EXPLANATORY MEMORANDUM TO

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

SR No.17

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Department of Health to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2. The Statutory Rule is made under section 2(2) of the European Communities Act 1972 and section 56 of the Finance Act 1973 and with the consent of the Department of Finance in respect of the powers conferred by section 56 and is subject to the negative resolution procedure.

2. Purpose

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

3. Background

3.1. European Council Directive 2013/59/EURATOM (BSSD, "the Directive") lays 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.

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

3.3. 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.

3.4. 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:

3.5. 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.

3.6. 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.

3.7. 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.

4. Consultation

4.1. The Department publically consulted on a draft of the Regulations from 24 October to 19 December 2017. The consultation questionnaire focused on new requirements of the Directive or proposals for consolidating requirements from other regulations. Eight substantive responses were received from professional bodies and individual healthcare professionals. A targeted stakeholder meeting was also held on 5 January 2018 to address any remaining concerns.

4.2. The meeting and 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.

4.3. UK-wide guidance for the Regulations is being developed by the Department of Health (England) and Public Health with continued input from devolved administrations and stakeholders.

5. Equality Impact

5.1. In accordance with guidance produced by the Equality Commission for Northern Ireland and in keeping with Regulation 75 of the Northern Ireland Act 1998, the proposals for the IR(ME)R (NI) 2018 have been screened for equality impact and it is concluded that a full Equality Impact Assessment is not required.

6. Regulatory Impact

6.1. A Regulatory Impact Assessment (RIA) screening was carried out prior to consultation. The screening concluded that the Statutory Rule will have negligible cost impact on businesses, charities, social economy enterprises or the voluntary sector in Northern Ireland and will not otherwise adversely affect these groups. The Department considers that a full RIA is not required.

7. Financial Implications

7.1. There will be negligible cost impact on businesses, charities, social economy enterprises or the voluntary sector in Northern Ireland. Some minimal cost are likely for the public sector in terms of increased training for MPEs but savings are also anticipated from the streamlining of licensing requirements that should allow a significant reduction in the overall time spent by medical staff making applications for authorisation to administer radioactive substances.

8. Section 24 of the Northern Ireland Act 1998

8.1. The Statutory Rule is not deemed to breach Section 24 of the Northern Ireland Act 1998 as it is considered to be compatible with any of the Convention rights or community law and does not discriminate against a person on the grounds of religious belief or political opinion.

9. EU Implications

9.1. This instrument is being made to implement a European obligation, set out in European Council Directive 2013/59/EURATOM, which has a transposition date of 6 February 2018

9.2. The Statutory Rule is required for transposition of the medical exposure aspects of the Directive into Northern Ireland legislation. It does not seek to exceed the Directive's requirements.

9.3. A UK-wide Transposition Note has been prepared to cover transposition of all pertinent aspects of the Directive. A separate Transposition Note for this instrument is therefore not required.

10. Parity or Replicatory Measure

10.1. Separate similar provision has been made to tranpose of the medical exposure aspects of the Directive into GB legislation.

11. Additional Information

11.1. Not applicable.