

**EXPLANATORY MEMORANDUM TO
THE IONISING RADIATION (MEDICAL EXPOSURE) (AMENDMENT)
REGULATIONS 2011**

2011 No. 1567

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 aims to ensure that asymptomatic individuals (people who do not have any symptoms of a relevant illness), who are exposed to medical x-rays for the purpose of health assessments, other than part of a national screening programme or for diagnostic purposes, are included within the Ionising Radiation (Medical Exposure) Regulations 2000 (“IRMER”), which this instrument amends. The amendment aims to make this explicit and beyond any doubt.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The principle of balancing risk and benefit (“justification”) is already enshrined in legislation (IRMER). A medical exposure may only be justified following an assessment that the benefit outweighs the risk. However these regulations are framed in terms of quite specific activities:

- The patient’s own diagnosis and treatment
- Occupational health surveillance
- Health screening programmes
- Volunteers in research programmes
- Medico-legal procedures

4.2 None of these specified activities explicitly captures these relatively new patient-initiated CT scanning services, which we propose to call “Individual Health Assessments” (IHA). This leaves open the possibility that IHA might be undertaken without due justification. To put matters beyond doubt, therefore, the regulations should be amended so as to include specifically the provision of IHA as an exposure requiring justification.

4.3 However, as IHA has no technical meaning it would have been inappropriate to use the term.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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 In 2007, the Committee on Medical Aspects of Radiation in the Environment (COMARE) published a report on the CT Scanning of Asymptomatic Individuals, which made a number of recommendations to the Department of Health. In summary, the Committee considered that some of these CT scans could be justified so that a flexible framework of regulation needed to be introduced that took rapid changes in technology and science into consideration.

7.2 The Committee drew a distinction between diagnostic exposures and these exposures of asymptomatic individuals. However, though the better interpretation of IRMER would be that IHAs were within it, it was not explicit. Further, as IHAs were a recent development, it was felt that it was in the interest of the public in general, persons who provided scanning and those whose duty it is to regulate these matters that the matter should be made explicit and beyond doubt. Accordingly, these regulations give effect to the Committee's advice.

- Consolidation

7.3 There are no plans to consolidate any regulations

8. Consultation outcome

8.1 On the advice of the Chief Medical Officer, The Department of Health (DH) held a 12 week consultation on COMARE's recommendations from 20 July 08 to 9 Sept 08 to discover if there was any new evidence available which might shape the intended course of action.

8.2 The main aim of the consultation was to assess whether any of the evidence emerging from the consultation raised new issues of science or medicine not included in COMARE's report. Officials consulted relevant UK experts on the evidence provided by the CT scanning companies and DH officials from Heart and Stroke team, Cancer, National Screening programmes and Diagnostic Imaging. The consensus (save for the scanning companies) was that COMARE's recommendations stood undiminished.

8.3 DH have drawn together the consultation response, the Department's conclusions and proposed next steps in consequence of the consultation responses on each of the nine recommendations. The report also includes the necessary Impact Assessment on equalities and was published on the DH website on April 6 2010. The Impact Assessment on resources recently agreed by a DH Minister is included with this EM.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_116721

9. Guidance

9.1 In parallel with the clarified legislation, DH have commissioned the development of guidance to practitioners reflecting the amended regulations and the policies underlying COMARE's recommendations. This guidance would make it clear how the balance on risks and benefits for justification should be addressed, what considerations the practitioner should take into account, what information should be given to the patient, and what feedback passed to the NHS, and so on. Such guidance would best come from the professions themselves, and DH has formally gained the agreement of the Royal College of Radiologists and the Royal College of Physicians to lead its preparation. The guidance should be ready late 2011 and because the amendment is only making the issue explicit, timing is not so critical.

10. Impact

10.1 The impact on business, charities or voluntary bodies has been assessed as minimal

10.2 The impact on the public sector is negligible

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the OPSI website.

11. Regulating small business

11.1 The legislation applies to small businesses, but there are no small businesses providing this kind of scanning and the amendment will therefore will have no impact on small businesses.

12. Monitoring & review

12.1 Feedback from the IRMER enforcement authorities will act as the monitoring mechanism. The Care Quality Commission enforces IRMER in England and each Devolved Administration operates their own respective enforcement authority. It is unlikely that any further action will need to be taken with IRMER but the guidance will need to be regularly reviewed to take any changes in scientific evidence and imaging technology into account.

13. Contact

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