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ETHICAL ISSUES IN THE PRACTICAL ASPECTS OF RADIATION PROTECTION IN MEDICINE




E. Vano

San Carlos University Hospital
Medical Physics Service
Complutense University
Radiology Department
Madrid/Spain (eliseov@med.ucm.es)

The author declares that he is not involved in a situation or action that could be considered as a potential conflict of interest with regard to the content of this lecture

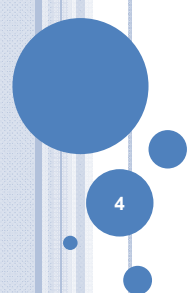
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1. Justification of medical exposures.
 - a) Low priority promoting and funding education and training programmes in RP for the health sector?.
 - b) New versus old technology in imaging and therapy.
2. Optimization of medical (and occupational) exposures.
 - a) Practices with ionizing radiation in Medicine without the necessary support of Medical/Health physicists?.
 - b) When to move from old to new technology in imaging and therapy systems?.
3. Should we accept the work in radiology without enough quality control (quality assurance) and without patient dose evaluations (including the use of DRLs)?
4. Interpreting the new European BSS Directive under the ethical perspective.



ICRP formed in October 2013, the TG 94 on “Ethics of Radiological Protection”

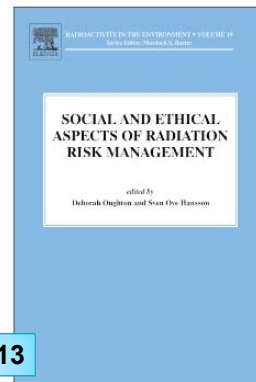
ICRP TG 94 Members (as listed at ICRP web site on 27 January 2015):
Deborah Oughton (Chair, Norwegian University of Life Sciences); Marie-Claire Cantone (University of Milan, Italy); Kun-Woo Cho (KINS, Korea); Sven Ove Hansson (Royal Institute of Technology, Sweden); Chieko Kurihara-Saio (NIRS, Japan); Thierry Schneider (CEPN, France); Richard Toohey (HPS, USA); Sidika Wambani (Kenyatta National Hospital, Kenya); Friedo Zölzer (University of South Bohemia, Czech Republic).
Corresponding Members: *Ms Renate Czarwinski (IRPA); Emilie van Deventer (WHO); Bernard Le-Guen (IRPA).*



JUSTIFICATION OF MEDICAL EXPOSURES

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One of the major ethical problems in radiology is justification of medical exposures in practice.



2013

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The British Journal of Radiology, 85 (2012), 523–538

Justification of diagnostic medical exposures: some practical issues. Report of an International Atomic Energy Agency Consultation

^{1,2}J MALONE, PhD, FIPEM, ³R GULERIA, MD, DM, ⁴C CRAVEN, ⁵P HORTON, PhD, FInstP, ⁶H JÄRVINEN, ⁷J MAYO, MD, ⁸G O'REILLY, MSc, PhD, ⁹E PICANO, MD, PhD, ¹⁰D REMEDIOS, FRCR, ¹¹J LE HERON, FACPSEM, ¹¹M REHANI, PhD, ¹¹O HOLMBERG, PhD and ¹¹R CZARWINSKI, MSc

- There is a **significant level of inappropriate usage**, and, in some cases, a **poor level of awareness of dose and risk** among some key groups involved.
- There is a **need for improved communication**, both within professions and **between professionals** on one hand, and **between professionals and the patients/public** on the other.
- The need **for good evidence-based referral guidelines or criteria of acceptability**.

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- Scandinavian audits have demonstrated a generally high rate, **approximately 20% or over, of inappropriate or unnecessary examinations**, and a very high rate, **up to 77%**, in the case of some specific examinations.
- In **paediatrics**, a recent straw poll among specialist radiologists suggested that **up to 30% of CT examinations may be inappropriately undertaken**.
- **Conclusion: justification would be facilitated by the "3 As": awareness, appropriateness and audit.**

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Table 1. Dose-risk communication: the Royal College of Radiologists (RCR) approach [17]

Investigation	Effective dose (mSv)	Equivalent no. of plain chest radiographs	Approximate equivalent period of natural background radiation ^a	Additional lifetime risk of fatal and non-fatal cancer ^b	RCR symbolic representation ^c
Plain postero-anterior chest radiograph	0.02	1	3 days	1:1000000	▲
Thyroid scintigraphy (^{99m} Tc)	1	50	6 months	1:10000	▲▲▲
CT chest (non-contrast)	8	400	3.6 years	1:1200	▲▲▲▲
CT abdomen	10	500	4.5 years	1:1000	▲▲▲▲
Multidetector CT cardiac (64 slice)	15	750	7 years	1:750	▲▲▲▲▲

^aAverage background radiation is 2.2–2.4 mSv per year.

^bThese examples relate to a 50-year-old man. Multiply by 1.38 for women, by 4 for children under 1 year of age, and by 0.5 in an 80-year-old man.

^c▲, <1 mSv; ▲▲, 1–5 mSv; ▲▲▲, 5–10 mSv; ▲▲▲▲, >10 mSv.

[17] Royal College of Radiologists. Making the best use of clinical radiology services, 6th edn. London; UK: RCR; 2007.

New Directive 2013/59/EURATOM. Art. 57 Responsibilities:

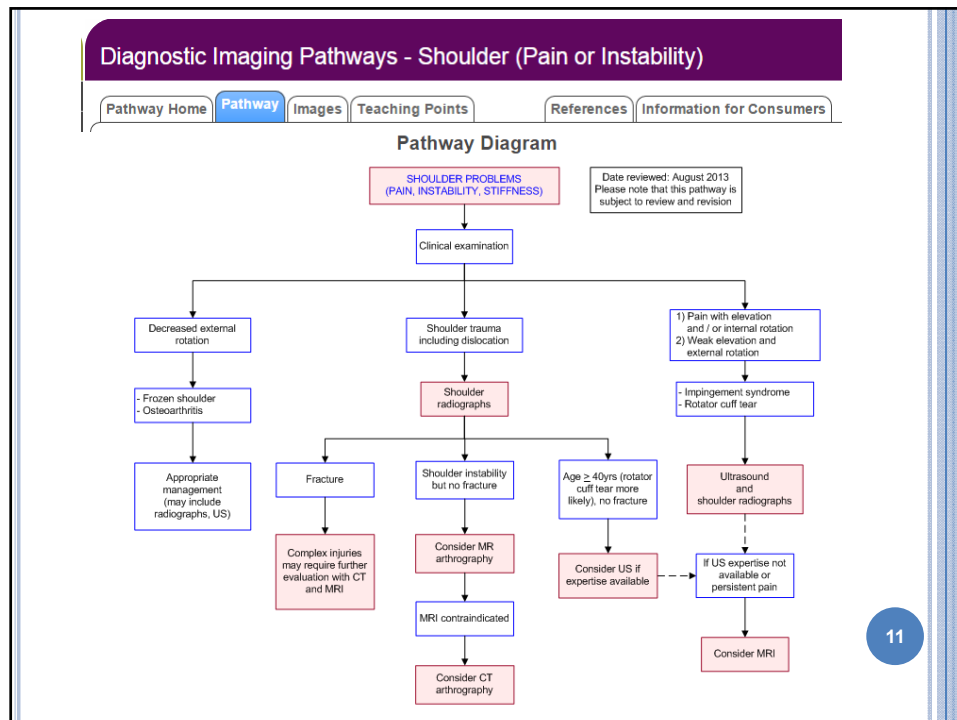
(d) wherever practicable and prior to the exposure taking place, the practitioner or the referrer, as specified by Member States, ensures that **the patient or their representative is provided with adequate information relating to the benefits and risks** associated with the radiation dose from the medical exposure.



- The European Society of Radiology considers referral guidelines for medical imaging essential for improving appropriateness and justification of radiological procedures.
- Particularly at a time of **increasing financial pressure** on European healthcare systems and **public concerns about the risks of exposure to radiation**.
- The ESR is developing ESR iGuide, a **clinical decision support (CDS) system** for European imaging referral guidelines.

Example: Diagnostic Imaging Pathways (DIP)
 – www.imagingpathways.health.wa.gov.au
 Electronic request/ decision support tool





ARE THE ICRP RECOMMENDATIONS CONSIDERED WHEN INTRODUCING NEW CLINICAL PROCEDURES?

- ICRP Publication 103 (paragraph 209) states:
 - The medical use of radiation should be justified, as is any other planned exposure situation, although that justification lies more often with the profession than with government or the competent regulatory authority.*
 - The principal aim of medical exposures is to do more good than harm to the patient, **due account being taken of the radiation detriment from the exposure of the radiological staff and of other individuals.***

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ETHICAL ASPECTS IN JUSTIFICATION OF IMAGING ... SOME ADDITIONAL ASPECTS

- Appropriate imaging in Medicine vs. Business in Medicine.
- Public Medicine vs. Private Medicine.
- Education in RP (for referrers and practitioners) including proper information for patients.
- Justification: could it be used "to reduce waiting lists" in some hospitals?.
- Is it considered the technology and expertise available in that Centre?.
- Are the previous images and clinical reports available?.
- Are the hospitals updating the technology and networks for the access of previous images?.

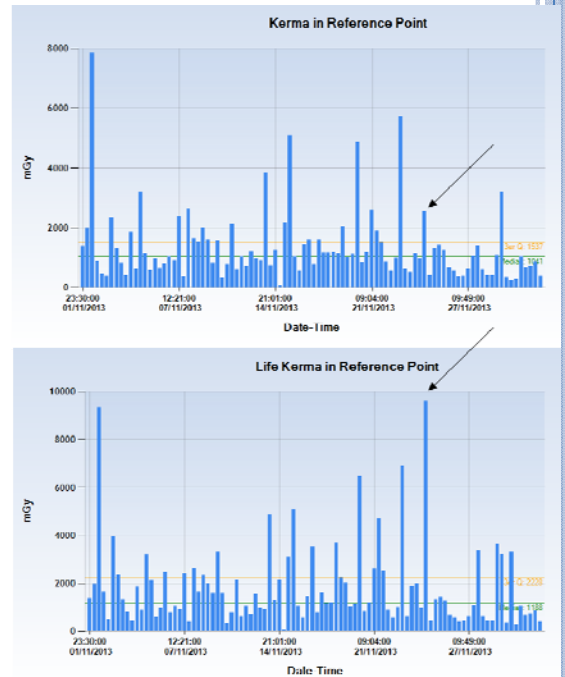
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DOLIR (Dose On Line in Interventional Radiology) Coordinated by the San Carlos University Hospital in Madrid



- 9 Cardiology labs
- 5 Vascular labs

COMPARISON OF
CUMULATIVE AIR
KERMA (CAK) (UPPER
GRAPH) AND LIFE CAK
(LOWER GRAPH)
CORRESPONDING TO
THE SAME PATIENTS.
NOTE AS INDICATED
WITH AN ARROW A
PROCEDURE WITH LESS
THAN 4 GY IN CAK
AND NEARLY 10 GY
WITH LIFE CAK



OPTIMIZATION OF MEDICAL (AND
OCCUPATIONAL) EXPOSURES

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ETHICAL ASPECTS IN OPTIMIZATION DURING MEDICAL PROCEDURES ... **ADDITIONAL ASPECTS**

- Doing procedures without the appropriate technology (considering patient and staff dosimetry).
- Doing procedures without the required support of trained radiographers and medical physicists.
- Doing complex procedures without the necessary expertise.
- Protection of patients vs. protection of staff.
- Criteria to decide if some procedures should be done by senior staff or by residents.
- Doing procedures without the proper occupational protection (and training in RP) of all the staff involved in the procedures (e.g. hybrid catheterization rooms).

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ARE THE ICRP RECOMMENDATIONS CONSIDERED WHEN INTRODUCING NEW CLINICAL PROCEDURES?

- ICRP Publication 105 (paragraph 69) states:
 - *Optimization (medical). The choice of protection option directly **alters the level of exposure of the patient, the staff, and sometimes the public.** However, the choice also alters the scale of resources applied to protection. These resources may be reflected directly in financial costs, but they may also involve **less easily quantified societal costs such as other health risks to staff.***

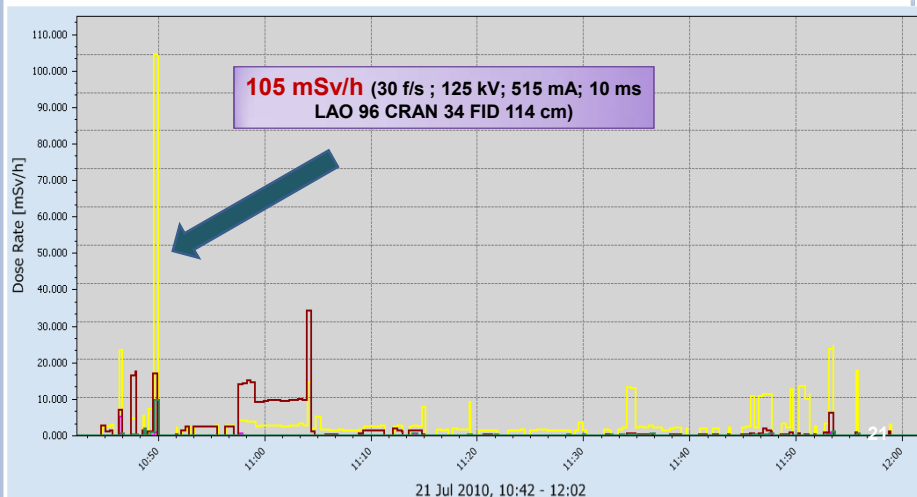
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**Staff doses
and scatter
dose rates
now available
in real time**

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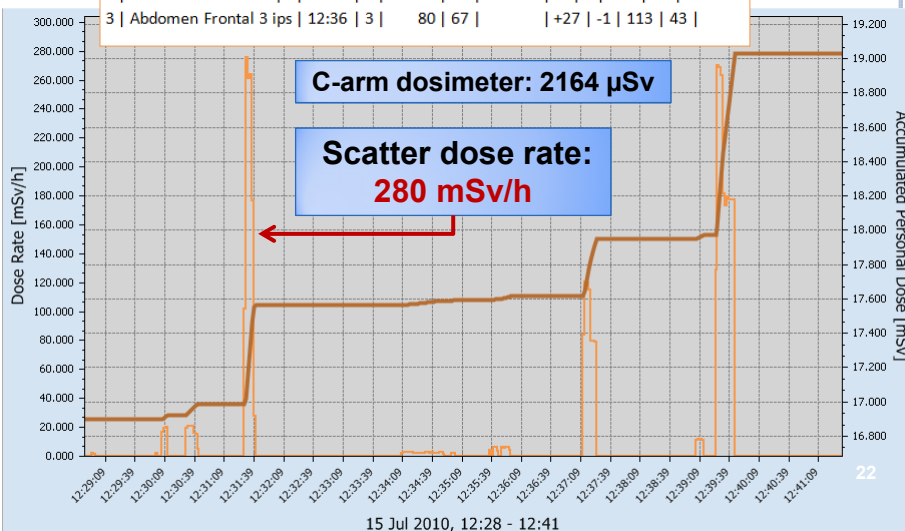
**Staff doses
in real time**

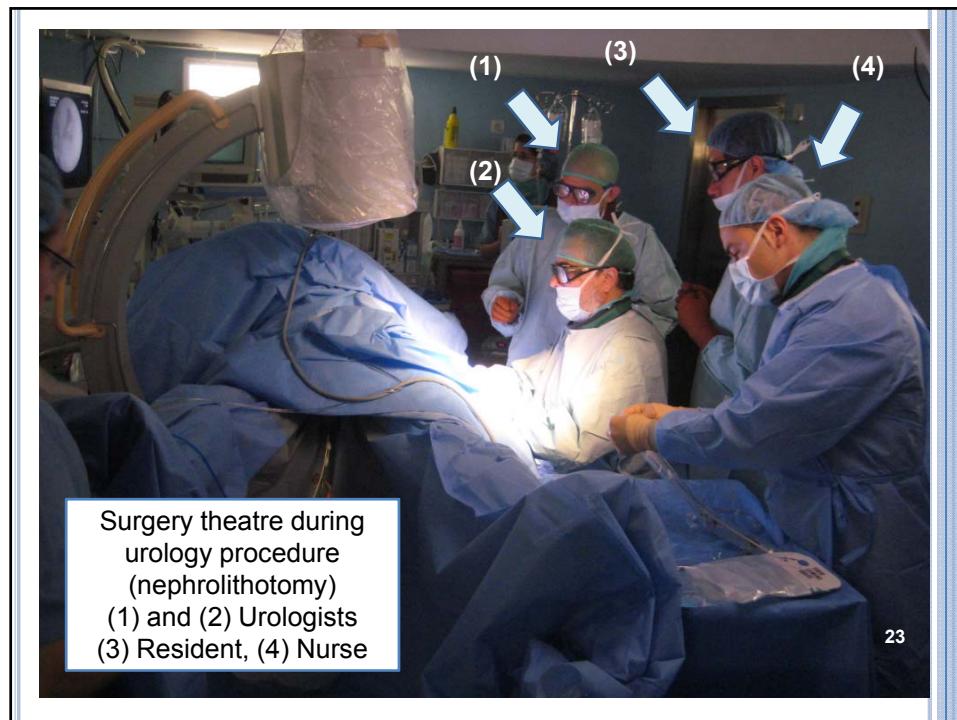
Cardiologist 40 μ Sv. High dose rate at the C-arm for a cardiology laboratory 105 mSv/h (accumulated at the C-arm: 1553 μ Sv). 10 μ Sv/Gy.cm²



Abdominal procedure 298 Gy.cm² ; 7.2 μ Sv/Gy.cm²

Nsec.	Procedim.	Tiempo hh:mm	Velocidad-ips	kV	mA	mAs	ms	Rotac.	Angulac.	DFI[cm]	N im
1	Abdomen Frontal	3 ips	12:28	3	99	83		-90	+2	120	23
2	Abdomen Frontal	3 ips	12:34	3	80	45		-2	0	113	30
3	Abdomen Frontal	3 ips	12:36	3	80	67		+27	-1	113	43





ETHICAL ASPECTS IN THE CASE OF UNINTENDED MEDICAL EXPOSURES (1)

- **Unintended exposure:** means medical exposure that is significantly different from the medical exposure intended for a given purpose (2013/59/Directive).
- Specially relevant for Radiotherapy and Interventional procedures.
- During interventional procedures, there is sometimes, a **lack of knowledge of the level of skin doses and their biological effects.**
- **High occupational (lens) doses** may also occur for some health professionals during these procedures.

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ETHICAL ASPECTS IN THE CASE OF UNINTENDED MEDICAL EXPOSURES (2)

- Control of patient doses during the procedures?.
- Knowledge of the trigger levels for potential radiation injuries and clinical follow-up?.
- Is it a system for reporting and alerting on patient doses?.
- Is it available the information (clinical and dosimetric) from previous procedures?.
- Enough knowledge of dose reduction possibilities of the used X-ray system?.
- Enough support from medical physicists and trained radiographers?.
- Quality Control of the X-ray system and updated Quality Assurance programme?.

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ICRP REPORT 85 (2001): AVOIDANCE OF RADIATION INJURIES FROM INTERVENTIONAL PROCEDURES

Photograph of the patient's back 21 months after a coronary angiography and two angioplasty procedures within three days; the assessed cumulative dose was 15 - 20 Gy

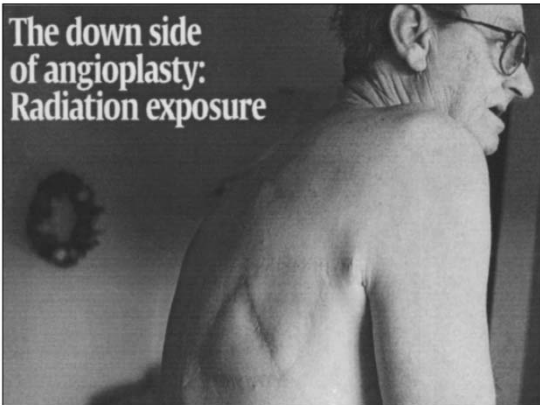
Radiation Cataract

American Journal of
Roentgenology, July 2001

Malpractice Issues in Radiology

Radiation-Induced Skin Injuries and Fluoroscopy

Leonard Berlin¹



The down side
of angioplasty:
Radiation exposure

Skin radiation injury
(considered as
medical malpractice)

Fig. 1.—Headline and photograph accompanying article published in *USA Today* [2] reporting jury award of \$1 million to 57-year-old man who sustained serious skin injury after two coronary artery angioplasties that occurred 5 months apart. Patient filed medical malpractice lawsuit alleging use of excessive fluoroscopy. (Reprinted with permission from Cohn J, Pittsburgh, PA)

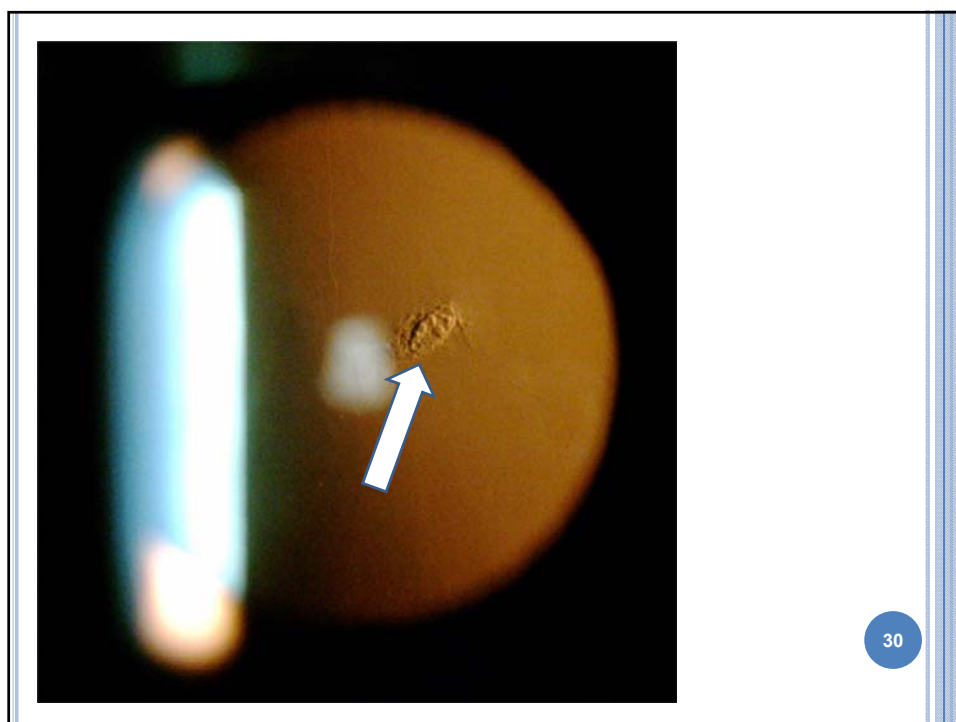
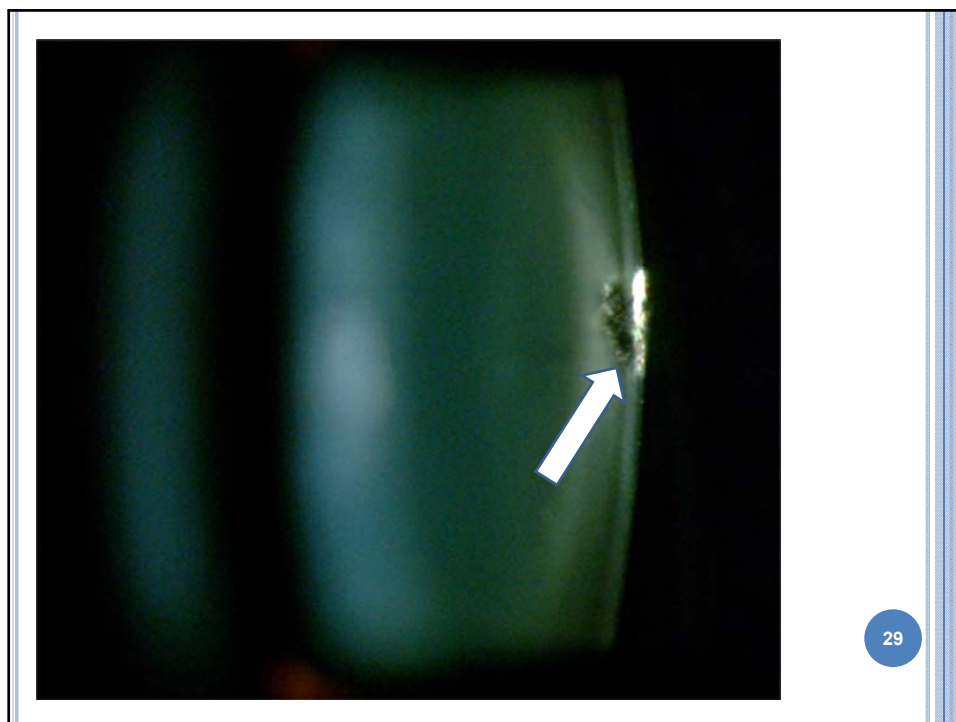
Radiation-associated Lens Opacities in Catheterization Personnel: Results of a Survey and Direct Assessments

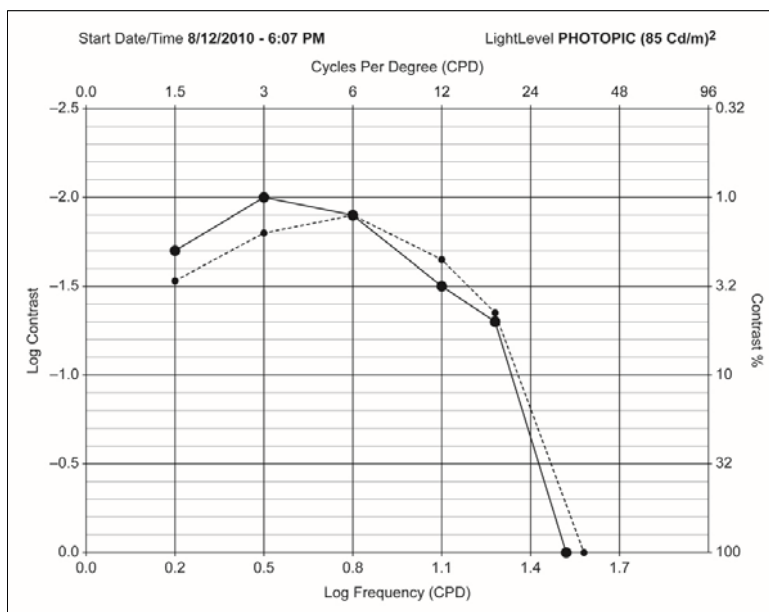
Eliseo Vano, PhD, Norman J. Kleiman, PhD, Ariel Duran, MD,
Mariana Romano-Miller, MD, and Madan M. Rehani, PhD

Posterior subcapsular lens changes
characteristic of ionizing radiation exposure
were found **in 50% of interventional
cardiologists and 41% of nurses** and
technicians compared with findings of similar
lens changes in < 10% of controls. Most lens
injuries result after several years of work
without eye protection.

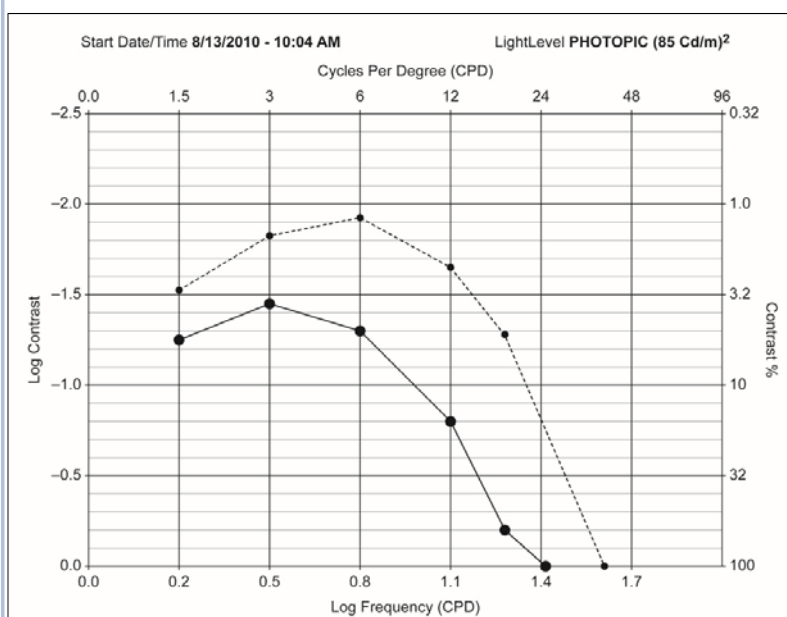
J Vasc Interv Radiol 2013;24:197–204

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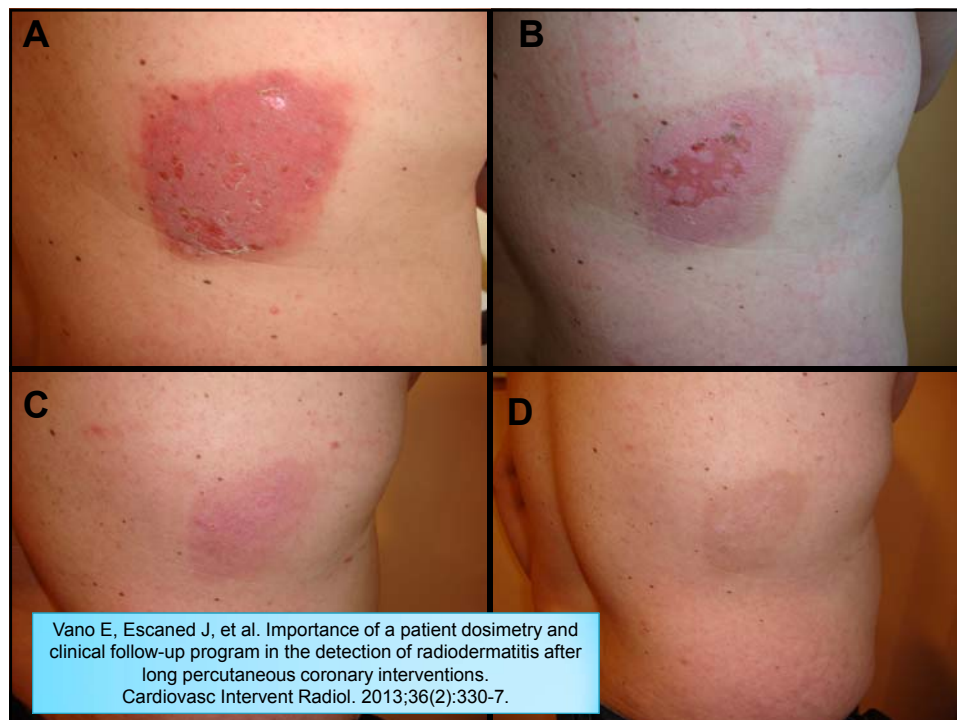
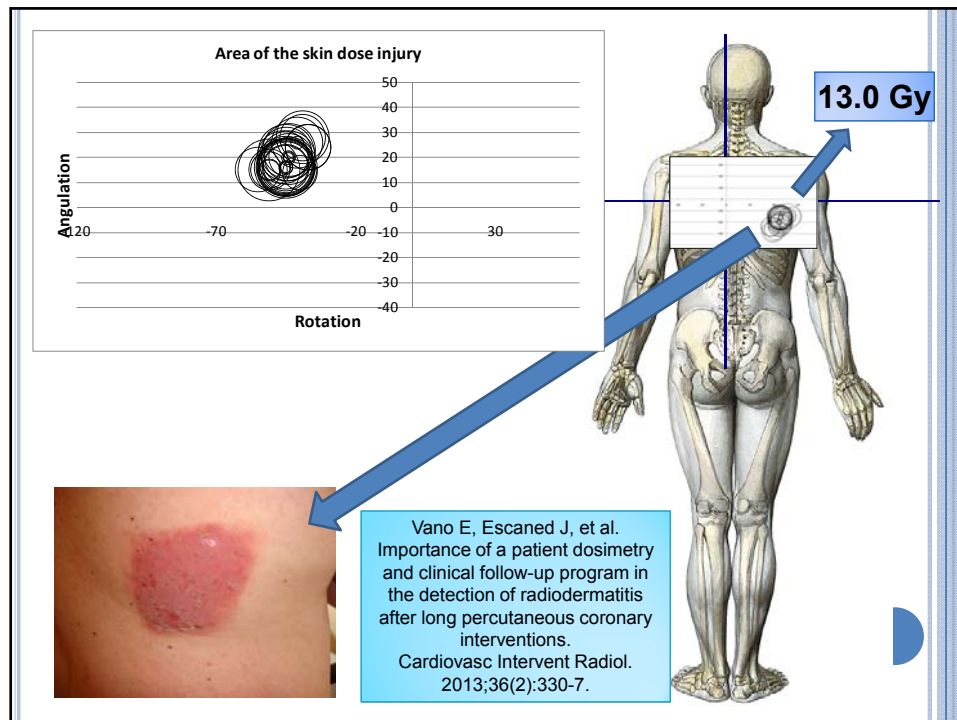


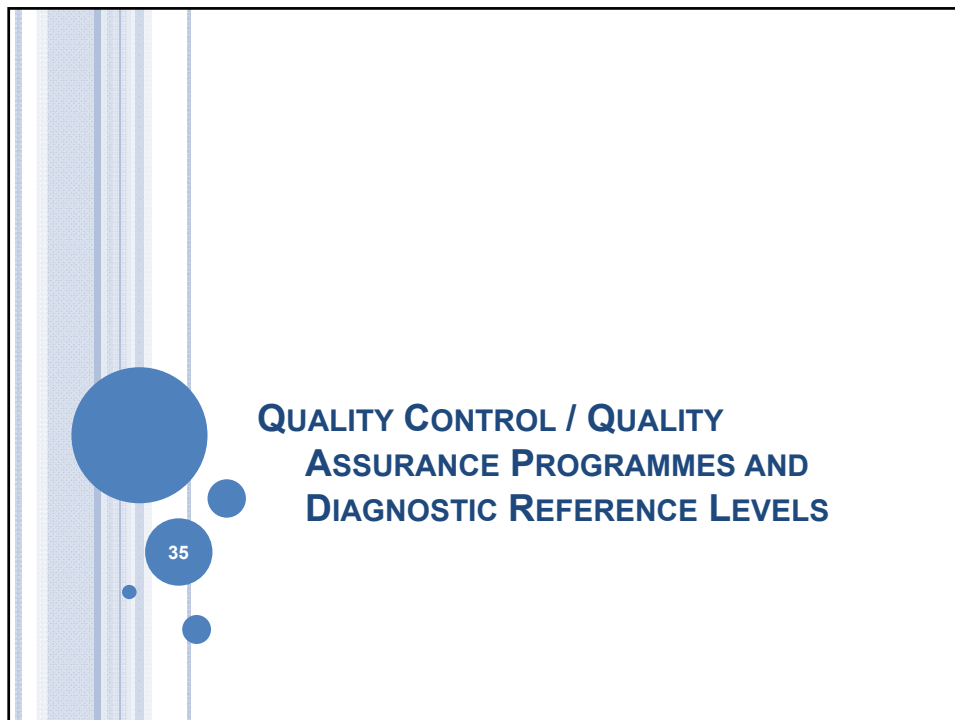


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ETHICAL ASPECTS AND QUALITY ASSURANCE PROGRAMMES

- If acceptance and constancy tests are not carried out, patients could receive unnecessary doses or bad image quality could be obtained.
- Initial training and regular re-training in RP shall be included.
- Audit of the appropriateness of the request for radiological procedures.
- Patient dose records and transfer to the clinical reports.
- System to detect accidental and unintended exposures and clinical follow-up of high doses.
- Optimization actions and use of DRLs.

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ASPECTS REQUIRED BY THE NEW EUROPEAN DIRECTIVE ON BSS AND ETHICAL APPROACH

- **BSS Directive 2013/59/Euratom**
- New dose limit for the lens of the eyes.
- Consideration of occupational doses in justification and optimization.
- Use of diagnostic reference levels and regular review.
- Role of Medical Physics Expert in imaging.
- Dosimetric information in all diagnostic systems and transfer to the patient report.
- Registry and analysis of the accidental or unintended irradiation of patients.
- **Good ethical approach**
- Anticipated evaluation and need of additional dosimetry
- Knowledge of ranges of occupational dose values.
- Knowledge and use of DRLs and regular audit of patient doses.
- Availability of MPEs.
- Manual/automatic and included in technical specifications.
- Local records and analysis.

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