Department of Health

Response to the Consultation on the draft Ionising Radiation (Medical Exposure) Regulations 2018

Transposing European Council Directive 2013/59/Euratom (Medical Exposures)

Prepared by Emergency Preparedness and Health Protection Policy Directorate

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Introduction

In July 2017 the Department of Health (DH) consulted on proposals for draft Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2018 to transpose and implement requirements of the European Council Directive 2013/59/Euratom with regard to medical exposures. The aim of the Directive is to update and consolidate five existing directives and one Commission recommendation relating to radiation protection into one Basic Safety Standards Directive (BSSD). The documentation associated with the public consultation on the draft IR(ME)R 2018 can be found on the DH website:

https://www.gov.uk/government/consultations/regulations-on-medical-exposure-to-ionising-radiation

The consultation ran from 13 July to 31 July 2017 and the questionnaire contained 15 substantive questions on the draft IR(ME)R 2018 regulations. Given the diversity of views anticipated, it was thought that a mixture of closed and open questions would provide the best way for all views to be expressed. Respondents were also provided with a free text space to explain their answers to each question.

We received 129 consultation responses through the online consultation questionnaire, a further 10 consultation responses were received by email, as well as additional comments which were outside of the scope of the consultation. We received feedback from both organisations (59%) and individual respondents (41%) from across the UK, with 58% of respondents based in England. The percentage based in Scotland, Wales and Northern Ireland were 15%, 3% and 2% respectively and 7% of respondents answered 'other' to this question, of which a majority were organisations with a UK-wide remit, whereas 16% did not respond to this question.

A number of key stakeholder organisations responded to the consultation, including The Royal College of Radiologists, the Royal College of Physicians, Institute of Physics and Engineering in Medicine (IPEM), The Society and College of Radiographers, British Institute of Radiology, the Society for Radiological Protection, British Nuclear Medicine Society and dental and chiropractic organisations.

All feedback received was read and logged. The following sections provide a short analysis of responses to closed questions and outline the major themes identified among the free text comments. Where the responses received have prompted revisions to the Regulations, such changes are explained. A brief summary of the range of additional comments received, which were outside of the scope of the consultation, is also included.

1. Duties of the employer with regard to accidental and unintended exposures

IR(ME)R 2018 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. The consultation invited input into three questions related to this topic:

1.1 Do you support reporting of significant events under IR(ME)R 2018, regardless of whether these result from equipment or procedural failure?

Response option	Percent
Yes	**94.3**
No	2.9
Don’t know	2.2
Not Answered	0.7

Table 1: Support for reporting of significant events under IR(ME)R 2018

79 relevant further comments were received, of which 78 were deemed relevant. The overall themes of the comments are summarised as follows:

Themes

- Reporting culture is important for learning and prevention
- Need to be explicit about what needs to be reported and where
- Clearer definitions of "accidental exposure" and "significant event" are required

Just over 94% of all respondents agreed with reporting of significant events under IR(ME)R 2018, citing reasons such as a strong reporting culture being important to enable learning from experience and implementation of preventative measures.

Comments from respondents focused on the need for clarity on the requirement in IR(ME)R 2018 in relation to that in Ionising Radiations Regulations (IRR) 2017 to avoid duplicate reporting to Health and Safety Executive (HSE) when the event is due to equipment failure. Concern regarding overlap was the most common reason given for those who responded 'no' or 'don’t know' to the question. Other comments focussed on the need to define "significant events" and "accidental exposure".

As both equipment and procedural failures expose individuals undergoing exposures using medical radiological equipment, DH and HSE officials agree that this requirement should be included in IR(ME)R 2018. Accompanying guidance will also address the above themes raised in relation to the meaning of certain terms.

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?

Response option	Percent
Yes	**64.8**
No	23.0
Don’t know	11.5
Not Answered	0.7

Table 2: Should the definition of "clinically significant" be the responsibility of professional societies?

82 further comments were received, of which 80 were deemed relevant. The overall themes of the comments are summarised as follows:

Themes

- A collaborative approach would be best
- The definition should be endorsed by the competent authority and included in guidance

Almost 65% of respondents agreed that the definition of “clinically significant” exposures should be the responsibility of scientific and medical societies. Almost all comments suggested that professional society stakeholders and the competent authority should be involved in the agreement process. Several suggested a multi-disciplinary working group should be set up as an appropriate forum to do this, with endorsement of the final definition by the competent authority. However, many respondents showed concern over the limited timeframe to come to such an agreement, as it is likely there would be a multitude of conflicting views.

Some respondents noted that DH published 'Guidance on investigation and notification of medical exposures much greater than intended' in January 2017, and suggested this should be used in IR(ME)R 2018. However, these Regulations deliberately go beyond the definition of much greater than intended, to include exposures in which doses are less than intended (see question 1.4 below). The definition of “clinically significant” will therefore be left for professional scientific and medical societies to determine, but with oversight by the Department and, if timings permit, can be included in future guidance.

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?

Response option	Percent
Yes	**79.9**
No	7.9
Don’t know	11.5
Not Answered	0.7

Table 3: Should any clinically significant exposure be considered as a significant event and reported to the Competent Authority?

58 further comments were received, of which 57 were deemed relevant. The overall themes of the comments are summarised as follows:

Themes

- Clearer definition of “significant event” is required
- Reporting enables learning from such events
- The resultant increase in reporting would be burdensome

Almost 80% of respondents agreed with any significant event being reported to the competent authority. There was a strong emphasis on the need to learn from such events and to monitor trends nationally. Of those who responded 'no' and provided comments, the reasons given can be broadly categorised as either feeling that this level of reporting would be too burdensome, due to limited resources, and could result in underreporting; or that professionals should be trusted to use their judgement in deciding what to report.

A number of respondents found the wording of the question ambiguous and thought that if this lack of clarity were to be carried over into the Regulations, it would cause confusion. However, the wording regarding reporting of accidental or unintended exposures in Regulation 8(4) on this matter is clear. As this is a requirement of the BSSD, this requirement will remain the IR(ME)R 2018 and what is meant by "significant" will be picked up when drafting the guidance.

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

Response option	Percent
Yes	**76.3**
No	5.8
Don’t know	16.6
Not Answered	1.4

Table 4: Support for reporting of significant events where doses are less than intended

78 further comments were received, of which 71 were deemed relevant. The overall themes of the comments are summarised as follows:

Themes

- Systemic failures such as equipment or staff error could be highlighted
- The clinical impact on the patient should be considered in deciding what to report

Just over 76% of respondents supported the requirement to report significant events in radiotherapy where doses are less than intended. Many of those who responded 'don’t know' said they didn’t feel they were able to answer as they were not in the field of radiotherapy.

A number of comments focussed on patient outcomes and expressed the opinion that there should be no requirement to report an exposure in which the dose is less than intended, provided it is correctable or not clinically significant. However, many felt that all incidents in which doses are less than intended could have an impact on treatment and so should be reported, noting that reporting could be useful to see patterns and uncover systemic failures.

Reporting of significant events to the enforcing authority, including those in which doses are less than intended, will therefore be included in IR(ME)R 2018, with appropriate guidance provided on the meaning of the term “significant”.

2. Duties of the employer with regard to quality assurance (QA) programmes for equipment when used in medical exposures

IR(ME)R 2018 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. The following question looked into this:

2.1 Do you support inclusion of these requirements within IR(ME)R 2018?

Response option	Percent
Yes	**87.8**
No	5.8
Don't know	5.8
Not Answered	0.7

Table 5: Support for inclusion of QA for medical radiological equipment under IR(ME)R 2018

57 further comments were received, of which 52 were deemed relevant. The overall themes of the comments are summarised as follows:

Themes

- Streamlining of the current system would be welcomed
- Burdensome dual-regulation: these areas appear in the draft IRR17
- There is potential for cross-over between the Medical Physics Expert (MPE) and Radiation Protection Advisor (RPA) roles

A large majority of respondents (87.8%) agreed with the inclusion of quality assurance programmes for equipment when used in medical exposures. It was noted that this fits more "naturally" under IR(ME)R 2018, and is more suitably aligned with the MPE role. One respondent commented that "we strongly support this as it reflects how we work in practice. It will simplify roles and responsibilities."

Of note within the explanatory comments was the need to avoid duplication with IRR17 and one respondent expressed concern that lack of clarity over the enforcing authority could result in confusion regarding what constitutes compliance. A number of respondents who answered 'yes' to this question emphasised that the corresponding requirements should be removed from the draft IRR17. Some commenters thought that areas of overlap with occupational exposures are easily dealt with, for example, through sub-division of acceptance testing and surveillance of medical radiological installations, according to whether they sit under IRR17 or IR(ME)R 2018.

A number of comments from stakeholders focussed on resource strain and a lack of expertise among inspectors for QA of equipment. This view was not echoed by most stakeholders, who seemed positive about the inclusion of this requirement in IR(ME)R 2018. Further to this, discussions with regulators in England have indicated that they would not expect this change to significantly add to the burden of their current work. Public Health England (PHE) has a pool of expertise which would be made available to inspectorates across the devolved administration which would mitigate the issue of capability.

DH is therefore of the view that requirements relating to QA of medical radiological equipment, should therefore be covered in IR(ME)R 2018. Collaboration and discussion with HSE and the devolved administrations on this matter has resulted in the removal of relevant requirements from the legislative texts to prevent overlap between IRMER and IRR. This issue will also be covered in guidance.

3. Medical physics experts

The BSSD is more prescriptive about the role of the medical physics expert (MPE). Two questions focussed on this topic in the consultation:

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

Response option	Percent
Yes	6.5
No	**88.5**
Don't know	5.0
Not Answered	0

Table 6: Should MPEs advise employers on compliance?

75 further comments were received, of which 74 were deemed relevant. The overall themes of comments are summarised as follows:

Themes

- The MPE is more knowledgeable than the employer so advising them makes sense
- The requirement to comply must ultimately remain with the employer
- Guidance would be helpful to outline how this requirement should operate in practice
- Terms such as "optimisation" and "closely involved" should be defined

The majority of all respondents (88.5%) agreed with our proposal and many comments noted that this reflects current practice. There was some concern over the practicalities of how this would work, particularly around the scope of the MPE role in relation to others, such as the RPA, and that the employer must be held responsible for compliance not the MPE. These themes, in addition to clarity of certain terms can be dealt with in guidance.

Several comments raised other aspects of the scope of the role of the MPE, for example that the Regulations should explicitly state that MPEs are responsible for dosimetry in addition to other responsibilities. There is a requirement in the Regulations for MPEs to give advice on dosimetry in Regulation 14(2)(e) and further detail, if required, can be included in guidance.

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

Response option	Percent
Yes	**90.7**
No	4.3
Don’t know	4.3
Not Answered	0.7

Table 7: Should employers ne required to appoint MPEs?

72 further relevant comments were received. The overall themes of the comments are summarised as follows:

Themes

- Explanation of terms in this context required, including “involved”, “high dose”, “interventional” and "high dose CT”
- Guidance is required to explain the extent of involvement and to outline responsibilities
- Employers should define the scope of practice of an MPE they appoint
- MPEs should also be responsible for dosimetry and optimisation of dose

Over 90% of respondents agreed that regulations should require employers to appoint MPEs. Comments focussed on requiring that MPEs are employed based on a particular scope of practice with their scope clearly defined. Ensuring that employers rather than MPEs pay for any recognition scheme was also noted by several respondents, however, this is outside the scope of these Regulations.

Additional comments (mainly from IPEM and IPEM sub-groups) focussed on the suggestion that MPEs should be responsible for dosimetry and optimisation of dose, which, as discussed above, has been covered in Regulation 14 and can be expanded in guidance to ensure current custom and practice is maintained. It should be noted that the requirements included in IR(ME)R 2018 need to be applicable to all modalities and outline the minimum requirements, hence a graded approach to MPE involvement has been included in IR(ME)R 2018. Guidance will also cover the other themes noted relating to definition of terms, scope of practice and responsibilities of the MPE.

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. The following question captured views on this issue:

4.1 Do you support the inclusion of requirements for carers and comforters within IR(ME)R 2018?

Response option	Percent
Yes	**82**
No	7.9
Don’t know	10.1
Not Answered	0

Table 8: Support for the inclusion of requirements for carers amd comforters in IR(ME)R 2018

61 further relevant comments were received, of which 59 were deemed relevant. The overall themes of the comments are summarised as follows:

Themes

- How the justification would be assessed needs to be made clear as it is different from a medical exposure
- Alignment with IRR17 and conflict with the definition there
- Guidance required for individual justifications and dose constraints

A strong majority (82%) of all respondents agreed with the inclusion of requirements for carers and comforters. Comments focussed on the necessity of guidance, particularly around avoiding duplication of requirements in IRR17 and what constitutes "appropriate guidance" to be provided by employers in Regulation 12(5). Some commenters expressed the view that as carers and comforters are not patients, they should be classed as members of the public under IRR. However, it was largely viewed that as such cases are planned and use medical radiological equipment, they are more appropriately aligned with requirements for medical exposures than exposures to the public.

While justification of medical exposures to carers and comforters was broadly supported, some respondents did not think it would be practicable to introduce individual justifications, as doses to carer and comforters are not significant, adding unnecessary burden to workloads and risking delays to patients' care. Other comments highlighted that additional guidance will be required as it will be more difficult to assess whether an exposure is of net benefit to the individual in the case of carers and comforters. Respondents also noted that the terminology changed throughout the regulations from "carers and comforters" to "comforters and carers".

The BSSD introduces justifications and dose constraints for carers and comforters and it is DH's view that this requirement should sit under IR(ME)R 2018. This issue will be included in conversations with HSE looking at removal of relevant overlapping requirements from the draft IRR17. The issues of justification of exposures and dose constraints for carers and comforters can be explored as guidance is drawn up. The Regulations have been checked thoroughly to ensure the term “carers and comforters” have been used consistently throughout.

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. Two questions from the consultation were included on non-medical imaging:

5.1 Do you support the inclusion of non-medical imaging using medical radiological equipment within IR(ME)R 2018?

Response option	Percent
Yes	**84.2**
No	3.6
Don't know	12.2
Not Answered	0

Table 9: Support for the inclusion of non-medical exposures using medical radiological equipment under IR(ME)R 2018

56 further relevant comments were received, of which 53 were deemed relevant. The overall themes of the comments are summarised as follows:

Themes

- Clarification that this replaces medico-legal exposures as defined in IRMER2000
- Clearer explanation of exactly the kinds of exposures this is intended to cover
- The definitions of certain words, such as "patient", "medical exposure", "medical radiological" and "non-medical imaging exposures" to be clearer

Just over 84% of respondents agreed with the inclusion of non-medical imaging using radiological equipment in IR(ME)R2108. Numerous comments referenced the importance of this to ensure that individuals undergoing non-medical imaging are adequately protected. However, many respondents asked for more clarity on what non-medical means and some suggested adding the indicative list of non-medical exposures included in Annex V of the BSSD.

Many commented that some regulations in IR(ME)R 2018 were not clear on whether they applied only to medical exposures or included non-medical exposures as well, for example some found the use of the word "patient" and "medical exposure" throughout the Regulations confusing. Some highlighted that the more guidance is needed on what sorts of exposures fall into this category, particularly regarding 'medico-legal' exposures and to distinguish between, for example, research or asymptomatic exposures. More than one comment stated that the Regulations need to be clear that they only apply to living humans.

Respondents showed some concern over individual justifications for such exposures and the ability of practitioners to assess net benefit which is not related to health of the individual,

without further training or guidance on criteria. The range of themes identified above, do not require any drafting changes and will be considered for inclusion in accompanying guidance.

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

Response option	Percent
Yes	**66.9**
No	10.8
Don’t know	17.3
Not Answered	5.0

Table 10: Should dose constraints of limits be applied to non-medical exposures?

66 further relevant comments were received, of which 64 were deemed relevant. The overall themes of the comments are summarised as follows:

Themes

- There was a preference for dose constraints over dose limits
- Not setting hard limits i.e. doses should be justifiable on a case by case basis
- The regulations already require the exposure to be justified and optimised
- Adequate clarification and guidance is required for any constraints

Almost 67% of respondents agreed with dose constraints or dose limits being applied to such exposures. Of those who responded 'yes' the majority expressed a preference for dose constraints accompanied by guidance, as dose limits are difficult to police and enforce. Others made the point that dose limits are legally enforceable, so dose constraints would be preferred as there needs to be the flexibility to ensure that exposures are optimised for the procedure, equipment and size of individual. The most popular reason given by those who supported dose limits was that dose constraints would not protect individuals from the detrimental effects of cumulative exposures.

Many commenters did not see the benefit of applying dose constraints or limits, as regulations already require justification, optimisation and setting of diagnostic reference levels for non-medical exposures and good practice is to keep exposures as low as reasonably possible. A minority of respondents stated the view that individuals undergoing non-medical exposures should be classed as members of the public and dose limits should therefore be applied

DH has considered this issue carefully, which the BSSD offers as an optional inclusion, and it is not intended for this requirement to be included in the Regulations.

6. Licensing for the administration of radioactive substances

IR(ME)R2000 and MARS1978 (and associated amending regulations) will be replaced by IR(ME)R 2018. 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. Three questions were included in the consultation to gather views on this topic.

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

Response option	Percent
Yes	**66.9**
No	13.0
Don't know	19.4
Not Answered	0.7

Table 11: Support for not charging for practitioner licence applications

65 further comments were received, however, only 57 comments were considered relevant. The overall themes of the comments are summarised as follows:

Themes

- Making a charge could discourage people from applying
- MPE's will be charged to be on a register so practitioners should be charged for licensing
- Practitioners in other modalities don't have to hold a licence so should not charge
- The cost for practitioner licences should be built into employer charges

Overall there is broad consensus not to charge for practitioner licences and 66.9% of respondents answered 'yes' to this question. Many respondents cited the reason for their opposition to practitioner fees being that charging would discourage people from applying for licences, which could lead to, or exacerbate existing, recruitment shortages.

A number of respondents, regardless of whether they answered 'yes' or 'no', highlighted the apparent inconsistency in the requirement to charge MPEs to register. It should be noted that all MPE's will be required to register, however, only a sub-set of practitioners will need to hold a licence. Any practitioner that justifies exposures involving the administration of radioactive substances will have to hold a licence under IR(ME)R 2018, whereas a practitioner that works in a different modality, e.g. external beam radiotherapy will not have to apply for a licence to act in this role. Up to this point there has been no charge levied against practitioners for certification, whereas employers have not previously required certificates. As employer and practitioner licence applications are to be assessed by the same body, the proposed model builds the costs

of processing practitioner licence applications into employers' licence fees, so there is no disparity between fees levied against practitioners in different modalities. There is currently no opportunity for a cross-charging capacity for RPA2000, the body who will assess applications for MPE recognition.

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

Response option	Percent
Issued for fixed period	29.5
Reviewed when amendments sought	**49.6**
Don't know	17.3
Not Answered	3.6

Table 12: Should employer licences be issued for a fixed period or reviewed only when amendments are sought?

77 further comments were received, however only 66 comments were considered relevant. The overall themes of the comments are summarised as follows:

Themes

- Guidance should include what constitutes an amendment/notification and whether it is the employer/site/installation/facility is required to be licenced?
- Licences should be reviewed when amendments submitted only
- Issuing licences for a fixed period of 5-10 years would prompt review of information
- Applications should not duplicate information provided in other regulations/licence applications

Just under half of the respondents (49.6%) thought that employer licences should only be reviewed when amendments are made. There were a range of benefits to this approach highlighted in the additional comments, including consistency with licensing under the Environmental Permitting Regulations (EPR), that large sites are likely to have regular amendments, removing the need for periodic renewal and that there are financial and administrative burdens of regular renewal. However, just under 30% of respondents thought that licences should be only be issued for a fixed term, in order to prompt a review of information supplied by employers and ensure facilities continue to be fit for purpose. A number of respondents stated that there is no need for employer licences under IR(ME)R, as this is covered in IRR2017, and others wanted more information on this question or felt that it was not clearly worded.

The Administration of Radioactive Substances Advisory Committee (ARSAC) will advise the licensing authority on employer licence applications and they support a 5 year renewal for employer licences. When any amendment is approved, the licence could be re-issued for 5 years from the date of approval rather than retaining the existing expiry date. This approach would provide a compromise between the two options presented and demonstrate value for money charged for submitting amendment applications. This system also has the additional benefit of staggering expiry dates of licences so no processing delays come about as a result of application being batched together.

Some respondents indicated that the information required within licence applications should not duplicate those requirements within other regulations e.g. IRR2017 and EPR2010. ARSAC is drafting the employer licence application forms at present and will work with HSE and the Environment Agencies to ensure there is no duplication of information requested. Final of the Regulations and guidance will clarify these requirements.

6.3 Do you support a single licence for practitioners?

Response option	Percent
Yes	**69.8**
No	6.5
Don’t know	22.3
Not Answered	1.4

Table 13: Support for a single licence for practitioners

64 further comments were received, however, only 55 comments were considered relevant. The overall themes of the comments are summarised as follows:

Themes

- Support for single practitioner licence to reduce administrative burden and allow multi-site working
- Potential problem of practitioners overstretching or acting as “corporate practitioners”
- Each licence should be site specific / purpose specific
- Potential problems for research

The majority of respondents supported a single licence for practitioners (69.8%) for reasons including simplicity compared to the current system, particularly for research using routine procedures. A number of respondents suggested areas where further guidance will be required and noted potential problems, such as the risk of practitioners overstretching or that licensing fees may act as a barrier to setting up research trials.

Issuing a single licence to practitioners will allow individuals to work across multiple sites. This happens at present but separate ARSAC certificates are required at each site. There is no limit to the number of ARSAC certificates that an individual can hold and moderation of the sites where applicants work is limited. ARSAC has discussed remote certification in the past and has

established internal guidance. In order to prevent 'corporate practitioners' from operating at too many sites, guidance will be required. If a practitioner is not carrying out their duties under IR(ME)R, they could have their licence revoked and this will act as a disincentive to overstretching.

ARSAC has comprehensively considered the implications for research in moving to a single practitioner licence. While removing the administrative burden of applying for separate research licences for every study, employers will need to ensure robust internal systems are in place to notify practitioners of research studies requiring the administration of radioactive substances. ARSAC is working with the Human Research Authority (HRA) to ensure early notification is provided and to ensure research and development departments are aware of their responsibilities.

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. The following question invited views on this requirement:

7.1 Do you support extending requirements in IR(ME)R 2018 to having regard to national DRLs as well as European values?

Response option	Percent
Yes	84.9
No	2.9
Don't know	12.2
Not Answered	0

Table 14: Support for requirements in IR(ME)R 2018 having regard to national DRLs in addition to European DRLS

66 further comments were received, of which all were 64 considered relevant. The overall themes of the comments are summarised as follows:

Themes

- DRLs are a useful tool in reducing radiation dose and can assist in optimisation
- National DRLs better reflect UK practice
- European DRLs should be used when national DRLs are not available
- Should be clear that DRLs are not to be used for individual patients

Almost 85% of respondents support requirements to having regard to national DRLs as well as European values. Respondents frequently pointed out the benefits of DRLs, including promoting appropriate optimisation of dose and image quality, and highlighted that UK DRLs tend to be lower than corresponding European values, implying a higher standard of optimisation. Others stressed that national DRLs are more suitable as they better reflect current UK practice.

A number of comments noted that national values should be used before European ones, where available, whereas other respondents suggested that guidance should give direction where European and national DRLs differ. Several commenters made the distinction that DRLs should only be applied to patient cohorts and cannot be used for individual exposures, which can be highly variable. These points will be taken into consideration while guidance is drafted.

8. Adequate training

Training requirements for practitioners and operators are listed in Schedule 4 of IR(ME)R 2018.

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.

A broad spectrum of comments were received and considered. These included comments on formatting, general approaches and specific entries within Schedule 4 that should be added or deleted. Many responses stated that the Schedule did not need changing. At least one respondent expressed the view that the Schedule was not required. As a consequence, Schedule 4 has been updated, simplified where possible and expanded as appropriate to reflect current practice.

9. Additional comments

We received additional general comments, including content outside the scope of the consultation, from 33 respondents by email. Of these, 24 were associated with responses on received via the online questionnaire. A large proportion of commenters expressed disappointment that the consultation did not permit the submission of free-text comments on the Regulations beyond the scope of the specific consultation questions.

The majority of comments received concerned drafting clarifications and were generally minor or more appropriately picked up in guidance. The need for comprehensive and timely guidance was emphasised by a high proportion of commenters. Much of the feedback received by email mirrored that received in response to the specific consultation questions, for example ambiguity around non-medical exposures and concern regarding overlap of certain requirements in other regulations. The most prevalent themes are summarised below.

We received a number of comments requesting the interpretation of “referrer” in Regulation 2 to be extended to include professions accredited by the Professional Standards Agency (PSA). This is based on the exclusion of clinical technologists under the requirement as it stands, which defines “referrer” as a registered health care professional according to section 25(3) of the National Health Service Reform and Health Care Professions Act 2002. After careful consideration of this issue, it was decided that this requirement acts as an important safeguard for those undergoing ionising radiation exposures. PSA accredited registers are not subject to the same rigorous standards of competence, conduct and training that regulated professions are. Expanding the requirement to include PSA accreditation would mean that registrants in occupations such as play therapy, homeopathy and hypnotherapy would be eligible to refer individuals for exposures using medical radiological equipment, which may not always be appropriate.

A number of respondents raised the issue of the requirement for the patient or their representative to be informed of any relevant clinically significant unintended or accidental exposure, in Regulation 8(1) and Schedule 2(i). Respondents stressed that provision should be made for a clinical decision to be made in cases where it is deemed this would not be of benefit to the patient, as long as there is written record of justification. This requirement has come from the Directive and, as such, must remain in these Regulations. It should be noted that in circumstances where is it is not in the patient's best interest to be informed of an unintended exposure, a representative can be informed instead.

There were several comments regarding the requirement in Regulation 11(1)(d) for research involving the administration of radioactive substances to be approved by an expert committee as well as an ethics committee. Many responders thought this is disproportionate compared to, for example, research involving radio diagnostic procedures, which would only need ethics committee approval. However, this has been deemed as an appropriate safeguard for those undergoing exposures as part of a research programme and will remain a feature of these Regulations.

One respondent also raised an important point related to unintended consequences of revoking The Medicines (Administration of Radioactive Substances) Regulations (MARS) 1978. There is currently an important exemption to Regulation 240 of the Human Medicines Regulations 2012 for operators administering prescription only medicines as part of a medical exposure, provided the authorising practitioner is certificated under MARS78. It is crucial that exemption is carried forward once IR(ME)R 2018 has come into force, and there will be a careful verification process to ensure any necessary consequential amendments are carried out.

Conclusion

The public consultation on the draft IR(ME)R 2018 found that for most of the areas of questioning, respondents agreed with DH's intentions. DH has taken the comments received during this consultation into account in the revision of the legislative text, where these are appropriate and in line with the Basic Safety Standards Directive. Only minor revisions to the legislative text have been made in light of the feedback received, and where this has happened, they have been explained above.

A need for timely and comprehensive non-statutory guidance was emphasised by a number of commenters, and a stakeholder workshop was held in September 2017 to identify priority areas for inclusion. We will develop this guidance with continued input from stakeholders to address areas of potential ambiguity and liaise with professional scientific and medical societies to progress work on reaching an agreed definition for the term "clinically significant".

The draft Regulations were submitted under Article 33 requirement to the European Commission on 29 August 2017. Work to finalise the statutory instrument is underway with a view to making IR(ME)R 2018 by the transposition deadline of 6 February 2018.