
STATUTORY INSTRUMENTS

1988 No. 778

HEALTH AND SAFETY

**The Ionising Radiation (Protection of Persons Undergoing
Medical Examination or Treatment) Regulations 1988**

<i>Made</i>	- - - -	<i>26th April 1988</i>
<i>Laid before Parliament</i>		<i>3rd May 1988</i>
<i>Coming into force</i>	- -	<i>1st June 1988</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 by that section, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988 and shall come into force on 1st June 1988.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“adequate training” means tuition leading to competence in radiation protection and appropriate instruction, including practical experience, in the diagnostic or therapeutic techniques to be used; and the expression “adequately trained” shall be similarly construed;

“clinically directing” means having clinical responsibility for the decision to effect a medical exposure;

“medical exposure” means exposure of a person to ionising radiation for a diagnostic or therapeutic purpose;

“patient” means a person undergoing medical examination or treatment;

“physically directing” means effecting the medical exposure; and the expression “a person physically directing a medical exposure” shall include a person acting in accordance with the directions of a doctor or dentist for the purposes of regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978⁽³⁾;

(1) S.I.1977/1718.
(2) 1972 c. 68.
(3) S.I. 1978/1006.

“radioactive medicinal product” has the meaning ascribed to it in the Medicines (Administration of Radioactive Substances) Regulations 1978.

(2) For the purposes of these Regulations any reference to an employer shall include a reference to a self-employed person and any duty imposed by these Regulations on an employer in respect of an employee shall extend to a self-employed person in respect of himself.

Application of these Regulations

3.—(1) These Regulations shall apply to all types of procedures resulting in a medical exposure.

(2) These Regulations shall not extend to the use of ionising radiation in the field of scientific research.

Requirement for medical exposures

4.—(1) Every medical exposure shall be carried out under the responsibility of a person who is clinically directing it and who shall see to it that the requirements of this regulation are satisfied.

(2) No person shall clinically or physically direct a medical exposure except in accordance with accepted diagnostic or therapeutic practice.

(3) Persons physically directing a medical exposure shall select procedures such as to ensure a dose of ionising radiation to the patient as low as reasonably practicable in order to achieve the required diagnostic or therapeutic purpose.

Training requirements for persons directing medical exposures

5.—(1) Subject to the following provisions of this regulation a person clinically or physically directing a medical exposure shall have received adequate training.

(2) Nothing in paragraph (1) above shall prevent a person from physically directing a medical exposure as part of practical training if this is done under the supervision of a person who himself has had adequate training.

(3) Within two years of the coming into force of these Regulations, medical, dental and other practitioners who, prior to the coming into force of these Regulations, have been clinically or physically directing medical exposures, but who were not adequately trained, either during their basic training or subsequently, shall take steps to acquire a core of knowledge in accordance with the Schedule to these Regulations.

(4) The Schedule to these Regulations, in which there is set out the core of knowledge as to the radiation protection of patients requisite for persons clinically or physically directing medical exposures shall have effect for purposes of this regulation and of regulation 6 below.

Proof of training

6. A certificate issued by an institute or person competent to award degrees or diplomas or to provide other evidence of training shall—

- (a) if such certificate attests that the person to whom it has been issued has received tuition in radiation protection to the extent set out in the Schedule to these Regulations be sufficient proof that such person has acquired competence in radiation protection; or
- (b) if such certificate so attests, be sufficient proof that the person to whom it has been issued has received instruction, including practical experience, in the techniques appropriate to his work.

Duty to ensure compliance with training requirements

7. It shall be the duty of every employer of persons clinically or physically directing medical exposures to ensure that such persons comply with the provisions of regulation 5 above.

Duty to keep record of training particulars

8. Within 1 year of the coming into force of these Regulations every employer of persons clinically or physically directing medical exposures shall put into effect procedures for recording and keeping up-to-date particulars showing the date or dates on which training qualifying as adequate training was completed by such persons before, and subsequent to, taking up employment with such employer, and the nature of the training.

Duty to record information concerning radiation equipment

9.—(1) Every employer of persons using radiation equipment shall keep and preserve at his place of work the information specified for the purposes of this paragraph and, when so requested, shall furnish it to the Secretary of State for the purposes of an inventory of radiation equipment to be drawn up and kept up-to-date by the Secretary of State.

(2) The following information is specified for the purposes of paragraph (1) of this regulation in relation to any equipment which delivers ionising radiation to a person undergoing a medical exposure and equipment which directly controls the extent of such exposure—

- (a) Name of manufacturer
- (b) Model number
- (c) Serial number or other unique identifier
- (d) Year of manufacture
- (e) Year of installation.

Duty to provide expert advice

10. Every employer of persons treating patients by radiotherapy or administering radioactive medicinal products to patients shall ensure that every such person has available to him the services of a person who holds a science degree, or its equivalent, awarded by the United Kingdom or other member State of the Communities (or a comparable overseas qualification) and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation.

Enforcement

11.—(1) The provisions of these Regulations shall be enforced as if they were health and safety regulations made under section 15 of the Health and Safety at Work etc Act 1974⁽⁴⁾ and, except as provided in paragraph (2) below, the provisions of that Act, as regards enforcement and offences, shall apply for the purposes of these Regulations.

(2) The enforcing authority for the purposes of regulation 4 of these Regulations, and as respects the application of these Regulations to the administration of any radioactive medicinal product, shall be the Secretary of State.

(4) 1974 c. 37.

Defence of due diligence

12. In any proceedings against any person for an offence consisting of the contravention of any of these Regulations it shall be a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.

26th April 1988

John Moore
One of Her Majesty's Principal Secretaries of
State

SCHEDULE

Regulations 5 and 6

CORE OF KNOWLEDGE AS TO RADIATION PROTECTION OF PATIENTS REQUISITE FOR PERSONS DIRECTING MEDICAL EXPOSURES

The following core of knowledge as to radiation protection of patients is that which a person physically directing medical exposures is expected to have acquired—

1. Nature of ionising radiation and its interaction with tissue.
2. Genetic and somatic effects of ionising radiation and how to assess their risks.
3. The ranges of radiation dose that are given to a patient with a particular procedure, the principal factors which affect the dose and the methods of measuring such doses.
4. The principles of quality assurance and quality control applied to both equipment and techniques.
5. The principles of dose limitation and the various means of dose reduction to the patient including protection of the gonads.
6. The specific requirements of women who are, or who may be, pregnant and also of children.
7. If applicable, the precautions necessary for handling sealed and unsealed sources.
8. The organisational arrangements for advice on radiation protection and how to deal with a suspected case of overexposure.
9. Statutory responsibilities.

For those clinically directing medical exposure, the following additional knowledge should be acquired—

10. In respect of the individual diagnostic and therapeutic procedures which the person intends to use, the clinical value of those procedures in relation to other available techniques used for the same or similar purposes.
11. The importance of utilising existing radiological information — films and/or reports — about a patient. value of those procedures in relation to other available techniques used for the same or similar purposes.
11. The importance of utilising existing radiological information — films and/or reports — about a patient.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement, as respects Great Britain, the provisions of Council Directive 84/466/Euratom (OJNo. L265, 5.10.84, p.1) laying down basic measures for the radiation protection of persons undergoing medical examination or treatment.

The Regulations require every exposure of a person to ionising radiation for a diagnostic or therapeutic purpose to be carried out under the responsibility of a person who is clinically directing such exposure and in accordance with accepted diagnostic or therapeutic practice (*regulation 4*).

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Only persons who have received adequate training may direct a medical exposure (*regulation 5*). Proof of adequate training may be provided by means of a certificate attesting to a person's training (*regulation 6*). Employers are under an obligation to ensure compliance with the training requirements; to keep a record of the particulars of training of persons they employ and a record of radiation equipment (*regulations 7, 8 and 9*); they must ensure that expert advice is available to their staff (*regulation 10*).

The Regulations are made enforceable as health and safety regulations under the Health and Safety at Work etc Act 1974, the enforcing authority being the Health and Safety Executive, except for regulation 4 and those aspects of the Regulations which relate to the administration of radioactive medicinal products (nuclear medicine), for which the enforcing authority is the Secretary of State (*regulation 11*). It is a defence to proceedings for an offence under the Regulations that all reasonable steps were taken and due diligence exercised (*regulation 12*).