## 2006 No. 2523

## **HEALTH AND SAFETY**

# The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006

Made - - - - 13th September 2006

Laid before Parliament 21st September 2006

Coming into force - - 1st November 2006

The Secretary of State, being the Minister designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) 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 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 the 1st of November 2006.

#### Interpretation

**2.** In these Regulations "the 2000 Regulations" means The Ionising Radiation (Medical Exposure) Regulations 2000(**c**).

#### Amendment of the 2000 Regulations

- **3.**—(1) The 2000 Regulations 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(d)";
  - (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(e),

<sup>(</sup>a) S.I. 1977/1718.

**<sup>(</sup>b)** 1972 c. 68.

<sup>(</sup>c) S.I. 2000/1059; amended by S.I. 2004/1031.

<sup>(</sup>d) 2003 c. 43.

<sup>(</sup>e) S.I. 2004/1031.

- (b) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000(a), or
- (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", for "medical practitioner, dental practitioner or other health professional" substitute "health care professional";
- (e) in the definition of "referrer", for "medical practitioner, dental practitioner or other health professional" substitute "health care professional" and replace the full-stop with a semi-colon;
- (f) after the definition of "referrer" insert the following definition—
  - ""registered health care professional" means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002."
- (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".

#### **Transitional provisions**

- **4.**—(1) As regards England, the Secretary of State shall continue to be the appropriate authority in respect of
  - (a) any notification, before the coming into force of regulation 3(2)(a), of an incident by an employer under regulation 4(5) of the 2000 Regulations;
  - (b) any investigation, proceedings or other matter, including an appeal in relation to such matters, which has not been completed or finally disposed of before the coming into force of regulation 3(2)(a) and the appointment of and exercise of functions by inspectors in relation to such matters.

Signed by authority of the Secretary of State for Health

Caroline Flint
Minister of State
Department of Health

13th September 2006

#### **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 3(2)(a) substitutes the Commission for Healthcare Audit and Inspection for the Secretary of State as the "appropriate authority". The "appropriate authority", amongst other things, has inspection and enforcement functions under the 2000 Regulations.

Regulation 3(2)(b) and (c) inserts a definition of "ethics committee" and omits the definition of "Local Research Ethics Committee". This is to reflect the substitution by regulation 3(3) of the term "an ethics committee" for "a Local Research Ethics Committee" in the main body of the 2000 Regulations. There is no change in the substantive definition itself.

Regulation 3(2)(d) and (e) omits the terms "registered medical practitioner" and "dental practitioner" from the definitions of "practitioner" and "referrer". It also substitutes the term "registered health care professional" for "health professional". The term "registered health care professional" would cover registered medical practitioners and dental practitioners. Accordingly there is no need to mention these categories separately.

Regulation 3(2)(f) inserts a definition of "registered health care professional".

Regulation 3(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).

Regulation 4 is a transitional provision in relation to incomplete investigations, proceedings, appeals and other matters including notifications, under regulation 4(5) of the 2000 Regulations by employers, of incidents of overexposure. It provides for the Secretary of State to continue to be the appropriate authority for such matters, as regards England.

### STATUTORY INSTRUMENTS

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