

Spanish requirements in radiological protection training for the practice of interventional radiology. A five years experience.

Eliseo Vano⁽¹⁾, Francisco Vargas⁽²⁾, Mercedes Bezares⁽²⁾, Luciano González⁽¹⁾, Antoni Segarra⁽³⁾

⁽¹⁾Complutense University, Spain

⁽²⁾Ministry of Health and Consumer Affairs, Public Health Directorate, Spain

⁽³⁾Spanish Society of Vascular and Interventional Radiology, Spain

Abstract

Spanish regulation requires since 1999 a specific "second level" of training in radiological protection (RP) to the medical specialists performing interventional procedures guided by fluoroscopy. The second level is additional to the basic one required to any practitioner using X ray systems for medical exposures. The Spanish Department of Health has sponsored several meetings with the medical specialists involved in these practices trying to promote this training in dedicated courses or during the residency period for some specialities. A formal procedure to certify these training courses by the Health Authority has already been established. The experience of the Spanish Society of Vascular and Interventional Radiology from three national courses is presented. Attendees recognise that the training was very useful and consider that their practice would be improved after the course. This positive experience is expected to be followed by other medical specialists practising fluoroscopically guided procedures.

1. Introduction

On 9 September 1994, the Food and Drug Administration of the United States issued a warning about possible skin radiation injuries to patients during fluoroscopically guided interventional procedures [1]. As part of the recommendations included in the warning document it was stated: "Assure appropriate credentials and training for physicians performing fluoroscopy". Later, on 30 September 1994 [2] a new advice was published at the FDA website on this topic, encouraging the distribution of the advisory note. It was highlighted that physicians should know that radiation-induced injuries from fluoroscopy are not immediately apparent. Other than the mildest symptoms, such as transient erythema, the effects of the radiation may not appear until weeks following the exposure. Physicians performing these procedures may not be in direct contact with the patients following the procedure and may not observe the symptoms when they occur. Missing the milder symptoms in some patients can lead to surprise at the magnitude of the absorbed doses delivered to the skin of other patients when more serious symptoms appear. Patients should also be advised to report signs and/or symptoms of radiation induced injury to their attending physician. On 30 September 2005 a new document on "Recording information in the patient's medical record that identifies the potential for serious x-ray-induced skin injuries" was published at the FDA website [3].

In 1995, the British Institute of Radiology and the World Health Organization (WHO) [4] promoted specific scientific meetings to address recommendations to improve safety during such procedures. The Council Directive 97/43/EURATOM on medical exposures highlighted these aspects in Europe [5] and consider interventional radiology (article 9) as a "special practice" involving high doses to the patient.

During 2000, the International Commission on Radiological Protection (ICRP) published its recommendations on this topic [6]. Also, the International Electrotechnical Commission issued a Standard on particular requirements for the safety of X-ray equipment for interventional procedures [7]. Furthermore, the European Commission published a guideline on education and training in radiation protection (RP) for medical exposures [8] containing specific recommendations for interventional radiology.

In addition, the International Conference on Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy, held in Malaga in 2001 [9], sponsored

by the International Atomic Energy Agency (IAEA) proposed to include interventional practices as a part of the International Action Plan on Radiological Protection of Patients. Important efforts have been made in the USA as well as Europe to produce training material [10-13]. The IAEA as part of the International Action Plan, is producing a set of training CD-ROMs addressing these topics (e.g. RP for interventional cardiology).

The WHO [4] and the European Directive (in its article 7) [5] specifically recommend this training in RP over and above that which is required by general radiologists. The European Guideline [8] gives recommendations about the training time required (20-30 hours) and the accreditation process. Interventional practices imply additional risks due to more complex procedures with more operator time near the patient during fluoroscopy screening, and the issue of deterministic effects to the patient. RP training of the specialists helps to minimise these risks.

2. Spanish Regulation

In Spain, a Royal Decree on Quality Criteria for Diagnostic Radiology was enacted in 1999 [14]. For interventional practices its requirements are:

- a) Laboratories or fluoroscopic screening rooms specifically designed for these procedures.
- b) Imaging systems specifically designed for interventional procedures (in compliance with International Electrotechnical Commission standards) [7].
- c) A system for measuring and registering doses received by the patients.
- d) An accreditation in RP (called "second level", to differentiate it from the first level which is mandatory for all the radiologists [15]) for the specialists conducting these procedures. This accreditation shall be supervised by the Health Authority.

3. Implication of the medical society

The Spanish Society of Vascular and Interventional Radiology (SERVEI) cooperated fully with the Spanish Ministry of Health during the drafting of the Royal Decree. Later the Society was active in supporting the application of the Royal Decree in clinical practice, whilst fulfilling its role as a leading medical society in aspects of radiation safety in fluoroscopically guided procedures.

In June 2000, SERVEI launched a first pilot course with a large practical content, in cooperation with the Radiology Department of the Complutense University of Madrid. The Health Authority gave the legal accreditation to the course. The intention was to offer this pilot course to the most senior Spanish interventional radiologists, then to decide if the duration and content could be appropriate for a wider audience, and further to establish the programme as part of the regular training for all specialists practising interventional procedures.

The proposal was for a 20 hour training course (over two and a half days). The programme (see annex) and specific educational objectives covered the items suggested by the European Guideline [8]. A final examination (comprising of a set of 50 multiple choice questions with 4 alternatives) was also included. Achievement of a set minimum score was a condition of accreditation.

The course was held in July, 2002 at the San Carlos University Hospital in Madrid. Eighteen senior interventional radiologists from nine Autonomous Communities of Spain participated in the course. One of the practical sessions was given over to the use of the MARTIR CD-ROM (Multimedia and Audiovisual Radiation Protection Training in Interventional Radiology) [13].

The SERVEI held a second course in June 2003 and the third version in January 2005. The certification process by the Health Authority was modified, requiring for the last course, the formal acceptance of the National Boards of Diagnostic Radiology and Medical Physics. A new version of the course is planned for November 2005.

For the last two courses, a practical session in an interventional room was included in the training activities. Different patient thicknesses were simulated with phantoms and test objects. Image quality, patient entrance dose and staff doses were measured for the different operating modes available for the X ray system. The impact of radiation protective tools (ceiling suspended screens, lead aprons,

thyroid protector, etc) was also evaluated. This practical demonstration was suggested by the senior radiologists after the pilot course.

At the end of the courses, an evaluation form is fulfilled by the attendants scoring the quality of the training activity in three aspects: global (including organising aspects, training material distributed, practical work, etc), lecturers and topics included in the course. The obtained results (over a maximum of 10 points) are shown in the table.

	Global	Lecturers	Interest of the topics
Pilot course July 2002	8.4	8.4	8.3
Second course June 2003	8.7	9.1	8.4
Third course January 2005	8.7	8.5	8.3

Two other similar courses have been organised outside the SERVEI, by Hospitals or sponsored by local Health Authorities.

At present, between 80 and 90 Spanish interventional radiologists (approximately a 50% of the members of the SERVEI) have already obtained the specific accreditation in radiation protection required by the national regulation.

3. Other medical specialities

Accreditation in RP of other professionals performing interventional procedures guided by fluoroscopy required by the Spanish Royal Decree 1976/1999 is one of the main objectives of the Ministry of Health in this area. Sometimes certain confusion arises between medical specialists due to the double accreditation requirement. The first from the Regulatory Nuclear Regulatory Body, mainly concerning with the aspects of occupational RP and the other from the Health Authority mainly addressing the aspects of RP of patients and quality assurance aspects. The Royal Decree 1891/1991, for the installation and use of X-ray equipment for medical diagnostic purposes [15] states in its article 14: "titleholders who direct the operation of X-ray facilities for the purpose of medical diagnosis and operators of the equipment who act under their supervision must accredit before the Council of Nuclear Safety their knowledge, training, and experience in matters of radiological protection".

The sections on interventional cardiology and electrophysiology of the Spanish Society of Cardiology have already maintained several contacts with the Ministry of health in order to launch the "second level" of training in RP following a process similar to the one started by the SERVEI.

4. Annex. Course Syllabus

- X-ray systems for interventional radiology (IR) (effect of additional filtration, operation of continuous and pulsed X-ray emission modes, road mapping, temporal integration and its benefits in terms of image quality, etc).
- Dosimetric quantities specific for IR (dose-area product (DAP), entrance dose and entrance dose rate, correlation between skin dose and DAP, relationship between DAP and effective dose, etc).
- Radiological risks in interventional radiology (deterministic effects which may be observed in IR, risks of deterministic effect induction as a function of the surface doses, relationship between received doses and deterministic effects in the lens of the eye, time intervals between irradiation and occurrence of the different deterministic effects, the required follow-up and control of patients, stochastic risks in interventional procedures and their age dependence, etc)..
- Radiological protection of the staff (factors which influence staff doses in IR laboratories, influence of the X-ray C-arm positioning on occupational doses, effects of using different fluoroscopy modes on occupational doses, effects of using personal protection, benefits and drawbacks of using articulated screens, importance of the suitable location of personal dosimeters, etc).
- Radiological protection of patients (correlation between fluoroscopy time and number of images and dose received by patients, effects of the focus to skin distance and patient image intensifier input

distance, dose reductions attainable by modifying the image rate in cine or in digital acquisition, typical examples of patient entrance dose value per image in different procedures, effect of using different magnifications in the patient dose, parameters which should be recorded in the patient history regarding the doses received, etc).

- Quality assurance (QA) in IR (difference between parameters that usually do not downgrade with time and those which could require periodical control, importance of establishing simple criteria to compare doses at the patient in different situations, importance in QA programs of the periodical control of patient dose and its comparison with reference dose levels, etc).
- Local and international rules for RP in IR (National and European regulations, recommendations of the ICRP and WHO, standardization documents, etc).
- Optimisation in IR (importance of optimisation in IR radiation procedures, importance of periodical patient dose control and comparison with reference levels, etc).

References

- [1] U.S. Food & Drug Administration (FDA). Avoidance of serious x-ray induced skin injuries to patients during fluoroscopically guided procedures. Issued 9 September 1994. Available at: http://www.fda.gov/cdrh/sep9_94.pdf (accessed on 29 Sep 05).
- [2] U.S. Food & Drug Administration (FDA). FDA Public Health Advisory on Serious X-Ray-Induced Skin Injuries. Issued 30 September 1994. Available at: <http://www.fda.gov/cdrh/fluor.html> (accessed on 29 Sep 05).
- [3] U.S. Food & Drug Administration (FDA). Recording information in the patient's medical record that identifies the potential for serious x-ray-induced skin injuries. Issued 15 September 1995. Available at: <http://www.fda.gov/cdrh/xrayinj.html> (accessed on 29 Sep 05).
- [4] Efficacy and Radiation Safety in Interventional Radiology. Geneva: WHO, 2000.
- [5] Council Directive 97/43 Euratom, on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466 Euratom. Official Journal of the European Communities No L 180, 9th July 1997, 22-27.
- [6] ICRP Publication 85. Avoidance of radiation injuries from medical interventional procedures. Elsevier. Ann ICRP 2000;30.
- [7] Medical electrical equipment. Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures. IEC 60601-2-43. First edition 2000-06. Geneva: International Electrotechnical Commission.
- [8] Guidelines on education and training in radiation protection for medical exposures. Radiation Protection 116, European Commission. Directorate General Environment, Nuclear Safety and Civil Protection. Luxembourg, 2000. Available at (accessed on 29 Sep 05): http://europa.eu.int/comm/energy/nuclear/radioprotection/publication/116_en.htm
- [9] International Conference on Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy. Malaga, 26-30 March 2001. IAEA-CN-85-196 and IAEA-CSP-7/CD. 2001.
- [10] Wagner LK and Archer BR. Minimising risks from fluoroscopic x rays. Third Edition. Partners in Radiation Management (R.M. Partnership). The Woodlands, TX 77381. USA 2000.
- [11] Balter S. Interventional fluoroscopy. Physics, technology and safety. Wiley-Liss, New York, 2001.
- [12] Balter S, Editor. Physical and Technical Aspects of Angiography and Interventional Radiology. A Categorical Course in Physics. Annual Meeting of the Radiological Society of North America. Chicago. RSNA, 1995.
- [13] MARTIR (Multimedia and Audiovisual Radiation Protection Training in Interventional Radiology). CD-ROM. Radiation Protection 119, European Commission. Directorate General Environment, Nuclear Safety and Civil Protection. Luxembourg, 2002. Free availability from the Publication Department of the European Commission, Office for Official Publications of the European Communities, Luxembourg.
- [14] Royal Decree 1976/1999, from the Health and Consumer Affairs Department, establishing quality criteria in radiodiagnostics. In Spanish State Official Bulletin ("Boletín Oficial del Estado") of January 29th 1999: 45891-45900 (in Spanish).

- [15] Royal Decree 1891/1991, from the Industry and Energy Department, on installation and utilisation X-ray devices for medical diagnostic purposes. In Spanish State Official Bulletin ("Boletín Oficial del Estado") January 3rd 1992: 138-48 (in Spanish).

Corresponding Author:

Prof. Eliseo Vano
Radiology Department
Medicine School
Complutense University
28040 Madrid
Spain
T: +34913941551
F: +34913941675
e-mail: eliseov@med.ucm.es