THE ROYAL COLLEGE OF RADIOLOGISTS

Response to:

Department of Health - *Regulations on medical exposure to ionising radiation*
July 2017

1. Duties of the employer with regard to accidental and unintended exposures
IR(ME)R2018 will expand requirements for reporting of incidents. This will require the Competent Authority to define significant events (in effect as now) but does not require it to define clinically significant accidental or unintended exposures.
1.1 Do you support reporting of significant events under IR(ME)R2018, regardless of whether these result from equipment or procedural failure?

Yes

1.2 Do you agree that the definition of clinically significant exposures should be the responsibility of professional scientific and medical societies rather than the Competent Authority?

Yes – but it must be the professional scientific and medical societies and not the individual. This should be specifically stated and defined in the guidelines.

1.3 Do you support the view that any such exposure should however be considered as a significant event and reported to the Competent Authority?

Yes.

1.4 Do you support the reporting of significant events in radiotherapy where doses are less than intended?

Yes - it is important to always remember that the patient is at the centre of all that we do and tailor our reporting of adverse events accordingly. If a patient's clinical condition deteriorates due to underlying malignancy or comorbidities then a lower dose than intended of radiation is delivered. Reporting of these issues are unlikely to engender learning opportunities in the community so would not need to be reported. This is not related to the quality of the therapy.

2. Duties of the employer with regard to quality assurance programmes for equipment when used in medical exposures
IR(ME)R2018 offers an opportunity to include in one set of Regulations requirements relating to medical exposure (rather than occupational or public exposure) associated with medical radiological equipment, including inventories, surveillance and quality assurance programmes.
2.1 Do you support inclusion of these requirements within IR(ME)R2018?

Yes – in an increasingly cash strapped NHS, there is the temptation for Trusts to fail to invest in new imaging equipment which can be expensive. This can lead to imaging being performed on older cameras which are inherently more unreliable. Additionally with the increasing use of hybrid imaging techniques, it is important that both components of the imaging are evaluated and maintained. Regulating equipment could help highlight these issues.

3. Medical physics experts

The BSSD is more prescriptive about the role of the medical physics expert.

3.1 Do you object to medical physics experts advising employers on compliance?

No, it is appropriate that the MPEs provide specialist advice to their Trusts.

3.2 Do you think the Regulations should require employers to appoint MPEs?

Yes – and to record reasons if advice is not followed

4. Carers and comforters

The BSSD defines medical exposure as including exposures made to carers and comforters and requires that such exposures are justified individually and subject to dose constraints.

4.1 Do you support the inclusion of requirements for carers and comforters within IR(ME)R2018?

Yes, guidance regarding the dose constraints for carers and comforters is appropriate and should be included in the BSSD, however there will be some areas, e.g. radium 223 where absolute constraints would not be appropriate and specialist guidance from the local MPE would be more appropriate.

5. Non-medical imaging

The BSSD has introduced non-medical imaging as a new type of exposure and categorises these exposures as those resulting from the use of medical radiological equipment and those that do not.

5.1 Do you support the inclusion of non-medical imaging using medical radiological equipment within IR(ME)R2018?

Yes

5.2 Do you think dose constraints or dose limits should be applied to such exposures?

Yes – non-medical exposure should only have an upper limit when it applies to a live organism.

6. Licensing for the administration of radioactive substances

IR(ME)R2000 and MARS1978 (and associated amending regulations) will be replaced by IR(ME)R2018. A dual licensing system will be introduced to satisfy more stringent requirements of the BSSD and charges for licences will need to be made on a cost recovery basis.

6.1 Do you agree that charges should not be levied on practitioners who wish to hold a licence?

Yes. If a charge is levied then this could be prohibitive. In the regulatory triage assessment (RTA) it states:

"The new BSSD requires licencing for the administration of radioactive substances for the purposes of diagnosis, treatment or research. The current regulatory system involves Doctors being issued with certificates by Health Ministers following the advice from the Administration of Radioactive Substances Advisory Committee (ARSAC) whose appointed members are mainly specialist doctors. The new requirements will mean the introduction of licences for both Doctors and Employers and a fixed fee. Most applicants will be from the NHS. The BSSD requires that arrangements are in place for the recognition of Medical Physics Experts. DH as the UK Competent Authority has asked a not-for-profit company known as RPA2000 to undertake the recognition of new MPEs from February 2018. Applicants will have to pay a fee to RPA2000 in order to undergo the recognition process."

This contradicts the regulations. Introducing fees for the licensing of individuals is an inappropriate way of the DH taxing doctors and physicists in order to do the job for which they spent many years training to do. The RTA also excludes the NHS in its impact assessment and therefore does not take into account the costs in both fees and time that the NHS will incur in implementing the BSSD.

If we estimate the cost to the NHS based on the RTA, then assuming the higher costs in the first year alone there will be a cost of £1,338,461. The cost to doctors and MPEs in the first year would be £261,000 and £37,050 respectively. The cost in time for the NHS and potential loss of clinical work will also be significant. The lack of acknowledgement of these costs is misleading. The conclusion that this presents a cost saving to the NHS is therefore incorrect.

This should also be extended to research applications, as a fee for this would potentially decrease a department's ability to participate in research and limit the number of research proposals being submitted.

6.2 Do you think licences for employers should be for a fixed period or reviewed only when amendments are sought?

Fixed period e.g. 5 years – or the same period as for practitioners.

6.3 Do you support a single licence for practitioners?

Yes but fees for MPEs and ARSAC are not appropriate. For a large department this could be prohibitive.

Fees for ARSAC would have a significant impact on research, individual consultants and trusts. In particular in Annex 1 it is not clear who is required to pay the fee for research. The size of the fee quoted would mean that many local research projects would not be able to be performed due to the lack of money in many departments to pay for an extra ARSAC application. Research is often about novel agents so would mean a new ARSAC for each new indication.

7. Diagnostic reference levels (DRLs)

The BSSD extends requirements for DRLs but retains the requirement that DRLs should have regard to European DRLs where available

7.1 Do you support extending requirements in IR(ME)R2018 to having regard to National DRLs as well as European values?

Yes, it is particularly important that we tie the UK legally into mirroring European values given that we are currently in the process of leaving the Euratom. This should provide us and the EU with some assurances that our governance will remain comparable.

It is also important to have National DRLs as detailed here https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/national-diagnostic-reference-levels-ndrls by Public Health England.

8. Adequate training

Training requirements for practitioners and operators are listed in Schedule 4.

8.1 Please provide comments on Schedule 4 – amendments and deletions - noting that the intention of the Schedule is not to replace or replicate the detail of established training programmes.

- ***The type-facing in Table 2 is currently inconsistent i.e. Diagnostic Radiology heading in italics and upper/lower lines, Radiotherapy and Nuclear Medicine sections are not and this should be corrected.***

- ***The suggested training components for Diagnostic Radiology and Nuclear Medicine seem reasonable but as these are all included within the core curriculum for Specialty Training in Clinical Radiology and/or Nuclear Medicine, FRCR could be taken/stated as equivalence for those having completed this. The more detailed list is more applicable to non-Radiology, non-Nuclear Medicine trained applicants for licensing e.g. Endocrinologists, Cardiologists etc.***

- ***There are now so many operators including medics who are not radiologists who may also be designated practitioners, we feel there should be more specification regarding the subjects listed in tables 1 and 2 with respect to different types of practitioner/operator.***

- ***There is considerable overlap between topics in each table. The topics for radiologists and radiotherapists are obvious but for instance a surgeon in theatre needs more focused training. This could be done in conjunction with the appropriate specialist bodies.***

- ***Ionic contrast media is rarely used in the UK now.***

Comments on Annex 1

- ***Reg12(4),(4),(d) – is that "receive a diagnostic or therapeutic benefit" correct? If these are research exposures or voluntary will there be any benefit to the participants in people undergoing experimental practice?***

The Royal College of Radiologists
July 2017