



WP2, Final Report

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Version/Document date: v1/July 25th 2012

Working Package: 2

WP 2 – Final report

Optimization of patient and occupational exposures in interventional radiology

Project	European Medical ALARA network (EMAN) Contract No. TREN/09/NUCL/SI2.542127
Document	Final report for Work package 2
WP start date	November 2009
WP end date	June 2012
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Executive summary

Medical procedures using ionising radiation constitute by far the largest contribution to people by man-made sources. Although the benefit for patients exposed will normally outweigh the risk associated with the radiation, there is concern that patients may undergo radiological examinations that will not have any impact on their health, or that unnecessarily high dose could be delivered with regard to the diagnostic outcome. Moreover, the increasing use of ionising radiation in the medical sector has also an impact on occupational exposures, and there are concerns that practices such as interventional procedures may cause high individual doses.

As part of the medical procedures using ionising radiation, interventional radiology and cardiology (IR and IC) procedures are performed in increasing large numbers worldwide. There are more and more different applications in a wide range of medical specialties using such techniques, which represent huge advantages for patients over invasive surgical procedures (lower risk of infection, shorter recovery time, etc). However, these procedures often imply high radiation doses to patients, but also to the healthcare personnel. This is reinforced by the fact that many of the specialists performing interventional procedures do not have proper education and training on radiation protection tasks. As a consequence, there are more and more concerns about radiation protection of patients and healthcare personnel using such techniques.

For patient exposures, large differences in the population dose from all medical exposures have been observed between developed countries. This was one of the reasons to set up a EU-funded project called Dose Datamed (2004-2007). In spite of these differences, the relative distribution with respect to imaging modalities and types of examination in European countries was found to be similar. In particular, CT, angiography and interventional procedures give the largest contribution to the total collective dose from all X-rays examinations. Both of these procedures contribute from 10% to 26% of the total population dose.

Workers exposed in medicine constitute a significant percentage of the European workforce that is occupationally exposed to radiation. Major areas of concern are the ones involving new methodologies especially interventional radiology and cardiology, resulting in high extremity doses to hands and legs, as well as to the eye lens of the physicians. Recent data on the effects of eye lens exposure increase the concerns about possible late effects such as lens injuries or cataracts for the medical staff.

EMAN Working Group on optimisation of patient and occupational exposure in IR and IC

In this context, within the EMAN project, a working group has been set up to investigate IR and IC practices within the European Medical ALARA Network including relevant stakeholders with the aim to exchange information and improve the optimisation of radiation protection in these practices.

The **Synthesis report** presents the work performed by the WG. After a general introduction setting the scene, the chapter 2 of this report proposes an **inventory of interventional procedures** of interest for radiation protection. Procedures are classified depending on the level of radiation risk.

The chapter includes data on the numbers of procedures and data on both patient and staff exposure.

Chapter 3 is dedicated to the **equipments used for interventional procedures**. It discusses the technical requirements that equipment should satisfy for radiation protection purposes, underlying the importance of parameters adjustment and the roles of manufacturers and users to improve it. Quality assurance and quality control are also discussed and finally, new developments in interventional radiology using CT are presented with their impact on the patient and staff dose.

Chapter 4 deals with **monitoring of patient and staff doses**. Concerning patient doses, it indicates that stochastic and deterministic effects need to be considered for monitoring. For every procedure, doses need to be documented. Specific rules for the monitoring of patient dose are also proposed according to the monitoring technology available. One important issue is the patient follow-up after an IR or IC procedure to detect and treat as soon as possible the occurrence of deterministic effects. Specific strategy and rules should be defined to organise this follow-up. Concerning staff doses, double dosimetry is recommended as well as extremity dosimetry for some procedures. The issue of eye lens dose is also discussed.

Chapter 5 is devoted to **radiation protection optimization during interventional procedures**. Some strategies to optimize patient and staff exposure are presented. Some recommendations from the ORAMED project are also listed. A procedure performance with quality assurance and quality indicators is addressed. The establishment of Diagnostic Reference Levels (DRLs) in interventional radiology is also discussed as well as its complexity.

Chapter 6 deals with **education and training**. International recommendations and guidelines (ICRP, IAEA, EC,...) are presented. The national requirements on education and training are described for France, Greece, Spain, Austria and Italy. Clinical audit is also addressed.

Chapter 7 addresses the **new developments associated with lens injuries**. The issue of the new dose limit is discussed as well as the need to develop new eye lens dosimeters.

Finally, in chapter 8, **recommendations to improve radiation protection in IR and IC** are proposed, identifying the main stakeholders to be involved for their implementation.

Recommendation to the EC

The main recommendations from the working group are presented below. The Working group notes that **many of these recommendations are the responsibility of national radiation protection authorities in cooperation with professional organizations**. However, the **European Commission has an important role to play in order to disseminate these recommendations and to support them through concerted actions, research programmes, recommendations, guidelines or even Directives**.

1. **Patient radiation dose reports** should be produced at the end of the procedures, and archived. A relevant quantity for the patient dosimetry is the absorbed dose in the skin at the site of maximum cumulative skin dose. A unique dose unit should be adopted by the manufacturers. EC could recommend a harmonization of the dose reports quantity and encourage manufacturers to adopt a uniform dose unit on their equipment

2. **Diagnostic Reference Levels (DRLs) should be developed** for all types of interventional procedures and different types of standardized patients (children, adults...).
The EC publication "EC Guidance on Diagnostic Reference Levels for Medical Exposure (RP 109)" could be revised to propose DRLs calculation methods specific to IR and IC procedures.
3. **Patient follow-up** should be organised to detect skin injuries (deterministic effects). Trigger levels have to be set up to start the detection procedure. In case of high doses radiologists and cardiologists are responsible to inform the patient and the dermatologist and to organize the patient follow up.
EC could make recommendations on the set up and the use of these trigger levels.
4. European guidelines should be formulated about the number of the **dosemeters that should be worn by the staff**, their position in IR and IC as well as on the relevant algorithm to be used to calculate the total effective dose. A special attention should be paid on the monitoring of lens dose and its evaluation.
EC could launch a concerted action to develop these guidelines.
5. The physicians and the medical physicists should be involved in the specification list of the **equipment** to be purchased. Manufacturers of interventional procedure equipment should work with the medical physicist, radiographers and health physicians to determine the optimised protocols in terms of dose rates and image quality adapted to the different IR procedures.
6. **Quality control of X-ray units for radiation protection purpose** should be mandatory. Even if protocols are integrated into European standards, some parameters are still missing (e.g. calibration of the ionising chamber) and should be integrated in these standards.
EU could propose a revision of the European standard of quality control to integrate the missing parameters associated with radiation protection
7. The implementation of the requirements described in EC directive 97/43/Euratom concerning the **quality audit** should be enhanced within all European countries.
EC could play a role in the promotion of these quality audits.
8. **Appropriate education and training** in radiation protection should be required for all healthcare professionals performing interventional procedures. The level of education and training should be adapted to the radiation risk and to the specificities of the procedure.
Training of the outside workers involved in the maintenance of the facilities should also be taken into account.
As the EC guideline 116 on education and training in radiation protection for medical exposure is under revision, EC could pay attention to the integration of specific training program for IC and IR personnel.
9. **The accreditation of radiation protection training programs** should be established by regulatory authorities at a national or a regional level, with the help of academic institutions, scientific and/or professional societies.

Conclusions from the workshop

WP2 prepared some introductory slides for each working group session to initiate the discussion. For the workshop session 3 “Problems and solutions”, the different issues identified by the WP2 team were presented. Recommendations from these issues were presented during workshop session 5 “Making solutions happen and action plan”. Finally, some proposals for future activities of EMAN were discussed during workshop session 7.

Problems and solutions / Making solutions happen

- **Patient dose:** It was concluded that DRLs are required for all interventional procedures and different standard patient sizes, including children. There is a need for international recommendations for the implementation of DRLs. It was suggested that dose reporting and archiving should be mandatory. Regulatory authorities should register the doses to establish national DRLs, especially in countries where there is a lack of medical physicists in radiology departments. It was also discussed whether other dose indicators such as interventional reference point or peak skin dose can be used. It was proposed that a harmonised and unique dose unit should be defined by the scientific societies and adopted by the manufacturers. It was suggested that for cases where a patient has received a high dose, a trigger level needs to be defined where actions are taken. For instance, the interventionist has to inform the patient and the dermatologist for follow-up.
- **Staff dose:** The suggestion was made to develop European guidelines which should, for each specific procedure, define the number and position of dosimeters and give the algorithm for estimating effective dose in interventional radiology/cardiology. It was pointed out that eye lens doses and the logistics for collecting the total dose of workers with different workplaces require special attention. It was emphasized that active dosimeters deserve more use since they add educative effect. The use of protective equipment was discussed and it was concluded that aprons must provide a minimum lead equivalency of 0.5 mm (in front)/0.25 mm (at back), collars, one of 0.35 mm, and glasses of 0.5 mm (including side panels). Protective gloves are not recommended; instead, fingers should be kept out of the X-ray beam and finger dosimeters are suggested. If screens or ceiling-suspended shields are used, the above-mentioned values can be reduced. It was pointed out that suspended floor-based and table-based shields need to be positioned correctly, which may be problematic with biplane systems. It was suggested that best practice needs to be disseminated by the professional societies.
- **Equipment:** It was concluded that during the purchasing process, the specification of new equipment and performance should involve physicians and physicists. Quality control of the equipment should be mandatory and follow standard European protocols that include calibration. There is a need for optimised protocols for interventional procedures and it was suggested that they should be defined by manufacturers and professionals in cooperation. Experience shows that cooperation between manufacturers and users regarding optimisation must be improved.

- **Audits and training:** It was pointed out that quality audits to fulfil EU Directive 97/43 Euratom need to be implemented in all member countries. It was suggested that all healthcare professionals using interventional fluoroscopy need to undergo appropriate education and training in radiation protection. Levels of education and training need to be adapted to the specific intervention and its radiation risk. It was concluded that professional societies have an important role in terms of arranging education and training courses.

Future activities for EMAN

It was concluded that a multidisciplinary approach creates better mutual understanding and a common language among stakeholders, resulting in improved optimisation. It was suggested that:

- EMAN may act as a consensus voice of experts for the EC.
- EMAN may serve as a discussion forum between medical physicists, radiographers, radiologists, other medical professionals, the industry and regulatory authorities.
- EMAN may provide contacts to European and national experts for radiation protection questions.
- EMAN should produce guidelines and synthesize guidelines with new research (but not duplicate existing guidelines). It should provide updated lists of literature on radiation protection.
- EMAN working groups should prepare documents that may be discussed and approved at meetings.

Administrative summary

The EMAN WP2 gathered representatives of relevant professional societies with regards to radiation protection optimization in interventional radiology: ESR, ESC, EFRS, EFOMP, EURADOS, ESNR, CIRSE, CEPN.

Members of Working Package 2:

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Laurent Donadille	EURADOS, European Radiation Dosimetry Group	France
Arnd Dörfler	ESNR, European Society of Neuroradiology	Germany
François Drouet (until May 2011)	CEPN, Centre d'étude sur l'Evaluation de la Protection dans le domaine Nucléaire	France
Fabrizio Fanelli	CIRSE, Cardiovascular and Interventional Radiological Society of Europe	Italy
Jose M. Fernandez-Soto	EFOMP, European Federation of organisations for Medical Physics	Spain
Helmut-Dietmar Glogar	ESC, European Society of Cardiology	Austria
Dimitris Katsifarakis	EFRS, European Federation of Radiographer Societies	Greece
Caroline Schieber	CEPN, Centre d'étude sur l'Evaluation de la Protection dans le domaine Nucléaire	France

Six WP face-to-face meetings took place, as well as several distant contacts:

- 1st meeting: Paris, 28 May 2010
- 2nd meeting: Valencia, 6 October 2010
- 3rd meeting: Paris, 24 January 2011
- 4th meeting: Munich, 14 September 2011
- 5th meeting: Paris, 13 March 2012
- 6th meeting: Paris, 22 May 2012

Networking challenges

It is now well recognised that the implementation of optimisation of radiation protection in the medical field, and more particularly in interventional procedures, need the involvement of various types of professionals (radiologists, cardiologists, radiographers, medical physicists, ...), working together to control and reduce patient and staff exposures.

EMAN WP2 on “optimisation of patient and occupational exposure in IR and IC” allowed gathering of representatives of relevant professions involved in this field. The experience revealed to be quite challenging and interesting.

The first challenge was to find the members of the group, and it appeared to be longer than expected to find representatives of some professional societies which were important for the subject. This explains why the first meeting of this WP took place only in May 2010.

When the group was finally created, its multi-disciplinary composition allowed to draw a quite comprehensive picture of the issues related to radiation protection in IC and IR as well as to elaborate, in common, recommendations to improve the situation. The face-to-face work group meetings were essential to discuss the issues and favour a common understanding of the roles and responsibilities of the various professionals. The elaboration of the synthesis report was made both during the meetings and in between, sharing the work to be done between the participants of the working group and using e-mail exchanges.

Attachments

- Minutes from each of the 6 working group meetings
- Synthesis document
- Interim report