UK Health Security Agency

UK Medical Ionising Radiation Regulatory Framework

SIMPLERAD project workshop
10th – 11th December 2023

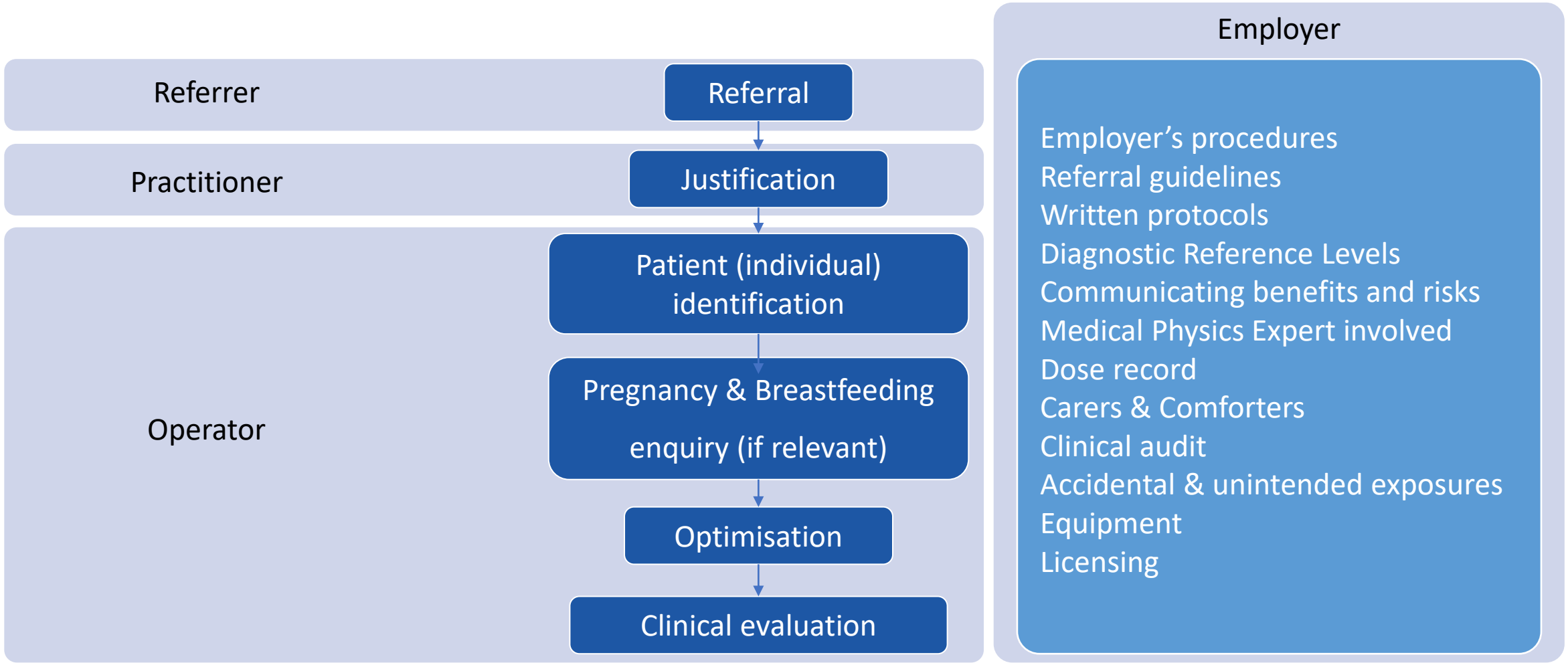
UK legislative framework

Standards	UK legislation	Regulatory area
2013/59/ EURATOM Basic Safety Standards Directive	Ionising Radiations Regulations 2017	Occupational and public exposures
	Ionising Radiation (Medical Exposure) Regulations 2017 IR(ME)R Northern Ireland 2018	Medical exposures and non-medical imaging
	Justification of Practices Involving Ionising Radiation Amendment Regulations 2018	Justification of practices
2001/83/EC	Human Medicines Regulations 2012	Safe use of medicines etc
2001/20/EC	Medicines for Human Use (Clinical Trials) Regulations 2004	Research and clinical trials

Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)

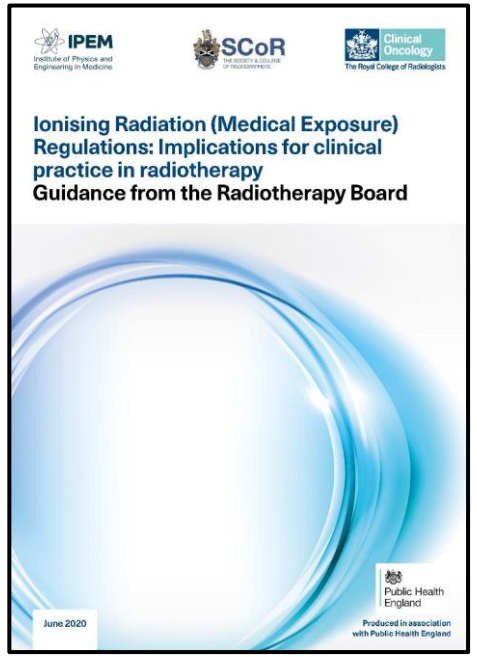
- IR(ME)R is concerned with the protection of individuals undergoing medical exposures and non-medical imaging using medical radiological equipment as part of routine care and research
- Key principles are:
  - justification of individual exposures
  - optimisation
  - adequate training
- Duty holders responsibilities defined:
  - Employer
  - Referrer
  - Practitioner
  - Operator
- Great Britain / Northern Ireland

IR(ME)R in the patient pathway



Treatment verification and dosimetry

IR(ME)R Regulation 12(2) - Optimisation
"In relation to all radiotherapeutic exposures the practitioner must ensure that exposures of target volumes are individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues must be as low as reasonably practicable and consistent with the intended radiotherapeutic purpose of the exposure."



Guidance from the Radiotherapy Board suggests optimisation includes:

- Assessment of the individual patient
- Use of established dosimetry techniques (where available), or
- Use of standard activities where this is consistent with professional guidance

https://www.rcr.ac.uk/about-us/partnership-working-in-clinical-oncology/radiotherapy-board/radiotherapy-board-publications/

IR(ME)R requirement to hold a licence

IR(ME)R Regulation 5

Employer must hold a licence at each radiological installation where radioactive substances will be administered for diagnosis, treatment or research

Practitioner must hold a licence to justify exposures involving the administration of radioactive substances for diagnosis, treatment or research

Licence applications are assessed by an independent expert committee – the Administration of Radioactive Substances Advisory Committee (ARSAC)

IR(ME)R Regulation 11

No person can carry out an exposure involving the administration of radioactive substances unless

- the practitioner and the employer are licenced for that administration
- in the case of an exposure as part of research, the research study has been approved by ethics and ARSAC

ARSAC guidance on treatment verification and dosimetry

- ARSAC recommends that:
  - (a) in cancer treatments with radioactive substances, the absorbed dose to the tumour, and to non-target volumes and tissues, following each administration should be measured and recorded, to permit subsequent optimisation of total doses
  - (b) for treatment of benign conditions or, where direct measurements are impossible, absorbed doses should be calculated or estimated and recorded
- Licence and research approval applications for therapy administrations both in routine clinical practice and research, are therefore expected to specify what dosimetry will be performed, per course, on an individual patient basis.
- Employers should ensure that appropriate resources are available.
- Guidance is reviewed and updated on an annual basis

https://www.gov.uk/government/publications/arsac-notes-for-guidance

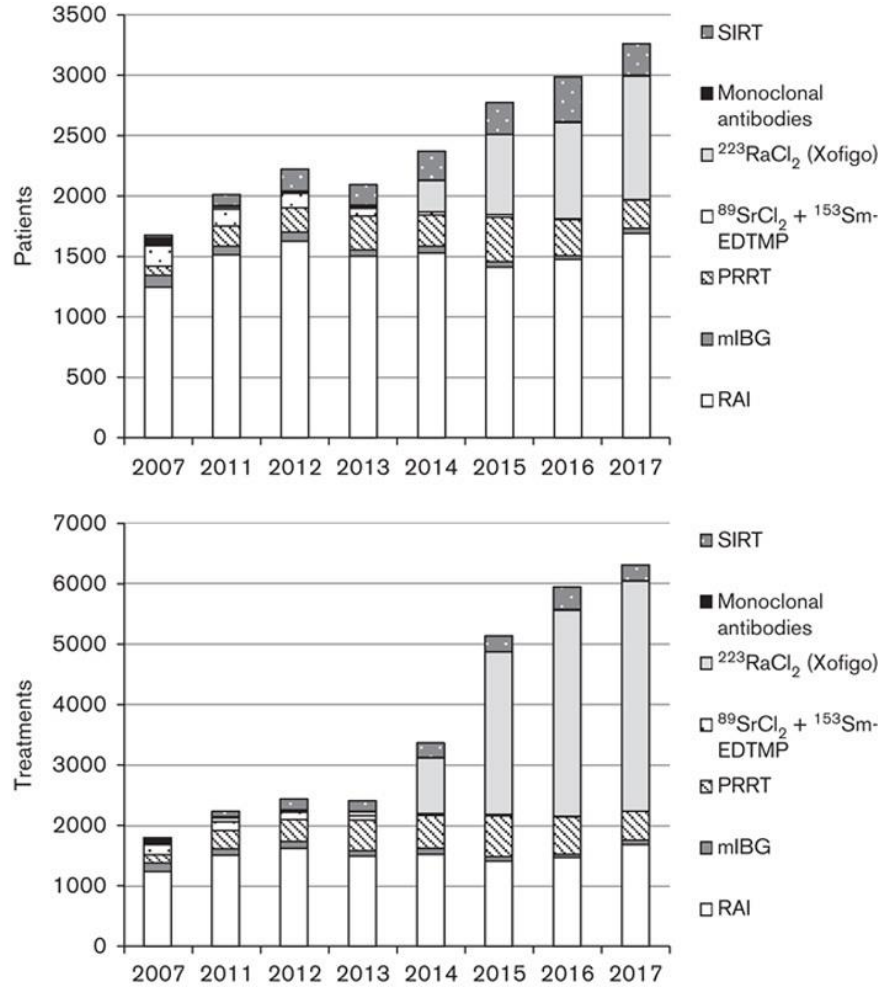
Licence applications

- Employers must include plans for imaging for dosimetry or verification
- Practitioners must include details of their training and local treatment protocols
- How is administered activity calculated?
  - fixed activity
  - uptake based dosimetry
  - weight based or BSA
- Details of method for calculation of dose to Organs at Risk (OaR)
  - established therapy
  - pre-administration calculation
  - post administration measurement
  - references (estimated)

7.	**Unsealed source therapy**		
b.	Please enter procedures requested that are not in the Notes for Guidance. (To apply for more than one procedure copy the block below and complete all question (i) to (xi) for each procedure.)		
i.	Radionuclide	Click here to enter text.	
ii.	Pharmaceutical or chemical form	Click here to enter text.	
iii.	Indication	Click here to enter text.	
iv.	Route	Click here to enter text.	
v.	How is administered activity calculated.	Choose an item.	Click here to enter text.
vi.	Organ(s) at Risk (OaR) (please indicate the most relevant).	Click here to enter text.	
vii.	Maximum dose likely to be received by specified OaR.	Click here to enter text.	
viii.	Details of method for calculation of dose to OaR.	Choose an item.	Click here to enter text.
ix.	Details of any dose limiting measures for the patient used locally (for example, thyroid blocking.)	Click here to enter text.	
x.	Number performed in last 12 months.	Click here to enter text.	
xi.	Predicted number performed in next 12 months.	Click here to enter text.	

Treatment verification and dosimetry

- Within the UK, the practice of routine patient-specific dosimetry for all molecular radiotherapies is not yet common
- Employers generally adopt an approach based on the risk of the exposure / feasibility of dosimetry
- Challenges for patient specific dosimetry:
  - staff resources
  - equipment
  - training
  - Standardisation in dosimetry practice
- Increasing numbers of patients and treatments in the UK



Rojas B et al. *Nucl Med Commun* 2019

Summary

- IR(ME)R implements medical aspects of EURATOM Basic Safety Standard Directive in the UK
- This requires that target volumes are individually planned, treatment delivery is appropriately verified and doses to non-target tissues are ALARP
- In practice, many therapeutic administrations are often prescribed as a fixed or weight-adjusted activity
- Challenges for patient specific dosimetry remain
- UK has a strong and dedicated workforce with a passion and desire to develop this field https://www.idug.org/home

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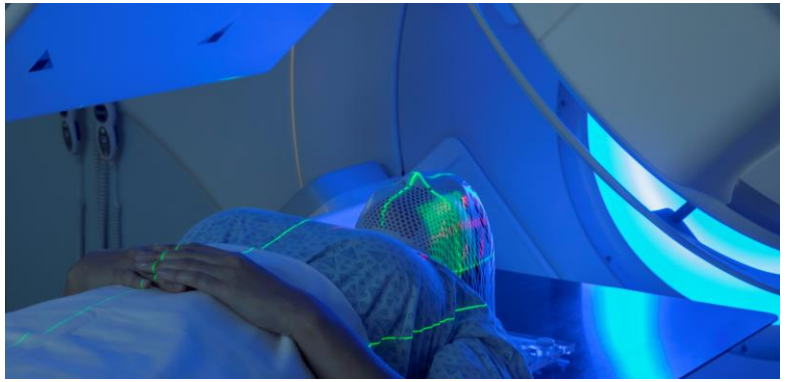
- medicalexposures@ukhsa.gov.uk
- https://www.ukhsa-protectionservices.org.uk/meg



Interrelations among Legal and Regulatory Frameworks

Discussion: 15:05-15:15

10 minutes

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This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0

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Coffee break!

15:15–15:45

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