

Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006: A consultation

Launch date : 9 January 2006

Closing date : 10 April 2006

Ministers have agreed that, as regards England, the inspectorate functions and enforcement powers of the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R 2000) should be transferred to the Healthcare Commission (in law the Commission for Healthcare Audit and Inspection).

In order to affect this change the definition of the term “appropriate authority” needs to be amended in the Regulations. DH is also taking the opportunity to make additional amendments to clarify other matters for those having to comply with IR(ME)R 2000.

The consultation letter is being sent in hard copy to those organisations listed below:

- British Chiropractic Association
- British Institute of Radiology
- British Nuclear Medicine Society
- Chartered Society of Physiotherapy
- General Chiropractic Council
- Health Professions Council
- Institute of Physics and Engineering in Medicine
- Royal College of General Practitioners (Edinburgh)
- Royal College of General Practitioners (London)
- Royal College of Nursing (Edinburgh)
- Royal College of Nursing (London)
- Royal College of Physicians (Edinburgh)
- Royal College of Physicians (London)
- Royal College of Physicians and Surgeons (Glasgow)
- Royal College of Radiologists
- Royal College of Speech and Language Therapists
- Society and College of Radiographers

The consultation document is available at www.dh.gov.uk/consultations and comments are welcome from all interested parties. A form is attached for your reply

Contact information

The deadline for responses to this consultation is **Monday 10 April 2006**.

Contact Patricia Brown
Address Area 520 Wellington House
133-155 Waterloo Road
London SE1 8UG

Email irmerconsult@dh.gsi.gov.uk

PROPOSALS FOR AMENDMENTS TO THE IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS 2000 (IR(ME)R 2000)

The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R 2000) largely implement European Council Directive 97/43/Euratom in Great Britain. The Directive lays down basic measures for the health protection of individuals against the dangers of ionising radiation in relation to medical exposure.

The purpose of this document is to seek comments on the draft regulations that are intended to transfer the enforcement powers of IR(ME)R 2000 to the Healthcare Commission (in law the Commission for Healthcare Audit and Inspection).

Currently the “appropriate authority” for England is defined in Regulation 2 as the Secretary of State for Health.

There are other changes which it may be appropriate to make at the same time to clarify matters for those having to comply with IR(ME)R. including:

Registered professional - in Regulation 2, Interpretation, currently it is not clear that the term “registered” applies to all of the three categories of staff listed under “practitioner” and “referrer” i.e. “registered medical practitioner, *registered* dental practitioner or other *registered* health professional who...”

This Consultation invites comments on the draft regulations attached at Annex A. Please complete a response form and attach your comments to this form.

Following the end of the consultation period a summary of responses will be prepared which will be available on the DH website.

It will be assumed that your comments can be made publicly available unless you indicate that you wish all or part of them to be treated as confidential and excluded from this arrangement.

Subject to the agreement of Parliament, we plan to implement the changes to the Regulations by Statutory Instrument in June 2006.

DH written, public consultations follow the Cabinet Office code of practice. The code includes the following criteria:-

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the time-scale for responses.
3. Ensure that your consultation is clear, concise and widely accessible
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department’s effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a regulatory impact assessment if appropriate.

Respondents are also invited to comment on the extent to which the criteria have been adhered to and to suggest ways of further improving the consultation process. If you have any comments or complaints about the consultation process, these should be directed to:

Steve Wells
Consultation Coordinator
Department of Health
Skipton House
80 London Road
London SE1 6LH

A Regulatory Impact Assessment is not required for these proposals because they will not impose a cost compliance on business, charities or the voluntary sector or result in a cost saving.

To: Patricia Brown
Department of Health
Area 520 Wellington House
133-155 Waterloo Road
London SE1 8UG

From: _____

Please indicate clearly if you are replying on behalf of a group or an organisation

**PROPOSALS FOR AMENDMENTS TO THE IONISING RADIATION
(MEDICAL EXPOSURE) REGULATIONS 2000 (IR(ME)R 2000)**

- * 1. I support the proposed amendments contained in the consultation document
- * 2. I have no comments to make on the proposed amendments contained in the consultation document
- *3. My comments on the proposed amendments are set out below/attached

- * My reply may be made freely available
- *My reply is confidential
- *My reply is partially confidential (indicate clearly in the text any confidential elements)

Signed: _____

- * Delete as appropriate

DRAFT REGULATIONS

 STATUTORY INSTRUMENTS

2006 No. ####

HEALTH AND SAFETY
**The Ionising Radiation (Medical Exposure) (Amendment)
Regulations 2006**

<i>Made</i> - - - -	***
<i>Laid before Parliament</i>	###
<i>Coming into force</i> - -	###

The Secretary of State, being the Minister designated⁽¹⁾ for the purposes of section 2(2) of the European Communities Act 1972⁽²⁾ in relation to the making of safety measures in regard to radioactive substances and the emission of ionising radiation, in exercise of the powers conferred upon her by that section, makes the following Regulations:

Citation and commencement

1.—These Regulations may be cited as the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 and shall come into force on

Amendment of the Ionising Radiation (Medical Exposure) Regulations 2000

2.—(1) The Ionising Radiation (Medical Exposure) Regulations 2000⁽³⁾ are amended as follows.

(2) In regulation 2 (interpretation) in paragraph (1)—

- (a) in the definition of “appropriate authority”, for “Secretary of State” substitute “the Commission for Healthcare Audit and Inspection established under section 41 of the Health and Social Care (Community Health and Standards) Act 2003⁽⁴⁾”;
- (b) after the definition of “equipment” insert the following definition—

““ethics committee” means:

- (a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004⁽⁵⁾,
- (b) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000⁽⁶⁾, or

(1) S.I. 1977/1718.

(2) 1972 c. 68.

(3) S.I. 2000/1059; amended by S.I. 2004/1031.

(4) 2003 c. 43.

(5) S.I. 2004/1031.

(6) 2000 asp.4.

(c) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State, the National Assembly for Wales or Scottish Ministers;”;

(c) the definition of “Local Research Ethics Committee” is omitted;

(d) in the definition of “practitioner”, after “medical practitioner,” insert “registered” and after “or other” insert “registered”;

(e) in the definition of “referrer”, after “medical practitioner,” insert “registered”, after “or other” insert “registered” and replace the full-stop with a semi-colon;

(f) after the definition of “referrer” insert the following definition—

““registered health professional” means a registered member of any healthcare profession to which section 60(2) of the Health Act 1999(7) applies.”.

(3) In regulation 6 (justification of individual medical exposures), in paragraph (1)(c), for “a Local Research Ethics Committee” substitute “an ethics committee”.

(4) In regulation 11 (training), in paragraph (4), after “record of” insert “all training undertaken by”.

Signed by authority of the Secretary of State for Health

Parliamentary Under Secretary of State
Department of Health

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Ionising Radiation (Medical Exposure) Regulations 2000 (“the 2000 Regulations”) including clarification and updating of certain references. The 2000 Regulations partially implement, as respects Great Britain, Council Directive 97/43/Euratom (OJ No L180, 9.7.97, p 22) on health protection of individuals against the dangers of ionising radiation in relation to medical exposure.

Regulation 2(2)(a) substitutes the Commission for Healthcare Audit and Inspection (known as the “Healthcare Commission”) for the Secretary of State as the “appropriate authority”. The “appropriate authority”, amongst other things, has inspection and enforcement functions under the 2000 Regulations.

Other definitions are added or amended or removed to reflect changes to the main body of the Regulations and include the following:

Regulation 2(2)(b) and (c) inserts a definition of “ethics committee” and omits the definition of “Local Research Ethics Committee”.

Regulation 2(2)(c) and (d) makes clear that, in the definitions of “practitioner” and “operator”, the terms “dental practitioner” and “other health professional” mean “registered dental practitioner” and “other registered health professional” respectively.

Regulation 2(2)(e) inserts a definition of “registered health professional”.

Regulation 2(3) substitutes in regulation 6 of the 2000 Regulations the term “an ethics committee” for “a Local Research Ethics Committee”.

Regulation 2(4) clarifies that the word “record” in regulation 11(4) of the 2000 Regulations refers to the record of training undertaken (which the employer is required to keep and have available for inspection by the appropriate authority).