Department of Health
An Roinn Sláinte
Männystrie O Poustie
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Summary of responses to the consultation on the

PROPOSED IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS (NORTHERN IRELAND) 2018

January 2018

HE1/18/6104

CONTENTS

1. INTRODUCTION

Consultation enables an assessment to be made of the views of those who are affected by policy decisions or changes to services. It can help policy makers to become aware of issues and problems, which policies may pose for various groups that the organisation might not otherwise discover.[1]

The Department of Health, referred to in this document as "the Department" or "DoH', ran a consultation from 24 October 2017 to 19 December 2017 to engage with patients, clinicians, stakeholders and the general public about proposed Ionising Radiation (Medical Exposure) Regulations for Northern Ireland. This report explains the approach to the consultation and provides a summary of the issues raised through written consultation responses and a stakeholder meeting.

2. BACKGROUND

This consultation relates to transposition and implementation, in Northern Ireland, of European Council Directive 2013/59/EURATOM of 5 December 2013 (BSSD) laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. The aim of the BSSD is to update and simplify existing arrangements for radiological protection by bringing five directives and a European Commission recommendation into one directive. The directives being replaced are currently implemented through a range of legislation.

In order to transpose the requirements of the Directive which relate to medical exposure to ionising radiation, the Department is proposing to revoke the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 (IR(ME)R (NI) 2000) and replace them with new regulations - the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 (IR(ME)R (NI) 2018).

A similar process has been undertaken in England, Scotland and Wales, led by the Department of Health in England (DH), in conjunction with the Health Departments of the Devolved Administrations in Wales and Scotland. This has concluded in the making of the Ionising Radiation (Medical Exposure) Regulations 2017[2], which will come into operation on 6 February 2018.

Other aspects of the Directive, not relating to medical exposure, are the responsibility of other Government Departments and Agencies and separate policy development and consultation processes are being/have been conducted. The Department is working with these other bodies and other UK administrations to ensure comprehensive transposition and implementation of the Directive.

The range of medical exposures to ionising radiation to which the Regulations will apply includes exposure of patients as part of medical diagnosis, such as the use of x-rays for medical or dental imaging, or treatment, such as the use of radiation therapy to treat

[1] NORTHERN IRELAND. OFMDFM Policy Innovation Unit. *Policy Toolkit: Effective Policy Making Workbook one: Justification and Set Up*. Section 2, p15, *The need for consultation.*

[2] http://www.legislation.gov.uk/uksi/2017/1322/contents/made

cancer. Also covered are exposure of individuals as part of health screening or research programmes, non-medical procedures that use medical radiological equipment, and individuals exposed while supporting or caring for someone undergoing a medical exposure.

While overall the Regulations broadly reflect existing provisions, they also introduce the following specific requirements which act to enhance protection for those undergoing medical exposures:

- Expansion of requirements for reporting of accidental or unintended exposures to ionising radiation to include doses that are less than intended. Although there have been very few recorded incidents in this category, it is expected that these requirements will enable enhanced learning and implementation of preventative measures. As such events are thought to be rare, the new reporting requirements are not expected to add to regulatory burden.
- Formalisation of recognition of Medical Physics Experts (MPEs). MPEs provide expert advice and play a vital role in optimising doses received by individuals subject to medical exposures. The Regulations require MPEs to be appropriately educated and trained. All employers who carry out medical exposures are required to appoint a MPE and their role in providing advice to the employer on the safe application of medical exposures is defined in the legislation.
- Introduction of requirements for licensing of the administration of radioactive substances to persons for diagnosis, treatment or research. The current certification system, in which medical practitioners performing these types of exposures are required to hold site-specific certificates, will be replaced with a digital licencing system for practitioners and employers. This is expected to streamline the system as a whole, while maintaining patient safety standards. There will be a fixed fee for employers but not for practitioners and it is anticipated that there will be a significant reduction in the overall time spent by medical staff making applications for authorisation to administer radioactive substances.

The consultation ran from 24 October to 19 December 2017 and the questionnaire contained 17 substantive questions on the draft IR(ME)R (NI) 2018 regulations. The consultation document was based on the *Consultation on the transposition of European Council Directive 2013/59/Euratom (Medical Exposures) - Laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation*, issued by the Department of Health in England (DH), whose assistance is gratefully acknowledged.

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. Responses were welcomed in any written format.

3. OVERVIEW OF CONSULTATION RESPONSES

In total eight written responses from a range of organisations and individuals were received by DoH. All eight responses were submitted via email. Six responses used the consultation questionnaire and two were received in a non-questionnaire written format. Responses were from both organisations (six) and individual respondents (two) from across the UK with four of the respondents based in Northern Ireland, one in England and one in Scotland. Of these a majority were organisations with a UK-wide remit.

A number of key stakeholder organisations responded to the consultation, including the Institute of Physics and Engineering in Medicine (IPEM), Society and College of Radiographers, British Nuclear Medicine Society and British Dental Association. A full list of respondents can be viewed at **Annex A**.

Both written responses and feedback gathered through the stakeholder meeting reflect a range of views that are broadly supportive of implementation of the draft IR(ME)R (NI) 2018 regulations.

4. SUMMARY OF WRITTEN CONSULTATION RESPONSES

This section provides a summary of the written responses received for each question set out in the consultation questionnaire and, for each question, the Department's consideration of the responses. There were a total of 17 questions in the consultation questionnaire as detailed below:

4.1. Definition of referrer

The Department is in discussion with the Republic of Ireland's Department of Health, Health and Social Care Trusts and health care profession representatives in Northern Ireland and the Departmental Solicitor's Office to agree a definition of referrer that will facilitate cross-border referrals from health care professionals for procedures involving exposure to ionising radiation.

Q1. Do you support the expansion of the definition of "referrer" in IR(ME)R (NI) 2018 to facilitate cross-border referrals?

Of the six responses that completed the consultation response questionnaire five supported this expansion to facilitate cross-border referrals. The remaining response asked for assurance that all referrals must still come from registered healthcare professionals. They stated:

"…it must be recognised that any entitled referrer has to be a registered healthcare professional. We would certainly not wish to see any barriers put in place that would facilitate timely patient care but would support a specific and clear definition that still ensures referrals are made by professional staff."

Following further discussion with colleagues in the ROI Department of Health, Health Trusts, health care profession representatives in Northern Ireland and the Departmental Solicitor's Office, the Department has revised the definition from the consultation draft to

ensure that referrals to the HSC from ROI which involve exposure to ionising radiation would be limited to medical practitioners registered with the Medical Council of Ireland and entitled by their employer's procedures to refer individuals for exposure. This reflects current practice.

Q2. Do you envisage any other cross-border issues pertaining to IR(ME)R (NI) 2018? If so, please give details.

No respondents to this question raised any issues but 67% did stress the importance of a reciprocal agreement regarding cross-border referrals. One commented:

"We could encourage a reciprocal relationship with RoI in their updated legislation to allow for the referral of NI patients to RoI (e.g. PET patients if the PET facility in NI is out of action)"

ROI legislation on protection from medical ionising radiation is also currently being reviewed to take account of BSSD. Discussions are continuing to agree a form of words for the reciprocal arrangements (referrals from NI to ROI).

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

IR(ME)R (NI) 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.

Q3. Do you support reporting of significant events under IR(ME)R (NI) 2018, regardless of whether these result from equipment or procedural failure?

All of the respondents who completed the consultation questionnaire supported this suggestion. Some comments included:

"One common reporting mechanism for all significant events would be welcome."

"There must be sufficient resources for the reported incidents to be handled and adequately followed up by the relevant enforcing authorities in NI."

Both equipment and procedural failures expose individuals undergoing exposures using medical radiological equipment. Therefore, the Department, the Regulation and Quality Improvement Authority (RQIA) (which will undertake enforcement and inspection activities on behalf of the Department) and Health and Safety Executive Northern Ireland (HSENI) officials (responsible for enforcement and inspection activities under The Ionising Radiations Regulations (Northern Ireland) 2017)[3] agree that this requirement should be included in IR(ME)R (NI) 2018.

[3] http://www.legislation.gov.uk/nisr/2017/229/contents/made

Q4. 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?

Of the six questionnaires returned, five agreed and the other one commented:

"While it is a joint responsibility, the clinical issues should be defined by clinically competent bodies such as appropriate Royal Colleges, professional, scientific and medical bodies."

In line with these responses and the conclusions reached by DH (England), following consultation on the equivalent GB regulations, the definition of "clinically significant" will be left for professional scientific and medical societies to determine. Oversight by DH and the devolved administrations will allow for development of UK-wide definitions which, if timings permit, can be included in future guidance.

Q5. Do you support the view that any such exposure should however be considered as a significant event and reported to the Competent Authority?

There was general agreement to this with the condition that it is a clinically significant exposure. However one respondent stated:

"No. The reporting of all events (rather than just clinically significant exposures) is highly unlikely to contribute to patient safety overall and would be an administrative burden."

As reporting of significant events to the Competent Authority is a requirement of the BSSD, this requirement will remain in IR(ME)R (NI) 2018 (Regulation 8(4)) and what is meant by "significant" will be addressed through guidance.

Q6. Do you support the reporting of significant events in radiotherapy where doses are less than intended?

100% of respondents supported this suggestion. One noted:

"Yes but only when clinically significant across the total treatment course."

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.

As above, reporting of significant events to the enforcing authority, including those in which doses are less than intended, will be included in IR(ME)R (NI) 2018, with appropriate guidance provided on the meaning of the term "significant".

4.3. Duties of the employer with regard to quality assurance programmes for equipment when used in medical exposures

IR(ME)R (NI) 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.

Q7. Do you support inclusion of these requirements within IR(ME)R (NI) 2018?

Again 100% of respondents who commented on this supported the inclusion of these requirements. Some comments made included:

"These requirements sit more naturally under medical exposures than under occupational exposures and they are well suited to the responsibilities of the MPE."

"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 (NI) 2018); and commissioning to provide baselines for future testing (under IR(ME)R (NI) 2018)."

"If these requirements do move, there will need to be consultation between enforcing authorities and regulatory bodies."

"Failure in QA can cause over/under exposures in patients. There needs to be work on the delineation of the role / responsibility of RPA and MPE in this."

"Equipment quality assurance is an important element in ensuring the protection of the patient from medical exposure and it is correct that the requirements for this are implemented in legislation in a way that is aligned with other provisions that ensure the safety and quality of medical radiological procedures and equipment."

Discussions with the RQIA 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 administrations which would mitigate the issue of capability.

The Department is therefore of the view that requirements relating to quality assurance of medical radiological equipment, should therefore be covered in IR(ME)R (NI) 2018. The Department has agreed with HSENI that the requirements will transfer from The Ionising Radiations Regulations (Northern Ireland) 2017) once IR(ME)R (NI) 2018 comes into operation (on 6 February 2018). This issue will also be covered in guidance.

4.4. Medical physics experts

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

Q8. Do you object to medical physics experts advising employers on compliance?

None of the respondents objected to this suggestion. Comments included:

"This is the most appropriate means of ensuring that advice is targeted appropriately to those with sufficient knowledge and authority, which should be standardised, to ensure compliance."

"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."

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. This, in addition to clarity of certain terms can be dealt with in guidance.

One respondent also 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. The Department would highlight that there is a requirement in the Regulations for MPEs to give advice on dosimetry in Regulation 14(2)(d) and further detail, if required, can be included in guidance.

Q9. Do you think the Regulations should require employers to appoint MPEs?

All 6 of the respondents who completed the questionnaire agree that employers should be required to appoint MPEs. Some commented as follows:

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

"Employers should have a medical physics expert (MPE). However there needs to be some independence of that designated person from the employer."

Additional comments from one respondent focussed on the role of MPEs in different practices and responsibility for dosimetry. As above the Department considers this has been covered in Regulation 14 (revised from the consultation draft to include matters formerly listed in Schedule 3) 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 (NI) 2018 need to be applicable to all modalities and outline the minimum requirements, hence a graded approach to MPE involvement has been included. Guidance will also cover the other themes noted relating to definition of terms, scope of practice and responsibilities of the MPE.

4.5. 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.

Q10. Do you support the inclusion of requirements for carers and comforters within IR(ME)R (NI) 2018?

Again all of the completed questionnaires showed support for this inclusion. Comments in these responses included:

"….the definition of what constitutes a "carer and comforter" could be more clearly defined in the regulation."

"Exposure should be risk assessed within the context of the justification of the exposure."

The BSSD introduces requirements for justifications and dose constraints for carers and comforters and it is the Department's view that these should be addressed with IR(ME)R (NI) 2018. The Department has agreed with HSENI that the requirements will transfer from The Ionising Radiations Regulations (Northern Ireland) 2017) once IR(ME)R (NI) 2018 comes into operation (on 6 February 2018). The issues of justification of exposures and dose constraints for carers and comforters can be explored as guidance is drawn up.

4.6. 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.

Q11. Do you support the inclusion of non-medical imaging using medical radiological equipment within IR(ME)R (NI) 2018?

100% of the respondents who commented support this inclusion. Some comments are noted below:

"The current wording needs to be clarified to ensure that all regulations appropriately cover non-medical imaging (e.g. the definition of employer currently appears to exclude non-medical imaging)."

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

"It seems entirely appropriate that there should be consistent safeguards irrespective of how such medical radiological equipment is used, providing the status of such equipment is unequivocal."

"We would also welcome reinforcement of the need for justification of these exposures, particularly when the employer may stand to gain financially from the exposure and may define net benefit as they see fit in their employer's procedures."

In line with DH (England), following consultation on the equivalent GB regulations, some drafting changes have been made to IR(ME)R (NI) 2018 to clarify definitions. Other issues raised will be considered for inclusion in guidance.

Q12. Do you think dose constraints or dose limits should be applied to such exposures?

All six respondents who answered this question on the questionnaire agreed that dose constraints or dose limits should be applied and four of them expressed a preference for dose constraints over dose limits. They commented:

"Dose constraints would seem most consistent. Overarching dose limits would only be appropriate if it were felt that the use of high dose procedures for non-medical purposes (e.g. CT) were not adequately controlled by other means."

"Guidance will be needed about how to apply dose constraints in practice. Will they apply to individuals or standard groups? How would the larger patient sub group be dealt with?"

Article 22(3) of the BSSD allows exemption of justified practices involving non-medical imaging exposure using medical radiological equipment from the requirement for dose constraints or dose limits and, in line with DH (England), following consultation on the equivalent GB regulations, the Department does not intend for this requirement to be included in the Regulations.

4.7. Licensing for the administration of radioactive substances

IR(ME)R (NI) 2000 and MARS 1978 (and associated amending regulations) will be replaced by IR(ME)R (NI) 2018 and similar regulations in England, Scotland and Wales. 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.

Q13. Do you agree that charges should not be levied on practitioners who wish to hold a licence?

All five responses that commented on this agreed that charges should not be levied on practitioners. Some comments made were as follows:

"This seems reasonable given there is no charge to be a radiotherapy practitioner and it may discourage individuals from becoming licensed in these roles."

"New practitioner license holders should not be charged."

One respondent 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 who justifies exposures involving the administration of radioactive substances will have to hold a licence under IR(ME)R (NI) 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. Applications for employer and practitioner licences in Northern Ireland will be managed by Public Health England (PHE) on behalf of the Department and assessed by the Administration of Radioactive Substances Advisory Committee (ARSAC). 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.

Q14. Do you think licences for employers should be for a fixed period or reviewed only when amendments are sought?

Opinions were divided on this questions with two of the responses that commented supporting fixed period licences and three believing licences should be reviewed only when amendments are sought. The following comments were made:

"For a fixed period. Given the details in Schedule1, regarding material changes, it seems likely there would need to be amendments every few years in any case so it would be better to use this as a driver."

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

Another response (not in questionnaire format) strongly disagreed with the proposed fee levels for employers' licences, set out in the consultation. Comments made included:

"While in England, our understanding is that a one-off licence fee of £25 is being proposed, the fee table indicates much higher proposals of up to £329 for 'new' employers. This would represent a wholly unacceptable and disproportionate additional financial burden being imposed on dental 'employers'."

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.

ARSAC is drafting the employer licence application forms at present and will work with Health and Safety Executives and the Environment Agencies to ensure there is no duplication of information requested (e.g. for EPR licensing). Guidance will clarify these requirements.

As noted in the consultation, PHE is developing a new IT system to allow applicants to submit their applications online and proposes to charge fees for some types of applications to cost recover for the design, operation and maintenance of this system. The total cost of the new IT system had not been finalised at the time of the consultation and, as noted in it, the fees included within IR(ME)R (NI) 2018 were subject to final confirmation. The fees, which will be identical throughout the UK, have now been revised downwards as set out in Table 1.

It should also be noted that licensing will only be required for employers and practitioners involved in the administration of radioactive substances and not for other modalities, e.g. external beam radiotherapy or x-ray radiography. It is unlikely, therefore, that dental facilities would be required to apply for either an employer's or practitioner's licence.

Table 1

Licence type (1)	*Application type (2)*	*Fee (£) (3)*
Employer	New	250
	Amendment of an existing licence	200
	Renewal of an existing licence	200
	Notification	0
Practitioner	New	0
	Amendment of an existing licence	0
	Renewal of an existing licence	0
	Particular patient request	0

Q15. Do you support a single licence for practitioners?

100% of the respondents who answered this question support a single licence for practitioners. Comments included:

"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."

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 (NI), they could have their licence revoked and this will act as a disincentive to overstretching.

ARSAC has also 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.

4.8. Diagnostic reference levels (DRLs)

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

Q16. Do you support extending requirements in IR(ME)R (NI) 2018 to having regard to National DRLs as well as European values?

Respondents who commented supported this suggestion. Some comments included:

"Some procedures have limited DRL data – certainly UK practice, we believe, is best practice in terms of patient safety."

"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 Europeans ones. If the national DRLs are higher, they provide and 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."

In line with DH (England), following consultation on the equivalent GB regulations, points made by respondents will be taken into consideration while guidance is drafted.

4.9. Adequate training

Training requirements for practitioners and operators are listed in Schedule 4 of the draft Regulations.

Q17. 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. As a consequence, Schedule 4 has been updated, simplified where possible and expanded as appropriate to reflect current practice.

4.10. Equality Implications

E1. Are the actions/proposals set out in this consultation document likely to have an adverse impact on any of the nine equality groups identified under Section 75 of the Northern Ireland Act 1998? If yes, please state which group or groups and provide comment on how these adverse impacts could be reduced or alleviated in the proposals.

E2. Are you aware of any indication or evidence – qualitative or quantitative – that the actions/proposals set out in this consultation document may have an adverse impact on equality of opportunity or on good relations? If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.

E3. Is there an opportunity to better promote equality of opportunity or good relations? If yes, please give details as to how.

E4. Are there any aspects of these recommendations where potential human rights violations may occur?

No respondents identified any equality implications. The Department is satisfied that this confirms its preliminary decision that a full Equality Impact Assessment is not required.

5. SUMMARY OF STAKEHOLDER CONSULTATION MEETING

A stakeholder meeting with health professionals who had previously expressed an interest in the new regulations through correspondence etc. was held on 5 January 2018. Discussion at the meeting focussed on the necessity of inclusion of a definition for "referrer" which would allow for cross-border referrals for medical exposures and the need for comprehensive and timely guidance on interpretation and implementation of the Regulations, particularly in regard to:

- Clarification of responsibilities in situations where there is more than one employer.
- Regulation of non-medical imaging using medical radiological equipment.
- Employers' procedures for providing information to patients prior to exposure.
- Definition of significant and clinically significant events.
- Clarification on the role of MPEs

Attendees were generally satisfied with the Department's proposals for definition of "referrer" and accepted that areas of potential ambiguity in the legislation would be addressed through guidance, with input and feedback from professional scientific and medical bodies.

6. CONCLUSION

The Department is grateful to all organisations and individuals who participated in this consultation and values the views of those with professional or personal experience in this field.

The responses to the public consultation on the draft IR(ME)R (NI) 2018 indicated that, for most of the areas of questioning, respondents agreed with the Department's intentions. DoH has taken the comments received during this consultation into account in revision of the legislative text, where these are appropriate and in line with the Basic Safety Standards Directive and the final version of the equivalent GB regulations. 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.

The need for timely and comprehensive guidance on the regulations was emphasised by a number of respondents and also at the stakeholder meeting held in January 2018. As the requirements of IR(ME)R (NI) 2018 mirror those in the equivalent GB legislation, the Department intends to continue to liaise with DH (England), PHE and the other devolved administrations in the development of guidance with continued input from stakeholders, including professional scientific and medical bodies to address and clarify areas of potential ambiguity.

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 were made on 1 February 2018 and came into operation on the transposition date of 6 February 2018. They are available at http://www.legislation.gov.uk/nisr/2018/17/contents/made.

Annex A

List of Respondents

Category 1	Representative Bodies
	Institute of Physics and Engineering in Medicine (IPEM)
	Institute of Physics and Engineering in Medicine (IPEM) Radiation Protection Special Interest Group (RP-SIG)
	British Nuclear Medicine Society
	British Dental Association NI
	Royal College of Physicians and Surgeons of Glasgow
	Society and College of Radiographers (SCoR)
Category 2	**Individuals and Groups of Individuals**
	Dr Phil Orr
	Adam Workman, Julie Smyth, Philip Doyle, Lesley Grattan