

## STATUTORY INSTRUMENTS.

S.I. No. 459 of 2010

EUROPEAN COMMUNITIES (MEDICAL IONISING RADIATION PROTECTION) (AMENDMENT) REGULATIONS 2010

# EUROPEAN COMMUNITIES (MEDICAL IONISING RADIATION PROTECTION) (AMENDMENT) REGULATIONS 2010

- I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom<sup>1</sup>, hereby make the following regulations:
  - 1. (a) These Regulations may be cited as the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations 2010.
    - (b) In these Regulations "Principal Regulations" means the European Communities (Medical Ionising Radiation Protection) Regulations 2002 (S.I. No. 478 of 2002).
    - (c) The European Communities (Medical Ionising Radiation Protection) Regulations 2002 to 2007 and these Regulations may be cited together as the European Communities (Medical Ionising Radiation Protection) Regulations 2002 to 2010.
- 2. Regulation 7 of the Principal Regulations is amended by substituting the following paragraph for paragraph (6):
  - "(6) (a) If a person proposes to provide a health screening programme that involves medical exposure, the person shall, not later than three months before commencing the programme, notify the Minister of the proposal and shall furnish to the Minister the following information in writing in respect of the programme:
    - (i) particulars of the person who is to provide the programme;
    - (ii) the purpose of the programme;
    - (iii) particulars of the class of individuals to whom the programme is to be offered;
    - (iv) particulars of the information regarding the programme to be given to the individuals to whom it is to be offered, including the form or document to be signed by such individuals to indicate their consent to participate in the programme;

<sup>1</sup>OJ L 180, 9.7.1997, p.22-27.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1st October, 2010.

- (v) the place or places in which the programme is to be provided;
- (vi) the duration of the programme;
- (vii) particulars of the radiological equipment, practical techniques and ancillary equipment that are to be used in the provision of the programme;
- (viii) particulars of the quality assurance programmes, including quality control measures and patient dose or administered activity assessments, that are to apply to the programme;
- (ix) particulars of the qualifications and training on radiological practices, as well as competence in radiation protection, of the persons who are to perform the medical exposure under the programme;
- (x) particulars of insurance cover held by the person in relation to the provision of the programme; and
- (xi) particulars of the information which the individuals who participate in the programme, and their general medical practitioners, are to be furnished with regarding the results of their screening under the programme.
- (b) Upon review of the proposal and information furnished by a person under paragraph (a), the Minister may request the person to furnish such further particulars for the purposes of this Regulation as may be required by the Minister.
- (c) The Minister may request the Radiation Safety Committee to review and assess the information furnished by a person under paragraphs (a) and, if appropriate, (b) and, within the period specified in the request, to provide such advice as the Committee considers appropriate to the Minister arising from that review and assessment.".
- 3. Regulation 22 of the Principal Regulations is amended by inserting the following paragraph after paragraph (8):
  - "(9) The Radiation Safety Committee shall, whenever requested to do so by the Minister, review and assess information furnished to the Minister under paragraphs (a) and, if appropriate, (b) of Regulation 7(6), and shall, within the period specified in the request, provide such advice as the Committee considers appropriate to the Minister arising from such review and assessment.".



GIVEN under my Official Seal, 27 September 2010.

MARY HARNEY,
Minister for Health and Children.

# EXPLANATORY NOTE.

(This note is not part of the Instrument and does not purport to be a legal interpretation)

These Regulations amend Regulation 7 of the European Communities (Medical Ionising Radiation Protection) Regulations, 2002 (S.I. No. 478 of 2002). They specify the information that must be provided to the Minister in relation to any health screening programme which exposes programme participants to ionising radiation and they set out the role of the Radiation Safety Committee in relation to reviewing and assessing this information and advising the Minister on the outcome of that process.

### BAILE ÁTHA CLIATH ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR

Le ceannach díreach ón

OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS, TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2, nó tríd an bpost ó

FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA, AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS, CONTAE MHAIGH EO,

(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843) nó trí aon díoltóir leabhar.

#### DUBLIN

PUBLISHED BY THE STATIONERY OFFICE

To be purchased directly from the

GOVERNMENT PUBLICATIONS SALE OFFICE

SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,

or by mail order from

GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION, UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO, (Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843) or through any bookseller.

€2.54

