



**Seminar on Radiation  
Protection on Patients**  
(Wednesday 22th October, 02:00 to 07:00 PM)

**ICRP and Diagnostic  
Reference Levels**

**E. Vano. San Carlos University  
Hospital. Complutense  
University. Madrid/ES**



# Content

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- **ICRP and Diagnostic Reference Levels**
- **DRL and Interventional Radiology**
- **European documents**
- **Challenges and the need to extend the use of Reference Levels. New ICRP document.**

# Annals of the ICRP

PUBLICATION 103

The 2007 Recommendations of the International  
Commission on Radiological Protection

Editor  
J. VALENTIN

PUBLISHED FOR

The International Commission on Radiological Protection

by



## ICRP Publication 103



ICRP Publication 103



The 2007 Recommendations of  
the International Commission on Radiological  
Protection

ICRP Publication 103

Approved by the Commission in March 2007

# Annals of the ICRP

ICRP PUBLICATION 105

Radiological Protection in Medicine

Editor  
J. VALENTIN

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by



**ICRP Publication 105**



ICRP Publication 105



Radiation Protection in Medicine

ICRP Publication 105

Approved by the Commission in October 2007

# ICRP: Diagnostic Reference Levels

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- **Diagnostic Reference Level (DRL) is used in medical imaging to indicate whether, the patient dose or administered activity (amount of radioactive material) from a specified procedure is unusually high or low for that procedure.**

# ICRP New Recommendations 2007

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- **Diagnostic reference levels and interventional radiology:**
  - **Diagnostic reference levels (DRL) are considered as a useful tool to help optimize Interventional Radiology (paragraph 334).**

# ICRP New Recommendations 2007

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- **ICRP Publication 105 gives more details (paragraph 89): “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.**

# ICRP New Recommendations 2007

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## ICRP Publication 105:

- A potential approach is to take into consideration not only the usual clinical and technical factors, but also the relative **‘complexity’ of the procedure**”.
- A diagnostic reference level that consists of **more aspects than the usual single dose-related quantity** may be needed to evaluate patient dose adequately.



# ICRP: Diagnostic Reference Levels

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- In the case of exposure from diagnostic and interventional medical procedures, the DRL has as its objective the optimisation of protection, but **it is not implemented by constraints on individual patient doses.**

# ICRP: Diagnostic Reference Levels

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- **DRLs values are selected on the basis of a percentile point on the observed distribution of doses to patients or to a reference patient.**

# ICRP: Diagnostic Reference Levels

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- **The values should be selected by professional medical bodies in conjunction with national health and radiological protection authorities and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions.**

# ICRP: Diagnostic Reference Levels

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- **Guidance for the use of DRLs for patients in medical exposure has been provided in ICRP Publications 60, 73, 103, 105 and Supporting ICRP Guidance 2.**

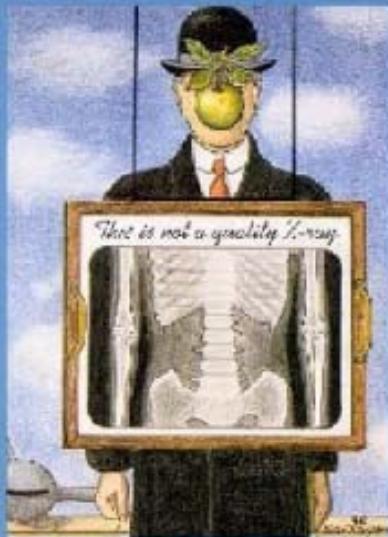
# Reference values allow:

- **To compare our practice (the level of radiological risk) with other centers.**
- **To realise if we have a certain margin for optimisation (to improve settings of our X rays system or to improve our protocols).**
- **To detect abnormal situations with high radiological risk for our patients.**



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TOMOGRAPHY**



EUR 16222 EN



# European Directive

- **Council directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure.**
- **Art 4 : Member States shall promote the establishment and the use of diagnostic reference levels for radiodiagnostic examinations.**



# European Directive

- **Diagnostic reference levels (DRLs) are defined in the Council Directive 97/43 Euratom as “dose levels in medical radiodiagnostic practices or, in the case of radiopharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied”.**



## **RADIATION PROTECTION 109**



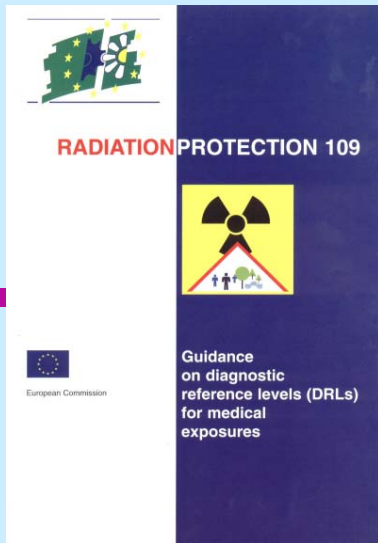
**Guidance  
on diagnostic  
reference levels (DRLs)  
for medical  
exposures**



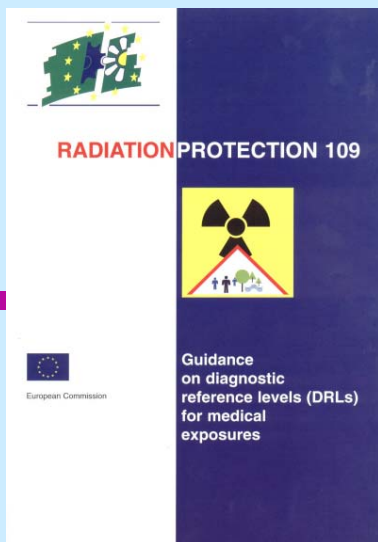
European Commission

**Available at:  
[http://ec.europa.eu/energy/nuclear/radioprotection/publication/109\\_en.htm](http://ec.europa.eu/energy/nuclear/radioprotection/publication/109_en.htm)**

**1999**



**Last but not least, human factors are involved. Doses can be unnecessarily high due to inattention, indifference or too much work pressure, although they may sometimes also be due to individual reluctance to accept generally-accepted standard procedures. DRLs can encourage changes in working procedures by showing what is possible in other departments.**



**Table 3.3** Fraction of adult administered activity for different age groups of children (see however, minimum amounts given in Table 3.4). Recommended by the Paediatric Taskgroup of the EANM (European Association of Nuclear Medicine) [Pie90]

**Table 3.4** Minimum amounts of administered activities FOR CHILDREN in MBq

**ANNEX I DIFFERENCES IN ADMINISTERED ACTIVITIES IN MEMBER STATES**

- General remarks: 1) if for a specific examination no value is given for a country it does not mean that this examination is not being performed in the country  
 2) values are presented for adults in a normal biological situation except regarding residual thyroid and cancers/metastases

Organ / Diagnosis	Radio-pharmaceutical	mSv (E) /100 MBq	Netherl. <sup>1</sup>	United Kingdom <sup>2</sup>	Spain	Finland <sup>3</sup>	Italy <sup>4</sup>	Ger. <sup>5</sup>	Port. <sup>6</sup>	Sweden <sup>7</sup>	France	Denmark <sup>8</sup>
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Joel E. Gray, PhD  
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For the American  
Association of Physicists  
in Medicine Task Group  
on Reference Values for  
Diagnostic X-ray  
Examinations<sup>2</sup>

Published online before print  
10.1148/radiol.2352020016  
Radiology 2005; 235:354–358

# Reference Values for Diagnostic Radiology: Application and Impact<sup>1</sup>

Reference values (RVs) are recommended by the American Association of Physicists in Medicine for four radiographic projections, computed tomography, fluoroscopy, and dental radiography. RVs are used to compare radiation doses from individual pieces of radiographic equipment with doses from similar equipment assessed in national surveys. RVs recommended by the American Association of Physicists in Medicine have been developed from the Nationwide Evaluation of X-ray Trends survey performed by the state radiation protection agencies with the cooperation and support of the U.S. Food and Drug Administration, the Conference of Radiation Control Program Directors, and the American College of Radiology. The RVs selected by the American Association of Physicists in Medicine represent, approximately, the 80th percentile of the survey data. Clinicians should be aware of the potential for using higher radiation doses for

**2005**

# AAPM Task Group (abstract)

- **Equipment exceeding the RVs is using higher radiation doses than is 80% of the equipment in the surveys.**
- **When the RVs are exceeded, the medical physicist should investigate the cause and determine, in cooperation with the responsible radiologist, whether these doses are justified or the imaging system should be optimized to reduce patient radiation doses.**
- **Comment: And procedures???**

# AAPM Task Group (summary)

- RVs provide a means for radiologists and medical physicists in the medical imaging community to **compare radiation exposure levels at their facilities with those at facilities** across the nation, while they bear in mind that the comparative data are state-of-the-practice data as opposed to state-of-the-art data.
- As imaging professionals, we should also ensure that our medical imaging equipment **and practices** are optimized and that they provide the necessary diagnostic information with exposures that are as low as reasonably achievable.

# 2006

2002 (Res. 20)  
Amended 2006 (Res. 16g,36)  
Effective 1/01/03

## ACR PRACTICE GUIDELINE FOR DIAGNOSTIC REFERENCE LEVELS IN MEDICAL X-RAY IMAGING

- **The establishment of diagnostic reference levels in this type of medical imaging requires close cooperation and communication between the physicians who are responsible for the clinical management of the patient and the medical physicist responsible for monitoring imaging quality and dose.**



# 2006

2002 (Res. 20)  
Amended 2006 (Res. 16g,36)  
Effective 1/01/03

## ACR PRACTICE GUIDELINE FOR DIAGNOSTIC REFERENCE LEVELS IN MEDICAL X-RAY IMAGING

- **Diagnostic reference levels are used to manage the radiation dose to the patient.**
- **The medical radiation exposure must be controlled, avoiding excessive radiation that does not contribute to the clinical objective of the procedure.**

# 2006

2002 (Res. 20)  
Amended 2006 (Res. 16g,36)  
Effective 1/01/03

## ACR PRACTICE GUIDELINE FOR DIAGNOSTIC REFERENCE LEVELS IN MEDICAL X-RAY IMAGING

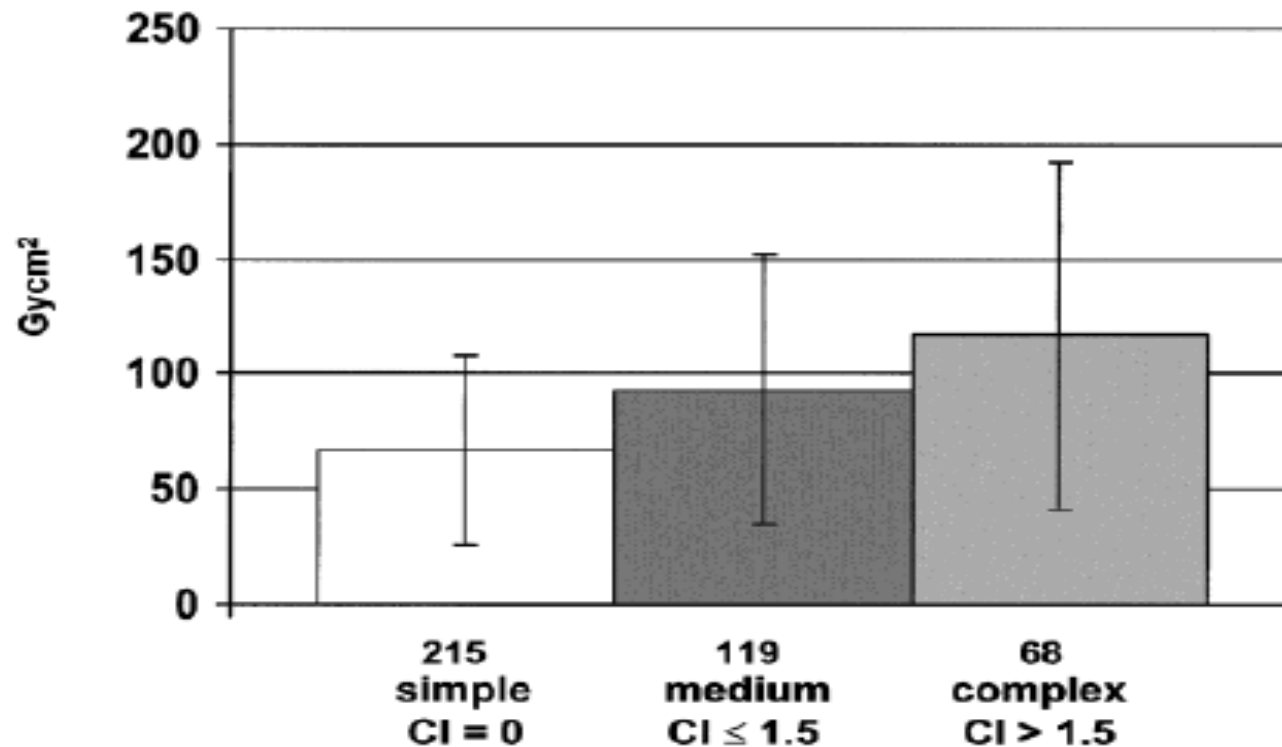
- The specific purpose of the reference level is to provide a **benchmark for comparison, not to define a maximum or minimum exposure limit.**
- The guideline recommends reference levels and suggests the methods of measurement for comparison for procedures in radiography, fluoroscopy, and computed tomography.

## Clinical and Technical Determinants of the Complexity of Percutaneous Transluminal Coronary Angioplasty Procedures: Analysis in Relation to Radiation Exposure Parameters

Guglielmo Bernardi,<sup>1\*</sup> MD, Renato Padovani,<sup>2</sup> PhD, Giorgio Morocutti,<sup>1</sup> MD, Eliseo Vaño,<sup>3</sup> PhD, Maria Rosa Malisan,<sup>2</sup> PhD, Massimo Rinuncini,<sup>1</sup> MD, Leonardo Spedicato,<sup>1</sup> MD, and Paolo M. Fioretti,<sup>1</sup> MD

2000

Complexity Determinants of PTCA Procedures



V. Neofotistou  
E. Vano  
R. Padovani  
J. Kotre  
A. Dowling  
M. Toivonen  
S. Kottou  
V. Tsapaki  
S. Willis  
G. Bernardi  
K. Faulkner

## Preliminary reference levels in interventional cardiology

2003

**Table 3** Preliminary reference levels proposed

	PTCA	CA
DAP (Gy×cm <sup>2</sup> )	94	57
FT (min)	16	6
No. of frames	1355	1270

## A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures

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Med. Phys. 35 (2), February 2008

2008

et al.

TABLE V. Suggested guidance levels (75th percentile).

Procedure	$P_{KA}$ (KAP) (Gy cm <sup>2</sup> )	Fluoroscopy time (min)	No. of images
CA	50	9	1000
(PCI)—moderate complexity	125	22	1700

**A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures**

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Med. Phys. 35 (2), February 2008

et al.

2008

TABLE III. Reference (guidance) levels for simple, medium and complex PCI procedures expressed in term of fluoroscopy time and  $P_{KA}$ .

Reference (guidance) levels			
Complexity group	Fluoroscopy time (min)	No. images	$P_{KA}$ (Gy cm <sup>2</sup> )
Simple CI=1 <sup>a</sup>	15	1500	100
Medium 1 < CI < =2	22	1700	125
Complex CI > 2	32	2300	200

<sup>a</sup>CI=complexity index.

# Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study

## Part I: Overall Measures of Dose

Donald L. Miller, MD, Stephen Balter, PhD, Patricia E. Cole, PhD, MD, Hollington T. Lu, MS, MA, Beth A. Schueler, PhD, Michael Geisinger, MD, Alejandro Berenstein, MD, Robin Albert, MD, Jeffrey D. Georgia, MD, Patrick T. Noonan, MD, John F. Cardella, MD, James St. George, MD,<sup>1</sup> Eric J. Russell, MD, Tim W. Malisch, MD,<sup>2</sup> Robert L. Vogelzang, MD, George L. Miller III, MD,<sup>3</sup> and Jon Anderson, PhD



J Vasc Interv Radiol 2003; 14:711-727

**2003**

Procedure	Cases	Mean fluoroscopy time (min)	Mean number of images	Mean DAP Gy.cm2	Mean cumulative dose Gy
TIPS	135	38.7	231	335.4	2.00
Biliary drainage	123	23.6	15	70.6	0.91
Renal stent	103	21.6	159	190.0	1.61
Iliac stent	93	18.4	241	212.8	1.34
Hepatic chemoembol.	126	16.8	216	282.3	1.41
Pelvic fibroid embol.	90	29.5	305	298.2	2.46
Vertebroplasty	98	16.2	77	78.1	1.25

**Seven academic medical centers; 2142 procedures**  
**In Europe, a similar survey (SENTINEL) has been finished**

# UK recommended national reference doses for complete examinations on adult patients 2000 review (NRPB)

- **Biliary drainage /intervention** **54 Gy.cm<sup>2</sup>**
  - **USA: 71 Gy.cm<sup>2</sup> (mean); Spain: 59 Gy.cm<sup>2</sup> (mean)**
- **Femoral angiogram** **33 Gy.cm<sup>2</sup>**
- **Coronary angiogram** **36 Gy.cm<sup>2</sup>**

**NRPB-W14**

**Doses to Patients from Medical X-ray Examinations  
in the UK – 2000 Review**

**D Hart, M C Hillier and B F Wall**



## **Radiation Protection Dosimetry Advance Access published February 29, 2008**

Radiation Protection Dosimetry (2008), pp. 1–4

doi:10.1093/rpd/ncn039

### **REFERENCE LEVELS AT EUROPEAN LEVEL FOR CARDIAC INTERVENTIONAL PROCEDURES**

R. Padovani<sup>1,\*</sup>, E. Vano<sup>2</sup>, A. Trianni<sup>1</sup>, C. Bokou<sup>3</sup>, H. Bosmans<sup>4</sup>, D. Bor<sup>5</sup>, J. Jankowski<sup>6</sup>, P. Torbica<sup>7</sup>, K. Kepler<sup>8</sup>, A. Dowling<sup>9</sup>, C. Milu<sup>10</sup>, V. Tsapaki<sup>11</sup>, D. Salat<sup>12</sup>, J. Vassileva<sup>13</sup> and K. Faulkner<sup>14</sup>

## **Radiation Protection Dosimetry Advance Access published February 20, 2008**

Radiation Protection Dosimetry (2008), pp. 1–7

doi:10.1093/rpd/ncn024

### **PATIENT DOSE IN INTERVENTIONAL RADIOLOGY: A EUROPEAN SURVEY**

E. Vano<sup>1</sup>, H. Järvinen<sup>2,\*</sup>, A. Kosunen<sup>2</sup>, R. Bly<sup>2</sup>, J. Malone<sup>3</sup>, A. Dowling<sup>3</sup>, A. Larkin<sup>3</sup>, R. Padovani<sup>4</sup>, H. Bosmans<sup>5</sup>, O. Dragusin<sup>5</sup>, W. Jaschke<sup>6</sup>, P. Torbica<sup>6</sup>, C. Back<sup>7</sup>, A. Schreiner<sup>7</sup>, C. Bokou<sup>7</sup>, S. Kottou<sup>8</sup>, V. Tsapaki<sup>9</sup>, J. Jankowski<sup>10</sup>, S. Papierz<sup>10</sup>, J. Domienik<sup>10</sup>, A. Werduch<sup>10</sup>, D. Nikodemova<sup>11</sup>, D. Salat<sup>12</sup>, K. Kepler<sup>13</sup>, M. D. Bor<sup>14</sup>, J. Vassileva<sup>15</sup>, R. Borisova<sup>15</sup>, S. Pellet<sup>16</sup>, and R. H. Corbett<sup>17</sup>

# Need of advice ...

- **Refine the use of Reference Levels in Interventional Radiology:**
  - Combine different imaging acquisition modalities (conventional fluoroscopy and cine or DSA series with rotational acquisitions).
  - Trigger levels for high skin doses (for some procedures)?.
- **Digital radiology: Different Reference Levels for different clinical tasks (and image quality)?.**
- **PET-CT: Combine and balance PET and CT reference levels?.**
- **CT: New dose quantities?.**
- **Paediatrics: need to be improved.**

# ICRP: Diagnostic Reference Levels

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- **Committee 3 of ICRP has considered to produce a document on “Widening the use of reference levels for interventional radiology, digital radiology and new technology”.**

An aerial photograph of the San Carlos University Hospital in Madrid, Spain. The image shows a large, complex of multi-story brick buildings with numerous windows, surrounded by parking lots filled with cars. In the background, there are more city buildings and a large green crane. The text "Thank you" is overlaid in a large, bold, dark blue font across the center of the image.

**Thank you**

San Carlos University Hospital Madrid