The Institute of Physics and Engineering in Medicine (IPEM) response to the Department of Health consultation on Regulations on medical exposure to ionising radiation

- IPEM is a professional association and Learned Society with 4,500 members who are physicists, engineers and technologists working with applications of physics and engineering applied to medicine and biology. Our members work in hospitals, academia and industry, and IPEM has a unique role in linking the three areas.
- As a charity, IPEM's aim is to advance the application of physics and engineering to medicine for the public benefit and to advance public education in this field. We do so by supporting and publishing research, and supporting the dissemination of knowledge and innovation through project funding and scientific meetings; and by setting standards for education, training and continuing professional development for healthcare scientists and clinical engineers.
- In preparing this response, we have consulted with members of IPEM's Special Interest Groups (SIGs): Radiation Protection SIG, Radiotherapy SIG, Nuclear Medicine SIG, Diagnostic Radiology SIG, together with the Radiotherapy Professional Standards Group and the Director of the Science, Research and Innovation Council.

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. It is not always clear whether a radiation incident has occurred due to equipment or procedural (operator) error. It should also be noted that some 'double' reporting (under IRR and IRMER) will still occur for accidental exposures in radiotherapy where high activity sources are in use and both staff and patients may be exposed.

Having one reporting mechanism removes the difficulty in deciding which enforcing authority the radiation incident should be reported to in such a case. A single submission portal to all the relevant bodies (HSE, CQC, MHRA) would be useful to centres.

Definition of what is significant should be clearly stated and should ensure that applies appropriately across all ionising radiation modalities.

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. Professional scientific and medical societies are best placed to define and provide examples of what a clinically significant exposure is. The definition and examples are likely to change over time as practices change.

The recent MGTI guidance was a good example of this process, and could readily be applied to IRMER 2018 with some amendments, e.g. including under-doses. Clinical significance should be assessed locally for the individual involved (with national guidance as appropriate).

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?

A clinically significant exposure should be considered as a significant exposure and reported to the Enforcing Authority in order to allow the community to learn from the event and to give a focus for employers to review their responsibilities.

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

Under-doses in radiotherapy and radionuclide therapy should be reported, but only where they are clinically significant across the total treatment course. Most under-doses or missed fractions are correctable and therefore not significant, so this should be reflected in any guidance.

Under-doses in radionuclide therapy should be reported.

Consideration should be given to significant doses less than intended for diagnostic exposures if they do not provide the required diagnostic outcome given that it would highlight failings of medical exposure procedures.

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. These requirements sit more naturally under medical exposures than under occupational exposures and they are well suited to the responsibilities of the MPE. Surveillance and quality assurance programmes are aligned with the role of the medical physics expert. Areas of overlap with occupational exposures are easily dealt with. For example, acceptance testing can be sub-divided into: critical examination of radiation safety features (under IRR 2017); acceptance testing against the manufacturer's specification (under IR(ME)R 2018); and commissioning to provide baselines for future testing (under IR(ME)R 2018). Surveillance of medical radiological installations also has two facets: patient dose surveys undertaken by the MPE under IR(ME)R 2018, and environmental and staff dose surveys undertaken by the RPA under IRR 2017.

Clarification is required on point 15.3a on whether prior testing refers to safety aspects (critical exam) or performance specification (commissioning).

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 important that Medical Physics Experts have a role in advising employers about compliance with medical exposure requirements. This was not clear under IR(ME)R 2000 and has led to advice being sought from other professionals (e.g. RPAs), which may not always be optimal. Clarity on this issue is welcome.

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

Yes. A formal appointment clarifies the role that the MPE needs to fulfil. This is beneficial to the employer, the MPE and other duty holders.

Clarification should be given however on whether this could be individual or group (corporate) MPEs. Given that MPEs act rather than advise (RPA/RWA), it is important that there are clear lines of responsibility in ensuring medical exposure compliance. The professional societies should issue guidance on the appropriate numbers of MPEs in a given setting.

Additional comments on the role of the medical physics expert

Regulation 14(2)(c)

In view of the arguments below, we would suggest the alternative wording "be involved in standardised therapeutic nuclear medicine practices, and in practices where high doses might occur, such as in diagnostic nuclear medicine, interventional radiology and computed tomography".

Background

BSSD article 57 says "in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in point (c) of Article 61(1), a medical physics expert shall be involved". Article 61(1) says "which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy"

Our understanding of this clause is that an MPE must be involved in standardised therapeutic nuclear medicine practices, and in practices where high doses might occur, such as in diagnostic nuclear medicine, interventional radiology and CT.

Our understanding of regulation 14(2)(c) is that an MPE must be involved in standardised therapeutic nuclear medicine practices, diagnostic nuclear medicine practices and high dose interventional radiology and high dose computed tomography.

In our opinion the transposition has introduced a subtle change in meaning. A consequence is that an employer may be required to establish what is meant by, for example, high dose CT, a decision which may be outside their area of competence. Another consequence is that

employers might involve MPEs to a lesser degree than they need on the grounds of cost. For example, an MPE may only be involved as appropriate in “low dose interventional radiology” or “low dose CT”. For example, coronary CT angiography can be carried out at doses between 1 mSv and 20 mSv, depending on the clinical indication and the patient’s heart rate. If 1 mSv were to be considered low dose, an employer generally carrying out exposures at this dose level might consider involving the MPE “as appropriate” although there is a potential for high doses because of the nature of the equipment and technique being used (the dose can change easily, for example if the practitioner changes).

In our opinion the regulation is much easier to implement if the employer is not forced to define “high dose procedures” but selects the degree of involvement of the MPE according to the potential for high doses. There is then still scope for the employer to involve the MPE “as appropriate” if there is no potential for high doses to the patient (e.g. because of the nature of the equipment being used).

Regulation 14(2)(d)

The phrase “for consultation…concerning the exposures, as required” is copied from IR(ME)R 2000 and is probably now superfluous in light of schedule 3.

Schedule 3, 1

We would request that article 83, clause 2 is included in its entirety in Schedule 3.

Please note that automatic numbering has failed.

Background

Imaging

The introductory sentence of article 83, clause 2 of the BSSD is missing from this schedule. It states

“Member States shall ensure that depending on the medical radiological practice, the medical physics expert takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following:”

Nowhere else in the draft regulations is it stated who is responsible for dosimetry. The directive gives a clear direction that it should be the medical physics expert. In regulation 14(2)(d) the MPE is “involved …for consultation on optimisation, including patient dosimetry”. However this clause applies only to “other radiological practices”, and being consulted on patient dosimetry is not the same as being responsible for dosimetry.

It could be argued that dosimetry is the responsibility of the medical physicist, but the medical physicist is not a duty holder under IRMER except as an operator. In large centres with medical physics teams, the medical physics experts will be the senior physicists in the team and it is appropriate that they take responsibility for dosimetry. Small centres will not have medical physicists except the medical physics expert appointed by the employer.

Therefore the most suitable person to be responsible for dosimetry is the medical physics expert in all cases.

Note that there is no mention of patient dosimetry in the list of matters other than the application and use of DRLs in optimisation. Absolute calibration of the equipment through physical measurement underpins all patient dosimetry; DRLs are meaningless if this first step is not carried out competently. Note also that DRLs have little relevance in radiotherapy. This means that there is nothing in schedule 3 that describes the most important function of the MPE in the practice that carries the highest radiological risks to patients.

Radiotherapy

In radiotherapy, safety of patients is ensured by accurate dosimetry, as recognised by Article 83 of the BSSD, which requires MPEs to:
"take responsibility for dosimetry, including physical measurements for the evaluation of the dose delivered to the patient and other individuals subject to medical exposure."

Although the other items in Article 83 have been reproduced verbatim in Schedule 3 of IRMER 2018, this item has been omitted, presumably because it is felt to be implied elsewhere. While the second point in article 83(1) regarding giving advice on medical radiological equipment can be adequately argued to be covered by other points in Schedule 3, accurate dosimetry cannot. **This represents a major issue for radiotherapy services around the country and we strongly urge that an additional point is added to the list in Schedule 3 to include the quoted sentence above.**

The importance of dosimetry is further emphasises by the need for MPEs to demonstrate competence in "dosimetry and dose calculation for medical exposures" (MPE recognition scheme statement, DoH July 2017), alongside other items which map to the list in Schedule 3. The responsibility for absolute dosimetry goes above and beyond any quality control tests performed by physics operators, and is essential to ensure safe and effective practice.

In clause (j) the term "radiation protection expert" is used, instead of radiation protection adviser and radiation waste adviser.

Triage assessment

We understand that the voluntary scheme referred in the annex "Recognition of Medical Physics Experts" has changed. It is not a grandfathering scheme, but a list of existing MPE appointed under IR(ME)R 2000. These MPEs will need to transition onto the MPE register at some unspecified cost to them which is not considered in the triage assessment.

An application fee of £300 has been quoted for MPE recognition. This is consistent with applications for RPA and RWA recognition. However it should be noted that an HCPC registered medical physicist will have already paid £210 or £300 for a certificate of attainment, and £63 for HCPC registration (at 2017 prices). This means that an HCPC-registered medical physicist pays in total £573 or £663 to become accredited as an MPE. This puts HCPC-registered medical physicists at a financial disadvantage compared to MPEs outside hospital-based healthcare. The Department of Health should consider a sliding scale for MPE accreditation which reflects that it will be more straightforward to assess MPEs who have already undergone a formal assessment of core competencies.

An annual maintenance fee of £30 is also quoted. This is inconsistent with the approach taken for RPAs and RWAs. The one-off fee of £300 should cover this charge, which amounts to £150 in a five year period and seems disproportionate to the amount of work involved (e.g. it could be an automated web-based process).

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, comforters and carers fall within the medical exposure area, and are typically given guidance by MPEs. They should therefore sit within IRMER rather than IRR as they were previously. Exposure should be risk assessed within the context of the justification of the exposure.

Furthermore, we believe that the definition of what constitutes a “carer and comforter” could be more clearly defined in the regulations.

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, however this could be better defined (e.g. similar to Annex 5 in the BSSD) and it should be clear that this only applies to human exposure.

The definitions of medical exposure, non-medical imaging exposure, medical radiological and medical radiological installation do not currently work well together. For example:

- The definition of “medical exposure” is confusing as there are too many subordinate clauses: for example “as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research “ suggests that the exposure is incurred by carers and comforters in medical or biomedical research. Would this work better as a list?
- “medical radiological” the use of “and”, “or”, and commas is confusing. A comma-separated list might be clearer?
- The definition for “non-medical imaging exposure” also applies to medical exposures of volunteers in medical or biomedical research where no medical benefit is expected.

Furthermore, the terms are not always used consistently, with some regulations applying to medical exposures when they probably apply to both medical and non-medical imaging exposures.

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

For non-medical imaging of individuals dose constraints should be retained for research exposures, but not seen as an upper limit, within the usual context of justification and optimisation. These will often be set at the same level as the DRL for an equivalent medical exposure.

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?

This seems reasonable given there is no charge to be a radiotherapy practitioner and it may discourage individuals from becoming licensed in these roles. However there is some potential disparity if there is a charge levied to act as an MPE.

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

These should be reviewed only when significant amendments are sought, to match EPR (and there should be a definition of ‘significant amendments’). However, we do not support an annual charge irrespective of any changes.

To stop overworking/overstretching of practitioners and the possibility of 'corporate' practitioners should there be a requirement for them to spend so many hours at particular sites, or a limit to the number of sites that they can work at.

6.3 Do you support a single licence for practitioners?

Yes. There should be sufficient detail in the licenses to compare ARSAC procedures in the practitioner and employer licenses to ensure that the appropriate training, staffing levels and provision of equipment are in place for each procedure.

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 more meaningful for one country to have regard to its national DRLs first and then to the European ones. If the national DRLs are lower, they are a better optimisation tool than

the European ones. If the national DRLs are higher, they provide an impetus to the radiological community to change their practice across the board as only such a change can bring national DRLs in line with European ones.

Additional comments on DRLs

Schedule 2, 7(f)

It would be useful to change “these are expected not to be exceeded for standard procedures” to “these are expected not to be exceeded for standard procedures and standard patients” to make it clear that DRLs are not to be used for individual patients. This reduces the potential for practices to be adopted which lead to detrimental consequences to patient dose and image quality.

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.

Diagnostic Radiology

The amendments / deletions made have brought the syllabus up-to-date. The following additional changes are suggested:-

Diagnostic radiology “specialised techniques” might now be better named “imaging techniques” and include radiography, fluoroscopy, mammography, tomosynthesis and CT. A new section called “specialised imaging techniques” can then include vascular imaging and interventional procedures (note that both these clinical procedures are now carried out with fluoroscopy or CT).

Image processing should be added to “fundamentals of image acquisition etc.”

Radiotherapy

The schedule should be updated to reflect current practice and the wording simplified.
In particular:

- General aspects could just list: Production of ionising radiation, use of radiotherapy for malignant and benign disease, external beam radiotherapy and brachytherapy.
- Radiobiology could be simplified to: fractionation, dose rate, individual sensitivity.
- Practical aspects of radiotherapy should add verification imaging and QA/QC.
- Radiation protection specific to radiotherapy is confusing. Side effects and toxicity could be merged. Better to say dose verification, and efficacy and toxicity (previously assessment of dose response).

Radiotherapy	
General	*Production of ionising radiations* *Use of radiotherapy for malignant and benign disease* *Use of external beam radiotherapy* *Use of brachytherapy*
Radiobiological Aspects for Radiotherapy	*Fractionation* *Dose rate* *Individual sensitivity*
Practical Aspects for Radiotherapy	*Equipment* *Treatment planning* *Verification imaging* *Quality assurance and quality control*
Radiation Protection Specific to Radiotherapy	*Dose verification* *Efficacy and toxicity (early and late)*

Nuclear Medicine

The following topics should be added:

- DRLs
- Image optimisation
- Radionuclide and Radiopharmaceutical production
- PET

Other comments on the draft IR(ME)R 2018 regulations

Regulation 2

Are both “accidental” and “unintended” required in the context of a medical exposure? The terms are always cited together. In “accidental exposure” the relevance of “other than emergency workers” is unclear.

Regulation 2(1)

The definition of Practitioner is too restrictive and out-dated, and would be better defined as: “practitioner” means a health care professional who is on an accredited register, recognised either directly or through the subordinate regulatory bodies, by the Professional Standards

Authority for Health & Social Care (PSA), as established by section 222 of The Health and Social Care Act 2012, who is entitled in accordance with the employer's procedures to take responsibility for an individual exposure;

The same applies to Referrers. This would be better changed from 'Statutorily Registered' personnel to registered under a PSA accredited register.

The current requirement (under both IR(ME)R 2000, and draft IR(M)ER 2018) for Practitioners to be HCPC registered is causing discrimination within the dosimetrist and technologist communities, specifically for those people that have followed the Clinical Technologist career path, rather than those from a Radiographer background. Whilst the Technologists are ineligible for HCPC registration (without acquiring additional educational qualification at considerable cost, both in terms of time and money, and yet which will not contribute to their professional integrity), they are eligible for inclusion on an Accredited Register overseen by the PSA. PSA is also responsible for overseeing the HCPC: The requirement for HCPC registration seems to be to solely to verify professional conduct, and as such the professional conduct of any individual who is either on an accredited register, administered by a PSA-accredited organisation, or whose competence is recognised by of one of the named regulatory bodies, will be subject to a similar level of scrutiny.

Assessment – This definition states a 'prior' determination, however in 8(4)(c) the term 'assessment' can only occur following the event.

Child - Why is the definition of 'child' different for Scotland to England/Wales? For assessment of paediatric exposures, the community tends to use age 16 as the cut-off for paediatric exposures. It is noted that this is the same as current IRMER2000 however the SIG feel this could be altered to reflect the current practice of the community.

Equipment – Should the definition state 'or' rather than 'and' between (a) and (b)?

Interventional radiology – could we have clarification as to where interventional therapeutic procedures fit in?

Non-medical imaging exposure – Should this be clarified further to state does not include research studies or screening but does cover medico-legal exposures? Important for research and screening as usually these exposures will not bring a health benefit to the individual. This may be useful to be clarified in guidance.

Unintended exposure – What is 'significantly different'? It is also noted that with the regulations, there is 'significant event' and 'clinically significant'. It would be useful to harmonise these terms and have good clear guidance on what they mean.

Regulation 4

It is noted that a facility with nuclear medicine must hold a licence under IRR17 for the administration of radiopharmaceuticals but also hold a licence under IRMER for the

administration of radiopharmaceuticals. It is suggested that these should have different names as this will cause confusion for Employers, RPAs and MPEs.

Regulation 6

This regulation places a duty on the employer to have written procedures, and to ensure that the procedures are complied with by the referrer, practitioner and operator, but there is no general duty placed on the employer to comply with their written procedures. There are some regulations which explicitly place duties on the employer that link nicely with the written procedures, e.g. Regulation 6(5)(c) for DRLs. However there are other regulations which identify what the procedure must cover, but not whose duty it is to comply with it. For example, regulation 12(4)(b) says that "the employer's procedures must provide that the individuals concerned are informed in advance about the risks of the exposure". Whose responsibility is it to ensure this happens? It is not the referrer's, the practitioner's or the operator's as information about the study is given to the participants at the time of consent by the principal investigator or a member of the research team. The employer could argue that in order to comply with this clause it is sufficient to write down that patients are informed of the risks (but not actually ensure that it happens). An Enforcing Authority could argue that there is a duty on the practitioner and operator to check that the patient has been informed about the risks before carrying out the exposure, but in practice the practitioner and operator have no access or control over the consent process.

Regulation 6(3)

Some consideration should be given to having a requirement or some guidance that Referrers are trained. This was not in IRMER2000 but would it be useful to make clear the requirement for employers to ensure that referrers are competent? It is noted that from the CQC 2015 review that 34% of MGTI were from referrers. If the regulation cannot be changed, it is suggested that this should be clear in guidance.

Regulation 6(5)(c)

This implies that DRLs should be available for all radiodiagnostic examinations however the definition of DRLs states typical examinations. Should this line include a 'where appropriate'?

Regulation 6(6)

This appears to suggest that a dose constraint should be established for all exposures. The DRSIG wish to highlight that effective dose does not have a degree of particular accuracy. Should this line include a 'where relevant' or specify only for research exposures or comforters and carers?

Regulation 6(6)

Should this clause be sub-clause (iii) under 6(5)(d) ? Having set the dose constraint for comforters and carers, should there be a duty on someone to use it?

Regulation 8(1)

Guidance currently states that the Employer may choose not to inform patient if there is a good reason not to do so but this decision must be recorded. This reg seems to state that the patient must be informed regardless. Also Schedule 2, 7(l). There could be envisaged a situation where a patient cannot comprehend an explanation of unintended exposure and they have no representative. This regulation should allow for a clinical decision to be made in cases where it is felt the information cannot be interpreted or would cause more harm than good, provided there is a written record of the justification of this.

Regulation 11(1)(d)

Ethics committees approve research studies, not exposures. Alternative wording: “in the case of an exposure as referred to in regulation 3(c), it is part of a research study approved by an ethics committee.”

Regulation 11(1)(f)

This regulation seems to make it a legal requirement to ask every female with childbearing potential if they are pregnant regardless of the exposure. Should this not include a clause 'where appropriate' or 'for exposures of pelvic / abdominal area' or 'where MPE has determined potential foetal exposure is significant'?

Regulation 12(1)

In IRMER2000, this regulation just says “except radiotherapeutic procedures”, and using the phrase “except those further to radiotherapeutic procedures” will cause confusion. It could imply imaging as a follow-up after radiotherapy. We suggest keeping the simple form in IRMER2000, or using “except those relating to radiotherapeutic exposures” instead.

Regulation 14(2)

What is the definition or difference between 'closely involved' and 'involved'? What is the definition of 'high dose'?

Is it the responsibility of the Employer to consult the appointed MPE on Schedule 3 matters or the responsibility of the MPE to proactively be involved on these matters?

Why have high does interventional and high dose CT been specified? Could these not be replaced with ‘high dose radiodiagnostic examinations’.

Regulation 15(5)

This and 16(3) appear to say the same thing but 16(3) only says interventional, whereas 15(5) also includes CT

Regulation 16(6)

This also appears to be a general statement saying what is already covered in 15(5), 16(3) & 16(5)

Regulation 16(6b)

Use of the word “examination” does not include radiotherapy, suggest “exposure” to cover both aspects, or “examination or treatment”.

Schedule 3 (1) (j)

“Radiation protection expert” should be changed to “Radiation Protection Adviser” to match UK legislation.

1(d), is installation design this not the role of the RPA? Should it not state something like 'with regard to patient exposure'?

1(e) what does ‘surveillance’ mean?

Should dosimetry not be included within this schedule. The list is copied from BSSD article 83 but omits 'dosimetry, including physical measurements for evaluation of the dose delivered to the patient'