601-2-43 [II–4]. All of these units incorporated then state of the art dose reduction features, including modern image intensifier video systems, pulsed fluoroscopy, low dose continuous fluoroscopy, spectral filtration, frame averaging, digital subtraction angiography without test exposures, variable frame rate digital subtraction angiography, visualization of collimator and filter positioning without radiation, and real time display of CD.

An initial comprehensive physics evaluation was conducted on each fluoroscopic unit to confirm that its dosimeter was functioning properly. This full evaluation compared the internal reference dose readout with an external ionization chamber over a range of exposure conditions. The comprehensive

[6] Since this annex is a summary taken from the IRD study, original expressions such as dose–area product and cumulative dose have been maintained, without replacing them by air kerma–area product and cumulative air kerma.

evaluation was repeated after any major equipment modifications and at the end of the study.

In addition, periodic consistency checks were performed on each unit every one to two weeks to verify the stability and consistency of the reference dose readout and the automatic brightness control. The data from each initial physics evaluation and each periodic consistency check were forwarded to a central site for tabulation. Procedural details have been published [II–1 to II–3].

Data were collected on 48 comprehensive physics evaluations and 581 periodic consistency checks from the 12 fluoroscopic units in the study. The root mean square error for fluoroscopy and fluorography was obtained by combining the standard deviations of the comprehensive and consistency data sets. The root mean square error in clinical measurement of CD is estimated at ±24%. This is well within the tolerances established by the IEC and is also within the ±25% limit recommended by others for overall uncertainty of patient dose measurements [II–2, II–5].

Demographic and radiation dose data were collected for 2142 instances of procedures during the period from April 1999 through January 2002. For each instance, data collected included patient data (weight, height and age), operator type (resident, fellow, staff), acquisition data (number of exposures, FT, DAP and CD), fluoroscopy mode used (continuous, pulsed, pulse rate) and procedure type. Some procedures were divided into subgroups. These subgroups were defined prospectively, prior to data collection.

Subjects ranged in age from 4 days to 104 years (mean, 55.3 years). Of the 2142 instances, 1019 (47.6%) were performed on male patients and 1123 (52.4%) were performed on female patients. Subjects' heights ranged from 30 cm to 208 cm (mean, 175 cm) for male patients and from 53 cm to 196 cm (mean, 162 cm) for female patients. Subjects' weights ranged from 1.8 kg to 186.0 kg (mean, 83.8 kg) for male subjects and from 3.6 kg to 215.0 kg (mean, 71.6 kg) for female subjects.

For different instances of the same procedure, there were wide variations in dose and statistically significant differences in FT, number of images, DAP and CD, depending on the nature of the lesion, its anatomic location and the complexity of the procedure. For the 2142 instances, observed CD and DAP correlated well overall ($r = 0.83$, $P < 0.000001$), but correlation in individual instances was poor. The same was true for the correlation between FT and CD ($r = 0.79$, $P < 0.000001$). The correlation between FT and DAP ($r = 0.60$, $P < 0.000001$) was not as good. In 6% of instances (128 of 2142), principally embolization procedures, transjugular intrahepatic portosystemic shunt (TIPS) procedures, and renal/visceral artery stent placements, CD was greater than 5 Gy.

Seven of the 12 interventional fluoroscopy units in this study incorporated skin dose calculation capability. These units were equipped with an additional dose measurement system (CareGraph; Siemens Medical Systems). This system is described in detail elsewhere [II–6]. The system provides information on the peak dose level (i.e. the PSD) and spatial distribution of the dose on the skin.

Skin dose data were recorded for a subset of 800 instances of 21 interventional radiology procedures. Wide variation in the PSD was observed for different instances of the same procedure. Some instances of each of the procedures studied resulted in a PSD greater than 2 Gy, except for nephrostomy performed for urinary obstruction, pulmonary angiography and inferior vena cava filter placement. Some instances of TIPS creation, visceral angioplasty and angiographic diagnosis and therapy of gastrointestinal haemorrhage produced a PSD greater than 3 Gy. Some instances of hepatic chemoembolization, other tumour embolization and neuroembolization procedures in the head and spine produced a PSD greater than 5 Gy.

Of the 800 procedures where skin dose was calculated, 588 procedures (74%) resulted in a PSD of 0.1 Gy or higher. The group includes 360 monoplane and 424 biplane procedures. These procedures are reanalysed in this report to discover relationships between the following observables:

(a) Total FT is the sum of the fluoroscopy times from both planes in the case of a biplane procedure (FT for a monoplane procedure).
(b) Maximum FT is the greater of the fluoroscopy times from either plane in the case of a biplane procedure (FT for a monoplane procedure).
(c) Total kerma–area product is the sum of the P_{KA} from both planes in the case of a biplane procedure (P_{KA} for a monoplane procedure).
(d) Maximum kerma–area product is the greater of the P_{KA}s from either plane in the case of a biplane procedure (P_{KA} for a monoplane procedure).
(e) Total CD is the sum of the cumulative doses from both planes in the case of a biplane procedure (CD for a monoplane procedure).
(f) Maximum CD is the greater of the cumulative doses from either plane in the case of a biplane procedure (CD for a monoplane procedure).

These relationships are shown in Figs II–1 to II–6. The associated linear regressions are shown in Table II–1.

It is seen that the PSD is least correlated with FT, with the maximum FT (from either plane in a biplane system) being somewhat better than the total FT. The remaining correlations are greater. It is noted that the slope of the line for maximum CD is higher (0.72) than that for the total CD. This implies a

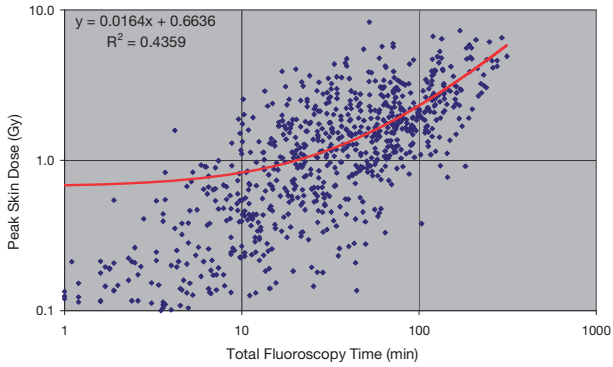

FIG. II–1. Peak skin dose versus total fluoroscopy time.

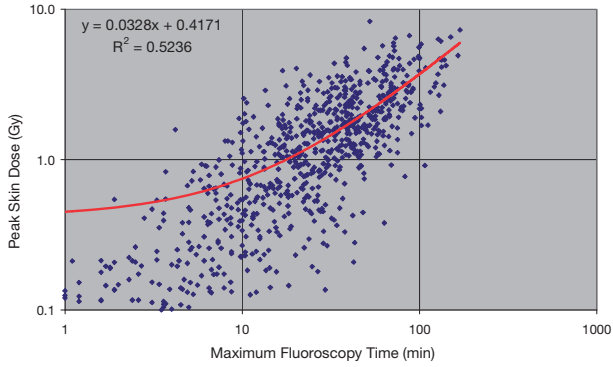

FIG. II–2. Peak skin dose versus maximum fluoroscopy time.

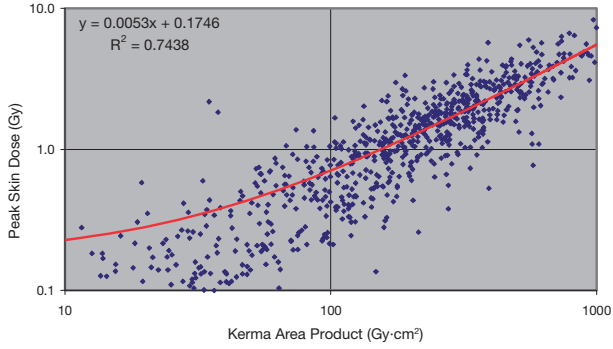

FIG. II–3. Peak skin dose versus total kerma–area product.

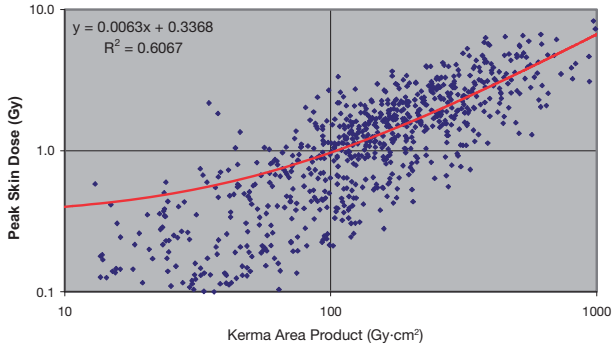

FIG. II–4. Peak skin dose versus maximum kerma–area product.

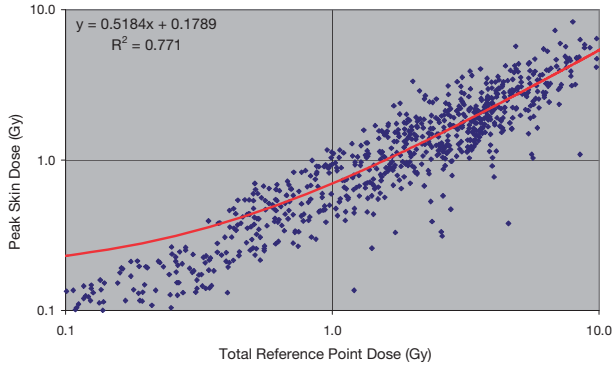

FIG. II–5. Peak skin dose versus total reference point dose (CD).

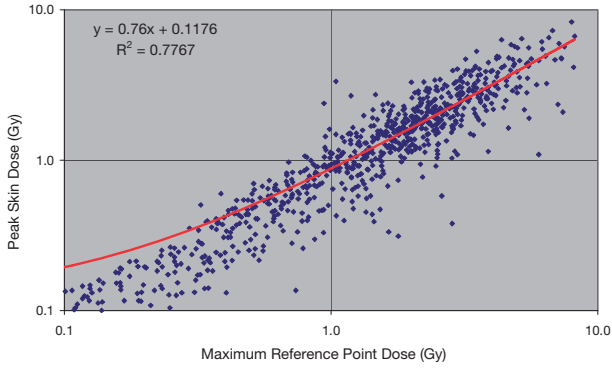

FIG. II–6. Peak skin dose versus maximum reference point dose (CD).

TABLE II–1. LINEAR REGRESSION FOR PEAK SKIN DOSE (PSD) FOR SELECTED DOSIMETRIC VARIABLES

Predicted	Variable	r^2	Linear fit
PSD (Gy)	Total fluoro time	0.44	PSD = 0.016 × total fluoro time + 0.66
PSD (Gy)	Maximum fluoro time	0.52	PSD = 0.033 × maximum fluoro time + 0.42
PSD (Gy)	Total kerma–area product	0.74	PSD = 0.0053 × total P_{KA} + 0.17
PSD (Gy)	Maximum kerma–area product	0.61	PSD = 0.0063 × maximum P_{KA} + 0.34
PSD (Gy)	Total CD	0.77	PSD = 0.52 × total CD + 0.18
PSD (Gy)	Maximum CD	0.78	PSD = 0.76 × maximum CD + 0.12

physically plausible correspondence between the PSD and the higher use plane.

However, there was wide variation of the actual PSD from the prediction for actual procedures. Therefore, predictions of the PSD in individual cases from regression equations for CD or DAP are imprecise.

The procedures associated with the highest CD were also associated with high PSD, indicating that they involved prolonged exposure of a single skin entrance site. Seventy-four per cent of TIPS, 86% of visceral arterial stent placements, 56% of embolization procedures outside the central nervous system and 81% of embolization procedures in the central nervous system resulted in a PSD > 1 Gy. Fifteen (1.9%) of the 800 instances of procedures where skin dose was measured had a PSD > 5 Gy. All of these 15 instances were embolization procedures. In particular, spine embolization was associated with very high PSD.

The RAD-IR study concluded that most of the procedures studied can result in clinically significant radiation dose to the patient, even when performed by trained operators with use of dose reducing technology and modern fluoroscopic equipment. Embolization procedures, TIPS creation and visceral artery stent placement are associated with a substantial likelihood of clinically significant patient dose.

An additional finding is directly relevant to the research in this report on the effects of complexity in interventional cardiology procedures. The RAD-IR study demonstrated statistically significant differences in various measures of overall dose among subgroups of various interventional radiology procedures, none of which were cardiac procedures. The subgroups were defined by various independent factors: the nature of the lesion being treated, the anatomic

location of the lesion, and the procedure complexity (whether or not angioplasty was accompanied by stent placement). It was already known that different mixes of straightforward and complex instances of the same procedure will yield different dose data because complex procedures are associated with higher radiation doses [II–7]. The RAD-IR study confirmed this observation for a variety of non-cardiac procedures, and the study reported in this report further confirms this finding for cardiac procedures.

REFERENCES TO ANNEX II

[II–1] MILLER, D.L., et al., Radiation doses in interventional radiology procedures: The RAD-IR study: Part II: Skin dose, J. Vasc. Interv. Radiol. **14** (2003) 977–990.

[II–2] BALTER, S., et al., Radiation doses in interventional radiology procedures: The RAD-IR study: Part III: Dosimetric performance of the interventional fluoroscopy units, J. Vasc. Interv. Radiol. **15** (2004) 919–926.

[II–3] MILLER, D.L., et al., Radiation doses in interventional radiology procedures: The RAD-IR study: Part I: Overall measures of dose, J. Vasc. Interv. Radiol. **14** (2003) 711–727.

[II–4] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Part 2-43: Particular Requirements for the Safety of X-ray Equipment for Interventional Procedures, Rep. 60601, IEC, Geneva (2000).

[II–5] TOIVONEN, M., Review of dosimetry instrumentation in digital and interventional radiology, Radiat. Prot. Dosim. **94** (2001) 147–150.

[II–6] DEN BOER, A., et al., Real-time quantification and display of skin radiation during coronary angiography and intervention, Circulation **104** (2001) 1779–1784.

[II–7] VEHMAS, T., Radiation exposure during standard and complex interventional procedures, Br. J. Radiol. **70** (1997) 296–298.

Annex III

THE DICOM–DOSE PROJECT

III–1. BACKGROUND

The DICOM–DOSE Project is a cooperative action between the IEC and the DICOM Standard Committee (DICOM). The current DICOM standard makes provisions for storing technical information in the headers of storable digital images. There were no specific dose related requirements in the standard. Thus the nature of the stored information varied from manufacturer to manufacturer, and often from model to model within a manufacturers' range. In addition, while some data elements were presented in public data fields (defined in the DICOM dictionary), other elements were contained in proprietary (private) fields. Here again, there was considerable variability between different equipment makes and models.

Individual facilities had variable success in decoding the portions of the DICOM header needed for patient exposure monitoring or reconstruction. In addition, these DICOM versions made almost no provision for archiving any data relating to fluoroscopy or radiographic images not archived in DICOM format [III–1].

The IEC decided to draft an international document defining dosimetric elements that should be included within the DICOM structure. Sets of radiation exposure related elements are grouped in a risk based hierarchy of compliance levels. The DICOM standard itself is maintained by the DICOM committee. Informal agreement was soon reached to develop the necessary extension of the DICOM standard based on IEC requirements. This standard was to have a formal structure containing only public data fields (as defined in the DICOM dictionary).

III–2. STRUCTURE

Two new elements have been introduced into the DICOM standard. These are the Radiation Dose Structured Report (RDSR) and its accompanying software Actor. The RDSR is a formal independent DICOM object designed for managing dose and related information. A compliant digital imaging system prepares and transmits an RSDR for each procedure irrespective of the archival storage of any images. The Actor is a software element designed to retrieve RDSRs from the network. Actors may simply

store RDSRs or provide added functionality such as statistical analysis or dose modelling.

The RDSR contains a header and a sequence of irradiation objects. The header includes general information about the patient and facility as well as summary dose data. Each irradiation object contains the geometric, electrical and dosimetric information describing a single foot pedal depression (e.g. fluoro run or cine sequence). An irradiation object is written to the RDSR whether or not the images themselves are archived. All fields in the RDSR are DICOM public fields; thus their contents are fully interpretable.

Formally, the Actor is a DICOM service element that can accept an RDSR and do something with it. Actors may be present on image storage systems (PACS), medical informatics systems (RIS, HIS, EMR) or as standalone devices. Actors are permitted on more than one network element. An Actor can process the data (e.g. produce a dose map) and update the RDSR.

REFERENCE TO ANNEX III

[III–1] VANO, E., et al., On the use of DICOM cine header information for optimisation: Results from the 2002 European DIMOND cardiology survey, Radiat. Prot. Dosim. Adv. **117** (2005) 162–165; Access published on 3 February 2006, DOI 10.1093/rpd/nci735

Annex IV

ANNOTATED REFERENCES

Numbers in square brackets refer to the main reference list and the reference lists to the annexes.

[3] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Diagnostic Reference Levels in Medical Imaging: Review and Additional Advice, ICRP Supporting Guidance 2, Pergamon Press, Oxford and New York (2001) 33–52.
Diagnostic reference levels (DRLs) should be used by regional, national and local authorised bodies. The numerical values of DRLs are advisory, however, implementation of the DRL concept may be required by an authorized body. The concept of DRLs allows flexibility in their selection and implementation. The present ICRP advice does not specify quantities, numerical values or details of implementation for DRLs. This is the task of the regional, national and local authorized bodies, each of which should meet the needs in its respective area. ICRP considers that any reasonable and practical approach, consistent with the advice, will improve the management of patient doses in medical imaging.

[6] SHOPE, T.B., Radiation-induced skin injuries from fluoroscopy, Radiographics **16** (1996) 1195–1199.
Since 1992, the US Food and Drug Administration (FDA) has received reports of radiation induced injuries to the skin in patients who had undergone fluoroscopically guided interventional procedures. The reports were investigated to determine the procedure- or equipment related factors that may have contributed to the injury. The injuries ranged in severity from erythema to moist desquamation to tissue necrosis that required skin grafting. They occurred after a variety of interventional procedures that required extended periods of fluoroscopy compared with those of typical diagnostic procedures. Medical facilities and physicians should be aware of the magnitude of radiation doses to the skin that can result from the long exposure times required by complex interventional procedures. The FDA recommends several steps for reducing these injuries, including establishing protocols for each procedure, determining radiation dose rates for specific fluoroscopy systems and operating modes, and monitoring cumulative absorbed doses to areas of the skin.

[9] KARAMBATSAKIDOU, A., et al., Skin dose alarm levels in cardiac angiography procedures: is a single DAP value sufficient? Br. J. Radiol. **78** (2005) 803–809.
Maximum estimated skin doses to patients undergoing coronary angiography procedures were obtained using radiographic slow film and diode dosimeters. Conversion factors of maximum entrance skin dose versus dose-area product (MESD/DAP) for diagnostic (coronary angiography (CA); 20 patients; 2 operators) and interventional procedures (percutaneous transluminal coronary angiography (PTCA); 10 patients; 1 operator) were 4.3 (mean value of 10 CA;

operator A), 3.5 (mean value of 10 CA; operator B) and 9.7 (mean value of 10 PTCA; operator B) mGy(Gy·cm^2)(-1), respectively. The results emphasise a need for both operator and procedure specific conversion factors. Compared with a single, global factor for all cardiac procedures and/or operators that is commonly applied today, such a refinement is expected to improve the accuracy in skin dose estimations from these procedures. Consequently, reference DAP values used in the clinic to define patients who could suffer from a radiation induced skin injury following a cardiac procedure, should be defined for each operator/procedure. The film technique was found to be superior to the diode in defining conversion factors in this study, and allowed for a rapid and accurate estimation of MESD for each patient. With appropriate positioning of the diode, a combined film/diode technique has a potential use in the training of new angiography operators. The patient body mass index (BMI) value was a good indicator of the variation in average lung dose (critical organ) between patients. The highest lung dose/DAP value was obtained for normal sized patients (BMI: 19-26), and was close to 1.5 mGy(Gy·cm^2)(-1) with both CA and PTCA procedures.

[10] CARSTENS, G.J., et al., Radiation dermatitis after spinal arteriovenous malformation embolization: case report, Neuroradiology **38** Suppl 1 (1996) S160–164.
Few cases of radiation injury related to lengthy interventional neuroradiologic procedures have been reported, although concern has been heightened, as evidence by a 1994 FDA Public Health Advisory. We report a case of radiation induced dermatitis in a patient undergoing multiple diagnostic and embolization procedures for treatment of a spinal arteriovenous malformation.

[11] KRASOVEC, M., TRUEB, R.M., Temporary roentgen epilation after embolization of a cerebral arteriovenous malformation, Hautarzt **49** 4 (1998) 307–309.
A patient with a large left-sided arteriovenous malformation underwent superselective angiography and therapeutic embolization. Sixteen days later he presented with an acute anagen dystrophic hair loss localized to the occipital and right parietal regions corresponding to the irradiated scalp area. The diagnosis of an acute radiation injury to the hair follicle from prolonged fluoroscopic imaging during the interventional neuroradiologic procedure was made. This reversible side effect occurs typically after single short term exposures of 300-400 cGy. Above single doses of 1200 cGy, the epilation is permanent. Patients have to be informed about the possibility of this reversible complication, which must be distinguished from alopecia areata, postoperative ischemic pressure alopecia and drug toxicity.

[12] KAWAKAMI, T., SAITO, R., MIYAZAKI, S., Chronic radiodermatitis following repeated percutaneous transluminal coronary angioplasty, Br. J. Dermatol. **141** (1999) 150–153.
We review three patients who developed chronic radiodermatitis subsequent to undergoing multiple percutaneous transluminal coronary angioplasties (PTCAs). All patients had had chronic ischemic heart disease (IHD) and had undergone lengthy PTCA on several occasions. The skin eruption was characterized by an

atrophic rectangular plaque on the left upper back, presenting as mottled hyper- and hypopigmentation with reticulate telangiectasia. Histologically, the eruption demonstrated epidermal atrophy, hyalinized and irregularly stained collagen, and telangiectasia of superficial vessels in the dermis. Although the risk of radiation injury in most patients undergoing cardiac catheterization is low, this danger should not be ignored. In particular, patients with long-standing IHD and numerous repeated catheterizations to only one or two occluded coronary arteries should be considered at high risk.

[13] O'DEA, T.J., GEISE, R.A., RITENOUR, E.R., The potential for radiation-induced skin damage in interventional neuroradiological procedures: A review of 522 cases using automated dosimetry, Med. Phys. **26** (1999) 2027–2033.
The FDA has recommended the monitoring of radiation skin dose to patients during procedures having the potential for radiation damage. Radiologists need information about typical radiation doses during interventional procedures. The skin doses to patients during 522 interventional neuroradiological procedures have been monitored using an automated dosimetry system. Estimated entrance skin doses (ESD) were binned into 0.5 Gy increments and compared to FDA recommended thresholds for inclusion in the patient record. Percentages of procedures exceeding the above mentioned thresholds are presented. In addition, the percentage of dose in each view and the percentage of dose in fluoroscopic and digital angiographic modes are shown. Six percent of embolization procedures and one percent of cerebral angiograms are estimated to have potential for main erythema (ESD>6 Gy). All types of procedures have potential for temporary erythema and exceed the threshold for inclusion in the patient record (ESD> 1 Gy) at the 95% percentile. The types of procedures with most potential for skin damage also have significant percentages of dose in the digital angiographic mode. Thus, monitoring fluoroscopic time alone underestimates the potential for skin injury. On the other hand, combining the doses in the posterior-anterior and lateral views, tends to overestimate the potential for radiation injury.

[16] TANAKA, J., The potential patient skin injuries from radiologically guided interventional procedure: The present condition and recommendable measure, Igaku Butsuri **22** (2002) 98–104.
Radiologically guided interventional procedures may result in excessive radiation dose for the patients. During the last decade, more than 70 cases of radiation skin injuries have been reported. This may be partly because the potential dangers of X radiation are not yet well recognized by the physicians, and also by lacking of practical and reliable way to monitor the dose of X ray radiation at the radiology suite. The author presents a few recommendable techniques to monitor the patient's radiation doses during interventional radiological procedures, which may be helpful in preventing patient's radiation injury.

[18] PARK, T.H., et al., Risk of radiation induced skin injuries from arrhythmia ablation procedures, Pacing Clin. Electrophysiol. **19** (1996) 1363–1369.

Catheter guided ablation of cardiac arrhythmias is an effective and safe procedure for the treatment of most supraventricular and selected ventricular tachycardias. Because catheter manipulation is fluoroscopically guided, there is risk of radiation induced injury, especially during prolonged procedures. The FDA has recently issued a bulletin warning of the risks of acute skin injury occurring during fluoroscopically guided procedures that result in an exposure level exceeding 2 Gray units (Gy). This study was performed as an investigation into the risk of radiation induced skin injury during arrhythmia ablation procedures. The amount of radiation exposure for 500 patients who underwent ablation was calculated based upon fluoroscopy times and the entrance dose of radiation (0.02 Gy/min). The mean radiation exposure was 0.93 ± 0.62 Gy. Although 5.6% of patients (n = 28) received enough radiation exposure[1] to reach the threshold dose (2 Gy) for early transient erythema, no clinical manifestations of acute radiation induced skin injury were observed. No patients achieved the threshold dose for irreversible skin injury. Patients undergoing AV node ablation or modification received significantly less radiation (0.39 ± 0.40 Gy and 0.79 ± 0.44 Gy, respectively) than patients undergoing other ablation procedures (0.94-1.45 Gy, $P < 0.05$). There was no association between the magnitude of radiation exposure and the presence of underlying heart disease. Patients undergoing ablation of accessory pathways were exposed to more radiation if there was a right-sided pathway (1.69 ± 0.93 Gy) compared to other sites (0.87–1.24 Gy, $P < 0.05$). This study demonstrates that the risk of significant radiation induced skin injury during arrhythmia ablation procedures is low provided that precautions are taken to minimize radiation exposure.

[19] SOVIK, E., et al., Radiation-induced skin injury after percutaneous transluminal coronary angioplasty. Case report, Acta Radiol. **37** 3 Pt 1 (1996) 305–306.
A 58-year-old man underwent percutaneous transluminal coronary angioplasties in June 1992 and May 1993. Approximately 3 weeks after the last procedure, a cutaneous lesion developed into an ulcer over the right scapular region. The ulcer failed to heal with conservative treatment; therefore, surgical excision was performed. The localization and the course of the development indicated injury caused by radiation, and this was confirmed by the histological examination. To avoid such injury in interventional procedures with long fluoroscopic time, several precautions should be taken. These include continuous surveillance of the X ray dosage, the use of different projections to avoid exposure to one skin area throughout the whole procedure, keeping the irradiated area as small as possible, and good planning of the procedure.

[1] In this annex, the expressions from the original papers in terms of "dose" have been maintained rather than replacing them by air kerma. However, as indicated in footnote 4, the instrument calibration is done in terms of air kerma. Consequently, quantities, when referred to air, are expected to be replaced in future by air kerma.

[20] ROSENTHAL, L.S., et al., Acute radiation dermatitis following radiofrequency catheter ablation of atrioventricular nodal reentrant tachycardia, Pacing Clin. Electrophysiol. **20** (1997) 1834–1839.
Radiation exposure during fluoroscopic imaging poses potential risks to patients and physicians, especially during protracted cardiovascular or radiological interventional procedures. We describe a woman with refractory paroxysmal supraventricular tachycardia who underwent radiofrequency catheter ablation of the slow pathway involved in atrioventricular nodal reentrant tachycardia. The patient subsequently returned four weeks later with acute radiation dermatitis that was retrospectively attributed to a malfunction in the fluoroscopy unit that lacked a maximum current output cut-off switch. Using dose reconstruction studies and her estimated biological response, we determined that she received between 15 and 20 Gy (1 Gy = 100 rad) to the skin on her back during the procedure. The exposure will result in an increase in her lifelong risk of skin and lung cancer. This article underscores the potential for radiation induced injury during lengthy therapeutic procedures using X ray equipment.

[21] ROSENTHAL, L.S., et al., Predictors of fluoroscopy time and estimated radiation exposure during radiofrequency catheter ablation procedures, Am. J. Cardiol. **82** (1998) 451–458.
The objective of this study was to identify factors that predict fluoroscopy duration and radiation exposure during catheter ablation procedures. The patient population included 859 patients who participated in the Atakr Ablation System clinical trial at 1 of 9 centres (398 male and 461 female patients, aged 36 ± 21 years). Each patient underwent catheter ablation of an accessory pathway, the atrioventricular junction, or atrioventricular nodal reentrant tachycardia using standard techniques. The duration of fluoroscopy was 53 ± 50 minutes. Factors identified as independent predictors of fluoroscopy duration included patient age and sex, the success or failure of the ablation procedure, and the institution at which the ablation was performed. Catheter ablation in adults required longer fluoroscopy exposure than it did in children. Men required longer durations of fluoroscopy exposure than did women. The mean estimated 'entrance' radiation dose was 1.3 ± 1.3 Sv. The dose needed to cause radiation skin injury was exceeded during 22% of procedures. The overall mean effective absorbed dose from catheter ablation procedures was 0.025 Sv for female patients and 0.017 Sv for male patients. This degree of radiation exposure would result in an estimated 1,400 excess fatal malignancies in female patients and 2600 excess fatal malignancies in male patients per 1 million patients.

[22] DEHEN, L., et al., Chronic radiodermatitis following cardiac catheterisation: A report of two cases and a brief review of the literature, Heart **81** (1999) 308–312.
Cardiac angiography produces one of the highest radiation exposures of any commonly used diagnostic x ray procedure. Recently, serious radiation induced skin injuries have been reported after repeated therapeutic interventional procedures using prolonged fluoroscopic imaging. Two male patients, aged 62 and 71 years, in

whom chronic radiodermatitis developed one to two years after two consecutive cardiac catheterisation procedures are reported. Both patients had undergone lengthy procedures using prolonged fluoroscopic guidance in a limited number of projections. The resulting skin lesions were preceded, in one case, by an acute erythema and took the form of a delayed pigmented telangiectatic, indurated, or ulcerated plaque in the upper back or below the axilla whose site corresponded to the location of the X ray tube during cardiac catheterization. Cutaneous side effects of radiation exposure result from direct damage to the irradiated tissue and have known thresholds. The diagnosis of radiation induced skin injury relies essentially on clinical and histopathological findings, location of skin lesions, and careful medical history. Interventional cardiologists should be aware of this complication, because chronic radiodermatitis may result in painful and resistant ulceration and eventually in squamous cell carcinoma.

[23] ARCHER, B.R., WAGNER, L.K., Protecting patients by training physicians in fluoroscopic radiation management, J. Appl. Clin. Med. Phys. **1** (2000) 32–37.
During the past 15 years, developments in X ray technologies have substantially enhanced the ability of practitioners to treat patients using fluoroscopically guided interventional techniques. However, many of these procedures require a greater use of fluoroscopy and serial imaging (cine). This has increased the potential for radiation induced dermatitis, epilation, and severe radiation induced burns to patients. It has also increased the potential for radiation injury and radiation-induced cancer in personnel. This work will describe a number of the cases that have appeared in the literature and current recommendations and credentialling requirements of various organizations whose members use fluoroscopy. Finally, a programme for implementing training of physicians in radiation management as a means of reducing the risk of injury to patients and personnel is recommended.

[24] NIKOLIC, B., et al., Patient radiation dose associated with uterine artery embolization, Radiology **214** (2000) 121–125.
PURPOSE: To evaluate the estimated absorbed radiation doses to the ovaries and skin entrance during uterine artery embolization (UAE) for leiomyomas. MATERIALS AND METHODS: Radiation dose was measured in 20 patients who underwent UAE for leiomyomas. Measurements were obtained by placing lithium fluoride dosimeters both into the posterior fornix of the vagina and on the skin at the beam entrance site. Patient doses were obtained with thermoluminescent dosimeters. RESULTS: The mean fluoroscopic time was 21.89 minutes, and the mean number of angiographic exposures was 44. The mean estimated absorbed ovarian dose was 22.34 cGy, and the mean absorbed skin dose was 162.32 cGy. These values compare to published values for the assessed absorbed ovarian dose during hysterosalpingography (0.04-0.55 cGy), fallopian tube recanalization (0.2-2.75 cGy), computed tomography of the trunk (0.1-1.9 cGy), and pelvic irradiation for Hodgkin's disease (263-3,500 cGy). CONCLUSION: The estimated absorbed ovarian dose during UAE is greater than that during common

fluoroscopic procedures. On the basis of the known risks of pelvic irradiation for Hodgkin disease, the dose associated with UAE is unlikely to result in acute or long-term radiation injury to the patient or to a measurable increase in the genetic risk to the patient's future children.

[25] TIMINS, J.K., LIPOTI, J.A., Radiation risks of high-dose fluoroscopy, New J. Med. **97** 6 (2000) 31–34.
Radiation-induced skin injury is an underdiagnosed, significant complication for patients undergoing fluoroscopy-guided interventional procedures. With proper equipment, fluoroscopic technique, and physician education, patient radiation exposure can be decreased by 75% or more and skin injuries can be minimized.

[26] WAGNER, L.K., ARCHER, B.R., COHEN, A.M., Management of patient skin dose in fluoroscopically guided interventional procedures, J. Vasc. Interv. Radiol. **11** (2000) 25–33.
PURPOSE: To simulate dose to the skin of a large patient for various operational fluoroscopic conditions and to delineate how to adjust operational conditions to maintain skin dose at acceptable levels. MATERIALS AND METHODS: Patient entrance skin dose was estimated from measurement of entrance air kerma (dose to air) to a 280-mm water phantom for two angiographic fluoroscopes. Effects on dose for changes in machine floor kVp, source-to-skin distance, air gap, electronic magnification, fluoroscopic dose rate control settings, and fluorographic dose control settings were examined. RESULTS: Incremental changes in operational parameters are multiplicative and markedly affect total dose delivered to a patient's skin. For long procedures, differences in doses of 8 Gy or more are possible for some combinations of operational techniques. CONCLUSIONS: Effects on skin dose from changes in operational parameters are multiplicative, not additive. Doses in excess of known thresholds for injury can be exceeded under some operating conditions. Adjusting operational parameters appropriately will markedly reduce dose to a patient's skin. Above all other operational factors, variable pulsed fluoroscopy has the greatest potential for maintaining radiation exposure at low levels.

[27] DEN BOER, A., et al., Real-time quantification and display of skin radiation during coronary angiography and intervention, Circulation **104** (2001) 1779–1784.
BACKGROUND: Radiographically guided investigations may be associated with excessive radiation exposure, which may cause skin injuries. The purpose of this study was to develop and test a system that measures in real time the dose applied to each 1 cm (2) area of skin, taking into account the movement of the X ray source and changes in the beam characteristics. The goal of such a system is to help prevent high doses that might cause skin injury. METHODS AND RESULTS: The entrance point, beam size, and dose at the skin of the patient were calculated by use of the geometrical settings of gantry, investigation table, and X ray beam and an ionization chamber. The data are displayed graphically. Three hundred twenty-two sequential cardiac investigations in adult patients were analyzed. The mean peak entrance dose per investigation was 0.475 Gy to a mean

skin area of 8.2 cm(2). The cumulative Kerma area product per investigation was 52.2 Gy/cm(2) (25.4 to 99.2 Gy/cm(2)), and the mean entrance beam size at the skin was 49.2 cm(2). Twenty eight per cent of the patients (90/322) received a maximum dose of <1 Gy to a small skin area (approximately 6 cm(2)), and 13.5% of the patients (42/322) received a maximum dose of >2 Gy. CONCLUSIONS: Monitoring of the dose distribution at the skin will alert the operator to the development of high-dose areas; by use of other gantry settings with non-overlapping entrance fields, different generator settings, and extra collimation, skin lesion can be avoided.

[28] NIKOLIC, B., et al., Uterine artery embolization: Reduced radiation with refined technique, J. Vasc. Interv. Radiol. **12** (2001) 39–44.
PURPOSE: To determine the estimated absorbed ovarian dose (EAOD) and absorbed skin dose (ASD) that occurs during uterine artery embolization (UAE) using pulsed fluoroscopy and a refined procedure protocol. MATERIALS AND METHODS: The absorbed dose was measured in 20 patients who underwent UAE procedures. Radiation was limited by using low frequency pulsed fluoroscopy, bilateral catheter technique with simultaneous injections for embolization as well as pre-and post-embolization exposures and focus on limitation of magnified and oblique fluoroscopy. Lithium fluoride dosimeters were placed both in the posterior vaginal fornix and on the skin at the beam entrance site. The vaginal dose was used to approximate the EAOD. Fluoroscopy time and exposures were recorded. The mean values for all patients were calculated and compared to our previous results obtained with conventional fluoroscopy and to threshold doses for the induction of deterministic skin injury. RESULTS: Mean fluoroscopy time was 10.95 min. (range 6-21.3 min.) and the mean number of angiographic exposures was 20.9 (range 14-53). The mean EAOD was 9.5 cGy (range 2.21-23.21 cGy) and the mean ASD was 47.69 cGy (range 10.83-110.14 cGy). This compares to previous results with non-pulsed fluoroscopy of an EAOD of 22.34 cGy (range 4.25-65.08 cGy) and an ASD of 162.32 cGy (range 66.01-303.89 cGy) as well as threshold doses for induction of deterministic radiation injury to the skin (400-500 cGy). CONCLUSION: When pulsed fluoroscopy is used with emphasis on dose reduction techniques, the EAOD and ASD can be substantially reduced to less than 1/2 (P = .017) and 1/3 (P < .0001) when compared to UAE performed with nonpulsed fluoroscopy. These radiation reduction tools should therefore be applied whenever possible.

[29] VANO, E., et al., Skin radiation injuries in patients following repeated coronary angioplasty procedures, Br. J. Radiol. **74** (2001) 1023–1031.
This study investigates the incidence of skin injuries and retrospectively estimates skin doses in a sample of patients who had multiple coronary angiographies and who underwent more than four percutaneous transluminal coronary angioplasties (PTCAs), performed primarily by the same team of cardiologists in a university hospital. A database of 7824 PTCAs performed during the last 14 years was analysed. Patients were selected and reviewed by a cardiologist and two

radiotherapists with experience in radiation-induced skin injuries. A retrospective analysis of skin doses was performed using data from the patients' files and from the quality assurance (QA) programme of the hospital, which includes periodic patient dose measurements. 14 patients were included in the study. Each patient had undergone between 4 and 14 coronary angiographies and between 5 and 10 PTCAs, performed over a period of 2-10 years. The estimated mean dose-area product per procedure was 46 Gy·cm^2 for coronary angiography and 82 Gy·cm^2 for PTCA. Mean values of maximum skin dose per procedure were 217 mGy for the diagnostic studies and 391 mGy for the PTCAs. Only a slight radiation skin injury was clinically demonstrated in one patient with a history of 10 coronary angiographies and 10 PTCAs (estimated maximum skin dose 9.5 Gy). Another patient who underwent 14 coronary angiographies and 10 PTCAs (estimated maximum skin dose 7.3 Gy) showed a slight telangiectasia and discrete pigmentation. Another patient with a cutaneous lupus erythematosus showed pigmentation in the area of the radiation field following seven coronary angiographies and six PTCAs (estimated maximum skin dose 5.6 Gy), as expected bearing in mind that skin tolerance to high doses may be altered for patients with this pathology. Each of the remaining 11 patients with no skin injuries had undergone between 5 and 7 PTCAs and between 5 and 14 additional angiographies. None of the 14 patients reported acute skin injuries and no necrosis or radiodermatitis was observed.

[30] McFADDEN, S.L., MOONEY, R.B., SHEPHERD, P.H., X-ray dose and associated risks from radiofrequency catheter ablation procedures, Br. J. Radiol. **75** (2002) 253–265.

The objectives of this study were to quantify the ionizing radiation exposure to patient and operator during radiofrequency (RF) catheter ablation and to estimate the risks associated with this exposure. The study consisted of 50 RF ablation procedures, all performed in the same electrophysiology laboratory. Occupational dose to two cardiologists who performed the procedures was measured using film badges and extremity thermoluminescent dosimeters (TLDs). Absorbed dose to the patients' skin was measured using TLDs. Dose-area product (DAP) was also measured. The effective dose to the cardiologists was less than 0.15 mSv per month. The mean equivalent dose to the cardiologists' left hand and forehead was 0.24 mSv and 0.05 mSv, respectively, per RF ablation procedure, which was more than twice the mean dose for the other cardiology procedures carried out in the centre. Yearly occupational dose to the cardiologists was much lower than the relevant statutory dose limits. The mean skin dose, fluoroscopy time and DAP to patients were 0.81 Gy, 67 min and 123 Gy·cm^2, respectively, with a maximum of 3.2 Gy, 164 minutes and 430 Gy·cm^2, respectively. Mean effective dose to patients was 17 mSv, from which the excess risk of developing fatal cancer is 0.1%. Six of the patients (12%) received a skin dose above the threshold dose for radiation skin injury (2 Gy), but no skin injuries were reported. Patient skin dose and DAP were closely correlated and this allows DAP to be used to monitor patient skin dose in real-time. DAP levels were locally

adopted as diagnostic reference levels (DRLs) that provide an indication during a procedure that a patient is at risk of suffering deterministic skin injury.

[31] METTLER, F.A., Jr., et al., Radiation injuries after fluoroscopic procedures, Sem. Ultrasound CT MR **23** (2002) 428–442.
Fluoroscopically guided diagnostic and interventional procedures have become much more commonplace over the last decade. Current fluoroscopes are easily capable of producing dose rates in the range of 0.2 Gy (20 rad) per minute. The dose rate often changes dramatically with patient positioning and size. Most machines currently in use have no method to display approximate patient dose other than the rough surrogate of total fluoroscopy time. This does not include patient dose incurred during fluorography (serial imaging or cine runs), which can be considerably greater than dose during fluoroscopy. There have been over 100 cases of documented radiation skin and underlying tissue injury, a large portion of which resulted in dermal necrosis. The true number of injuries is undoubtedly much higher. The highest dose procedures are complex interventions such as those involving percutaneous angioplasties, stent placements, embolizations, and TIPS. In some cases skin doses have been in excess of 60 Gy (6000 rad). In many instances the procedures have been performed by physicians with little training in radiation effects, little appreciation of the radiation injuries that are possible or the strategies that could have been used to reduce both patient and staff doses. Almost all of the severe injuries that have occurred were avoidable.

[32] MILLER, D.L., et al., Minimizing radiation-induced skin injury in interventional radiology procedures, Radiology **225** (2002) 329–336.
Skin injury is a deterministic effect of radiation. Once a threshold dose has been exceeded, the severity of the radiation effect at any point on the skin increases with increasing dose. Peak skin dose is defined as the highest dose delivered to any portion of the patient's skin. Reducing peak skin dose can reduce the likelihood and type of skin injury. Unfortunately, peak skin dose is difficult to measure in real time, and most currently available fluoroscopic systems do not provide the operator with sufficient information to minimize skin dose. Measures that reduce total radiation dose will reduce peak skin dose, as well as dose to the operator and assistants. These measures include minimizing fluoroscopy time, the number of images obtained, and dose by controlling technical factors. Specific techniques-dose spreading and collimation-reduce both peak skin dose and the size of skin area subjected to peak skin dose. For optimum effect, real-time knowledge of skin-dose distribution is invaluable. A trained operator using well-maintained state-of-the art equipment can minimize peak skin dose in all fluoroscopically guided procedures.

[33] AERTS, A., et al., Chronic radiodermatitis following percutaneous coronary interventions: A report of two cases, J. Eur. Acad. Dermatol. Venereol. **17** (2003) 340–343.
We describe two patients in whom chronic radiodermatitis with therapy-resistant ulceration of the right scapular region developed, following percutaneous coronary

intervention with fluoroscopic imaging. Contrary to most reported cases in the literature, which involve numerous cardiac catheterization procedures, in both patients described here the total radiation dose was given during two successive procedures, involving difficult and prolonged coronary intervention with stent implantation. In both cases, local treatment of the ulcerative lesions was insufficient, necessitating excision of the radiodermatitis area and replacement with a skin graft, with good therapeutic result. The incidence of radiodermatitis after percutaneous coronary interventions is rising with the increasing number and complexity of these procedures. The main risk factor is a long duration of fluoroscopy using the same incidence. The skin lesions encompass a wide spectrum, ranging from erythema, telangiectasia, atrophy, hyperpigmentation and hypopigmentation to necrosis, chronic ulceration and squamous cell carcinoma. The lesions can appear from 15 days to 10 years after the procedure. To prevent radiation-induced injury, the radiation dose has to be limited and monitored. Also, careful inspection of the skin at the site of exposure is necessary and the radiographic beam has to be restricted to the smallest field size. A good clinical follow-up at regular intervals is important after long and complicated procedures.

[35] NEOFOTISTOU, V., et al., Preliminary reference levels in interventional cardiology, Eur. Radiol. **13** (2003) 2259–2263.
This article describes the European DIMOND approach to defining reference levels (RLs) for radiation doses delivered to patients during two types of invasive cardiology procedures, namely coronary angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA). Representative centres of six European countries recorded patients' doses in terms of dose-area product (DAP), fluoroscopy time and number of radiographic exposures, using X-ray equipment that has been subject to constancy testing. In addition, a DAP trigger level for cardiac procedures which should alert the operator to possible skin injury, was set to 300 Gy·cm^2. The estimation of maximum skin dose was recommended in the event that a DAP trigger level was likely to be exceeded. The proposed RLs for CA and PTCA were for DAP 45 Gy·cm^2 and 75 Gy·cm^2, for fluoroscopy time 7.5 min and 17 min and for number of frames 1250 and 1300, respectively. The proposed RLs should be considered as a first approach to help in the optimisation of these procedures. More studies are required to establish certain "tolerances" from the proposed levels taking into account the complexity of the procedure and the patient's size.

[36] CASTRONOVO, F.P., Jr., A fluoroscopic credentialing/safety programme at a large research hospital, Health Phys. **86** 5 Suppl (2004) S76–79.
The Brigham and Women's Hospital is an approximately 700 bed broad-scope licensed facility with a vigorous fluoroscopy service. Concomitant with this service is an equally robust quality management programme to safeguard both patient and personnel from excessive radiation doses. The FDA, in an attempt to avoid serious skin injury for certain fluoroscopically guided procedures, issued a Public Health Advisory in 1994. Four years later the institutional Radiation Safety

Committee voted to expand an existing fluoroscopic safety course to include a more formal credentialing/safety requirement. The specific parameters associated with this programme follow.

[37] CRAWLEY, M.T., SAVAGE, P., OAKLEY, F., Patient and operator dose during fluoroscopic examination of swallow mechanism, Br. J. Radiol. **77** (2004) 654–656.
Dose-area product (DAP) measurements were made for 21 patients undergoing a modified barium swallow. The procedures were performed by a radiologist and speech and language therapist, to characterize swallowing disorders in patients with head or spinal injury, stroke, other neurological conditions or simple globus symptoms, in order to inform feeding strategies. The DAP values were used to estimate effective dose to the patient, in order to provide a measure of the radiation risk associated with the procedure. Whole body doses to operators, together with equivalent doses to extremities and eyes were also measured to inform the employer's risk assessment. Median DAP for the series was 3.5 (3.1-5.2) Gy·cm^2 with a corresponding effective dose to the patient of 0.85 (0.76-1.3) mSv, and a low associated risk, mainly of cancer induction, of about 1 in 16 000. The organ receiving the greatest dose was the thyroid, with a calculated median equivalent dose of 13.9 (12.3-20.7) mSv. Median screening time was 3.7 (2.5-4.3) min. Mean operator doses were 0.5 mSv equivalent dose (eyes), 0.9 mSv (extremities), and less than 0.3 mSv whole body dose. Extrapolating for an annual workload of 50 patients per year, this work will lead to annual operator doses of less than 0.6 mSv whole body dose, and approximately 1 mSv equivalent dose (eyes) and 1.8 mSv (extremities), against corresponding legal dose limits of 20 mSv, 150 mSv and 500 mSv, respectively.

[38] CRAWLEY, M.T., et al., Calibration frequency of dose–area product meters, Br. J. Radiol. **74** (2001) 259–261.
Calibration of patient dose monitoring devices in diagnostic radiology has become increasingly important in the light of new legislation that requires monitoring of patient dose against local and national diagnostic reference levels. An investigation was conducted into the long-term stability of 41 dose-area product (DAP) meters over a period of approximately 5 years, to assess the suitability of an annual calibration regimen. For DAP meters fitted to overcouch X-ray tubes, 77% of calibrations were within 10%, while for undercouch tubes only 50% of calibrations were within 10%. These findings suggest that annual calibration may be too infrequent. Suitable calibration frequencies for different clinical workloads are discussed.

[39] FUKUDA, A., et al., Method of estimating patient skin dose from dose displayed on medical X-ray equipment with flat panel detector, Nippon Hoshasen Gijutsu Gakkai Zasshi **60** (2004) 725–733.
The International Electrotechnical Commission has stipulated that medical X-ray equipment for interventional procedures must display radiation doses such as air kerma in free air at the interventional reference point and dose area product to establish radiation safety for patients (IEC 60601-2-43). However, it is necessary

to estimate entrance skin dose for the patient from air kerma for an accurate risk assessment of radiation skin injury. To estimate entrance skin dose from displayed air kerma in free air (incident air kerma, K_i) at the interventional reference point, it is necessary to consider effective energy, the ratio of the mass-energy absorption coefficient for skin and air, and the backscatter factor. In addition, since automatic exposure control is installed in medical X-ray equipment with flat panel detectors, it is necessary to know the characteristics of control to estimate exposure dose. In order to calculate entrance skin dose under various conditions, we investigated clinical parameters such as tube voltage, tube current, pulse width, additional filter, and focal spot size, as functions of patient body size. We also measured the effective energy of X-ray exposure for the patient as a function of clinical parameter settings. We found that the conversion factor from incident air kerma to entrance skin dose is about 1.4 for protection purposes.

[40] SOARES, D.P., GILLIGAN, P., Ionizing radiation. The question of responsible use: Pandora's box revisited, West Indian Med. J. **53** (2004) 118–121.
For over one hundred years, ionizing radiation has assisted in medical diagnostics. Recently, there have been reports of radiation injury in patients undergoing fluoroscopic procedures. It is time to review some of the risks of ionizing radiation as well as some of our practices at the University Hospital of West Indies (UHWI). In this review, we discuss the relative risks associated with common radiological examinations as well as explore the relative merits of various clinical protocols for the radiological investigation of common diseases seen at the UHWI.

[41] CAMPBELL, R.M., et al., Quantifying and minimizing radiation exposure during pediatric cardiac catheterization, Ped. Cardiol. **26** (2005) 29–33.
This study reports findings from evaluations of new technologies to measure radiation exposure during pediatric cardiac catheterization procedures. A strategy of pulsed fluoroscopy and low power settings resulted in significantly lower patient radiation exposure compared to conventional 60 frames/sec, high-power settings during fluoroscopy. During radiofrequency ablation procedures, thyroid and thoracic skin sites outside the direct fluoroscopic field received minimal radiation exposure. intrathoracic radiation exposure was measured with the use of an esophageal dosimeter. In conclusion, strategies to reduce total radiation exposure should be employed, radiation dose should be measured, and assessment of radiation skin injury should be included in post-catheterization assessment.

[42] SUZUKI, S., et al., Radiation exposure to patient's skin during percutaneous coronary intervention for various lesions, including chronic total occlusion, Circ. J. **70** (2006) 44–48.
Background Radiation skin injuries have been reported as a result of various procedures, so in the present study the patients' entrance skin dose (ESD) during percutaneous coronary intervention (PCI) was evaluated. Methods and Results ESDs were assessed during 97 procedures (13 for chronic total occlusion (CTO), 14 for multivessel stenoses, 22 for single-vessel multiple stenoses, and 48 for single

stenosis). The patients wore jackets that had 48 or 52 radiosensitive indicators placed on the back during the PCI procedures, with 8 other indicators placed on both upper arms. After the procedure, the color of the indicators was analysed with a colour measuring instrument, and the patients' ESDs were calculated from the color difference of the indicators. The average maximum ESDs of the patients were 4.5±2.8 Gy (median: 4.6 Gy) for CTO, 2.3±0.7 Gy (median: 2.4 Gy) for multivessel stenoses, 1.8±1.0 Gy (median: 1.5 Gy) for single-vessel multiple stenoses, and 1.4±0.9 Gy (median: 1.2 Gy) for single stenosis. Conclusions Skin injury can occur during PCI, especially for CTO, so it is important to estimate each patient's ESD and attempt to reduce it. (Circ. J. 2006; **70**: 44–48).

[43] SUZUKI, S., et al., Radiation dose to patients and radiologists during transcatheter arterial embolization: Comparison of a digital flat-panel system and conventional unit, Am. J. Roentgenol. **185** (2005) 855–859.
OBJECTIVE: The objective of our study was to evaluate the exposure doses to patients and radiologists during transcatheter arterial embolization (TAE) for hepatocellular carcinoma (HCC) using a new angiographic unit with a digital flat-panel system. SUBJECTS AND METHODS: Doses were assessed for 24 procedures: 12 using a new unit with a digital flat-panel system and 12 using a conventional unit. Doses to patients' skin were evaluated with thermoluminescent dosimeters behind the left, middle, and right portions of the liver. The doses to the radiologists were measured by an electronic personal dosimeter placed on the chest outside a lead protector. The maximal skin doses to the patients and the dose equivalents, Hp(0.07), to the radiologists were compared between the two procedure groups with each angiographic unit. RESULTS: For procedures with the new unit, the mean maximal skin dose to the patients was 284 ± 127 (SD) mGy (range, 130-467 mGy), and Hp(0.07) to the radiologists was 62.8 ± 17.4 muSv. For procedures with the conventional unit, the maximal skin dose to the patients was 1,068 ± 439 mGy (range, 510-1882 mGy), and Hp(0.07) to the radiologists was 68.4 ± 25.7 muSv. The maximal skin dose to the patients was significantly lower with the new unit than with the conventional unit ($p < 0.0005$). There was no significant difference in the Hp(0.07) to the radiologists between the two procedure groups. CONCLUSION: The new digital flat-panel system for angiographic imaging can reduce the radiation dose to patients' skin during TAE for HCC as compared with the conventional system.

[44] PADOVANI, R., et al., Retrospective evaluation of occurrence of skin injuries in interventional cardiology procedures, Radiat. Prot. Dosim. **117** (2005) 247–250.
Interventional cardiology procedures can involve high doses to patients and, in particular, to patients' skin, the tissue at greatest risk of deterministic injuries. The evaluation of skin dose from interventional procedures is recommended, but difficult because of the amount of different X-ray fields and projections used in a procedure. For this reason, a retrospective follow-up study has been developed to identify skin injuries in patients submitted to one or more cardiac interventions in the Udine hospital between 1998 and 2002. Seventy-eight

patients with a cumulative dose-area product >300 Gy·cm^2 were selected from 3332 patients, who underwent 5039 procedures. In this group the maximum skin dose was 6.7 Gy. The clinical follow-up, performed using the LENT-SOMA methodology, has not detected skin injuries and this result allows a frequency to be estimated for skin injuries in patients undergoing repeated cardiac procedures of <3_10_4 in our centre.

[45] TRIANNI, A., et al., Patient skin dosimetry in haemodinamic and electrophysiology interventional cardiology, Radiat. Prot. Dosim. **117** (2005) 241–246.
With the increase in number and complexity of interventional cardiology (IC) procedures, it is important to monitor skin dose in order to decrease skin injuries. This study investigated radiation doses for patients undergoing IC procedures, compare results with the literature and define a local dose–area product trigger level for operators to identify situations likely to exceed the threshold for transient skin erythema of 2 Gy. Dosimetric data were collected for 77 haemodynamic and 90 electrophysiological procedures. Mean maximum local skin doses (MSDs) were 0.28 Gy for coronary angiography, 1.03 Gy for percutaneous transluminal coronary angioplasty (PTCA), 0.03 Gy for pacemaker insertion, 0.17 Gy for radiofrequency ablation for nodal tachycardia, 0.10 Gy for WPW and 0.22 Gy for atrial flutter. Since MSD values for the other procedures were well below the deterministic effect limit, a trigger level of 140 Gy·cm^2 was derived for PTCA procedures alone.

[46] PADOVANI, R., QUAI, E., Patient dosimetry approaches in interventional cardiology and literature dose data review, Radiat. Prot. Dosim. **117** (2005) 217–221.
Interventional radiology contributes a significant proportion of the collective dose of the population from medical exposures. Interventional radiology procedures are usually fluoroscopy-guided diagnostic and therapeutic interventions. When complex procedures are performed or procedures are repeated for the same patient, high-radiation dose levels can occur because procedures often require long fluoroscopy times and require high-quality images. For all of these reasons, dosimetric evaluations in interventional radiology are widely increasing. Patient dosimetry methods currently used in interventional radiology may be divided into three categories according to dosimetry purpose: (I) dosimetry for stochastic risk evaluation, (II) dosimetry for quality assurance and (III) dosimetry to prevent the deterministic effects of radiation. A short description of dosimetric methods used in interventional cardiology practice and relevant published dosimetric data are reported.

[51] BERNARDI, G., et al., A study to validate the method based on DIMOND quality criteria for cardiac angiographic images, Radiat. Prot. Dosim. **117** (2005) 263–268.
A method based on image quality criteria (QC) for cine-angiography was developed to measure the quality of cine-angiograms (CA). A series of 30 CA for left ventriculography (LV) and left and right coronary angiography (LCA, RCA) have been scored and 172 readings were obtained. Standard deviation of quality

scores indicated the reproducibility of the method. Each part of CA was examined separately, giving scores for LV, LCA and RCA and a total score (TS), with clinical (C) and technical (T) criteria defined and examined separately. In 83% of the studies TS was >0.8 and with standard deviation from 0.02 to 0.21. In general, LV had a lower score and greater disagreement compared with RCA and LCA. Disagreement was greater in T, compared with C. In conclusion, these results indicate that QC, translated into a scoring system, yields reproducible data on the quality of cardiac images.

[52] BERNARDI, G., et al., Image quality criteria in cardiology, Radiat. Prot. Dosim. **117** (2005) 162–165.
Image quality evaluation plays a key role in the process of optimisation in radiological procedures. Image quality criteria for cardiac cine-angiography were recently agreed as part of a European Research Project, and a scoring system based on these criteria has been developed to allow an 'objective' measurement of the quality of cardiac angiograms. Two studies aimed at the evaluation of the methodology have been completed, demonstrating that the method can be applied to cardiac images and translated into a scoring system that yields reproducible data. Based on the results of these studies, quality criteria have been further reviewed by DIMOND III panel and the updated version is presented in this paper.

[56] PETERZOL, A., et al., Reference levels in PTCA as a function of procedure complexity, Radiat. Prot. Dosim. **117** (2006) 54–58.
The multicentre assessment of a procedure complexity index (CI) for the introduction of reference levels (RLs) in percutaneous transluminal coronary angioplasties (PTCA) is presented here. PTCAs were investigated based on methodology proposed by Bernardi et al. Multiple linear stepwise regression analysis, including clinical, anatomical and technical factors, was performed to obtain fluoroscopy time predictors. Based on these regression coefficients, a scoring system was defined and CI obtained. CI was used to classify dose values into three groups: low, medium and high complexity procedures, since there was good correlation ($r = 0.41$; $P < 0.001$) between dose-area product (DAP) and CI. CI groups were determined by an ANOVA test, and the resulting DAP and fluoroscopy time third quartiles suggested as preliminary RLs in PTCA, as a function of procedure complexity. PTCA preliminary RLs for DAP are 54, 76 and 127 Gy cm(2), and 12, 20 and 27 min for fluoroscopy time, for the three CI groups.

[57] CHAPPLE, C.L., BROADHEAD, D.A., FAULKNER, K., A phantom based method for deriving typical patient doses from measurements of dose-area product on populations of patients, Br. J. Radiol. **68** (1995) 1083–1086.
One of the chief sources of uncertainty in the comparison of patient dosimetry data is the influence of patient size on dose. Dose has been shown to relate closely to the equivalent diameter of the patient. This concept has been used to derive a prospective, phantom based method for determining size correction factors for measurements of dose-area product. The derivation of the size correction factor

has been demonstrated mathematically, and the appropriate factor determined for a number of different X-ray sets. The use of phantom measurements enables the effect of patient size to be isolated from other factors influencing patient dose. The derived factors agree well with those determined retrospectively from patient dose survey data. Size correction factors have been applied to the results of a large scale patient dose survey, and this approach has been compared with the method of selecting patients according to their weight. For large samples of data, mean dose-area product values are independent of the analysis method used. The chief advantage of using size correction factors is that it allows all patient data to be included in a survey, whereas patient selection has been shown to exclude approximately half of all patients. Reduction of the size of the data set may lead to mean dose-area product values that are less reliable indicators of typical practice. The use of size correction factors will be of particular benefit in the analysis of paediatric dosimetry data, where a wide range of sizes exist, even within accepted age bands.

[60] EVANS, D.S., et al., Threshold contrast detail detectability curves for fluoroscopy and digital acquisition using modern image intensifier systems, Br. J. Radiol. **77** (2004) 751–758.
Threshold contrast detail detectability (TCDD) test objects are a commonly used tool to assess image quality of imaging systems. FAXIL (The Facility for the Assessment of X-ray imaging, Leeds) produced updated standard TCDD curves, for fluoroscopy systems in good adjustment, in 1992. Fluoroscopy curves can be corrected to account for the effect of image intensifier input air kerma rate and field size. This paper presents updated TCDD curves for fluoroscopy and new curves for digital acquisition. The results for digital acquisition suggest that the TCDD curves should not be corrected for input air kerma, as the quantum noise is not dominant and system noise is significant. These curves will prove useful for accepting new equipment, to give an indication of the expected image quality for a new image intensifier system.

[61] BALTER, S., et al., A new tool for benchmarking cardiovascular fluoroscopes, Catheter Cardiovasc. Interv. **52** (2001) 67–72. [Record as supplied by publisher.]
This article reports the status of a new cardiovascular fluoroscopy benchmarking phantom. A joint working group of the Society for Cardiac Angiography and Interventions (SCA&I) and the National Electrical Manufacturers Association (NEMA) developed the phantom. The device was adopted as NEMA standard XR 21-2000, 'Characteristics of and Test Procedures for a Phantom to Benchmark Cardiac Fluoroscopic and Photographic Performance' in August 2000. The test ensemble includes imaging field geometry, spatial resolution, low-contrast iodine detectability, working thickness range, visibility of moving targets, and phantom entrance dose. The phantom tests systems under conditions simulating normal clinical use for fluoroscopically guided invasive and interventional procedures. Test procedures rely on trained human observers.

[63] SERVOMAA, A., KARPPINEN, J., The dose-area product and assessment of the occupational dose in interventional radiology, Radiat. Prot. Dosim. **96** (2001) 235–236.
This study used dose-area product (DAP) data to determine the relationship between the dose received by radiologists and the DAP. The working conditions were simulated by phantom measurements. The doses of scattered radiation were measured using various scattering angles, distances and tube voltages. The calculated doses of scattered radiation were compared with the measured doses of scattered radiation. To test the validity of using such data for assessing occupational doses, the scatter dose on the radiologist or cardiologist was calculated from the DAP using the measured scatter factors. The dose to the lenses of the eyes may exceed the annual limit, and may therefore restrict the number of interventional procedures. A relation between the DAP and the occupational dose is difficult to establish, especially because staff doses are associated with the use of protective devices, positions of projections with respect to the patient, and working methods. However, the DAP may provide a good reference value for the dosimetric monitoring of staff.

[64] WAGNER, L.K., POLLOCK, J.J., Real-time portal monitoring to estimate dose to skin of patients from high dose fluoroscopy, Br. J. Radiol. **72** (1999) 846–855.
Since doses to skin of patients from fluoroscopically-guided interventional procedures can be very high, real-time monitoring of skin dose is important for both patient management and quality control. The use of a scintillation detector, placed on the X-ray port to measure potential skin dose, was investigated, focusing on the uncertainties related to the technique. Sources of uncertainty include performance characteristics of the dosimeter, errors in calibration, patient set-up and changes during the procedure. Some of the largest sources of error include uncertainty in source-to-skin distance, heel effect, difficulty in identifying the area of skin principally exposed, calibration error, energy dependence of the dosimeter and the dose rate dependence of the monitor. This technique is found to be beneficial for radiation management, but users must be cognizant of the potential errors of the method and the limitations that these place on quality control and patient management. Knowing the limitations and minimizing the sources of error enhance the utility of the technique.

[65] VAN DE PUTTE, S., et al., Correlation of patient skin doses in cardiac interventional radiology with dose-area product, Br. J. Radiol. **73** (2000) 504–513.
The use of X-rays in cardiac interventional radiology has the potential to induce deterministic radiation effects on the patient's skin. Guidelines published by official organizations encourage the recording of information to evaluate this risk, and the use of reference values in terms of the dose-area product (DAP). Skin dose measurements were made with thermoluminescent dosimeters placed at eight different locations on the body. In addition, DAP was recorded in 100 patients for four types of interventional radiology procedures. Mean, median and third quartile for these results are presented. Maximum skin dose values found

were 412 mGy, 725 mGy, 760 mGy and 1800 mGy for coronary catheterization, coronary catheterization with left ventricle investigation, and percutaneous transluminal angiography without and with stenting, respectively. Median DAPs for these same procedures were, respectively, 5682 cGy·cm^2, 10 632 cGy·cm^2, 10 880 cGy·cm^2 and 13 161 cGy·cm^2. The relationship between DAP and skin dose was investigated. We found a poor correlation of DAP with maximum skin dose ($r = 0.77$) and skin dose indicator ($r = 0.78$). Using conversion factors derived from Monte Carlo simulations, skin dose distributions were calculated based on the measured DAPs. Agreement between the calculated skin dose distribution, using DAP values averaged over a group of patients who underwent coronary catheterization and left ventricle investigation, and the measured skin dose averaged over the same group of patients was very good. However, there were large differences between the calculated skin doses using the individual DAP data per patient and measured skin doses for individual patients ($r = 0.66$). Hence, calculation of individual skin doses based on the specific DAP data per patient is not reliable and therefore measuring skin dose is preferable.

[66] CASTELLANO, I.A., et al., Assessment of organ radiation doses and associated risk for digital bifemoral arteriography, Br. J. Radiol. **68** (1995) 502–507.
An assessment has been made of the absorbed dose associated with femoral arteriography using a digital imaging system. A bilateral femoral arteriogram was performed on 17 patients, using a filmless 1024 matrix digital image acquisition system with a discrete stepping tube-stand and 40 cm image intensifier. A standardized protocol of manual patient/tube-stand positioning under fluoroscopic control and automatic stepping digital acquisition was followed. Skin entry doses were measured with a dose-area product meter for each stage of the procedure, and the total gonad dose was assessed with thermoluminescent dosimeters (TLDs). Published Monte Carlo simulations were supplemented with further calculations to evaluate organ doses from the dose-area products measured. Comparison with the TLD measurements indicated that this technique over-estimated organ doses by about 30%. A mean effective dose of 3.1 ± 1.8 mSv was calculated for the procedure, with the greatest dose burden being imposed by fluoroscopy during catheter manipulation. The related radiation detriment is 0.018%, which is insignificant when compared with the overall mortality from peripheral vascular disease.

[67] VEHMAS, T., Radiation exposure during standard and complex interventional procedures. Br. J. Radiol. **70 (**1997) 296–298.
Radiation doses given during standard and complex interventional procedures were compared. Screening times, dose-area products, and radiologists' forehead and finger doses were recorded during 28 standard percutaneous drainages and 10 complex drainages (eight combined procedures and two failed procedures). The median screening times (8.75 min) and finger doses (84 μGy) during standard drainages were less than those during complex drainages (20.5 min, $p = 0.0005$ and 163 μGy, $p = 0.0003$). Dose-area products and forehead doses were also lower, but

not significantly. Previously published series on radiation measurements lack data on complex procedures. This may bias the results, since combined and failed interventions, which are common, are associated with higher radiation exposure than are standard procedures.

[68] RUIZ-CRUCES, R., et al., Patient dose in radiologically guided interventional vascular procedures: Conventional versus digital systems, Radiology **205** (1997) 385–393.
PURPOSE: To calculate the difference in the patient radiation dose in radiologically guided interventional vascular procedures between conventional and digital systems and to estimate the effective dose and the energy imparted with the digital system. MATERIALS AND METHODS: A total of 318 procedures (in 318 patients) in 15 different examination groups were analysed. The dose-area product was determined by using a transmission chamber fitted to an X ray tube light-beam diaphragm; the effective dose was determined by using software. RESULTS: Urinary and biliary tract procedures showed small differences in the average dose-area product between conventional and digital systems. The dose-area products in the vascular procedures were higher with the digital than with the conventional system. The average effective dose and energy imparted were 0.88 mSv and 129 mJ, respectively, in the subcutaneous placement of a reservoir for analgesic administration and as much as 25.7 mSv and 829 mJ, respectively, in spermatic vein embolization. CONCLUSION: The dose-area product was higher with the digital system than with the conventional system in 13 of the 15 groups. To reduce the patient dose in vascular interventional radiology procedures, the training of personnel and the frequent use of conventional fluoroscopy and low-dose imaging are required.

[69] VANO, E., et al., Patient dosimetry in interventional radiology using slow films, Br. J. Radiol. **70** (1997) 195–200.
A method for the evaluation of patient doses in interventional radiology procedures is presented and discussed. The method requires the analysis of slow non-screen films such as those used in radiotherapy. Dose area product and patient skin dose can be estimated with fair accuracy depending on the interventional procedure type. The agreement between the slow film method and diamentor measurement is better than 5% after the application of appropriate corrections. The cost is reasonable making it a worthwhile option in patient dosimetry, especially when the X-ray equipment does not include any fixed dose-area measuring device. Additional valuable information which may be applied to optimization of procedures (e.g. irradiated areas, number and types of projections check of appropriate use of beam limiting devices) is achieved by examining the different irradiation fields on the film.

[71] GEISE, R.A., O'DEA, T.J., Radiation dose in interventional fluoroscopic procedures, Appl. Radiat. Isot. **50** (1999) 173–184.
Vascular interventional procedures carried out under fluoroscopic guidance often involve high radiation doses. Above certain thresholds, radiation can cause

significant damage to the skin including hair loss and severe necrosis. Such damage has been reported by several investigators. Many attempts have been made to quantitate the radiation doses to the skin involved with these procedures, but dosimetry methods are often flawed. To improve the situation better monitoring of radiation doses, fluoroscopist education, and changes in technology and methods are needed.

[74] HWANG, E., et al., Real-time measurement of skin radiation during cardiac catheterization, Cathet. Cardiovasc. Diagn. **43** (1998) 367–370; discussion 371.
A novel skin dose monitor was used to measure radiation incident on maximal X ray exposed skin during 135 diagnostic and 65 interventional coronary procedures. For the diagnostic studies (n = 135), mean skin dose was 180 ± 64 mGy; for PTCA (n = 35), it was 1021 ± 674 mGy, single stents (n = 25) 1529 ± 601 mGy, and multiple stents with rotational atherectomy (n = 5) 2496 ± 1028 mGy. The dose independently increased with more cine runs, more fluoroscopy, and greater patient weight. Physicians should consider the potential for adverse radiation exposure when planning coronary interventional cases and deciding on the X ray mode and angles used.

[72] MILLER, D.L., et al., Radiation doses in interventional radiology procedures: The RAD-IR study: Part II: Skin dose, J. Vasc. Interv. Radiol. **14** (2003) 977–990.
PURPOSE: To determine peak skin dose (PSD), a measure of the likelihood of radiation-induced skin effects, for a variety of common interventional radiology and interventional neuroradiology procedures, and to identify procedures associated with a PSD greater than 2 Gy. MATERIALS AND METHODS: An observational study was conducted at seven academic medical centres in the United States. Sites prospectively contributed demographic and radiation dose data for subjects undergoing 21 specific procedures in a fluoroscopic suite equipped with built-in dosimetry capability. Comprehensive physics evaluations and periodic consistency checks were performed on each unit to verify the stability and consistency of the dosimeter. Seven of 12 fluoroscopic suites in the study were equipped with skin dose mapping software. RESULTS: Over a 3-year period, skin dose data were recorded for 800 instances of 21 interventional radiology procedures. Wide variation in PSD was observed for different instances of the same procedure. Some instances of each procedure we studied resulted in a PSD greater than 2 Gy, except for nephrostomy, pulmonary angiography, and inferior vena cava filter placement. Some instances of transjugular intrahepatic portosystemic shunt (TIPS) creation, renal/visceral angioplasty, and angiographic diagnosis and therapy of gastrointestinal hemorrhage produced PSDs greater than 3 Gy. Some instances of hepatic chemoembolization, other tumor embolization, and neuroembolization procedures in the head and spine produced PSDs greater than 5 Gy. In a subset of 709 instances of higher-dose procedures, there was good overall correlation between PSD and cumulative dose (r = 0.86; P <.000001) and between PSD and dose-area-product (r = 0.85, P <.000001), but there was wide variation in these relationships for individual instances.

CONCLUSIONS: There are substantial variations in PSD among instances of the same procedure and among different procedure types. Most of the procedures observed may produce a PSD sufficient to cause deterministic effects in skin. It is suggested that dose data be recorded routinely for TIPS creation, angioplasty in the abdomen or pelvis, all embolization procedures, and especially for head and spine embolization procedures. Measurement or estimation of PSD is the best method for determining the likelihood of radiation-induced skin effects. Skin dose mapping is preferable to a single-point measurement of PSD.

[75] NICHOLSON, R., TUFFEE, F., UTHAPPA, M.C., Skin sparing in interventional radiology: The effect of copper filtration, Br. J. Radiol. **73** (2000) 36–42.
Complex and lengthy interventional radiological techniques have resulted in a number of patients developing skin reactions in recent years. To safeguard against these side effects, we have investigated the degree to which entrance skin dose can be reduced by inserting 0.18 mm and 0.35 mm copper filtration in the incident beam. The potential reduction was measured on a 22 cm water phantom for each of eight models of a fluoroscopy unit. Using the catheter laboratory fluoroscopy unit on which radiofrequency ablations are routinely performed, we assessed the relative effectiveness of adding filtration and increasing the kV:mA ratio. Image quality was subjectively assessed for diagnostic and therapeutic acceptability in two groups of 10 patients undergoing radiofrequency ablations, pacemaker insertions or electrophysiology studies. One of the groups was screened with 0.35 mm copper filtration in place and the other group acted as the control. Maximum patient skin dose proved difficult to measure directly because of the unpredictable dose pattern. This pattern was studied in four patients using a film method in conjunction with thermoluminescent dosimeters. Copper filtration 0.35 mm thick inserted in the beams of the eight fluoroscopy units produced a mean reduction in entrance dose to the phantom of 58% with a mean increase in tube loading of 29%. At 100 kV the increased loading on the X-ray tube was equivalent to increasing the anteroposterior separation of the patient by 2 cm. Measurements on the catheter laboratory unit showed that the tube voltage would need to be raised above the normal diagnostic range to obtain an equivalent entrance dose reduction without the filter. The blackening of films under the patients showed complex patterns, but the estimated skin doses were consistent with those predicted by the phantom experiments. All six cardiologists considered there to be insignificant detriment to image quality in the procedures investigated.

[76] FAJARDO, L.C., GEISE, R.A., RITENOUR, E.R., A survey of films for use as dosimeters in interventional radiology, Health Phys. **68** (1995) 595–599.
Analysis of radiation doses in interventional radiological procedures that can lead to deterministic radiation effects such as erythema and epilation would assist physicians in planning patients care after exposure and in reducing doses. Photographic films used to measure skin exposure in the past are too sensitive for the high doses involved in interventional procedures. Seventeen different types of films, many of which are generally available in hospitals, were surveyed to see if

any would meet the demands of interventional radiology. Sensitometric curves obtained demonstrate that most films are inappropriate for high dose procedures. Using Kodak Fine Grain Positive and Dupont duplicating films and automatic processing, doses as high as 2.8 Gy could be measured with reasonable accuracy. Similar results can be obtained by manually processing Kodak XV-2 verification film at room temperature.

[77] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Avoidance of Radiation Injuries from Medical Interventional Procedures, Publication 85, Pergamon Press, Oxford and New York (2001) 7–67.
Interventional radiology (fluoroscopically-guided) techniques are being used by an increasing number of clinicians not adequately trained in radiation safety or radiobiology. Many of these interventionists are not aware of the potential for injury from these procedures or the simple methods for decreasing their incidence. Many patients are not being counselled on the radiation risks, nor followed up when radiation doses from difficult procedures may lead to injury. Some patients are suffering radiation-induced skin injuries and younger patients may face an increased risk of future cancer. Interventionists are having their practice limited or suffering injury, and are exposing their staff to high doses. In some interventional procedures, skin doses to patients approach those experienced in some cancer radiotherapy fractions. Radiation-induced skin injuries are occurring in patients due to the use of inappropriate equipment and, more often, poor operational technique. Injuries to physicians and staff performing interventional procedures have also been observed. Acute radiation doses (to patients) may cause erythema at 2 Gy, cataract at 2 Gy, permanent epilation at 7 Gy, and delayed skin necrosis at 12 Gy. Protracted (occupational) exposures to the eye may cause cataract at 4 Gy if the dose is received in less than 3 months, at 5.5 Gy if received over a period exceeding 3 months. Practical actions to control dose to the patient and to the staff are listed. The absorbed dose to the patient in the area of skin that receives the maximum dose is of priority concern. Each local clinical protocol should include, for each type of interventional procedure, a statement on the cumulative skin doses and skin sites associated with the various parts of the procedure. Interventionists should be trained to use information on skin dose and on practical techniques to control dose. Maximum cumulative absorbed doses that appear to approach or exceed 1 Gy (for procedures that may be repeated) or 3 Gy (for any procedure) should be recorded in the patient record, and there should be a patient follow-up procedure for such cases. Patients should be counselled if there is a significant risk of radiation-induced injury, and the patient's personal physician should be informed of the possibility of radiation effects. Training in radiological protection for patients and staff should be an integral part of the education for those using interventional techniques. All interventionists should audit and review the outcomes of their procedures for radiation injury. Risks and benefits, including radiation risks, should be taken into account when new interventional techniques are introduced. A concluding list of recommendations is given. Annexes list procedures, patient

and staff doses, a sample local clinical protocol, dose quantities used, and a procurement checklist.

[80] MA, C.M., et al., AAPM protocol for 40-300 kV x-ray beam dosimetry in radiotherapy and radiobiology, Med. Phys. **28** (2001) 868–893.
The American Association of Physicists in Medicine (AAPM) presents a new protocol, developed by the Radiation Therapy Committee Task Group 61, for reference dosimetry of low- and medium-energy x rays for radiotherapy and radiobiology (40 kV < or = tube potential < or = 300 kV). It is based on ionization chambers calibrated in air in terms of air kerma. If the point of interest is at or close to the surface, one unified approach over the entire energy range shall be used to determine absorbed dose to water at the surface of a water phantom based on an in-air measurement (the 'in-air' method). If the point of interest is at a depth, an in-water measurement at a depth of 2 cm shall be used for tube potentials > or = 100 kV (the 'in-phantom' method). The in-phantom method is not recommended for tube potentials < 100 kV. Guidelines are provided to determine the dose at other points in water and the dose at the surface of other biological materials of interest. The protocol is based on an up-to-date data set of basic dosimetry parameters, which produce consistent dose values for the two methods recommended. Estimates of uncertainties on the final dose values are also presented.

[82] ROPOLO, R., et al., Evaluation of patient doses in interventional radiology, Radiol. Med. **102** (2001) 384–390.
PURPOSE: To verify the suitability of indicative quantities to evaluate the risk related to patient exposure, in abdominal and vascular interventional radiology, by the study of correlations between dosimetric quantities and other indicators. MATERIALS AND METHODS: We performed in vivo measurements of entrance skin dose (ESD) and dose area product (DAP) during 48 procedures to evaluate the correlation among dosimetric quantities, and an estimation of spatial distribution of exposure and effective dose (E). To measure DAP we used a transmission ionization chamber and to evaluate ESD and its spatial distribution we used radiographic film packed in a single envelope and placed near the patient's skin. E was estimated by a calculation software using data from film digitalization. RESULTS: From the data derived for measurements in 27 interventional procedures on 48 patients we obtained a DAP to E conversion factor of 0.15 mSv/Gy·cm^2, with an excellent correlation (r=0.99). We also found a good correlation between DAP and exposure parameters such as fluoroscopy time and number of images. The greatest effective dose was evaluated for a multiple procedure in the hepatic region, with a DAP value of 425 Gy·cm^2. The greatest ESD was about 550 mGy. For groups of patients undergoing similar interventional procedures the correlation between ESD and DAP had conversion factors from 6 to 12 mGy Gy^{-1}/cm^{-2}. CONCLUSION: The evaluation of ESD and E by slow films represents a valid method for patient dosimetry in interventional radiology. The good correlation between DAP and fluoroscopy time and number of images confirm the suitability of these indicators as

basic dosimetric information. All the ESD values found are lower than threshold doses for deterministic effects.

[81] McPARLAND, B.J., A study of patient radiation doses in interventional radiological procedures, Br. J. Radiol. **71** (1998) 175–185.
Patient radiation doses received during interventional radiological procedures can be significant. To aid in the establishment of reference dose levels, a patient dose survey has been conducted of such procedures. A total of 288 non-coronary procedures (177 classified as diagnostic and 111 as therapeutic) were accrued into the study. For each procedure, the fluoroscopy screening time and the fluoroscopic and digital radiographic dose-area products were recorded in a computer database. For example, median dose-area product values (due to fluoroscopy and digital radiography combined) of 24.2, 27.9, 69.6 and 74.7 Gy·cm^2 were obtained for nephrostomy, biliary stent removal/insertion, cerebral angiography and percutaneous transhepatic cholangiography procedures. While the effective dose is not an accurate measure of patient risk, it is convenient for comparing the radiological risks associated with various procedures. Effective doses were estimated from the total dose-area products. The respective median estimated effective dose values for the four procedures noted above were 3.9, 4.5, 7.0 and 12.0 mSv. While an infrequently performed procedure at this institution (n = 4 during this survey), the transjugular intrahepatic portosystemic shunt (TIPS) procedure had the greatest median dose-area product and effective dose values: 347 Gy·cm^2 and 55.5 mSv, respectively. Excluding the extreme case of TIPS, it was found that among commonly-performed procedures, those that are categorized as therapeutic do not necessarily present a statistically significant greater radiation risk than those which are diagnostic. Comparisons between dose-area product values obtained from this study are made with data from other interventional radiology patient dose surveys and reasons for some differences noted are discussed.

[83] BROADHEAD, D.A., et al., The impact of cardiology on the collective effective dose in the north of England, Br. J. Radiol. **70** (1997) 492–497.
Two cardiology X-ray rooms were monitored with dose-area product meters as part of a Regional Patient Dosimetry Programme. Dose-area product measurements on over 2000 patients undergoing examinations in the cardiology rooms are presented. The data have been corrected according to patient size where possible. In room A mean dose-area product values for coronary angiography, coronary angioplasty, radiofrequency ablation and mitral valvuloplasty were found to be 47.7, 72.2, 91.1 and 161.9 Gy·cm^2 respectively. In room B mean dose-area product values for coronary angiography and coronary angioplasty were found to be 23.4 and 51.6 Gy·cm^2 respectively. Observational studies were used to deduce the typical projections and technique factors. This typical examination was used to simulate an angiogram from which it was possible to derive factors to convert measured dose-area product values into estimates of effective dose. In room A, the effective doses were estimated to be 9.4, 14.2, 17.3 and 29.3 mSv for coronary angiography, coronary angioplasty, radiofrequency ablation and mitral valvuloplasty, respectively. The effective doses

during coronary angiography and coronary angioplasty, performed in room B, were found to be 4.6 and 10.2 mSv, respectively. A regional survey of the frequency of these cardiac procedures was performed. It was deduced that the annual collective effective dose from these cardiac procedures in the North of England, the former Northern Region, was 45.7 manSv.

[II-2] BALTER, S., et al., Radiation doses in interventional radiology procedures: The RAD-IR Study. Part III: Dosimetric performance of the interventional fluoroscopy units, J. Vasc. Interv. Radiol. **15** (2004) 919–926.
PURPOSE: To present the physics data supporting the validity of the clinical dose data from the RAD-IR study and to document the performance of dosimetry-components of these systems over time. MATERIALS AND METHODS: Sites at seven academic medical centres in the United States prospectively contributed data for each of 12 fluoroscopic units. All units were compatible with International Electrotechnical Commission (IEC) standard 60601-2-43. Comprehensive evaluations and periodic consistency checks were performed to verify the performance of each unit's dosimeter. Comprehensive evaluations compared system performance against calibrated ionization chambers under nine combinations of operating conditions. Consistency checks provided more frequent dosimetry data, with use of each unit's built-in dosimetry equipment and a standard water phantom. RESULTS: During the 3-year study, data were collected for 48 comprehensive evaluations and 581 consistency checks. For the comprehensive evaluations, the mean (95% confidence interval range) ratio of system to external measurements was 1.03 (1.00-1.05) for fluoroscopy and 0.93 (0.90-0.96) for acquisition. The expected ratio was 0.93 for both. For consistency checks, the values were 1.00 (0.98-1.02) for fluoroscopy and 1.00 (0.98-1.02) for acquisition. Each system was compared across time to its own mean value. Overall uncertainty was estimated by adding the standard deviations of the comprehensive and consistency measurements in quadrature. The authors estimate that the overall error in clinical cumulative dose measurements reported in RAD-IR is 24%. CONCLUSION: Dosimetric accuracy was well within the tolerances established by IEC standard 60601-2-43. The clinical dose data reported in the RAD-IR study are valid.

[II-3] MILLER, D.L., et al., Radiation doses in interventional radiology procedures: The RAD-IR study: Part I: Overall measures of dose, J. Vasc. Interv. Radiol. **14** (2003) 711–727.
PURPOSE: To determine patient radiation doses for interventional radiology and neuroradiology procedures, to identify procedures associated with higher radiation doses, and to determine the effects of various parameters on patient doses. MATERIALS AND METHODS: A prospective observational study was performed at seven academic medical centres. Each site contributed demographic and radiation dose data for subjects undergoing specific procedures in fluoroscopic suites equipped with built-in cumulative dose (CD) and dose-area-product (DAP) measurement capability compliant with International

Electrotechnical Commission standard 60601-2-43. The accuracy of the dosimetry was confirmed by comprehensive measurements and by frequent consistency checks performed over the course of the study. RESULTS: Data were collected on 2,142 instances of interventional radiology procedures, 48 comprehensive physics evaluations, and 581 periodic consistency checks from the 12 fluoroscopic units in the study. There were wide variations in dose and statistically significant differences in fluoroscopy time, number of images, DAP, and CD for different instances of the same procedure, depending on the nature of the lesion, its anatomic location, and the complexity of the procedure. For the 2,142 instances, observed CD and DAP correlate well overall ($r = 0.83$, $P < .000001$), but correlation in individual instances is poor. The same is true for the correlation between fluoroscopy time and CD ($r = 0.79$, $P < .000001$). The correlation between fluoroscopy time and DAP ($r = 0.60$, $P < .000001$) is not as good. In 6% of instances (128 of 2,142), which were principally embolization procedures, transjugular intrahepatic portosystemic shunt (TIPS) procedures, and renal/visceral artery stent placements, CD was greater than 5 Gy. CONCLUSIONS: Most procedures studied can result in clinically significant radiation dose to the patient, even when performed by trained operators with use of dose-reducing technology and modern fluoroscopic equipment. Embolization procedures, TIPS creation, and renal/visceral artery stent placement are associated with a substantial likelihood of clinically significant patient dose. At minimum, patient dose data should be recorded in the medical record for these three types of procedures. These data should include indicators of the risk of deterministic effects as well as the risk of stochastic effects.

[II-5] TOIVONEN, M., Review of dosimetry instrumentation in digital and interventional radiology, Radiat. Prot. Dosim. **94** (2001) 147–150.
Some dosimetry instruments and products are reviewed, the main emphasis being on patient dosimetry, recommendations for accuracy in different measurement applications and the results of some intercomparisons. It seems to be a common problem that the users of the general purpose air kerma meters, dose-area product (DAP) meters or products such as thermoluminescence (TL) dosimeters are not always able to select the correct ionisation chamber, the calibration factor of a DAP meter or the TL dosimeter material and type, respectively, for different radiation conditions. The combined DAP and Ka meters developed recently, as well as the exposure data acquisition systems designed for monitoring one or more quantities or for determining the effective dose of a complicated examination, are described briefly. The most advanced software of these systems is able to display the dose distributions for the most exposed areas of the skin, on-line.

[III-1] VANO, E., et al., On the use of DICOM cine header information for optimisation: Results from the 2002 European DIMOND cardiology survey, Radiat. Protect. Dosim. Adv. **117** (2005) 162–165.
The paper explores the level of information contained within the DICOM header in images from various cardiology systems. Data were obtained in the European DIMOND survey on image quality (Italy, Ireland, Belgium, Greece and Spain).

Images from five standard diagnostic cardiology procedures carried out in six European hospitals have been analysed. DICOM header information was extracted to a database in order to analyse how it could help in the optimisation of the procedures. The level of data contained in the headers differs widely between cardiology systems. None of the X-ray systems in the 2002 survey archives the dosimetric data in the DICOM header. The mean number of runs per procedure ranges between 7.5 and 15.4 and the mean number of frames per procedure between 575 and 1417. Differences in kVp, mA, pulse time, distances and C-arm angulations are substantial and suggest that there exists a wide range for optimization.

GLOSSARY

clinical image quality. The suitability and adequacy of the displayed image for managing the clinical needs of the patient being imaged.

complexity. Complexity is an objective measure of the mental and physical effort required to perform a procedure. A complex procedure is more complicated in performance and structure than a simple procedure. An example would be placement of a guide wire or catheter in an extremely tortuous vessel or across a severe, irregular stenosis. Complexity is due to patient factors (anatomic variation, body habitus) and lesion factors (location, size, severity), but is independent of operator training and experience. Complexity can be estimated from a review of the images obtained during a procedure or with the use of other objective, operator independent measures. (See difficulty.)

constancy check. Constancy checks are defined as those checks that are undertaken either regularly or after maintenance or repair to detect whether change in the performance of the equipment has occurred, in order that corrective action can be initiated. These tests are a subset of quality assurance tests and can be carried out by a radiographer or a technician.

cumulative dose[7] **(cumulative air kerma).** The total air kerma to the interventional reference point (a location defined by the International Electrotechnical Commission in standard 60601-2-43). Cumulative air kerma is an incident air kerma (i.e. without backscatter).

DICOM. The DICOM standard facilitates interoperability of medical imaging equipment by specifying:

- For network communications, a set of protocols to be followed by devices claiming conformance to the standard.
- The syntax and semantics of commands and associated information that can be exchanged using these protocols.
- For media communication, a set of media storage services to be followed by devices claiming conformance to the standard, as well as

[7] As indicated in previous footnotes, the absorbed dose to a point in air is difficult to measure and the instruments are calibrated in terms of air kerma rather than absorbed dose to air. Quantities such as cumulative dose, when referred to air, are expected to be replaced in the future by cumulative air kerma.

a file format and a medical directory structure to facilitate access to the images and related information stored on interchange media.
— Information that must be supplied with an implementation for which conformance to the standard is claimed.

difficulty. Difficulty is an indicator of the operator's subjective opinion of the work involved in performing a procedure. An inexperienced operator may consider a specific procedure difficult in a certain patient, while a more experienced operator would not. Sources of difficulty include operator factors (inadequate clinical experience), equipment factors (technical limitations of devices such as catheters, guide wires and stents) and patient factors (inability to cooperate with the operator, anatomical abnormalities, procedure complexity). Note that inappropriate X ray equipment is seldom a justification for increased difficulty. (See complexity.)

entrance surface air kerma (K_e). The air kerma (measured or calculated) at the point on the patient's entrance surface where the X ray beam enters the patient. K_e is reported 'with backscatter'. For typical fluoroscopic beams, K_e is about 30% greater than incident air kerma K_i, which, by definition, is without backscatter (free in air).

extended. As applied to a procedure, this is a measure of the amount or number of additional procedure components required to accomplish the goal of the procedure. An example would be additional vessels that must be imaged or additional views that must be obtained. The additional work may or may not increase the complexity or difficulty of the procedure.

interventional guidance (reference) levels. Guidance (reference) levels are values derived from surveys of patient populations that have undergone a specific procedure. The interventional reference level is obtained by observing the dose delivered during a large series of nominally identical procedures on patients of relatively homogeneous body mass. These values are corrected for complexity. The interventional guidance (reference) level is set at the 75% percentile of the corrected distribution. Guidance (reference) levels are not designed for or appropriate for use in individual patients. They should be compared with dose values derived from a survey of other patient populations. Reference [guidance] levels are intended for use in quality assurance and quality improvement programmes, as a guide to help determine if a detailed review of local equipment or operator performance is warranted.

kerma–area product (P_{KA}) [8]. The integrated flux of the useful X ray beam. It is approximated by measuring the field size of the X ray beam at a given distance and multiplying this value by the air kerma in the centre of the beam at the same distance.

Leeds test object [60]. Used for television fluoroscopy and fluorography; enables the following checks to be made (e.g. TOR-18FG):

- Monitor brightness and contrast adjustments;
- Resolution limit (up to 5 line pairs per mm);
- Low contrast sensitivity (18 details, 11 mm diameter);
- Circular geometry (check of TV scan linearity).

maximum entrance surface air kerma ($K_{e,max}$). See peak skin dose.

NEMA XR-21 phantom [61]. The phantom and test procedures described in these standard test systems under conditions simulating a range of fluoroscopically guided invasive and interventional procedures. These tools provide simultaneous objective measurements of image quality and phantom entrance dose.

peak skin air kerma. The maximum air kerma found at any portion of the entrance surface as the result of an interventional procedure. This quantity is calculated by a dosimetry model. It can be used to calculate peak skin dose.

peak skin dose. The highest skin absorbed dose delivered to any portion of a patient's skin as the result of an interventional procedure. This includes scatter contributions from the patient support and backscatter from the patient. The most severe deterministic effect will occur at the site of the peak skin dose.

PMMA. Polymethylmethacrylate

reference point air kerma [62]. The total air kerma accumulated at a defined reference point during a fluoroscopically guided procedure. In previous publications, reference point dose was used. As indicated in footnote 5, absorbed dose to a point in air is difficult to measure and the quantity is replaced by air kerma.

skin dose. The absorbed dose of radiation delivered to a patient's skin as the result of an interventional procedure. This includes scatter contributions from the patient support and backscatter from the patient. The distribution of skin dose on the patient is non-uniform because of beam collimation, gantry angulations and table motion during the procedure. Local deterministic effects, such as skin injury and hair loss, are related to the dose delivered to each portion of the patient's skin. Analogues of skin dose include entrance surface air kerma at the location of the patient's skin.

ABBREVIATIONS

AEC	automatic exposure control
BMI	body mass index
CA	coronary angiography
CD	cumulative dose
CDRH	Center for Devices and Radiological Health, USA
CI	complexity index
CRCPD	Council of Radiation Control Programme Directors
DAP	dose–area product
DICOM	Digital Imaging and Communications in Medicine
DIMOND	Measures for Optimizing Radiological Information and Dose in Digital Imaging and Interventional Radiology
DRL	diagnostic reference level
FOV	field of view
FT	fluoroscopy time
IGL	interventional guidance level
IRP	international reference point
KAP or P_{KA}	kerma–area product
LCA	left coronary angiography
LV	left ventriculography
MTF	modulation transfer function
NEMA	National Electrical Manufacturers Association
NEXT	Nationwide Evaluation of X-ray Trends in the United States
PMMA	polymethylmethacrylat
PSD	peak skin dose
PTCA	percutaneous transluminal coronary angioplasty
PCI	percutaneous cardiovascular intervention
RCA	right coronary angiography
SNR	signal to noise ratio
TCDD	threshold contrast detail detectability
TIPS	transjugular intrahepatic portosystemic shunt

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