The Abdus Salam
International Centre for Theoretical Physics

United Nations
Educational, Scientific and
Cultural Organization

IAEA
International Atomic Energy Agency

2166-Handout

College on Medical Physics. Digital Imaging Science and Technology to Enhance Healthcare in the Developing Countries

13 September - 1 October, 2010

The Medical Exposures Directive

Cornelius LEWIS
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London
United Kingdom

The Medical Exposures Directive

Dr Cornelius Lewis
King's College Hospital
London, UK

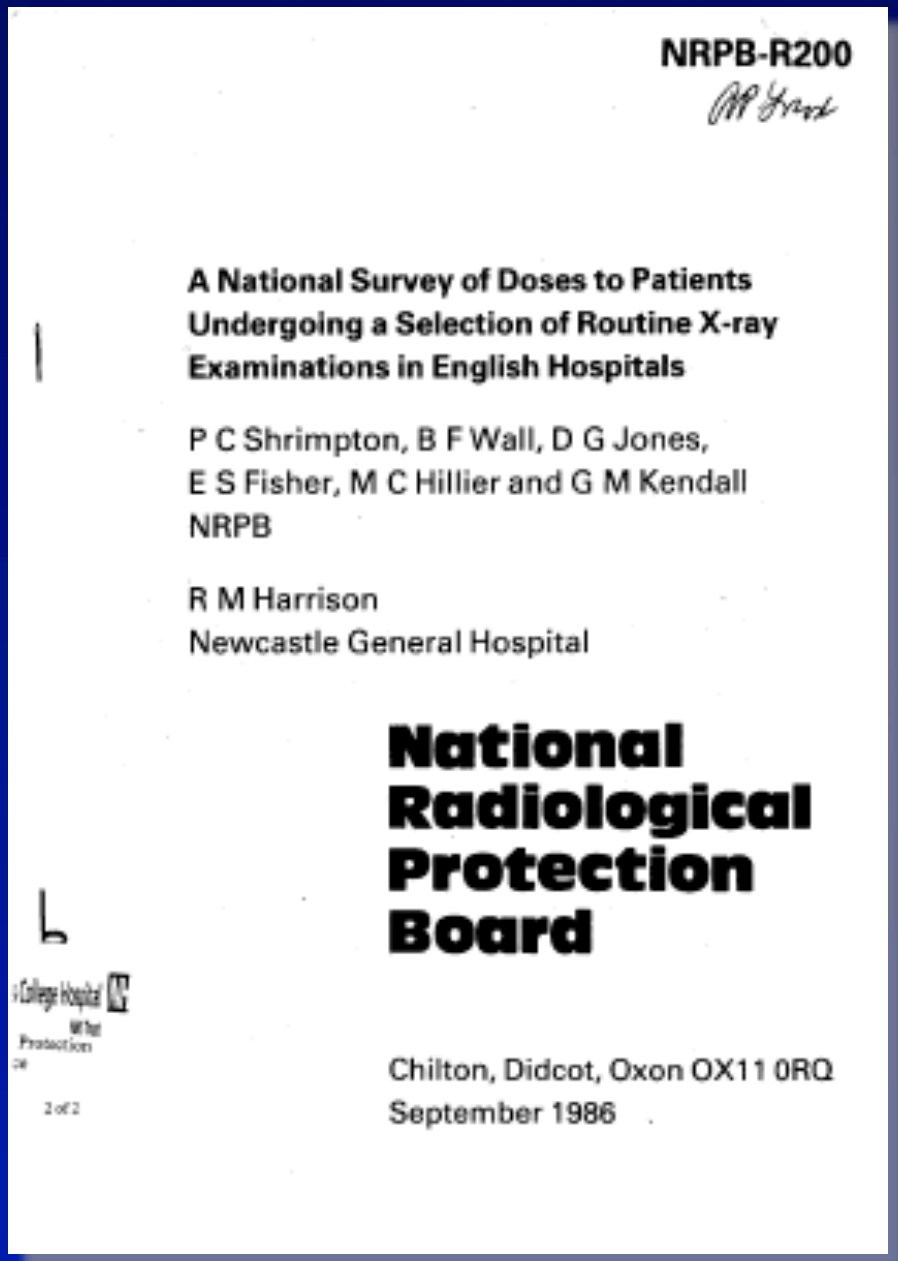
King's College Hospital NHS
NHS Trust

Medical Exposures Directive

“A framework for the operational control of medical exposures to ionising radiation”

Why?

- 1984 Survey by UK National Radiological Protection Board
- Effective doses calculated for
  - 6 ‘simple’ procedures
  - 6 ‘complex’ procedures



NRPB-R200

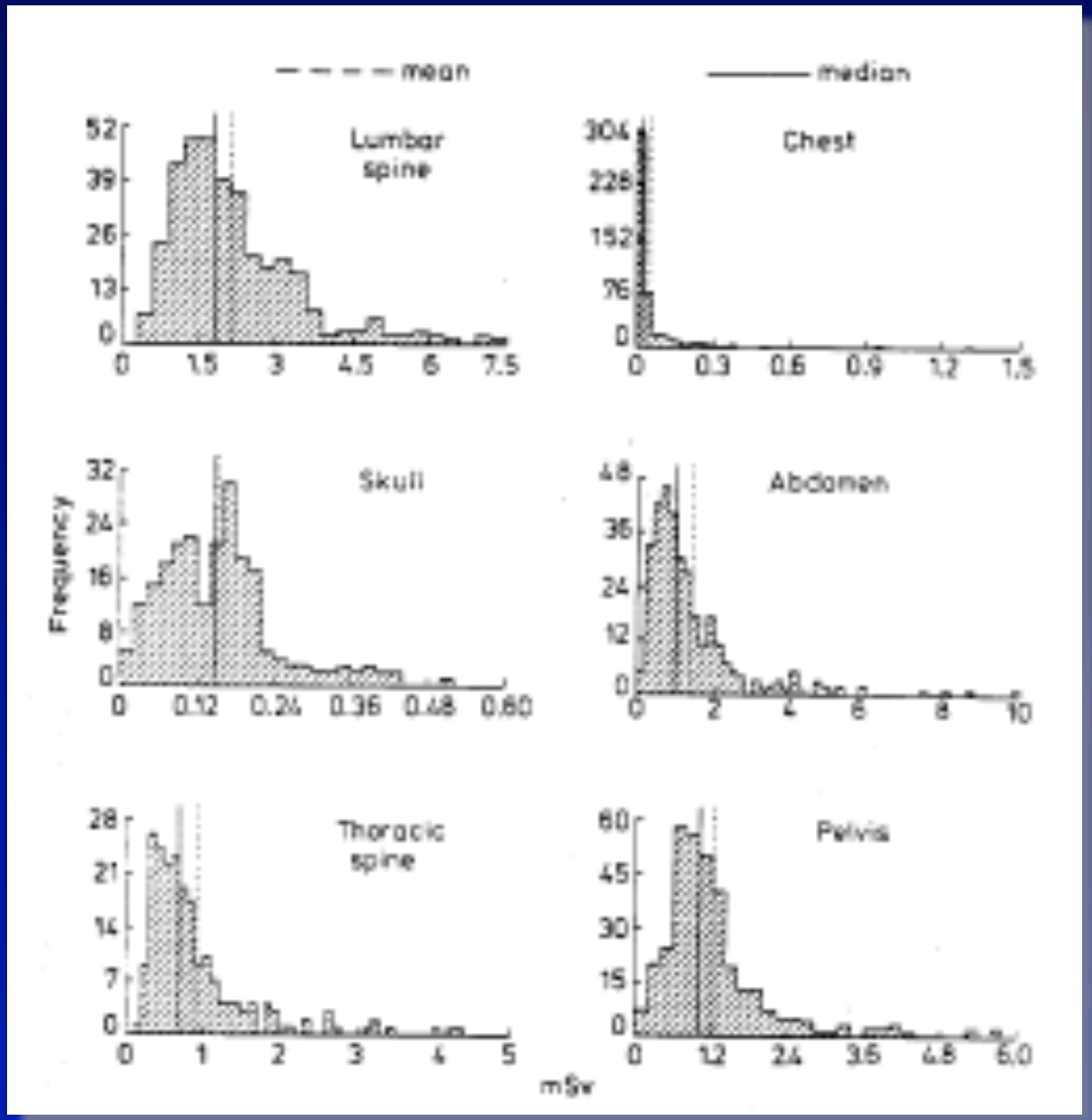
A National Survey of Doses to Patients Undergoing a Selection of Routine X-ray Examinations in English Hospitals

P C Shrimpton, B F Wall, D G Jones,
E S Fisher, M C Hillier and G M Kendall
NRPB

R M Harrison
Newcastle General Hospital

National Radiological Protection Board

Chilton, Didcot, Oxon OX11 0RQ
September 1986


mean
median
Lumbar spine
Chest
Skull
Abdomen
Thoracic spine
Pelvis
Frequency
mSv

Doses for ‘Simple’ Examinations

Exam.	Effective Dose (mSv)			Range (max/min)
	Mean	Min.	Max.	
Chest	0.05	<0.01	1.32	462
Lumbar Spine	2.15	0.37	7.37	20
Skull	0.15	0.01	0.5	36
Abdomen	1.39	0.12	9.94	84
Thor. Spine	0.92	0.16	4.39	28
Pelvis	1.22	0.09	5.77	65

Doses for ‘Complex’ Examinations

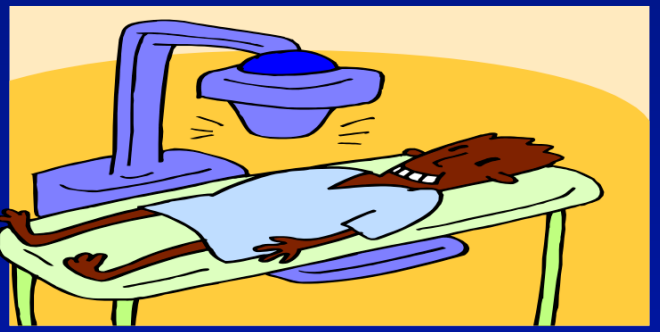
Exam.	Effective Dose (mSv)			Range (max/min)
	Mean	Min.	Max.	
IVU	4.36	1.4	35.05	25
Ba Meal	3.83	0.6	24.39	41
Ba Enema	7.69	2.92	33.64	11
Cholangio.	2.59	0.44	9.06	20
Cholecyst.	0.95	0.13	5.01	40

Structure of the MED

- 16 Articles
- Replaces Patient Protection Directive (84/466)
- Implementation on 13th May 2000

Article 1 : Scope

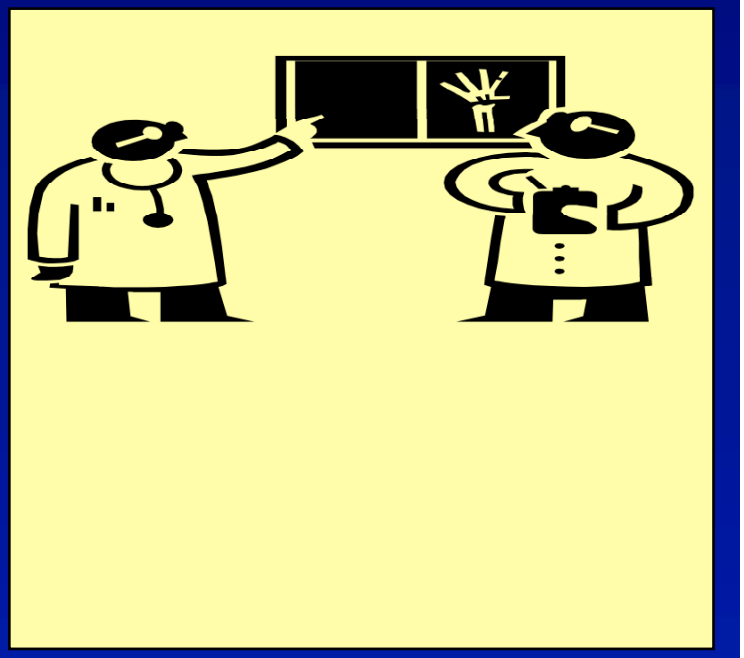
- Diagnosis and treatment
- Occupational health surveillance
- Health screening
- Research
- Medico-legal exposures



Article 2 : Definitions

…… and in particular

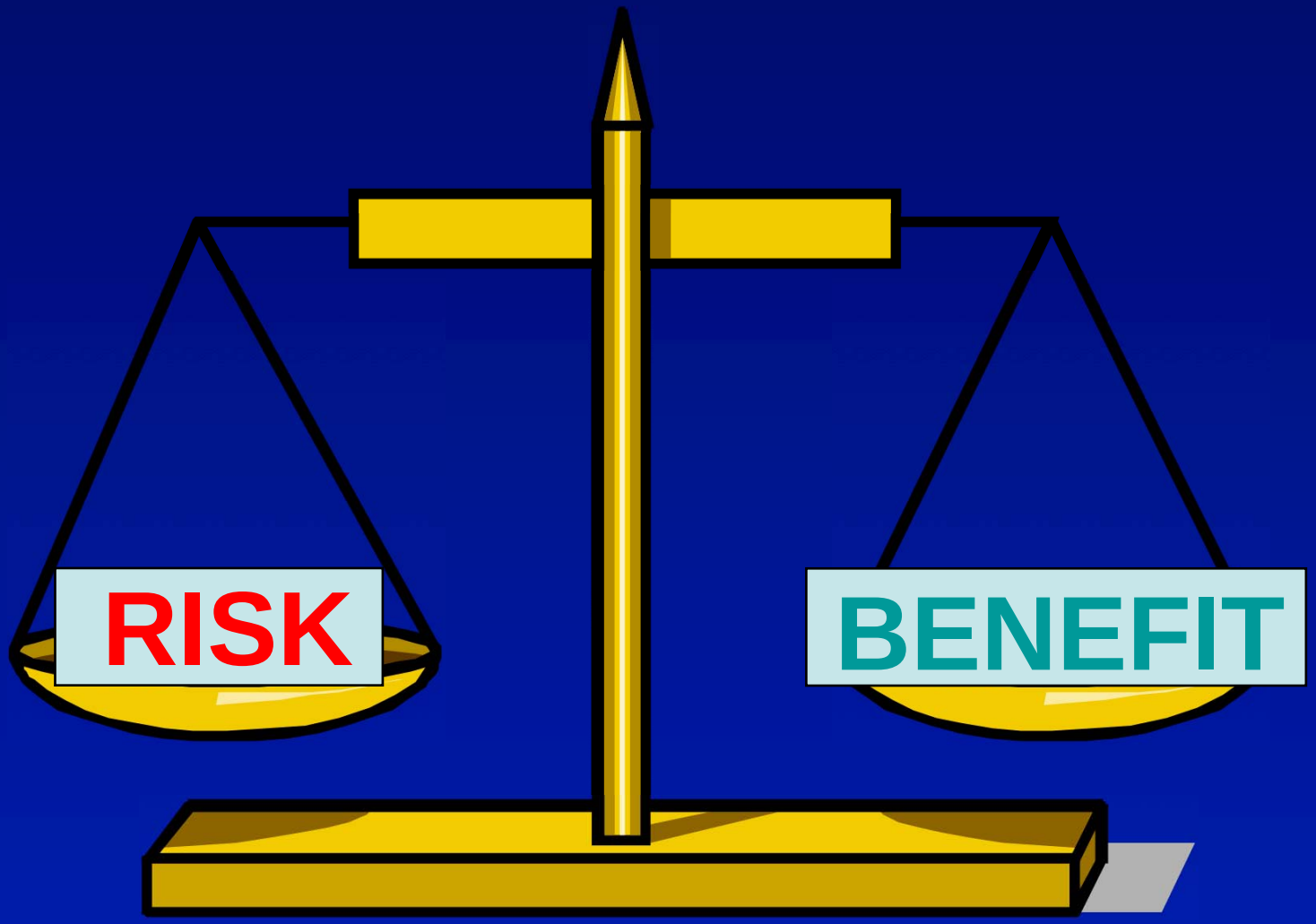
- practitioner
  - responsible for justification
- prescriber
  - entitled to refer
- medical physics expert
  - required for advice



Article 3 : Justification

- all new practices
- review existing practices
- Ethics committee involvement in research
- special attention to medico-legal exposures

What is Justification?



What is Justification?

Royal College of Radiologists (UK)

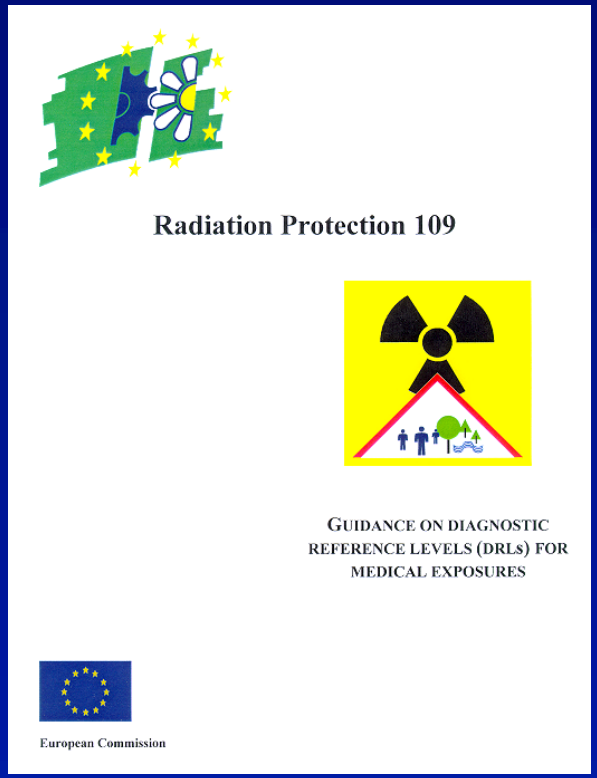
- Appropriateness of request
- Optimisation of imaging strategy
- Risk versus benefit
- Immediate and cumulative radiation effects
- Age specific issues
- Urgency of exposure
- Efficacy of imaging in different situations
- Appropriate delegation

Article 4 : Optimisation

- ALARA
- establishment and use of DRLs
- dose constraints in research
- optimisation of practical aspects
- dose constraints for comforters and carers
- information for NM patients

EU Guidance on DRLs (RP109)

- DRLs assist in optimisation
- DRLs are not to be applied to individual exposures
- DRLs are supplements to professional judgement
- DRLs only apply to diagnostic procedures



http://europa.eu.int/comm/environment/radprot

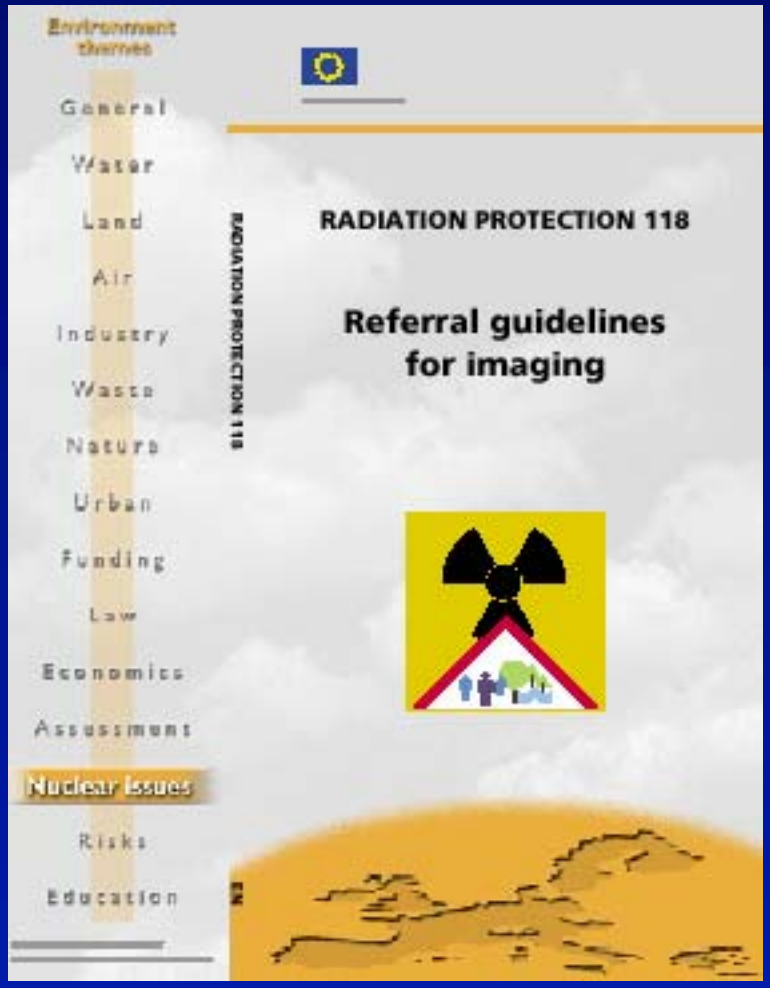
Article 5 : Responsibilities

- Justification
  - practitioner and prescriber
- Clinical responsibility
  - practitioner
- Practical aspects
  - delegated
- Procedures for medico-legal
  - must be specified

Article 6 : Procedures

- Written protocols for standard procedures
- referral criteria (including radiation doses)
- involvement of medical physics expert
  - R/T : closely involved
  - NM : available
  - DR : consultation as appropriate
- clinical audits
- review of DRLs

EU Referral Guidelines



http://europa.eu.int/com/environment/radprot/118/ rp-118-en.pdf

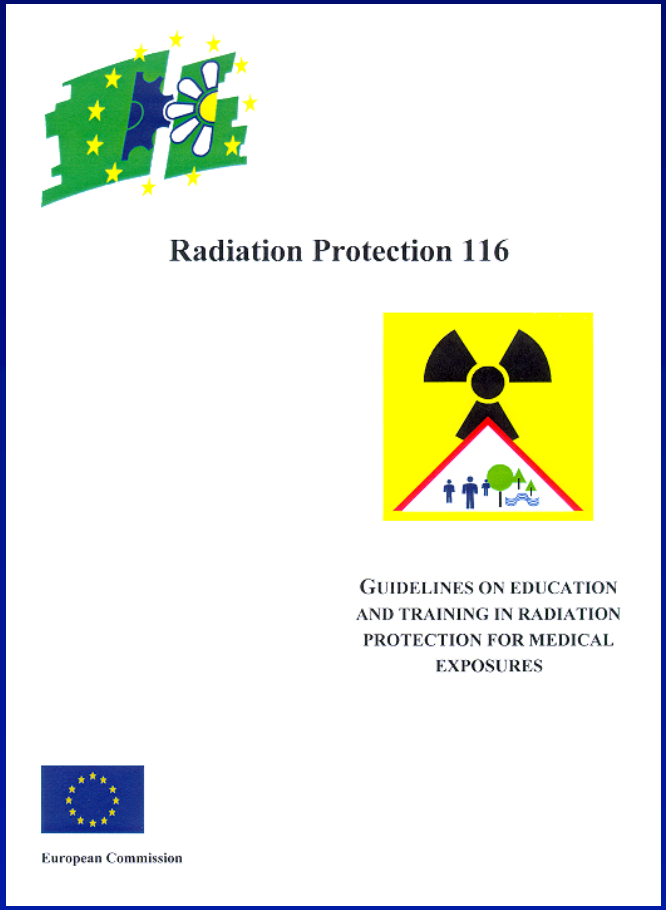
Extract from Referral Guidelines

CLINICAL PROBLEM	INVESTIGATION (DOSE)	RECOMMENDATION (GRADE)	COMMENT
Thoracic spine			
Pain without trauma: degenerative disease	*XR (I)*	Not indicated routinely (B)	Degenerative changes are invariable from middle-age onwards. Examination rarely useful in the absence of neurological signs or pointers to metastases or infection. Consider more urgent referral in elderly patients with sudden pain to show osteoporotic collapse or other forms of bone destruction. Consider NM for possible metastatic lesions.
C5	*MRI (0)*	Specialised investigation (B)	MRI may be indicated if local pain persists, difficult to manage or if there are long tract signs.
Lumbar spine			
Chronic back pain with no pointers to infection or neoplasm	*XR (II)*	Not indicated routinely (C)	Degenerative changes are common and non-specific. Main value in younger patients (e.g. less than 20, spondylolisthesis, ankylosing spondylitis, etc.) or in older patients e.g. >55.
C6	*MRI (0) or CT (II) or NM (II)*	Specialised investigation (C)	In cases where management is difficult. Negative findings may be helpful.

Article 7 : Training

- Adequate training for practitioners and “operators”
- Requirement for suitable formal training courses
- Requirement for Continuing Education
- Encourage training in Medical School

EC Guidelines on Training

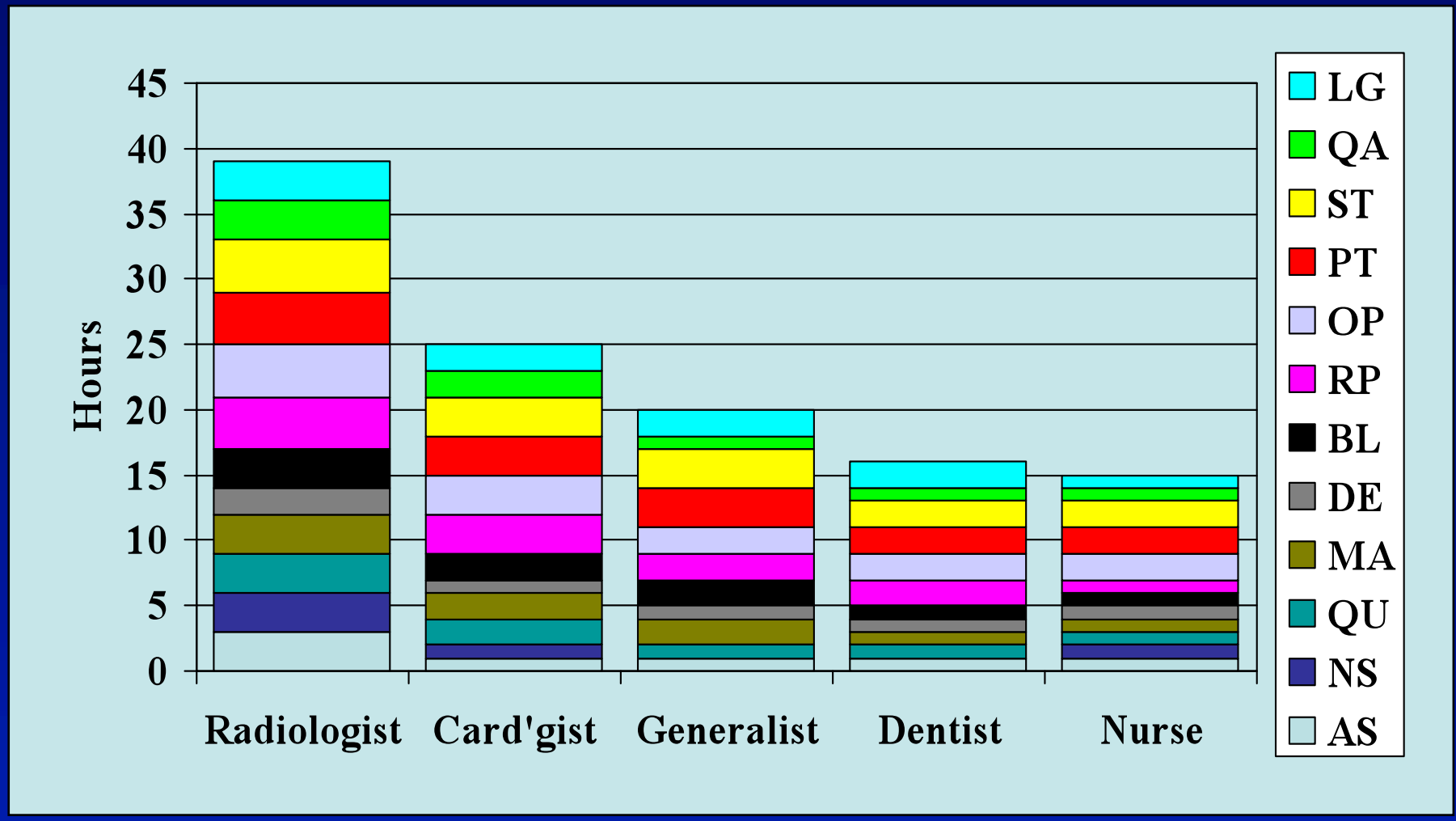


http://europa.eu.int/comm/environment/radprot

Specific Subject Training

- Atomic structure & x-ray production
- Nuclear structure and radioactivity
- Radiological quantities and units
- Physical characteristics of equipment
- Fundamentals of radiation detection
- Biological effects
- Principles of radiation protection
- Operational radiation protection
- Protection of patients
- Protection of staff
- Quality assurance and quality control
- Legislation

Duration of Training



Practical Training

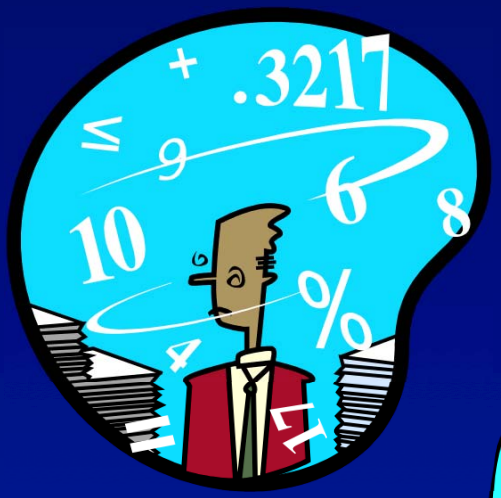
…..adequate theoretical and practical training…..

MED Article 7.1

King's College Hospital NHS
NHS Trust

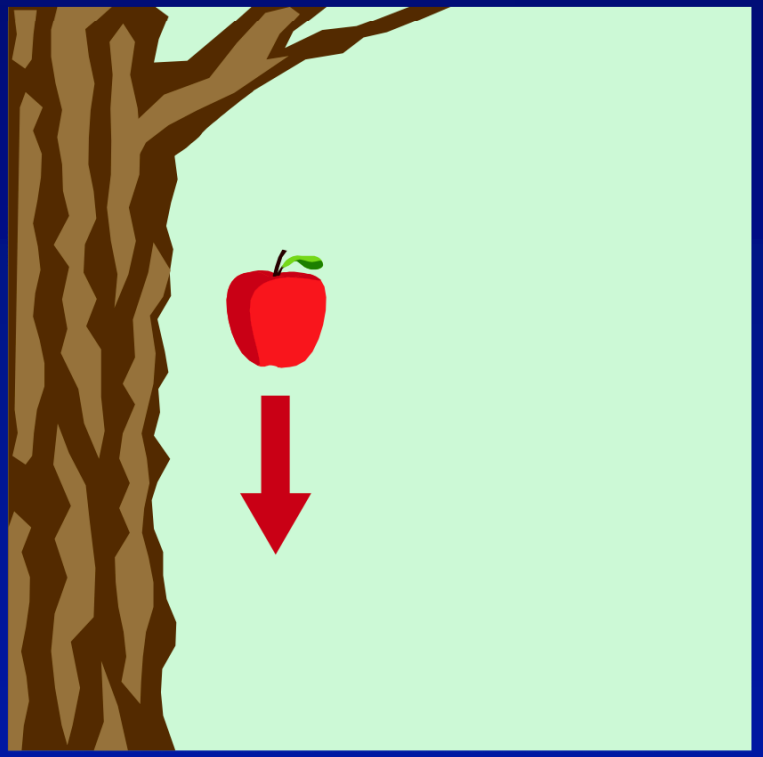
Requirements

- Theoretical training
  - Core of knowledge
- Practical training
- Register



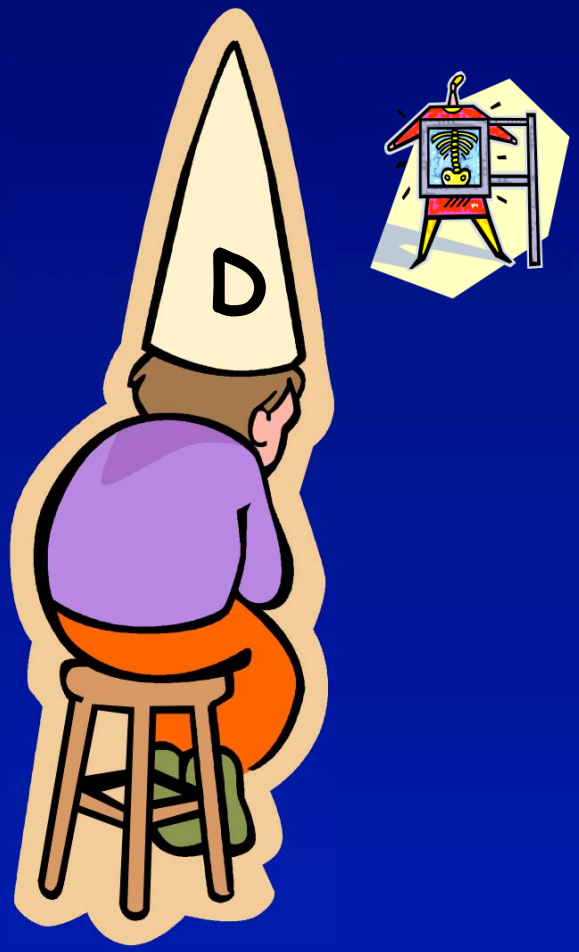
The value of theoretical training

- BMJ 327, August 2003
  - Shiralkar *et al*
- 2 hospitals (different regions)
- 130 Drs
  - 40 SHO, 40 SpR, 40 Consultants
  - 10 Consultant Radiologists
- Chest x-ray dose, quantity and unit
- Doses for other procedures (16) (incl MRI & U/S) in units of CXRs.

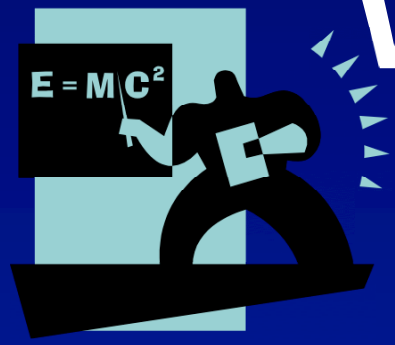


.....the results

- 0% knew the dose quantity and unit of a chest x-ray
- 95% correct answer for U/S abdo.
- 92% correct answer for MRI
- All x-ray procedures (12), < 10% correct

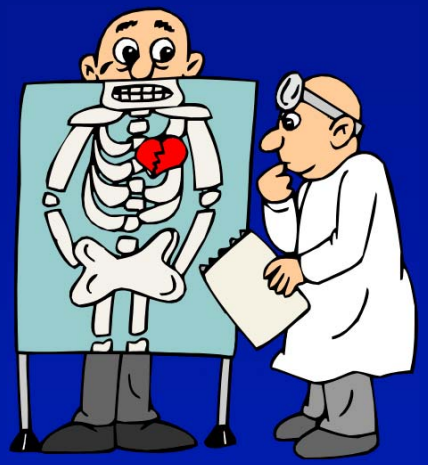


The Lessons



We shouldn't teach *(too much)* theory

We should teach practice



IRR99: Restriction of Exposure

The ALARP Principle

The employer is required to ensure that the exposure of employees and the public to ionising radiation is restricted "so far as is reasonably practicable". This is commonly referred to as "as low as reasonably practicable" (ALARP).

ALARP should be achieved by engineering controls, design features and systems of work.

Personal Protective Equipment

The exposure of employees should be further restricted by the use of personal protective equipment (PPE) - such as lead aprons - where appropriate.

Dose Constraints

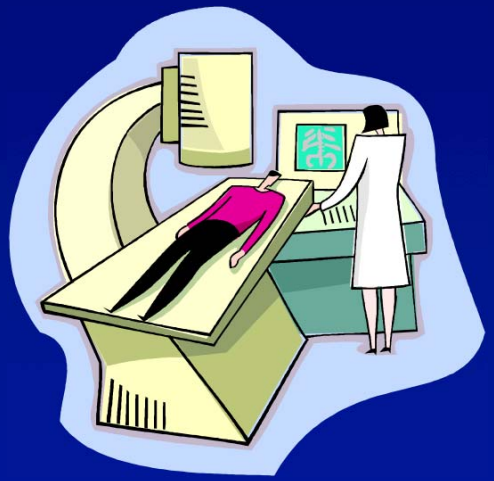
A dose constraint is a level, below the relevant dose limit, used in the

Practical Training

- Specialty/technique specific
  - Cardiology (pacing/angiography)
  - Use of image intensifier
  - Nuc. Med. injecting
- Individual or small group tutoring
- Trust nominated trainers

Article 8 : Equipment

- Avoid unnecessary proliferation
- Inventory
- Life history care
  - acceptance testing
  - QA/QC
  - servicing and maintenance
- Dose monitoring facility on new equipment



Article 9 : Special Practices

- Exposures of children
- Health screening
- High dose procedures
  - Interventional rad.
  - CT

Article 10 : Pregnancy

- Determination of pregnancy
- Special justification in pregnancy
- Breast feeding
- Awareness

Article 11 : Potential Exposures

- Reduce probability of unintended exposures
- Main emphasis in R/T

Article 12 : Estimates of Population Dose

- Calculate collective dose

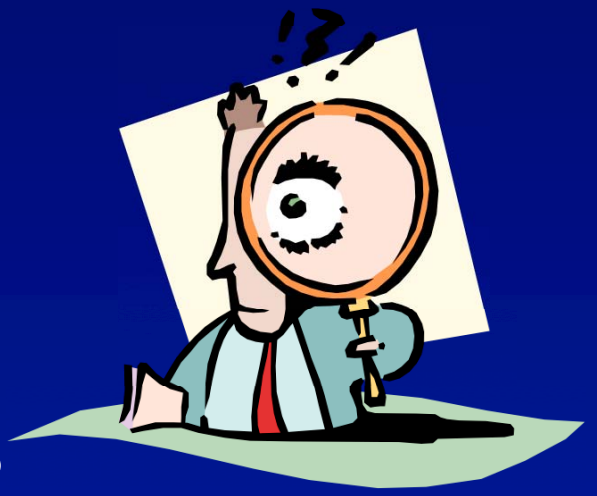
Article 13 : Inspection

- System of inspection for enforcement

Inspection Issues

- Patient Journey
- Policy v Procedures
  - what is to be done
  - how is it done
  - who does it

Inspection issues



- Possible questions on referrals
  - provide a list of referrers
  - show us your referral guidelines
  - how do you handle ‘CXR please’?
  - how do you handle telephone requests ?
  - show us your review process for requests with inadequate information
  - electronic requests

Inspection issues

- Questions on justification
  - list of practitioners
  - justification guidelines
  - out-of-hours
  - staff in training posts

Inspection issues

- Possible questions on patient identification procedures:
  - in-patient by wrist-band or by accompanied ward staff or relative
  - out-patient process
  - non-native language-speaking
  - hearing/speech/mentally impaired

Inspection issues

- Other possible questions:
  - are DRLs set
  - are doses recorded
  - any x-rays not reported by Radiologists?
  - how are staff updated on protocols?
  - are there specific protocols for children?

Healthcare Commission 2008

Diagnostic Radiology (including CT) -241 incidents

- X-raying the wrong patient
  44%
- Failing to follow the correct procedure
  35%
- Imaging the wrong part of the body
  10%
- Unnecessary repeats
  10%

Healthcare Commission 2008

Radiotherapy – 66 incidents

- Treatment error

  64%

- Planning mistakes

  20%

- Referral mistakes

  11%

- Other

  5%

Healthcare Commission 2008

Nuclear Medicine – 23 incidents

- Wrong radiopharmaceutical

  52%

- Wrong patient

  35%

- Unintended foetal exposure

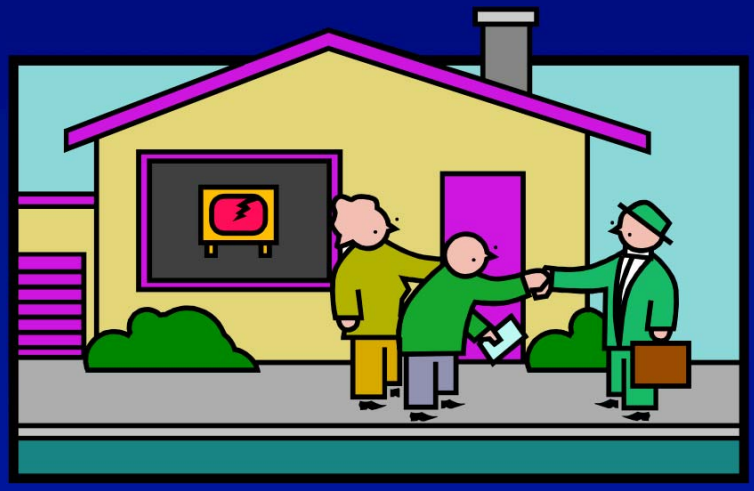
  13%

Revision of MED

- MED is EU directive 97/43
- Consolidation of MED with 4 other directives
  - Basic Safety Standards
  - Radiological Emergencies
  - Outside Workers
  - HASS (High Activity Sealed Sources)
- Consideration of ICRP 103
- Referred to as ‘Recast’ Directive

Radon in Dwellings

- Existing dwellings
  - 300 Bq m^{-3}
- New dwellings
  - 200 Bq m^{-3}
- Natural radioactivity in building materials



Aircrew /Spacecrew

- Directive extended to include operation of spacecraft

Graded approach to regulatory control

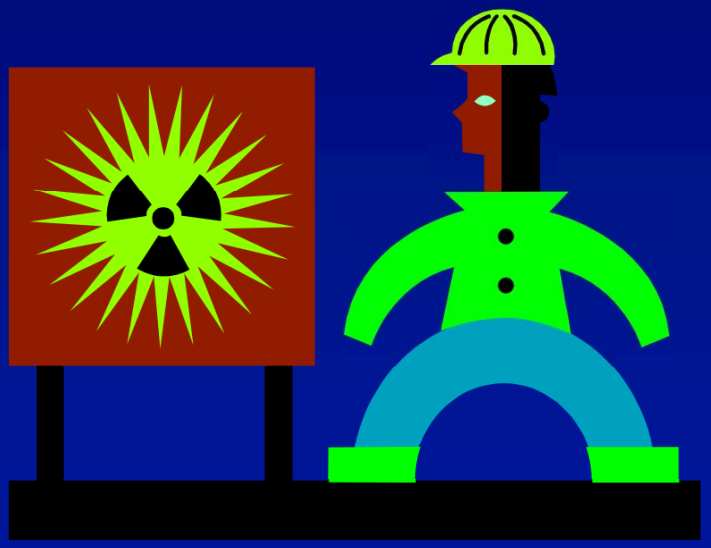
- Graded levels of control
  - Notification
  - Regulation
  - Licensing
- Amendment to exemption and clearance levels

Exposure to Biota

- Exposure pathways for humans

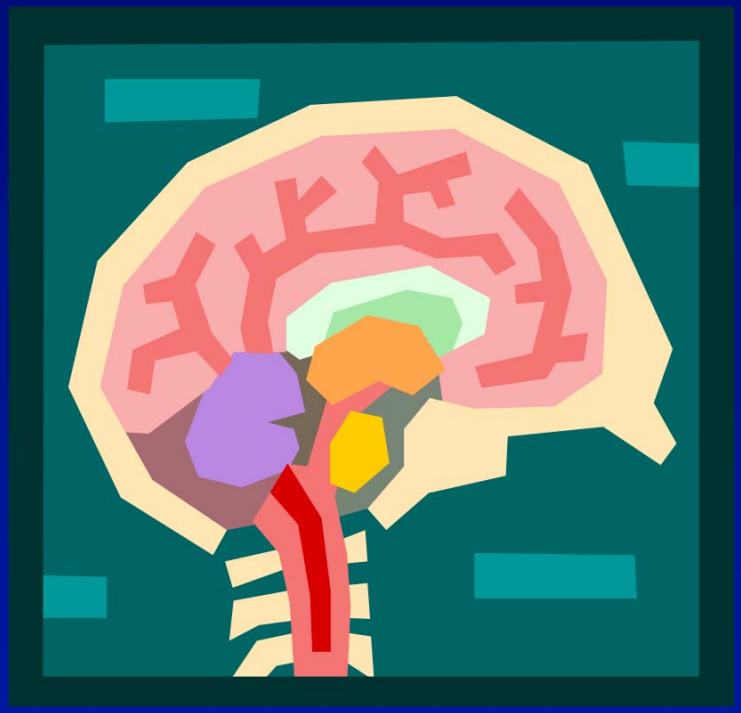
Exposure Limit

- 20 mSv whole body
- No 5 year average



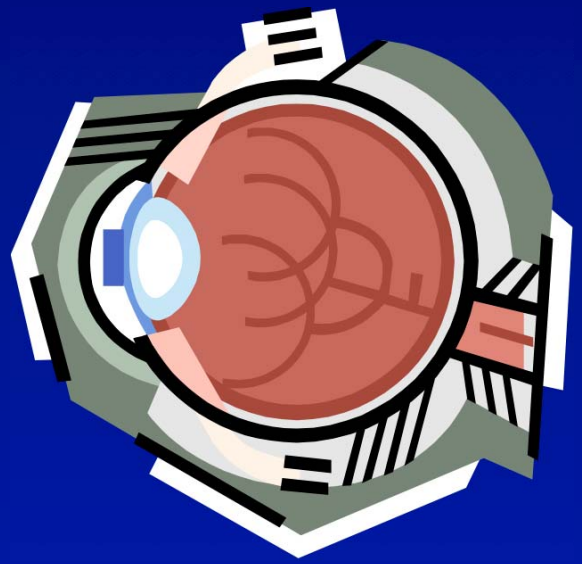
Organ Doses

- Optimisation of doses to organs



Exposure to Eyes

- Reduction of occupational dose to lens of eye



Revision of Roles

- Radiation Protection Expert
- Medical Physics Expert
- Radiation Protection Officer

Greater Justification

- Asymptomatic patients
- Interventional radiology

Also need for more / improved information to patients