EXPLANATORY MEMORANDUM TO

THE IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS 2017

2017 No. 1322

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument transposes and implements the medical exposures aspects of European Council Directive 2013/59/EURATOM[1] and thereby ensures safe use of radiological procedures such as medical imaging or radiological treatments.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

4.1 This instrument is being made to implement a European obligation, set out in European Council Directive 2013/59/EURATOM ("the Directive"). The Directive updates and consolidates five existing directives and one European Commission recommendation relating to radiation protection into a single Basic Safety Standards Directive (BSSD), which has a transposition date of 6 February 2018.

4.2 The BSSD covers several aspects of radiation protection including medical, public and occupational exposures and emergency preparedness and response. Co-ordination of and overall responsibility for revision and transposition of the BSSD lies with the Department for Business, Energy and Industrial Strategy, and the Department of Health has led transposition of the medical exposure elements of the BSSD. Other Departments are responsible for transposing the remaining aspects of the BSSD.

4.3 This instrument is linked to the Ionising Radiations Regulations 2017[2] which are the responsibility of the Health and Safety Executive and transpose the elements of the BSSD relating to occupational exposures. A number of other instruments, which will be laid in Parliament in the coming months by other Departments, including two from BEIS and one from the Department for Transport, will transpose the remaining requirements of the BSSD and will be covered by separate Explanatory Memoranda.

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013L0059
[2] http://www.legislation.gov.uk/uksi/2017/1075/contents/made

4.4 A Transposition Note and Scrutiny History are submitted with this Explanatory Memorandum.

5. Extent and Territorial Application

5.1 The Ionising Radiation (Medical Exposures) Regulations 2017 ("the Regulations") will extend to England, Scotland and Wales. Separate similar provisions will apply in Northern Ireland.

5.2 The Ionising Radiation (Medical Exposures) Regulations 2017 ("the Regulations") will apply to England, Scotland and Wales. Separate similar provisions will also apply in Northern Ireland.

6. European Convention on Human Rights

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

7. Policy background

What is being done and why

7.1 The primary policy objective is to ensure that individuals are protected when exposed to ionising radiation from medical equipment for imaging or treatment purposes. The BSSD incorporates the recommendations of the International Commission on Radiological Protection[3] and updates and consolidates existing measures relating to radiation protection into a single Directive. The medical exposure elements of the BSSD lay down minimum safety standards for protection against the dangers arising from exposure to ionising radiation which would take place at hospitals or other establishments such as dental surgeries.

7.2 The requirements of the BSSD for medical exposures were negotiated by the Department to align with existing UK administrative processes and good practice within healthcare. Implementing the medical aspects of the BSSD offers the Department an opportunity to update the existing regulations relating to medical exposures and consolidate them into a single set of regulations. Modernising the regulations in this way will make the legislative framework simpler and easier to understand, while strengthening protection for people who are subject to medical radiological procedures.

7.3 The range of medical exposures to ionising radiation to which the Regulations apply are detailed in regulation 3 and include exposure of patients as part of their 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 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.

7.4 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:

[3] http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103

- the Regulations expand 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, addressed in Regulations 8 and 9, 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;
- the Regulations formalise the recognition of Medical Physics Experts (MPEs) (see regulation 14). 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. It is estimated that there are currently around 900 individuals entitled to act as MPEs within Great Britain and that there will be around 50 new applications for recognition as an MPE each year after the instrument comes into force; and
- the Regulations introduce 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 by regulation 5 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.

Consolidation

7.5 The Regulations repeal and replace the Ionising Radiation (Medical Exposure) Regulations 2000 (S.I. 2000/1059), the Medicines (Administration of Radioactive Substances) Regulations 1978 (S.I. 1978/1006) and the Medicines (Radioactive Substances) Order 1978 (S.I. 1978/1004) as they apply in Great Britain.

8. Consultation outcome

8.1 The Department publically consulted on a draft of the Regulations from 13 July to 31 July 2017, consistent with an open and transparent approach to decision making and appropriate regulation in matters relating to health. A targeted stakeholder consultation meeting ensured that the correct bodies and professions were able to contribute during the consultation period. The consultation asked 15 substantive questions, which focused on new requirements of the Directive or proposals for consolidating requirements from other regulations.

8.2 The Department received 139 consultation responses in total, from organisations, including key professional bodies, and individual respondents from across the UK. The consultation responses did not raise any significant issues that needed changes to the overall implementation approach. Minor revisions to the legislative text made in light of feedback received have been explained in the published response document[4].

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

9. Guidance

9.1 Non-statutory guidance which accompanies the Ionising Radiation (Medical Exposure) Regulations 2000 will be revised to reflect the changes made by the new Regulations and new guidance will be published to accompany the Regulations. This will be available online in February 2018 on the GOV.UK website.

9.2 The content of guidance has been informed by views gathered during consultation and stakeholder input from a guidance workshop. The Department has worked with stakeholders throughout negotiation and transposition of the BSSD and will continue to do so to ensure the relevant people are aware of the changes and what constitutes compliance.

10. Impact

10.1 The impact on business, charities and voluntary bodies is expected to cost less than £500,000 over a ten year period.

10.2 The impact on the public sector is estimated to be a saving of around £1,500,000 across the healthcare system as a whole, over the same period, which is likely to bear an opportunity benefit in terms of health.

10.3 Consistent with better regulation framework scrutiny processes and guidance for low cost EU measures, a Regulatory Triage Assessment has been prepared rather than a full Impact Assessment. This will be submitted with this Explanatory Memorandum and published on the legislation.gov.uk website.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by a certain small businesses, such as independent dental surgeries that provide imaging services.

11.2 No specific action is proposed to minimise regulatory burdens on these small businesses, as it would not be beneficial to reduce protection for individuals undergoing medical exposures. The legislation includes a commitment to review the objectives of the legislation in relation to small buisnesses.

12. Monitoring and review

12.1 A statutory review provision has been included in this instrument to be carried out within 5 years. A commitment to review the arrangements for licence fees after one year has been made by Public Health England, who will issue licences on the Department's behalf. The regulatory framework reflects best practice and clinical procedures which are, in effect, subject to continuous review through ongoing engagement with professional bodies and enforcement agencies.

13. Contact

13.1 Trudy Netherwood at the Department of Health (Trudy.Netherwood@dh.gsi.gov.uk) can answer any queries regarding the instrument.