IAEA
International Atomic Energy Agency

IAEA activities on RP in interventional procedures

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Image guided interventional procedures

Number of procedures is growing fast

- According to the UNSCEAR 2008 Report, approximately 3.6 million interventional radiology procedures were undertaken annually worldwide.

- According to the UNSCEAR 2020/2021 Report, the estimated total annual number of interventional radiology procedures is about 24 million.

- This is more than a sixfold increase!

Fluoroscopically Guided Interventional Procedures:

A Review of Radiati… Effects on Patients' Skin and H…

Stephen Balter, PhD
John W. Hopewell, DSc
Donald L. Miller, MD
Louis K. Wagner, PhD
Michael J. Zelefsky, MD

…adiology

Most advice current… skin reactions is bas… caveats in that repor… tions, and subseque… sights. This review i… tific data. Expected … are presented in tal… dose and time after … cate the variability … ages of injuries to s… and animals are pr… to the National Can… ing a basis for desc… in interventional fluo… severity. For a sing… dividuals, noticeable … mately 1 month afte… grays. The degree o… sue increases with …

National Cancer Institute (NCI)

Table 1

Tissue Reactions from Single-Delivery Radiation Dose to Skin of the Neck, Torso, Pelvis, Buttocks, or Arms

Band	Single-Site Acute Skin-Dose Range (Gy)*	NCI Skin Reaction Grade†	Approximate Time of Onset of Effects			
			Prompt	Early	Midterm	Long Term
A1	0–2	NA	No observable effects expected	No observable effects expected	No observable effects expected	No observable effects expected
A2	2–5	1	Transient erythema	Epilation	Recovery from hair loss	No observable results expected
B	5–10	1–2	Transient erythema	Erythema, epilation	Recovery; at higher doses, prolonged erythema, permanent partial epilation	Recovery; at higher doses, dermal atrophy or induration
C	10–15	2–3	Transient erythema	Erythema, epilation; possible dry or moist desquamation; recovery from desquamation	Prolonged erythema; permanent epilation	Telangiectasia‡; dermal atrophy or induration; skin likely to be weak
D	>15	3–4	Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required	Erythema, epilation; moist desquamation	Dermal atrophy; secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required; at higher doses, dermal necrosis, surgical intervention likely to be required	Telangiectasia‡; dermal atrophy or induration; possible late skin breakdown;wound might be persistent and progress into a deeper lesion; surgical intervention likely to be required

Balter et al Radiology 2010

Figure A1: NCI skin toxicity grade 1. Tw

Figure 5: NCI skin toxicity grade 2 (see Appendix).

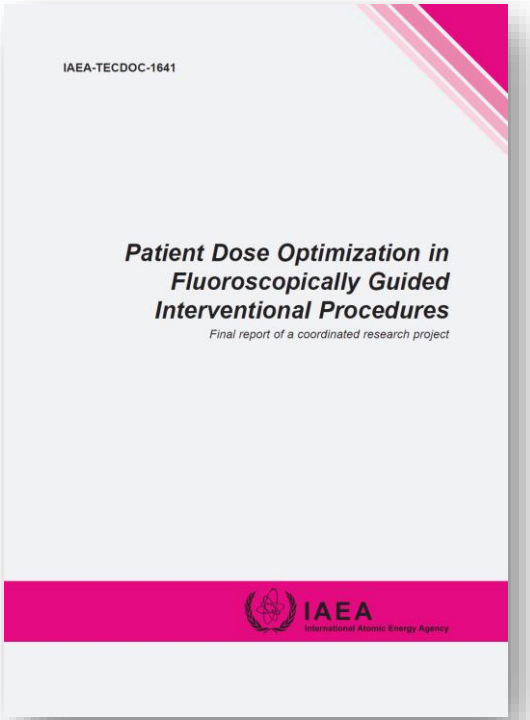
Figure A5: NCI skin toxicity grade 3. Increased severity

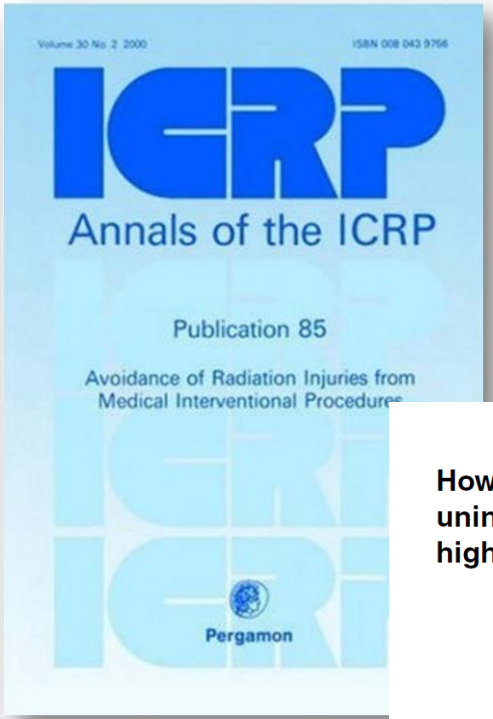
a. b.

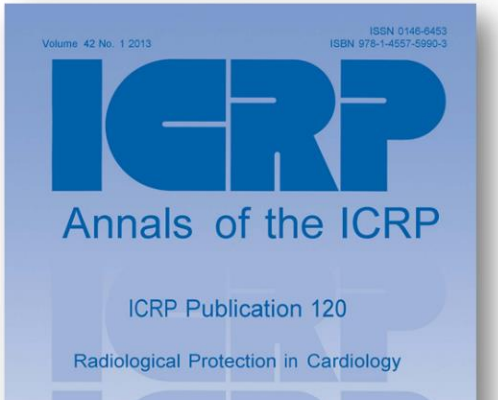
Figure A8: NCI skin toxicity grade 4. (a) Central area of deep necrosis surrounded by indurated and

How often do injuries happen?

The frequency of major radiation injuries is estimated to be between 1:10,000 and 1:100,000 procedures







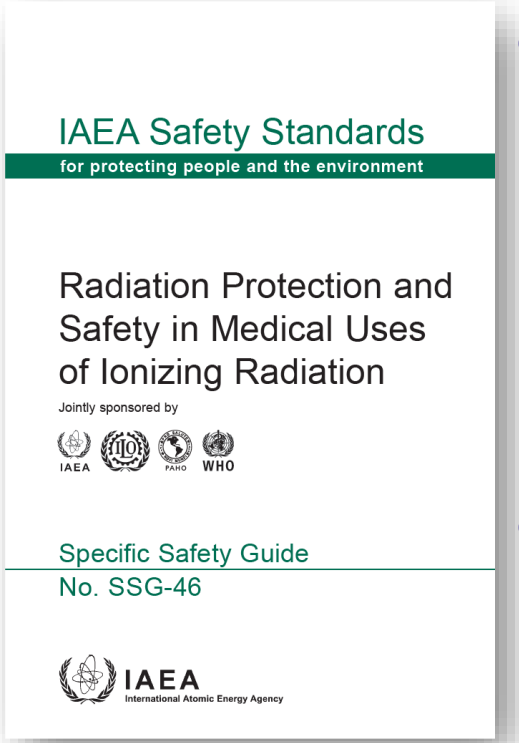

Review

How often does it happen? A review of unintended, unnecessary and unavoidable high-dose radiation exposures

Ola Holmberg[1,*] and Miroslav Pinak[2]

[1] Radiation Protection of Patients Unit, International Atomic Energy Agency, Vienna, Austria
[2] Radiation Safety and Monitoring Section, International Atomic Energy Agency, Vienna, Austria

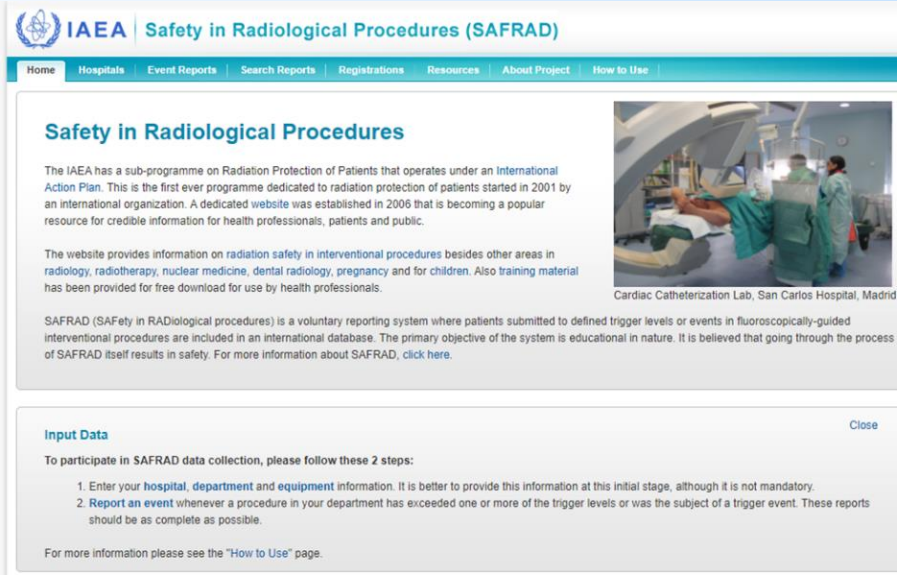
Safety Guide SSG-46



- Facilities at which image guided interventional procedures are performed should have systems in place for identifying patients who may be at risk of late radiation injuries, typically based on estimates of peak skin dose, cumulative reference air kerma or air kerma–area product, which take account of the fact that patients have different sensitivities to radiation.
- For these patients, information should be added to their medical records so that appropriate observation and follow-up is ensured.

SAFRAD (SAFety in RADiological procedures)

- International web-based voluntary and anonymized reporting system for FGI procedures
- Developed 2009-2011; Piloted 2011-2012
- Improvements 2012
- Additional modifications 2015-2017
- Promotion through IAEA meetings and TC events, and during relevant meeting and congresses



SAFRAD (SAFety in RADiological procedures)

- The primary objective of SAFRAD event reporting system is educational in nature
  - Identify patients at risk for deterministic effects
  - Encourage follow-up examinations for adverse side effects
  - Educate physicians/other medical personnel
  - Encourage physicians to educate patients at risk
  - Minimize adverse side effects based on awareness
  - Lessons can be learned and shared
- Confidentiality is maintained by the IAEA

SAFRAD (SAFety in RADiological procedures)

Resources

- RPOP Home
- International Safety Standards
- Publications
- Posters and leaflets
- Bonn Call for Action platform
- Smart Card
- Recurrent imaging
- RELID Study
- Training material
- Webinars
- Online Training
- Databases and Learning Systems
  - SAFRON
  - SAFRAD
  - ISEMIR-IC

SAFRAD (SAFety in RADiological procedures) is a voluntary reporting system aiming to sustain a database of comprehensive data such as patient's dose report and other relevant data when these patients are submitted to defined trigger levels or events in fluoroscopically-guided diagnostic and interventional procedures. The primary objective of the system is educational. It is believed that going through the process of SAFRAD itself results in safety and quality of service.

All data furnished by participants (hospitals, regulators) will remain accessible to the participant. The participant will have access periodically to analysed results. The IAEA will publish overall summary reports of SAFRAD data from time to time. SAFRAD will not supply identifiable data to any governmental authority or other third party.

» Introduction to the project
» How to use SAFRAD
» Guidelines and forms

How to use SAFRAD

Overview

SAFRAD website provides you with on-line forms to be filled in order to

Related resources

- Access SAFRAD
- SAFRAD new triggers

Guidelines and forms

Download:

- Guidelines for the interventionalist
- Guidelines for the treating physician
- Instructions for the coordinator
- Patient information leaflet
- Patient data collection form

https://www.iaea.org/resources/rpop/resources/databases-and-learning-systems/safrad

SAFRAD triggers for reporting (initial set)

1	Fluoroscopy time	> 60 minutes
2	KAP (DAP) values	> 300 Gy.cm^2 (cardiac and neuro) > 500 Gy.cm^2 (other procedures)
3	$K_{a,r}$ (total air kerma at the interventional reference point)	> 5000 mGy (5 Gy)
4	Measured skin dose	> 3 Gy
5	Number of series or cine runs	> 20
6	Multiple procedures within 12 months	

https://rpop.iaea.org/safrad/

SAFRAD status (March 2023)

319 events reported to date from 25 hospitals

- 19 recognized tissue reactions
- 2 severe erythema; 2 ulceration; 9 skin erythema (transient); 6 epilation
- 11 PCI; 3 CTO, 3 neuroembolizations head; 1 Arteriovenous malformations (embolization); 1 ICD implantation
- In 6 patients 4 triggers exceeded, in 3 patients 3 triggers exceeded

  CD: known in 11: in 10 with >5 Gy; in 1 < trigger

  KAP: known in 15: in 12 with > 300 Gy.cm^2 and 10 with >500 Gy.cm^2; in 3 < trigger)

  FT: known in all; 10 with > 60 min, 10 < trigger)

Future of SAFRAD

- Many more reports needed to define more realistic trigger dose indicators for different types of interventional procedures
- SAFRAD database needs upgrade to simplify reporting and provide analyses of reported events
- Update of trigger level values needed based on evidence

- The Meeting of consultants in May 2021 advised the IAEA to design an international study

International study of patient doses and tissue reactions from FGI procedures

Objectives:

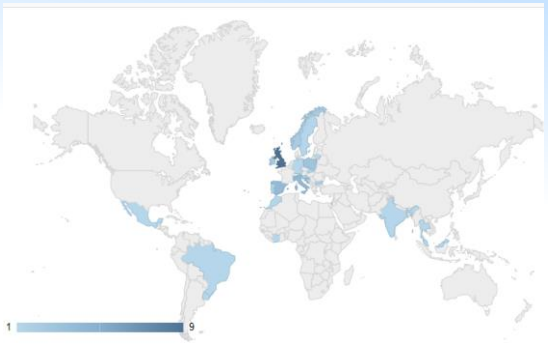
- Improve the information about the frequency of occurrence of tissue reactions in patients from different type of FGI procedures (cardiac, neuro, and body) performed in different parts of the world.
- Study the relationship between the tissue reactions and the radiation exposure metrics, procedure factors and patient related factors.
- Use the results of the study to update trigger level values for patient follow up for skin reactions.
- Update recommendations for improving radiation protection of patients.
- Provide feedback for the needed development of SAFRAD.

Expert panel:

D. Miller, S. Balter, K. Jones, R. Sánchez, M. Mahesh, A. Rogers; IAEA staff
Study coordinator: J. Vassileva

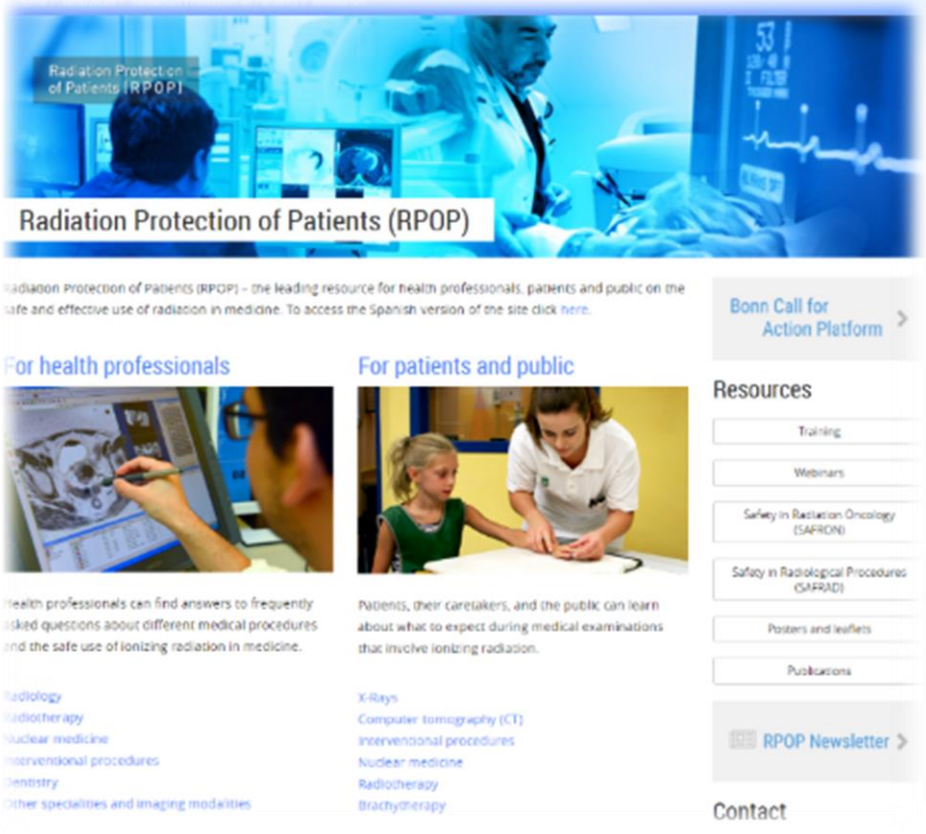
Current status (May 2023)

- Midterm report (6 months)
- Total 55,849 procedures, out of them:
  - 33,691 cardiac
  - 8,828 non-cardiac vascular
  - 6,658 non-vascular
  - 3,716 neurovascular
  - 632 FG-tumor therapy
- 7 facilities reported 12 cases of tissue reactions (3% of all patients followed)
- Results under analysis



	Total number of procedures	Patients followed-up for tissue reactions	Tissue reaction
Cardiac	34,691	234 (0.7%)	1
Non-cardiac vascular	8,828	62 (0.7%)	0
Non-vascular	6,658	9 (0.1%)	0
Neurovascular	**3,716**	**83 (2.2%)**	**10**
FG-tumor therapy	632	18 (2.8%)	1
Total	54,525	406 (0.7%)	12

Public website http://rpop.iaea.org



Annually: 1 million pageviews

- Contains useful information and FAQs for health professionals, patients and public
- Links to resources: training material, posters, webinars, videos, etc.

Public website http://rpop.iaea.org

2 entries – 2 different audiences

For health professionals

Health professionals can find answers to frequently asked questions about different medical procedures and the safe use of ionizing radiation in medicine.

- Radiology
- Radiotherapy
- Nuclear medicine
- Interventional procedures
- Dentistry
- Other specialities and imaging modalities

For patients and public

Patients, their caretakers, and the public can learn about what to expect during medical examinations that involve ionizing radiation.

- X-Rays
- Computer tomography (CT)
- Interventional procedures
- Nuclear medicine
- Radiotherapy
- Brachytherapy

Bonn Call for Action Platform

Resources

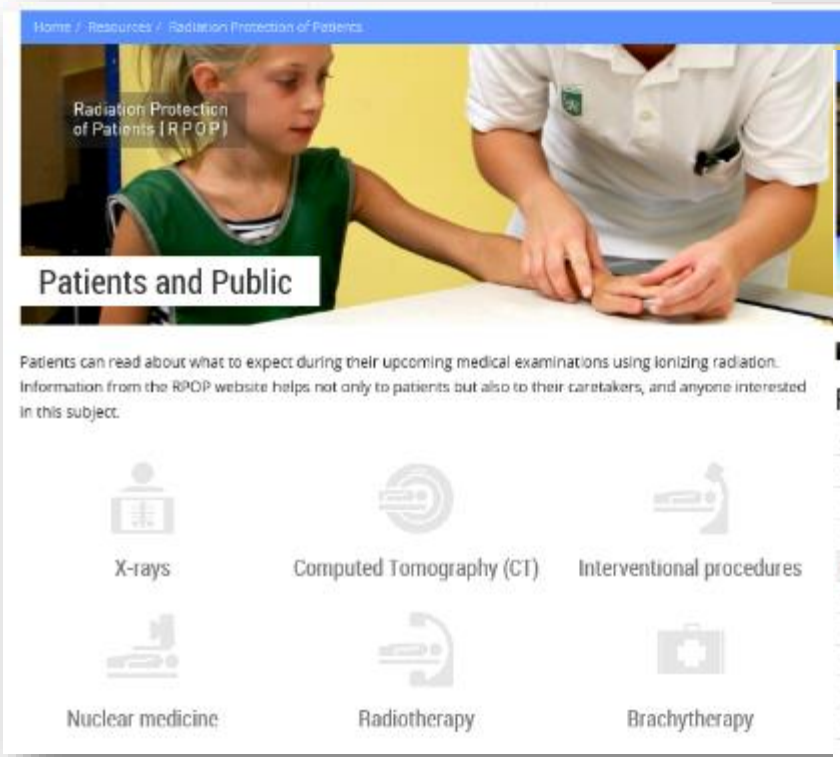
- Training
- Webinars
- Safety in Radiation Oncology (SAFRON)
- Safety in Radiological Procedures (SAFRAD)
- Posters and leaflets
- Publications

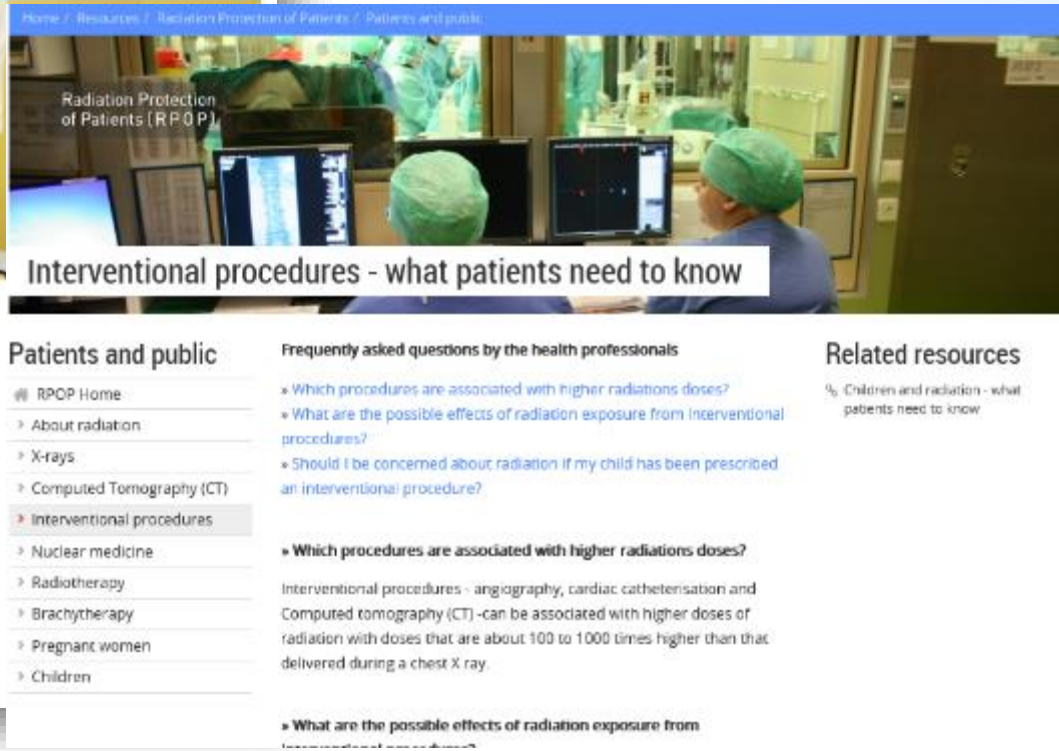
RPOP Newsletter

Contact

Public website http://rpop.iaea.org

Patients and public





Public website http://rpop.iaea.org

Interventional procedures

Health professionals

- RPOP Home
- Radiology
- Radiotherapy
- Nuclear medicine
- Interventional procedures
  - Safety
  - Radiation doses
  - Good practices
  - Staff
  - Interventional cardiology
- Dentistry
- Other specialities and imaging modalities

The use of fluoroscopically guided interventional procedures is increasing around the world. These minimally invasive procedures are used as an alternative to conventional surgery, resulting in reduced patient morbidity and mortality. Radiation doses to patients from fluoroscopically guided interventional procedures may be high enough to cause skin injuries and increased probability of developing cancer in future years. There is also a risk to staff members of deterministic effects such as cataract formation.

Although many fluoroscopically guided interventional procedures are conducted in radiology departments, they are increasingly performed by non-radiologists in other areas of the hospital, such as hybrid operating rooms. It is important to ensure that adequate radiation protection training and support services are provided to staff members involved in fluoroscopically guided interventional procedures in all areas of the hospital.

Related resources

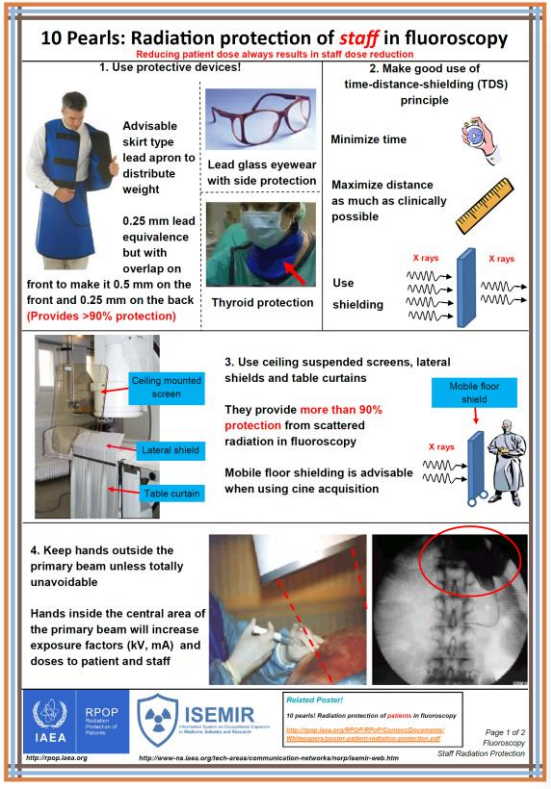
- Interventional cardiology

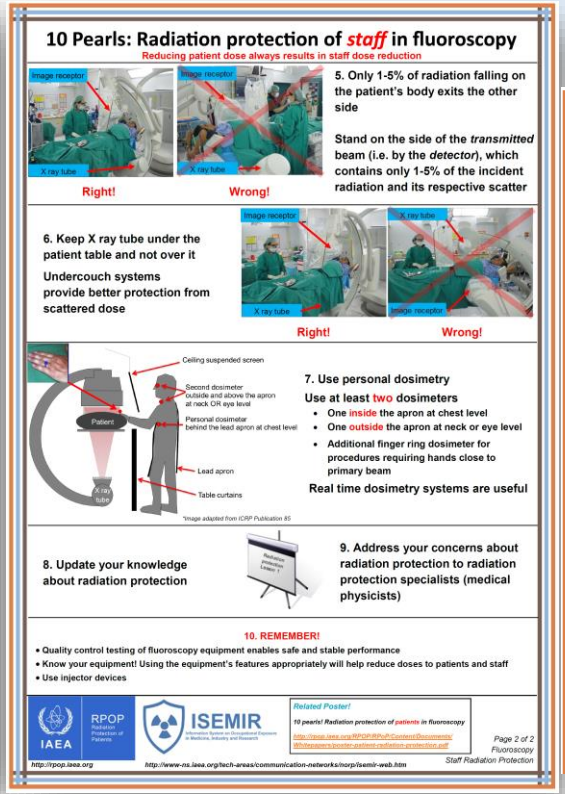
Training resources

- Doctors using fluoroscopy outside radiology
- Posters and leaflets about radiation protection

https://www.iaea.org/resources/rpop/health-professionals/interventional-procedures

Posters on radiation protection topics

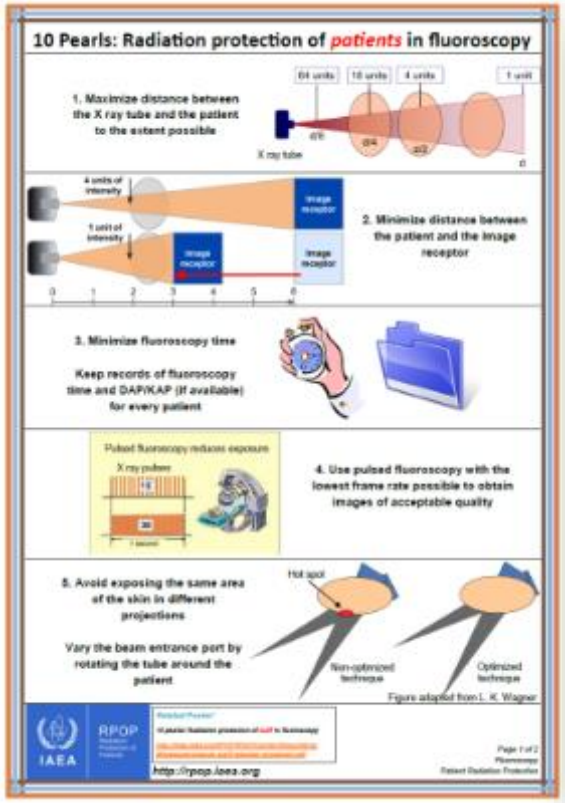


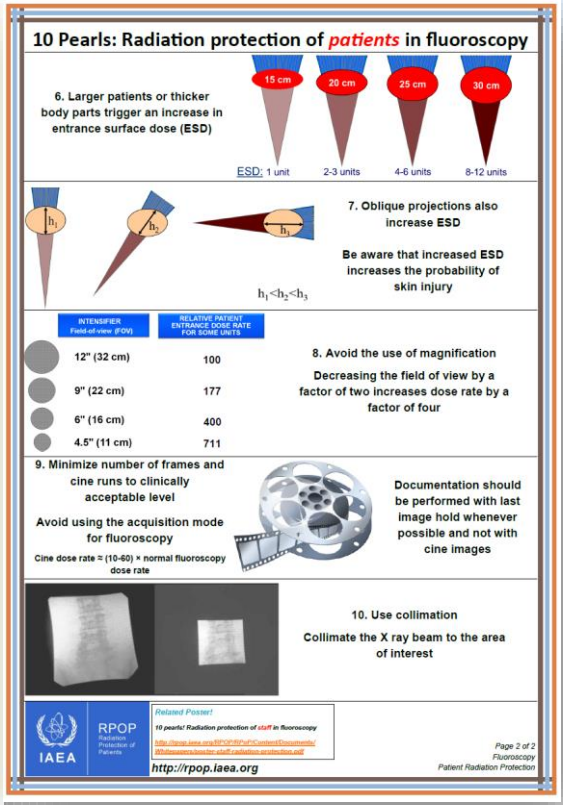


Available in 31 languages

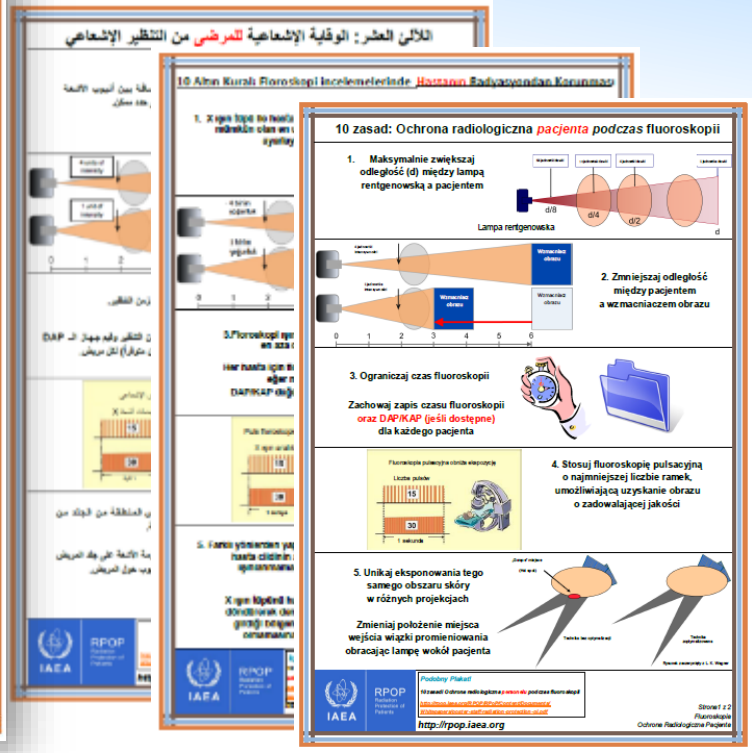
https://www.iaea.org/resources/rpop/resources/posters-and-leaflets

Posters on radiation protection topics



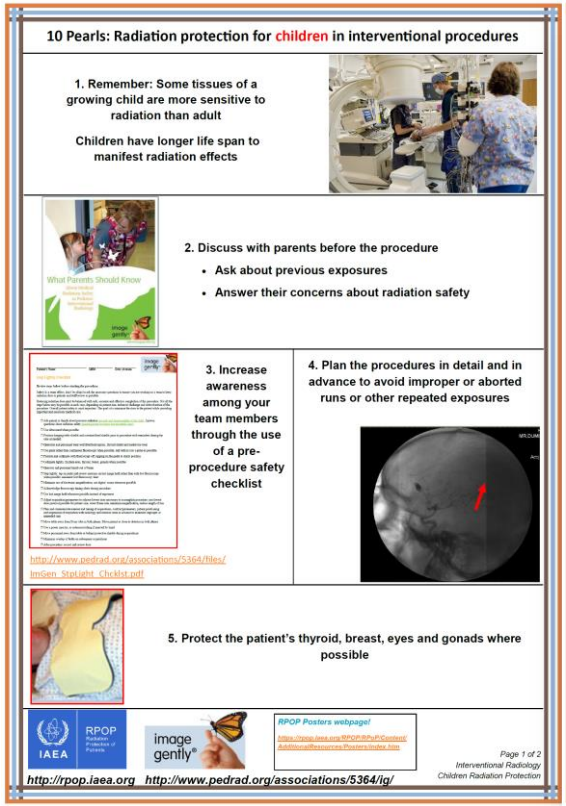


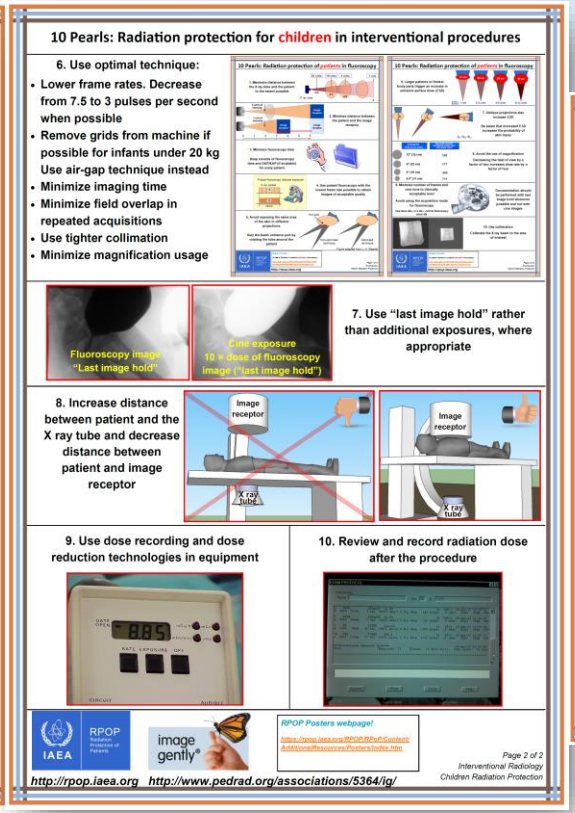
Available in 30 languages



https://www.iaea.org/resources/rpop/resources/posters-and-leaflets

Posters on radiation protection topics





Available in 26 languages

https://www.iaea.org/resources/rpop/resources/posters-and-leaflets

Posters on radiation protection topics

Available in 30 languages

https://www.iaea.org/resources/rpop/resources/posters-and-leaflets

IAEA free training resources

https://www.iaea.org/resources/rpop/resources/training-material

Diagnostic and interventional radiology

Lectures →

Exercises →

Lectures (in Spanish) →

Exercises (in Spanish) →

Lectures (in Russian) →

Exercises (in Russian) →

Paediatric radiology

Lectures →

Lectures (in Spanish) →

Cardiology

Lectures →

Lectures (Russian) →

Lectures:

01. Why talk about radiation protection in cardiology?
02. Talking about radiation dose
03. What radiation effects are possible? (besides skin injuries)
04. X ray production and angiography equipment
05. Patient dose management: Part 1-2
06. Standards and guidance
07. Occupational exposure and protective devices
08. Image quality in cardiac angiography
09. Optimization of radiation protection in cardiology
10. Radiation protection in paediatric interventional cardiology
11. Cardiac CT - radiation doses, dose management and practical issues
12. Examples of Good & Bad Practice (physical factors): Part 1-2

Doctors using fluoroscopy outside radiology

Lectures →

Lectures (in Spanish) →

Lectures:

- 01. Overview of radiation protection
- 02. Understanding radiation units
- 03. What can radiation do?
- 04. Anatomy of fluoroscopy & CT Fluoroscopy Equipment
- 05. How do I reduce my radiation risk?
- 06A. Radiation protection for patients in orthopaedic surgery
- 06B. Radiation Exposure in Gastroenterology
- 06C. Other medical specialties that use fluoroscopy
- 07. International standards and recommendations

Providing training

Training courses and workshops under TC regional and national projects

- Regional training courses
- National training courses
- Main target audience: health professionals in hospitals







RPOP webinars

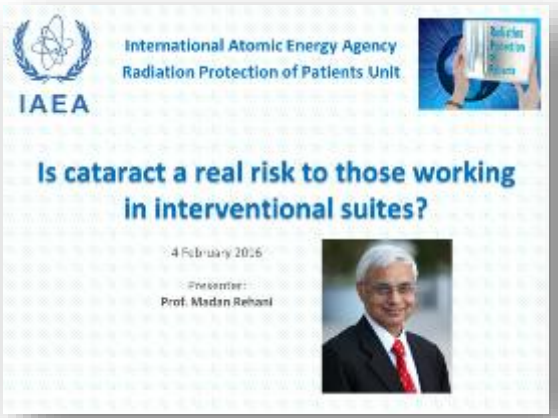
- Online lectures on topics in radiation protection of patients and staff
- In English, Spanish, Portuguese, Russian
- Held in cooperation with Image Gently, ESR (EuroSafe Imaging), LatinSafe, EFRS, IOMP, CIRSE
- Free registration and attendance
- Recording available for viewing

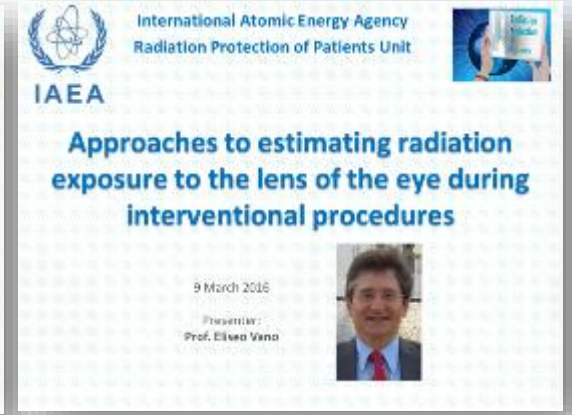
Since February 2016 → **76** webinars covering various topics → over **25,000** participants attended from **100** Member States

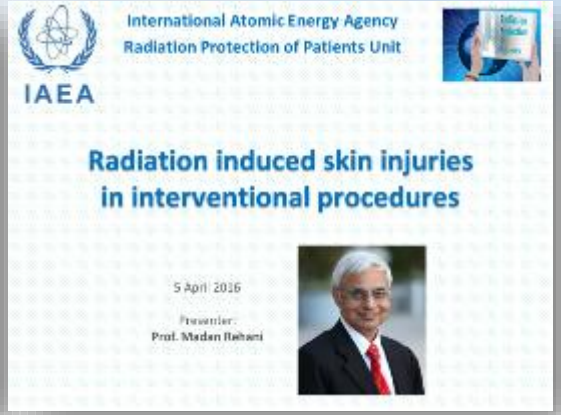
https://www.iaea.org/resources/rpop/resources/webinars

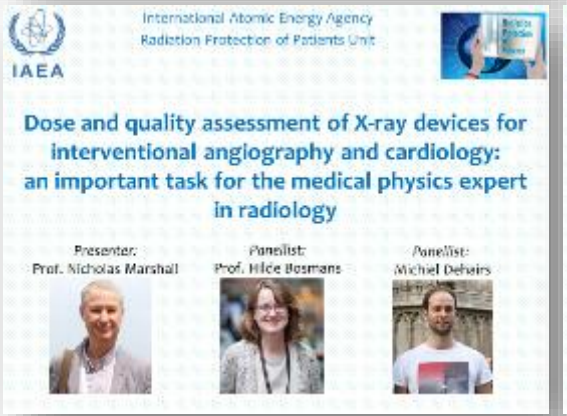
RPOP webinars (2016-2019)

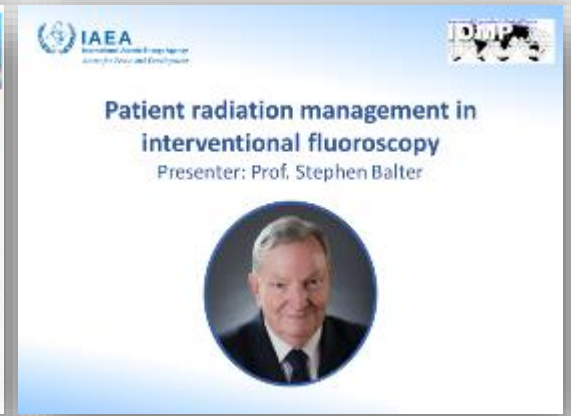
https://www.iaea.org/resources/rpop/resources/webinars





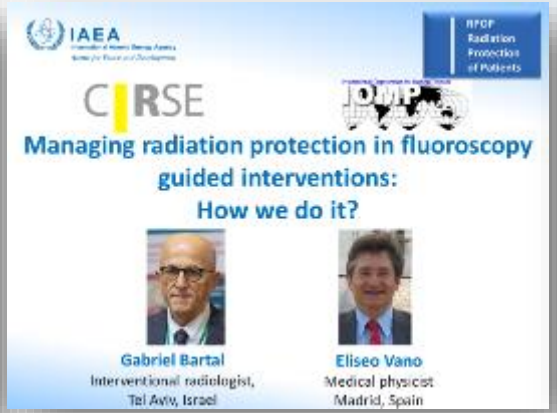


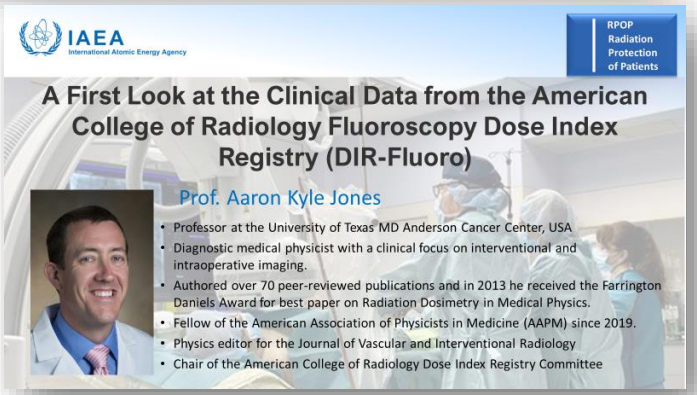




RPOP webinars (2020-)

https://www.iaea.org/resources/rpop/resources/webinars





E-learning with certification

Radiation Protection in interventional radiology (2019)

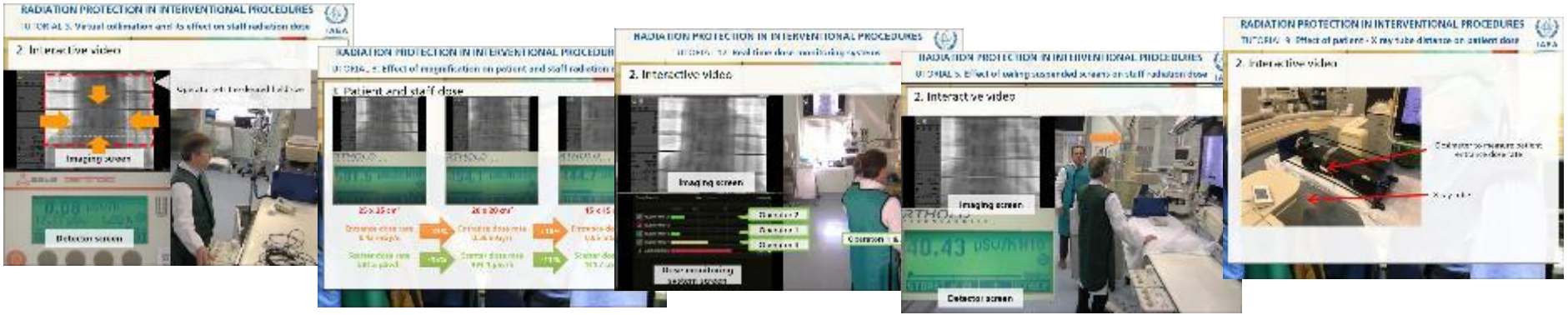
- Based on the 6 webinars
- Final quiz
- Certificate of completion if >80% correct answers
- Available from the e-learning platform of the IAEA

https://www.iaea.org/resources/rpop/resources/online-training

E-learning with certification

- 13 short practical tutorials, 4-8 minutes each with interactive videos
- To learn effect of various factors on patient and staff dose
- Available also for viewing without registration and for free download and use by trainers

https://www.iaea.org/resources/rpop/resources/online-training

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Information for health professionals and public
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