EXPLANATORY MEMORANDUM TO

The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010

SR No. 2010 No. 29

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Department of Health Social Services and Public Safety 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 is subject to the negative resolution procedure.

2. Purpose

2.1. The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010 (the Regulations) amend the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 (the 2000 Regulations).

2.2. The Regulations pass enforcement powers under the 2000 Regulations to the Health and Social Care Regulation and Quality Improvement Authority. They also make amendments to certain definitions in the 2000 Regulations in order to clarify their meaning and reflect changes to terminology used in the 2000 Regulations.

3. Background

3.1. It is a requirement under the EC Directive EURATOM for each Member State to have proactive inspections of practises in the use of radiation for medical purposes. In Northern Ireland, this obligation has been fulfilled under the 2000 Regulations, which covers issues such as the identification of patients who are having x-rays, the training of the operators of the radiological equipment, and the correct completion of referral forms. The Department of Health, Social Services and Public Safety (the Department) was designated as the enforcing authority under the 2000 Regulations.

3.2. As regulations to implement the EURATOM Directive were developed, it was agreed by the health departments in each part of the United Kingdom that Department of Health (DoH) inspectors would provide the necessary proactive inspections of radiological departments, while the enforcement role would be carried out by the health department in each country. The status of enforcing authority under the 2000 Regulations empowers the Department to take action, including prosecution under health and safety legislation, in the event of a breach of the 2000 Regulations.

3.3. The reorganisation of functions carried out by DoH in 2004 saw the relevant inspectorate team move to the Health Protection Agency (HPA) and their role change to be purely advisory. The loss of the DoH inspectorate required Northern Ireland to make new arrangements for inspection and enforcement.

3.4. It was agreed that the enforcement powers for Northern Ireland should be transferred to the Health and Social Care Regulation and Quality Improvement Authority.

4. Consultation

4.1. A public consultation was carried out between 12 May - 8 July 2009.

4.2. Only two responses were received; one confirming receipt of the consultation but making no comment, and the other noting the consultation and giving a amended name for an organisation.

5. Equality Impact

5.1. The changes proposed under the Regulations have been screened for equality implications and it has been concluded that they do not have a significant impact on equality of opportunity and therefore do not require a full equality impact assessment.

6. Regulatory Impact

6.1. A regulatory impact assessment is not required for the Regulations as they will not impose a cost compliance on business, charities ot the voluntary sector or result in a cost saving.

7. Financial Implications

7.1. The transfer of functions will incur an increase in funding of £35,000, which has been made available. The increased funding will support a broader programme of inspections than previousley, allowing inspections of practices outside health service hospital settings.

8. Section 24 of the Northern Ireland Act 1998

8.1. The Regulations do not breach section 24 of the Northern Ireland Act 1998.

9. EU Implications

9.1. The Regulations amend the 2000 Regulations, which partially implemented Council Directive 97/43/Euratom.

10. Parity or Replicatory Measure

10.1. In England, Ministers approved the making of new regulations to enable the Commission for Healthcare, Audit and Inspection (the Commission) to become the enforcing authority, transferring that responsibility from DoH, and for the Commission to also conduct the necessary inspections of radiological services. The new Regulations came into force in England on 1 November 2006. Wales has similarly made new arrangements for inspection and enforcement, while Scotland is rolling out a new system of inspection.

11. Additional Information

11.1. Not applicable.