EXPLANATORY MEMORANDUM TO

THE IONISING RADIATION (MEDICAL EXPOSURE) (AMENDMENT) REGULATIONS 2024

2024 No. 896

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Andrew Gwynne, Parliamentary Under-Secretary of State at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

2.2 Will Jones, Deputy Director for ORC Risk, Governance and Capabilities and UKHSA Sponsorship, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Priya Iype at the Department of Health and Social Care email: priya.iype@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument makes several amendments to the Ionising Radiation (Medical Exposure) Regulations 2017 ("IR(ME)R 2017") to reflect current healthcare delivery practices. IR(ME)R imposes duties on employers and those with responsibilities for administering ionising radiation to protect persons undergoing medical exposures, for examples X-rays, CT scans or radiotherapy. This may be as part of their own medical diagnosis or treatment, research, non-medical imaging using medical radiological equipment or as carers and comforters of persons undergoing medical exposures.

4.2 This instrument delivers the recommendations of the statutory five-year post-implementation review and is required to maintain continued patient safety for those undergoing medical exposure procedures. The changes include clarifying definitions, strengthening training responsibilities of employers, incorporating Artificial Intelligence as an optional equipment, and introducing new information sharing requirements between employers. The instrument also contains an uplift to licence application fees for sites administering radioactive substances in line with inflation.

4.3 Upon consulting with the SI Registrar, this instrument is being issued under the free issue procedure as this instrument corrects a defect contained in the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018 (S.I 2018/121) which renumbered regulation 3 in the IR(ME)R 2017 but failed to update all cross

references. This instrument will therefore be issued free of charge to those who purchased the S.I 2018/121.

Where does the legislation extend to, and apply?

4.4 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales, and Scotland.

4.5 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales, and Scotland.

5. Policy Context

What is being done and why?

5.1 Ionising radiation is used widely within healthcare settings to help diagnose and treat conditions. For example, in diagnostic radiology, X-rays and CT scans are used to obtain images of the patient's body to assist diagnosis, in nuclear medicine, radioactive substances are administered into the patient for diagnosis and treatment, and in radiotherapy, targeted ionising radiation is used to cure or relieve symptoms of cancer and other diseases. IR(ME)R 2017 was established to protect individuals from potential harm when being exposed to ionising radiation during medical procedures and ensures UK compliance with Basic Safety Standards requirements of the International Atomic Energy Agency. The Regulations set out the responsibilities of duty holders (the employer, referrer, practitioner, and operator) for radiation protection and the basic standards of safety that duty holders must meet.

5.2 DHSC conducted a post-implementation review of IR(ME)R 2017 in 2022/23 in collaboration with UK medical regulators, UK Health Security Agency, and professional bodies. The review identified key areas for reform to ensure the Regulations better reflected recent developments in medical techniques and technologies. This included the incorporation of artificial intelligence (AI) as an optional equipment choice for medical exposures, strengthened duties on employers for quality assurance, and enhanced training requirements. This instrument is intended to deliver the improvements recommended by the post-implementation review (published November 2023) https://www.legislation.gov.uk/uksi/2017/1322/pdfs/uksiod_20171322_en_001.pdf.

Amendments to Interpretation

5.3 This instrument updates definitions of commonly used terms within the Regulations to minimise confusion and resolve any potential ambiguity in interpretation.

5.4 In accordance with the recommendations of the post-implementation review, the definition of 'equipment' is extended to include 'software' that assists operators to carry out clinical evaluation. By explicitly regulating its use as an equipment to be used by an operator, it extends employer responsibilities to support the safety, efficacy, and suitability of equipment, to include 'software'. This amendment is required to ensure continued patient safety considering the increasing prevalence of healthcare facilities using AI to assist medical exposures.

Clarifies application for non-medical imaging exposures

5.5 The instrument standardises the approach between medical and non-medical imaging exposures by extending the radiation protection requirement on employers to cover all

exposures regulated under IR(ME)R 2017. This includes establishing appropriate guidelines for the referral of non-medical imaging exposures and requiring equipment to be tested before first use. While it was not the policy intention, IR(ME)R 2017 only explicitly required these measures to be undertaken for medical exposures. Therefore, this amendment is required to align the Regulations with the policy intention to better protect individuals undergoing medical and non-medical imaging exposures from the potential harm from ionising radiation.

Amendments to Employer's duties regarding the establishment of general procedures, protocols, and quality assurance programmes

5.6 IR(ME)R 2017 requires employers to provide written procedures and protocols to practitioners and operators. This instrument strengthens employer responsibilities regarding referral guidelines extending the requirement to include all exposures to which the Regulations apply to clarify expectations on duty holders. It also introduces a new requirement on employers to regularly review and make available dose reference levels for radiotherapy procedures. Dose reference levels are used to provide an indication of the expected radiation dose for an average-sized patient undergoing a radiotherapy procedure to support optimisation of the exposure. This amendment standardises approach for radiotherapy in line with existing requirement to collect diagnostic reference levels for diagnostic imaging procedures

Introduction of co-operation between employers

5.7 This instrument formalises the requirement for co-operation between employers to share relevant patient information, this includes sharing the justification for the exposure so that all aspects of patient care are given due regard when there are multiple employers providing aspects of exposure.

Amendment to Employer's duties regarding Clinical Audit and Accidental or unintended exposures

5.8 IR(ME)R 2017 requires employer's procedures to include provision for the clinical audit. This is a systematic review of medical radiological procedures to improve quality and outcome of patient care. This instrument builds on this intention by explicitly requiring employers to ensure established provisions to undertake appropriate action following audit.

5.9 A similar requirement is also introduced to Regulation 8: Employer's duties regarding accidental or unintended exposure, which requires employers to establish systems for analysis of these incidents. The amendment strengthens the employer's responsibility to not only review incidents or near-misses but to take appropriate action as a result of the findings. These amendments improve patient safety by requiring employers to act on learnings to improve their practices and reduce likelihood of errors.

Amendment to Optimisation

5.10 Regulation 12 of IR(ME)R 2017 sets out requirements for the Optimisation of medical exposures, requiring that ionising radiation doses provided to individuals are kept as low as reasonably practicable for the intended purpose. This means that doses provided to individuals should be sufficient to meet the intentions but should not exceed so as to expose the individual to undue radiation or be so low as to not adequately serve its purpose. With this objective in mind, this instrument strengthens the requirements operators have with regards to optimisation, and requires they have

due regard to diagnostic reference levels when undertaking interventional radiology practices, and dose reference levels when undertaking radiotherapeutic practices.

5.11 Regulation 12 (4) requires employers to make provisions for the safeguarding of individuals involved in medical and biomedical research programmes, including the need for informed consent and for the establishment of dose constraints for individuals for whom the exposure is not expected to provide direct medical benefits. As the 2017 regulations did not specify instances where individuals lacked capacity to consent, this instrument clarifies the need for informed consent to be collected either from individual, or on their behalf as appropriate, prior to participation in medical and biomedical research programmes. This clarification is required to minimise potential for confusion in research involving paediatrics or adults with incapacity.

5.12 Similarly, this instrument clarifies the need for employers to ensure written information is provided to persons with parental responsibility, if the individual receiving exposure is under the age of 16, or an appropriate person if the individual is an adult, who lacks capacity or competence to consent to their treatment or diagnosis. In accordance with variation within GB law, the instrument uses specific terms to clarify differing basis for consent, and its application between England and Wales, and Scotland.

Amendment to general duties of the employer with regards to equipment

5.13 To complement the addition of 'software' as an optional equipment for medical exposure in Regulation 2, this instrument imposes duties on employers to specify information regarding the software to be collected as part of inventory. The inventory will be used by hospitals to aid equipment recall and to perform analyses following incidents. This is critical to ensuring continued patient safety and supports hospitals and manufacturers to perform post-market surveillance.

Uplift in Licence Fees

5.14 IR(ME) R 2017 provides that sites, including NHS and private healthcare facilities, which perform nuclear medicine that involves the administration of radioactive substances to patients, must hold a valid employer licence. Sites are required to pay a fee to UKHSA for all license applications to compensate for the administration of the licensing regime. The instrument introduces a minor uplift to the fees associated with license applications in line with inflation.

5.15 DHSC modelling based on the number of employer license applications received by UKHSA over the last five-year period, indicated that the total direct cost to all sites over the upcoming five-year period will be £180k. To further minimise burden on businesses and the NHS, this cost will be proportionally distributed across all employer licence applications, amounting to an increase of approximately £50 per application, with new employer licence fees going from £250 to £298. This is an uplift of approximately £30k from the current cost over the next five-years and is expected to have minimal impact on businesses and the NHS.

Enhanced Training requirements

5.16 The minimum training standards set out in Schedule 3 of IR(ME)R 2017 are updated to reflect developments in techniques and practices. Additions to this Schedule includes modules on the use of Contrast Media for all three medical exposure modalities, and Practical Aspects for diagnostic radiology and nuclear medicine. This

amendment requires practitioners and operators involved in the delivery of the exposure are adequately trained to maintain quality and care of patients.

6. Legislative and Legal Context

How has the law changed?

6.1 IR(ME)R 2017 (as amended) transposed the medical exposures elements of European Council Directive 2013/59/EURATOM which lay down minimum safety standards for protection against the dangers arising from exposure to ionising radiation. The IR(ME)R 2017 was made using powers under s2(2) of the European Communities Act which contained provision for, or in connection with, the charging of fees of other charges that were made under s2(2) of the European Communities Act 1972 and s56 of the Finance Act 1973.

6.2 This instrument makes amendments using powers under the 15(1) and (2), 52(2), 82(3)(a) of, and paragraph 13(2) and 20 of Schedule 3 to, the Health and Safety at Work etc. Act 1974. In relation to amendment to licence fee applications, the instrument uses powers under paragraph 7 of Schedule 4 and paragraph 21(a) and (b) of Schedule 7 to the European Union (Withdrawal) Act 2018.

6.3 The amendments reflected in paragraphs 5.3 to 5.16 are being made following a statutory five-year post implementation review which identified key areas of reform. The instrument provides an uplift in licence application fees in line with inflation since commencement in 2018.

Why was this approach taken to change the law?

6.4 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 As per requirements under Section 50(1AA) of the Health and Safety at Work etc Act 1974, DHSC undertook consultation with Health and Safety Executive (HSE) and the Office for Nuclear Regulation (ONR) on the proposed changes over a period of three weeks beginning on the 21st of February 2024. Those consulted were provided a Keeling Schedule and document detailing the intentions of the proposed changes with questions to support consideration. Respondents replied via email and were content with the proposal with no concerns regarding the changes.

7.2 In accordance with Article 36(4) of UK General Data Protection Regulation, Assimilated Regulation (EU) 2016/679 (UK GDPR), DHSC undertook consultation with the Information Commissioners Office (ICO) in April 2024 on Regulation 6A: Co-operation between employers as this new requirement relates to the processing of personal data. Consultation was completed with no concerns raised.

7.3 Furthermore, DHSC has undertaken targeted engagement with devolved administrations, UK medical regulators, UKHSA, and professional bodies to develop this instrument, including review of Keeling Schedule to support drafting.

8. Applicable Guidance

8.1 DHSC are updating the IRMER guidance that is available on GOV.uk to reflect the changes made by this instrument. The updated guidance will be published in June

2024 to coincide with the laying and in advance of commencement on 1 October 2024. It can be found via Ionising Radiation (Medical Exposure) Regulations 2017: guidance - GOV.UK (www.gov.uk)[1]

8.2 Additional non-statutory guidance produced by a working party of representatives from professional bodies and radiation protection experts will be updated once the amendments come into force.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because there is minimal impact to businesses and the NHS as a result of this instrument. The costs or benefits to business are expected to be significantly lower than £5m in any one financial year. While this instrument does include an inflationary uplift in employer license fees for the administration of radioactive substances, it is expected to have minimal impact as the increase amounts to approximately £50 per application. Furthermore, as AI is already being utilised in medical settings to assist medical exposure services, the proposed amendment to regulate the use of AI is not considered 'contentious' and does not require a full impact assessment.

9.2 In line with the minimal impacts associated with this instrument, DHSC has completed a de-minimis assessment.

Impact on businesses, charities and voluntary bodies

9.3 There is no, or no significant, impact on business, charities or voluntary bodies because of the reasons set out in 9.2.

9.4 The legislation does not impact small or micro businesses.

9.5 There is no, or no significant, impact on the public sector. The instrument includes an uplift to employer license fees for sites undertaking nuclear medicine procedures in line with inflation. This is estimated to result in a direct cost of £180k across all sites over the next five-year period. To minimise the burden on businesses, this figure will be proportionally distributed across all employer license applications. As a result, individual sites will experience an increase of approximately £50 per application: £298 (previously £250) for a new employer licence, and £244 (previously £200) for an amendment or renewal of an existing licence. As licenses are typically valid for 5 years, this is not expected to place additional burdens on small business.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 This instrument does not include a dedicated review clause; however, IR(ME)R 2017 includes a statutory review provision which must be undertaken within five-year intervals. This instrument does not make any amendments to this provision, and subsequent reviews will be undertaken at intervals not exceeding five-years.

[1] https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is made under paragraph 7 of Schedule 4 and paragraph 21(a) and (b) of Schedule 7 to the European Union (Withdrawal) Act 2018. It therefore relates to the withdrawal of the United Kingdom from the European Union. No statement is required by the Minister in accordance with that Act.