

The Medical Exposures Directive



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Medical Exposures Directive

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



Structure of the MED

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

Article 1 : Scope

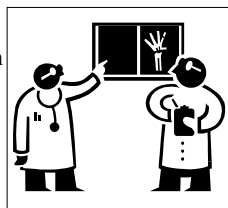
- Diagnosis and treatment
- Occupational health surveillance
- Health screening
- Research
- Medico-legal exposures



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



Royal College of Radiologists

- 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



Article 5 : Responsibilities

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

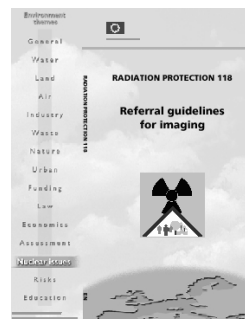


Article 6 : Procedures

- 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/comm/environment/radprot/118/rp-118-en.pdf>

Extract from Referral Guidelines

Condition	Investigation	Indication	Notes
Congenital disorders <i>(for children see Section M)</i>	MRI (B)	Indicated (C)	Definitive exam for all malformations and avoids re-irradiation. 3D CT may be needed for bone anomalies. Sedation usually required for young children. Consider US in neonates.
Cerebrovascular accident (CVA) stroke	CT (D) MRI (B) and NM (B) IS (carefully) (B)	Indicated (C) Specialised investigation (B) Not indicated routinely (C)	CT adequately assesses most areas and shows haemorrhage. MRI and NM more sensitive than CT in early infarctions and for posterior fossa lesions. Exception for (a) those with full recovery in whom causal surgery is contemplated. In an evolving CVA where diagnosis or embolus suspected.
Transient ischaemic attack (TIA) <i>(see also B5)</i>	IS (carefully) (B)	Indicated (B)	If doubt about diagnosis or surgery contemplated. Musty depends on local policy and available expertise. US with Colour Doppler provides functional data about infarction disease. Angiography, MRA and CTA are more sensitive alternatives to show the vessels. MRI and NM can be used to show function.

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



Radiation Protection 116



GUIDELINES ON EDUCATION AND TRAINING IN RADIATION PROTECTION FOR MEDICAL EXPOSURES

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

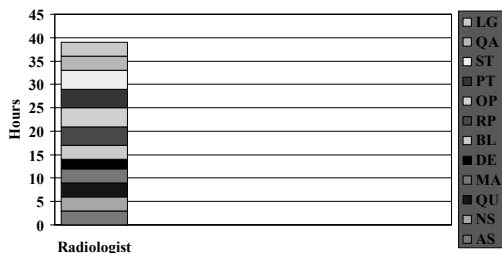


Specific Subject Training

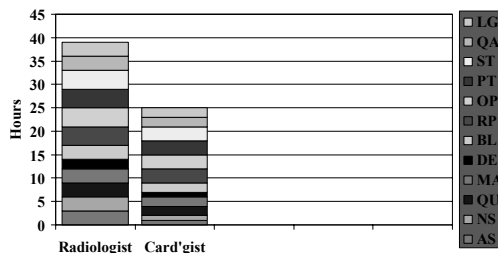
- Atomic structure & x-ray production
- Nuclear structure and radioactivity
- Radiological quantities and units
- Physical characteristics of equipment
- Fundamentals of radiation detection
- Biological effects
- Principles of radiation protection
- Operational radiation protection
- Protection of patients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



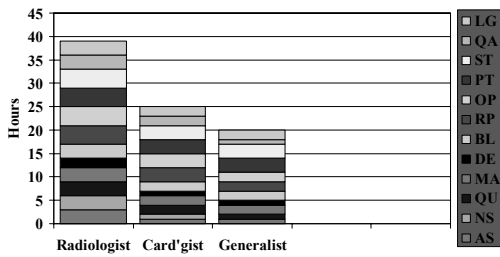
Duration of Training



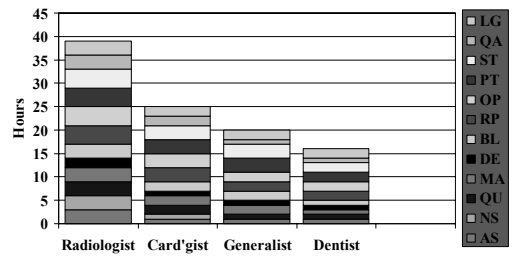
Duration of Training



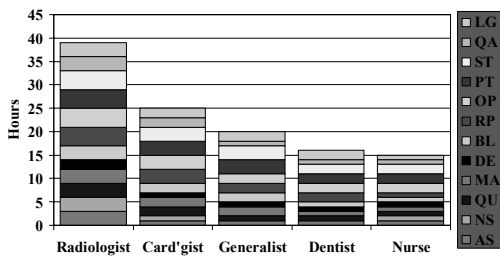
Duration of Training



Duration of Training



Duration of Training



Practical Training

.....adequate theoretical and practical training.....

MED Article 7.1



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



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

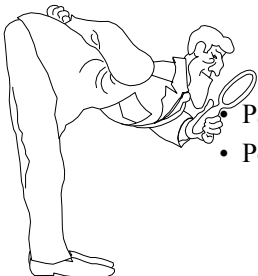


Article 13 : Inspection

- System of inspection for enforcement



Inspection Issues



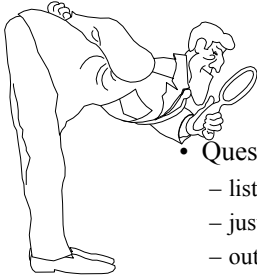
- Patient Journey
- Policy v Procedures
 - what is to be done
 - how is it done
 - who does it

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-English-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?

