

**EXPLANATORY MEMORANDUM TO THE
IONISING RADIATION (MEDICAL EXPOSURE)
(AMENDMENT) REGULATIONS 2006**

2006 No. 2523

1. Introduction

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

2. Description

2.1 The Ionising Radiation (Medical Exposure)(Amendment) Regulations 2006 (“the Regulations”) amend the Ionising Radiation (Medical Exposure)Regulations 2000, S.I. 2000/1059 (“the 2000 Regulations”). They pass the enforcement powers under the 2000 Regulations in respect of England to the Commission for Healthcare, Audit and Inspection (“the Healthcare Commission”). The Regulations 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.

2.2 The Regulations are subject to a negative procedure.

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

3.1 None.

4. Legislative Background

4.1 The 2000 Regulations partially implement, as respects Great Britain, Council Directive 97/43/Euratom laying down basic measures for the health protection of individuals against the dangers of ionising radiation in relation to medical exposure. The 2000 Regulations are made enforceable as if they were health and safety regulations made under the Health and Safety at Work etc. Act 1974, except that the enforcing authority is the Secretary of State as regards England. The Regulations effect the change of the enforcing authority to the Healthcare Commission by amending the definition of the term “appropriate authority”.The enforcing authorities for Scotland and Wales remain unchanged.

4.2 The Regulations amend the definitions of “practitioner” and “referrer” in the 2000 Regulations to clarify that they refer to a registered health care professional. The 2000 Regulations currently define these in terms of

“registered medical practitioner, dental practitioner or other health professional”. However, the terms “medical practitioner” and “dental practitioner” are encompassed in “health care professional” such that they do not need to be mentioned separately. This change also clarifies that “health professional” (now “health care professional”) refers to someone who is registered. The Regulations also make amendments to reflect a change in the terminology used to describe the ethics committees whose approval is needed in the case of exposure for research purposes under the 2000 Regulations – these are now known as “ethics committees” instead of “Local Research Ethics Committees”.

4.3 The Regulations also make transitional provision for incomplete matters or matters not finally disposed of before the Regulations come into force.

5. Extent

5.1 This instrument applies to Great Britain.

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

7.1 DH has responsibility for the 2000 Regulations and will continue to do so, however in 2003 Ministers agreed that the enforcement powers and inspection functions under the 2000 Regulations should pass in 2005/2006 to the Healthcare Commission.

7.3 To this end draft amending regulations were drawn up and a consultation held (January -10 April 2006) to allow interested parties to comment on the proposal and the draft regulations. The consultation document was sent to various organisations such as the British Chiropractic Association, the British Institute of Radiology, the British Nuclear Medicine Society, the Chartered Society of Physiotherapy, the General Chiropractic Council, the Health Professions Council and so on. A full list of the organisations can be found at http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4133881&chk=FwEOrP.

7.4 The consultation document was also made available on the DH consultations website. Out of 31 replies, 24 supported the proposal. A few replies pointed out certain errors in the terminology and numbering in the Explanatory Note which have been corrected. Some replies suggested a clarifying amendment to the definition of “ethics committees” but in accordance with advice from the Central Office for Research Ethics (COREC) this was not done. Some replies raised concerns around the definition of the term “referrer” and on the status of clinical technologists who are currently not registered health professionals.

The registration of this group is in hand. One reply suggested a change to the definition of the term “medical physics expert” but this has not been taken up. Two replies queried the transfer of the enforcement and inspection functions to the Healthcare Commission and one reply did not support the Regulations. A link to the summary of the consultation can be found at http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4133881&chk=FwEOrP

7.5 Stakeholders are being advised of the changes by correspondence and via the DH website, and through editorials and articles in the relevant professional journals and websites.

8. Impact

8.1 A Regulatory Impact Assessment is not required as the impact of these Regulations on the private, or voluntary sector is expected to be negligible.

9. Contact

9.1 Any enquiries about the contents of this memorandum should be addressed to Patricia Brown at the Department of Health, Wellington House, 133-155 Waterloo Road, London, SE1 8UG. Tel: 020 7972 4572 (e -mail: Patricia.Brown@dh.gsi.gov.uk).