

**EXPLANATORY MEMORANDUM TO**  
**THE IONISING RADIATION (MEDICAL EXPOSURE) (AMENDMENT)**  
**REGULATIONS 2018**

**2018 No. 121**

**1. Introduction**

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

**2. Purpose of the instrument**

- 2.1 This instrument amends the Ionising Radiation (Medical Exposure) Regulations 2017<sup>1</sup>, which relate to the safe use of radiological procedures such as medical imaging or radiological treatments. The amending instrument corrects a significant error identified in those Regulations which requires urgent amendment in advance of their coming into force on 6 February 2018.

**3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory Instruments*

- 3.1 In order for the amendments to come into force to correct the Ionising Radiation (Medical Exposure) Regulations 2017, it is necessary to breach the 21 day rule for Parliamentary Scrutiny of this instrument. This is necessary and justifiable because as currently drafted, the Ionising Radiation (Medical Exposure) Regulations 2017 would put certain health professionals acting under the Regulations at risk of committing criminal offences. The effects of this error are at odds with the intended policy objective and would expose clinical staff and their employers to a risk of prosecution.

*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 amends the Ionising Radiation (Medical Exposure) Regulations 2017 which transpose the medical exposures elements of European Council Directive 2013/59/EURATOM, laying down minimum safety standards for protection against the dangers arising from exposure to ionising radiation. The Ionising Radiation (Medical Exposure) Regulations are due to come into force on 6 February 2018.
- 4.2 An error has been identified in Schedule 4 to the Ionising Radiation (Medical Exposure) Regulations 2017, which makes consequential amendments to regulation 240 of the Human Medicines Regulations 2012<sup>2</sup>. Urgent amendment of the Ionising

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<sup>1</sup> <http://www.legislation.gov.uk/uksi/2017/1322/contents/made>

<sup>2</sup> <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

Radiation (Medical Exposure) Regulations 2017 is required to ensure that clinical staff are not guilty of criminal offences arising from the error.

## **5. Extent and Territorial Application**

- 5.1 This instrument extends to England, Wales, Scotland and Northern Ireland as specified in the legislation, in agreement with the Devolved Administrations.
- 5.2 This instrument applies to England, Wales, Scotland and Northern Ireland as specified in the legislation, in agreement with the Devolved Administrations.

## **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 of the Ionising Radiation (Medical Exposure) Regulations 2017 is to provide safeguards when individuals are exposed to ionising radiation from medical equipment for imaging or treatment purposes. Such exposures routinely take place at hospitals or other establishments such as dental surgeries.
- 7.2 This amending statutory instrument will correct a significant error in the consequential amendments to the Human Medicines Regulations 2012. A number of other minor technical errors will also be corrected.
- 7.3 Regulation 214(2) of the Human Medicines Regulations 2012 restricts administration by injection (known as parenteral administration) of a prescription only medicine to an appropriate practitioner or in accordance with the directions of an appropriate practitioner (a doctor, a dentist, or other specified prescriber). However, this provision is subject to a number of exemptions including, in Regulation 240, radioactive substances or other prescription only medicines which are administered as part of a medical exposure, if five conditions are met.
- 7.4 These five conditions relate to accordance with procedures and protocols set out under the Ionising Radiation (Medical Exposure) Regulations 2000, and authorisation by a practitioner certificated under the previous certification system. This is an important element of the legislative framework as specialist clinical staff in nuclear medicine departments, such as radiographers, clinical technologists and clinical scientists are able to carry out parenteral administration of radioactive substances and other medicines as part of medical exposures.
- 7.5 The Ionising Radiation (Medical Exposure) Regulations 2017 Regulations insert revised conditions into regulation 240. The policy is that one of the revised conditions should be that '*in the case of a prescription only medicine that is not a radioactive substance, it is specified in the protocols*', which are set out in the Ionising Radiation (Medical Exposure) Regulations 2017. This policy is not accurately reflected by the Ionising Radiation (Medical Exposure) Regulations 2017. The new condition simply states that '*the prescription only medicine is not a radioactive substance*'.
- 7.6 The effect of this condition is that clinical staff, who are not on the appropriate practitioners list, who parenterally administered radioactive substances which are prescription only medicines, would be committing a criminal offence. This would

have very undesirable consequences for nuclear medicine departments where virtually all administrations are carried out by radiographers, clinical technologists, clinical scientists or other staff who are not included in the list of appropriate practitioners.

- 7.7 Therefore we have prepared an urgent amending Statutory Instrument (SI) to correct this error. A small number of technical errors have also been identified which would be corrected at the same time. Amendments are also made in the light of the Northern Irish version of the Ionising Radiation (Medical Exposure) Regulations 2017.

### ***Consolidation***

- 7.8 The amendments presented in this instrument do not need consolidation at present.

## **8. Consultation outcome**

- 8.1 This statutory instrument has not been publically consulted on; however the Department ran a public consultation on the Ionising Radiation (Medical Exposure) Regulations 2017 from 13 July to 31 July 2017. The original policy intention of the legislation is unchanged and this statutory instrument is correcting the original text.

## **9. Guidance**

- 9.1 Non-statutory guidance which accompanies the Ionising Radiation (Medical Exposure) Regulations 2000 has been revised to reflect the changes made by the new Regulations and new guidance will be published to accompany the Regulations.

## **10. Impact**

- 10.1 The impact on business, charities or voluntary bodies is unchanged.
- 10.2 The impact on the public sector is unchanged.
- 10.3 This instrument will come into force on 6 February 2018, immediately after the Ionising Radiation (Medical Exposure) Regulations 2017, to correct the errors and avoid the risk of unintended criminal offences.
- 10.4 Consistent with better regulation framework scrutiny processes and guidance for low cost EU measures, a regulatory triage assessment<sup>3</sup> has been prepared for the Ionising Radiation (Medical Exposure) Regulations 2017, rather than a full Impact Assessment.
- 10.5 The regulatory triage assessment has not been updated as the original intended impact will not be changed by the amending statutory instrument.

## **11. Regulating small business**

- 11.1 The Ionising Radiation (Medical Exposure) Regulations 2017 apply to activities that are undertaken by a certain small businesses, such as independent dental surgeries that provide imaging services. These amendments regulations do not impact small businesses as these are correcting the original statutory instrument.

## **12. Monitoring and review**

- 12.1 A statutory review provision has been included in the Ionising Radiation (Medical Exposure) Regulations 2017, to be carried out within 5 years.
- 12.2 There is no additional review provision in the amending statutory instrument.

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<sup>3</sup> [http://www.legislation.gov.uk/uksi/2017/1322/pdfs/uksiod\\_20171322\\_en.pdf](http://www.legislation.gov.uk/uksi/2017/1322/pdfs/uksiod_20171322_en.pdf)

### **13. Contact**

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