UK Medical Ionising Radiation Regulatory Framework

SIMPLERAD project workshop
10th – 11th December 2023
UK legislative framework

Standards

- 2013/59/EURATOM Basic Safety Standards Directive
- 2001/83/EC
- 2001/20/EC

UK legislation

- Ionising Radiations Regulations 2017
- Ionising Radiation (Medical Exposure) Regulations 2017
  IR(ME)R Northern Ireland 2018
- Justification of Practices Involving Ionising Radiation Amendment Regulations 2018
- Human Medicines Regulations 2012
- Medicines for Human Use (Clinical Trials) Regulations 2004

Regulatory area

- Occupational and public exposures
- Medical exposures and non-medical imaging
- Justification of practices
- Safe use of medicines etc
- 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

Referrer
- Referral

Practitioner
- Justification
  - Patient (individual) identification
  - Pregnancy & Breastfeeding enquiry (if relevant)
  - Optimisation
    - Clinical evaluation

Operator

Employer
- Employer’s procedures
- Referral guidelines
- Written protocols
- Diagnostic Reference Levels
- Communicating benefits and risks
- Medical Physics Expert involved
- Dose record
- Carers & Comforters
- Clinical audit
- Accidental & unintended exposures
- Equipment
- Licensing
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

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)

### Unsealed source therapy

<table>
<thead>
<tr>
<th>b.</th>
<th>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.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>i</td>
<td>Radionuclide</td>
</tr>
<tr>
<td>ii</td>
<td>Pharmaceutical or chemical form</td>
</tr>
<tr>
<td>iii</td>
<td>Indication</td>
</tr>
<tr>
<td>iv</td>
<td>Route</td>
</tr>
<tr>
<td>v</td>
<td>How is administered activity calculated.</td>
</tr>
<tr>
<td>vi</td>
<td>Organ(s) at Risk (OaR) (please indicate the most relevant).</td>
</tr>
<tr>
<td>vii</td>
<td>Maximum dose likely to be received by specified OaR.</td>
</tr>
<tr>
<td>viii</td>
<td>Details of method for calculation of dose to OaR.</td>
</tr>
<tr>
<td>ix</td>
<td>Details of any dose limiting measures for the patient used locally (for example, thyroid blocking.)</td>
</tr>
<tr>
<td>x</td>
<td>Number performed in last 12 months.</td>
</tr>
<tr>
<td>xi</td>
<td>Predicted number performed in next 12 months.</td>
</tr>
</tbody>
</table>
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
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](https://www.idug.org/home)
• Louise.fraser@ukhsa.gov.uk

• medicalexposures@ukhsa.gov.uk

• https://www.ukhsa-protectionservices.org.uk/meg
Interrelations among Legal and Regulatory Frameworks

Discussion: 15:05-15:15
10 minutes
Coffee break!

15:15–15:45

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.869532.