

IRMER

The Ionising Radiation (Medical Exposure) Regulations 2000

Regulations and Guidance compiled by HEYH Radiation Protection Service

Notes

NoGP = Department of Health Notes on Good Practice, July 2000 (*taken from www.doh.gov.uk/irmer.htm*)

Regs = *The Ionising Radiation (Medical Exposure) Regulations 2000*, SI 2000 No. 1059 (taken from www.legislation.hmso.gov.uk/si/si2000/20001059.htm)

Footnotes are comments by John Saunderson, Oct 2000

Amendments introduced by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, on 1/11/06 are indicated in **blue**.

The single amendment introduced by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011, on 25/07/11 is indicated in **purple**.

This document follows the same order as that of the Regulations.

The Ionising Radiation (Medical Exposure) Regulations 2000

Regs.	<i>Made</i>	<i>13th April 2000</i>
	<i>Laid before Parliament</i>	<i>14th April 2000</i>
	<i>Coming into force except for regulation 4(1) and 4(2)</i>	<i>13th May 2000</i>
	<i>regulation 4(1) and 4(2)^a</i>	<i>1st January 2001</i>
<i>The Secretary of State, being the Minister designated for the purposes of section 2(2) of the European Communities Act 1972 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: -</i>		

NoGP	1. Introduction
	1.1. This document provides guidance on the Ionising Radiation (Medical Exposure) Regulations 2000 (the Regulations) and notes on good practice. The guidance is not intended to be binding and cannot take the place of legal advice. It sets out the Department's view of how certain provisions of the Regulations should be interpreted but the ultimate arbiter in any case of doubt would be the Court. Only it could make a definitive ruling.
	1.2. The Regulations implement for Great Britain the majority of the provisions of Council Directive 97/43/Euratom of 30 June 1997 (the "Medical Exposures Directive") laying down the basic measures for the radiation protection of persons undergoing medical exposures. The remainder is implemented in the Ionising Radiations Regulations 1999 ("IRR 1999"). The Directive reflects the 1990 Recommendations of the International Commission on Radiological Protection.
	1.3. The Regulations revoke and replace the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988.
	2. Justification
	2.1. The Medical Exposures Directive requires that all medical exposures to ionising radiation must be justified prior to the exposure being made. The Directive refers to two levels of justification; justification of types of practice and justification of individual medical exposures.
	2.2. The Regulations apply only to individual medical exposures. Hence, justification of types of practice is not addressed within the Regulations.
	2.3. It is intended that justification of types of practice involving medical exposures will be covered by amendment to IRR 1999.
	3. The Private Sector
	3.1 Practice involving the use of ionising radiation in the NHS and the private sector of healthcare is broadly consistent. Whilst this guidance is drafted with specific reference to the NHS, the Regulations and guidance apply to both the NHS and the private sector.

^a Reg. 4(1) demands written procedures. Reg. 4(2) demands written protocols for standard radiological practice for each equipment.

Citation and commencement

Reg 1

1. - (1) These Regulations may be cited as the Ionising Radiation (Medical Exposure) Regulations 2000 and shall come into force -

(a) except for regulation 4(1) and 4(2) on 13th May 2000;

(b) as regards regulation 4(1) and 4(2) on 1st January 2001.

Interpretation

Reg 2

2. - (1) In these Regulations -

"ADEQUATE TRAINING" means training which satisfies the requirements of Schedule 2; and the expression "ADEQUATELY TRAINED" shall be similarly construed;

"APPROPRIATE AUTHORITY" means the ~~Secretary of State~~^b the Commission for Healthcare, Audit and Inspection established under section 41 of the Health and Social Care (Community Health and Standards) Act 2003 (2003 c. 43.) as regards England, the National Assembly for Wales as regards Wales, or the Scottish Ministers as regards Scotland;

NoGP

5.2.1. Since the Regulations apply to England, Scotland and Wales, it was necessary to provide for different authorities in each of these areas for enforcement and reporting purposes. The definition accordingly states the relevant entity for each of England, Scotland and Wales.

Reg 2

"ASSESSMENT" means prior determination of amount, parameter or method;

"CHILD" means a person under the age of eighteen in England and Wales or a person under the age of sixteen in Scotland;

"CLINICAL AUDIT" means a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, intended to lead to modification of practices where indicated and the application of new standards if necessary;

"DIAGNOSTIC REFERENCE LEVELS" means dose levels in medical radiodiagnostic practices or, in the case of radioactive medicinal products, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;

NoGP

5.3.1. The Regulations require the employer to set diagnostic reference levels and provide procedures on how they are to be used. A diagnostic reference level should be set for each standard radiological investigation. They should also be set for interventional procedures, nuclear medicine investigations and radiotherapy planning procedures.

5.3.2. Diagnostic reference levels should be expressed in quantities which are directly applicable and relevant to the examination in question to enable the resulting patient dose to be calculated e.g. dose area product, screening time etc. Diagnostic reference levels can be decided on by an employer after considering local exposures or administered activities of standard radiological examinations. Records of exposures or activities used previously can be used for this purpose. However, regard must be had to European data where available when setting local diagnostic reference levels (see also regulation 4(3)(c)).

Reg 2

"DOSE CONSTRAINT" means a restriction on the prospective doses to individuals which may result from a

^b As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, coming into force on 1/11/06

defined source;

"THE DIRECTIVE" means Council Directive 97/43/Euratom laying down measures on health protection of individuals against the dangers of ionising radiation in relation to medical exposure;

Reg 2

"EMPLOYER" means any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation;

NoGP

5.4.1. This definition is not as used conventionally in employment law. In most circumstances within the NHS, a Trust will be considered to be the employer.

5.4.2. If an employer, e.g. an NHS Trust, contracts a third party to provide services (including the provision of operators) then the Trust will be the employer as regards the operators for the purposes of the Regulations, but the third party is the employer of the operators for employment law purposes.

5.4.3. Equipment ownership has no impact on the employer responsibilities under these Regulations.

Reg 2

"EMPLOYER'S PROCEDURES" means the procedures established by an employer pursuant to regulation 4(1);

"EQUIPMENT" means equipment which delivers ionising radiation to a person undergoing a medical exposure and equipment which directly controls or influences the extent of such exposure;

NoGP

5.5.1. Equipment, as referred to in these Regulations, includes that equipment used for nuclear medicine procedures, such as gamma cameras etc. In diagnostic radiology auxiliary equipment that can indirectly affect the exposure such as grids, cassettes, tables, cameras, monitors and imaging software is included.

Reg 2

^c"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),

(b) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000 (SI 2004/1031), 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;;

"EVALUATION" means interpretation of the outcome and implications of, and of the information resulting from, a medical exposure;

"HEALTH SCREENING" means a procedure using ionising radiation for early diagnosis in population groups at risk;

"INDIVIDUAL DETRIMENT" means clinically observable deleterious effects that are expressed in individuals or their descendants the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance;

"IONISING RADIATION" means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less or a frequency of 3×10^{15} hertz or more capable of producing ions directly or indirectly;

"MEDICAL EXPOSURE" means any exposure to which regulation 3 applies and which involves an individual being exposed to ionising radiation;

"MEDICAL PHYSICS EXPERT" means a person who holds a science degree or its equivalent and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation;

^c As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, coming into force on 1/11/06

NoGP 5.7.1. The science degree or its equivalent referred to in this definition should be relevant to the use of ionising radiation as applied to medical exposures. The medical physics expert (MPE) is required to have been adequately trained (as defined in the Regulations) for his involvement in medical exposures under the Regulations. The MPE is expected to undertake tasks such as giving advice on patient dosimetry, development and use of new and/or complex techniques, as well as other matters related to radiation protection concerning medical exposures.

5.7.2. The MPE should not be confused with the Radiation Protection Adviser as identified under the IRR 1999. The functions are different although, in practice, it is possible that the same person may undertake both roles.

Reg 2 *"MEDICO-LEGAL PROCEDURE" means a procedure performed for insurance or legal purposes without a medical indication;*

NoGP 5.6.1. This category of exposure will include those required for legal purposes of any kind e.g. those required in connection with legal proceedings or those required prior to emigration.

Reg 2 *"OCCUPATIONAL HEALTH SURVEILLANCE" means medical surveillance for workers;*

"OPERATOR" means any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects including those to whom practical aspects have been allocated pursuant to regulation 5(3), medical physics experts as referred to in regulation 9 and, except where they do so under the direct supervision of a person who is adequately trained, persons participating in practical aspects as part of practical training as referred to in regulation 11(3);

NoGP 5.8. **"operator"**

5.8.1. An operator is anyone who carries out a practical aspect. The range of functions covered by the term 'practical aspects' is broad. It is unlikely that a single operator will carry out all these functions for any individual medical exposure.

5.8.2. Nevertheless, an operator usually will carry out a variety of functions and therefore it is essential that the functions and responsibilities of individual operators are clearly defined within standard operating procedures. The operators who can undertake certain tasks may be identified in a variety of ways in the employer's procedures, for example, by profession, grade, or individual name. In some cases, detailed job descriptions may help.

5.8.3. In some cases, the practitioner may also undertake practical aspects of an exposure e.g. fluoroscopic screening. In these circumstances, the practitioner becomes an operator with regard to these specific functions.

5.8.4. Examples of operators include doctors, medical physicists, medical physics technicians, nurses, radiographers and radiopharmacists. Third party service engineers would not normally be considered as operators. Where significant changes to equipment have been made, these should be checked where practicable by an operator (e.g. an employee of the NHS Trust) before equipment is brought into clinical use.

Reg 2 *"PATIENT DOSE" means the dose concerning patients or other individuals undergoing medical exposure;*

"PRACTICAL ASPECT" means the physical conduct of any of the exposures referred to in regulation 3 and any supporting aspects including handling and use of radiological equipment, and the assessment of technical and physical parameters including radiation doses, calibration and maintenance of equipment, preparation and administration of radioactive medicinal products and the development of films;

NoGP	5.9.1. The range of functions covered by this term is extensive and includes the supporting functions prior to the exposure taking place e.g. the calibration of equipment that emits ionising radiation, the preparation of radioactive medicinal products, computer planning and calculation of monitor units to be delivered in radiotherapy etc, as well as of performing the exposure itself.
Reg 2	<i>"PRACTITIONER" means a registered health care professional^d medical practitioner, dental practitioner or other health professional who is entitled in accordance with the employer's procedures to take responsibility for an individual medical exposure;</i>
NoGP	5.10.1. Decisions on who is entitled to act as a practitioner should be taken at local level by agreement between the employer and the healthcare professionals involved in medical exposures. Such decisions should be based on the type of medical exposure and on specific circumstances and may be restricted e.g. it may be appropriate to agree that certain health professionals can act as a practitioner for radiographic procedures for extremities, but not for complex interventional examinations. 5.10.2. The primary responsibility of the practitioner is to justify medical exposures. This requires the practitioner to have a full knowledge of the potential benefit and detriment associated with the procedure under consideration. Clearly all practitioners need to be adequately trained to undertake this function
Reg 2	<i>"QUALITY ASSURANCE" means any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and safely complying with agreed standards and includes quality control;</i> <i>"QUALITY CONTROL" means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of performance;</i> <i>"RADIODIAGNOSTIC" means pertaining to in vivo diagnostic nuclear medicine, medical diagnostic radiology and dental radiology;</i> <i>"RADIOACTIVE MEDICINAL PRODUCT" has the meaning given in the Medicines (Administration of Radioactive Substances) Regulations 1978;</i> <i>"RADIOLOGICAL" means pertaining to radiodiagnostic and radiotherapeutic procedures and interventional radiology or other planning and guiding radiology;</i>
NoGP	5.11.1 By stating that the term 'radiological' applies to planning and guiding radiology, activities such as those associated with radiotherapy simulation, the planning of radiotherapy treatments etc are included as well as those associated with interventional radiology.
Reg 2	<i>"RADIOLOGICAL INSTALLATION" means a facility containing equipment;</i> <i>"RADIOTHERAPEUTIC" means pertaining to radiotherapy including nuclear medicine for therapeutic purposes;</i> <i>"REFERRER" means a registered health care professional^e medical practitioner, dental practitioner or other health professional who is entitled in accordance with the employer's procedures to refer individuals for medical exposure to a practitioner.</i> <i>^f"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</i>

^d As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, coming into force on 1/11/06

^e As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, coming into force on 1/11/06

^f As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, coming into force on 1/11/06

NoGP	<p>5.12.1. As with practitioners, decisions on who is entitled to act as a referrer should be taken at local level by agreement between the employer and the healthcare professionals involved in medical exposures. Such decisions should be based on the type of medical exposure and on specific circumstances and entitlement to act as a referrer may be restricted e.g. it may be agreed for example, that certain health professionals can act as a referrer for radiographic procedures for extremities, but not for complex CT examinations. Further examples, where agreed locally, might include certain requesting of specific planning procedures involving ionising radiation for patients on whom it has already been agreed that radiotherapy is appropriate.</p> <p>5.12.2. The range of procedures that can be requested by a referrer should be agreed locally between the referrer and the employer of the radiological installation. It is intended that the healthcare professionals involved in imaging and/or therapy as appropriate at that site will advise that employer.</p> <p>5.12.3. In situations where an individual, following an invitation, undergoes an exposure as part of a national screening programme, there is no requirement in practice for a named referrer.</p>
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Reg 2	<p>(2) <i>In these Regulations -</i></p> <p>(a) <i>any reference to a numbered regulation or schedule is a reference to a regulation of or Schedule to these Regulations;</i></p> <p>(b) <i>any reference in a regulation to a numbered paragraph is a reference to the paragraph so numbered in that regulation.</i></p>
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Reg 3	<p>Application</p> <p>3. <i>These Regulations shall apply to the following medical exposures -</i></p> <p>(a) <i>the exposure of patients as part of their own medical diagnosis or treatment including any exposure of an asymptomatic individual^g;</i></p> <p>(b) <i>the exposure of individuals as part of occupational health surveillance;</i></p> <p>(c) <i>the exposure of individuals as part of health screening programmes;</i></p> <p>(d) <i>the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;</i></p> <p>(e) <i>the exposure of individuals as part of medico-legal procedures.</i></p>
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NoGP	<p>4.1. This regulation lists the medical exposures to which the Regulations apply. Compared to the 1988 Regulations, these Regulations cover an increased range of exposures to ionising radiation, and in particular include exposures for the purpose of medical or biomedical research.</p> <p>4.2. The Directive covers "exposure of individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of individuals undergoing medical exposure". Such exposures are not covered by these Regulations but are covered by IRR 1999.^h</p>
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^g As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011, coming into force on 25/07/11

^h "Comforter & carers" (C&Cs) are "Individuals who (*other than part of their occupation*) knowingly and willingly incurs an exposure to ionising radiation resulting from the support and comfort of another person who is undergoing or who has undergone any medical exposure." There is no dose limit for C&Cs,

Duties of Employer

Reg 4

4. - (1) The employer shall ensure that written procedures for medical exposures including the procedures set out in Schedule 1 are in place and -

(a) shall take steps to ensure that they are complied with by the practitioner and operator; or

(b) where the employer is concurrently practitioner or operator, he shall comply with these procedures himself.

NoGP

6.1.1. This regulation requires the employer to establish written standard operating procedures. These procedures are intended to provide a framework under which professionals can practice. It is recommended that the employer seek advice from professional colleagues from the fields of radiology, radiotherapy and nuclear medicine in establishing the procedures.

6.1.2. In practice, the employer may ask a practitioner or operator to produce a written procedure. However, it is important to note that while the task may be delegated, the responsibility remains with the employer e.g. the task of producing a patient identification procedure can be delegated by the employer, but if the procedure is not produced in fact then the employer remains responsible under the Regulations. Procedures should be specific where necessary but allow freedom for professional judgment where appropriate. Examples are given in guidance to Schedule 1. However the matters listed in Schedule 1 are not exhaustive and may be considered a minimum requirement. As a matter of good practice, the procedures should be reviewed at regular intervals and be signed and dated accordingly.

6.1.3. In some cases, the employer is the same person as the practitioner and/or the operator (for example, some dental practitioners). Such an individual is still required to establish the procedures required by this regulation and to comply with them.

Reg
4(2)

(2) The employer shall ensure that written protocols are in place for every type of standard radiological practice for each equipment.

NoGP

6.2.1. The protocols required under this regulation should not be confused with employer's procedures required by regulation 4(1). Protocols cannot be absolute or totally comprehensive as it is not possible to produce detailed and rigid protocols for every examination. However, they should be specific to each examination and machine as appropriate, e.g. in diagnostic practice, for a particular x-ray room, x-ray exposure factors for a specific examination (PA chest: 120kV 2mAs). They must be written down and their status clear. Protocols should allow latitude for professional judgment but where the latitude provided is exceeded and exposure factors varied, it would be advisable to record the changes made. Where, on commissioning, exposure values are programmed via the console into the x-ray generator, it is recommended that a record of the values be kept in the department together with any changes to these values, whether for individual patients, or as a result of agreed protocol changes.

6.2.2. In radiotherapy, the protocols might refer to standard dose regimes, energies and beam projections and may be specific to each consultant if necessary. Such protocols would not negate the need for individual planning to produce the intended therapeutic effect.

but IRR99 states that their doses should be ALARP, and dose constraints should be set. NRPB recommend a generic dose constraint of 5 mSv from experience. Pregnant women should not normally act as C&Cs, but if it is appropriate a dose constraint of 1 mSv is recommended.



Reg 4 (3) *The employer shall establish -*
(a) *recommendations concerning referral criteria for medical exposures, including radiation doses, and shall ensure that these are available to the referrer;*

NoGP 6.3.1. In establishing the referral criteria for medical exposures required under this regulation, it will be appropriate to consult and agree with those professionals involved in medical exposures. It is expected that most departments already have criteria in place for many procedures. For example, the Royal College of Radiologists have produced recommendations for diagnostic practice and these would be an acceptable foundation on which to base local criteria.
6.3.2. The locally agreed criteria must be made available to all referrers to that department. There is an obligation to produce these criteria regardless of the size or type of the department, types of examinations performed, or whether the employer, referrer, practitioner and operator are the same person.

Reg 4 (3) (b) *quality assurance programmes for standard operating procedures;*

NoGP 6.4.1. The quality assurance programmes required by this regulation are for standard operating procedures, not equipment, which is dealt with under IRR 1999. All procedures should be regularly reviewed to ensure that they are effective and appropriate and to identify any necessary amendments..

Reg 4 (3) (c) *diagnostic reference levels for radiodiagnostic examinations falling within regulation 3(a), (b), (c) and (e) having regard to European diagnostic reference levels where available;*ⁱ

NoGP 6.5.1. This regulation requires the employer to establish diagnostic reference levels for standard radiodiagnostic examinations. National reference levels may be taken into account in doing so, for example, in nuclear medicine procedures, data produced by ARSAC (Administration of Radioactive Substances Advisory Committee) will be relevant. The Regulations require that regard be had to European levels, where available

Reg 4 (3) (d) *dose constraints for biomedical and medical research programmes falling within regulation 3(d) where no direct medical benefit for the individual is expected from the exposure.*

NoGP 6.6.1. The dose constraints to be established by the employer under this regulation should be applied to research protocols involving standard radiodiagnostic procedures. Such research should be subject to a dose constraint based on the total dose from all radiodiagnostic procedures included in the protocol.

ⁱ Regulation 3(a), (b), (c) and (e) cover diagnosis, occupational health surveillance, health screening programmes and medico-legal procedures (but not research).

The NRPB have issued some initial recommendations for DRLs in X-radiology and dentistry - "Guidelines on Patient Dose to promote the Optimisation of Protection for Diagnostic Medical Exposures.", Documents of the NRPB, Vol. 10, No. 1, 1999. ARSAC advice is relevant for Nuclear Medicine.

Reg 4 (4) *The employer shall take steps to ensure that every practitioner or operator engaged by the employer to carry out medical exposures or any practical aspect of such exposures -*
(a) *complies with the provisions of regulation 11(1)^j; and*

Reg 4 (b) *undertakes continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements; or*
(c) *where the employer is concurrently practitioner or operator, he shall himself ensure that he undertakes such continuing education and training as may be appropriate.*

NoGP 6.7.1. This regulation requires the employer to ensure that practitioners and operators are both adequately trained and undertake continuing education and training. With regard to the latter, it is to be noted that the duty is not on the employer to provide continuing education and training himself. The obligation will be satisfied if he takes steps to ensure that the practitioner and operator seek out and attend such education and training. Where the employer is also the practitioner and/or operator, he must himself ensure that he undertakes appropriate continuing education and training.
6.7.2. In cases where the employer engages sub-contractors, the obligation to ensure compliance with this regulation will be satisfied by the employer if he includes a clause in the contract stipulating that the practitioner or operator to be engaged by him must have been adequately trained and undertake continuing education and training. Records of previous and continuing education and training must be kept by the sub-contracted company (or in the case of the self-employed, themselves) e.g. for agency staff, the agency employer is responsible for keeping up-to-date training records on the staff supplied by the agency. These records also must be made available to the employer, upon request. See also regulation 11.
6.7.3. Requirements for continuing education are integral to the functions of health professionals and employers should make provisions for such training.

Reg 4 (5) *Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.*

NoGP 6.8.1. This regulation requires the employer to carry out investigations of incidents and appropriate reviews. In most cases, the term 'much greater than intended' as used in this regulation should be interpreted as for IRR 1999. HSE has published specific guidance on doses which are likely to be much greater than intended for particular types of medical exposure. While this guidance was not developed for this purpose, application of this guidance is appropriate. Incidents which occur as a result of equipment malfunction or breakdown must still be reported to the HSE under IRR 1999.
6.8.2. Patients who undergo a procedure that was not intended, as a result of mistaken identification or other procedural failure, and consequently have been exposed to an ionising radiation dose, should be considered as having received an unintended dose of radiation.
6.8.3. The detailed investigation required by the Regulations should be aimed at: -
establishing what happened - identifying the failure - deciding on remedial action to minimise the chance of a similar failure - estimating the doses involved.

^j Regulation 11(1) states, “11.-(1) *Subject to the following provisions of this regulation no practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained.*”

6.8.4. The notification is required to be made directly to the appropriate authority appointed for these Regulations.

6.8.5. As a matter of good practice, patients who have been exposed to a dose of ionising radiation much greater than intended, should be informed of the incident, unless there is a good reason for them not to be. It should be a local decision on how, when and by whom the patient is notified, but the practitioner and referring clinician should be involved. When the patient is unable to understand the information given, it may be more appropriate to inform the patient's representative or parent/guardian. It would be advisable to record decisions not to inform the patient or the patient's representative or parent/guardian in the patient's case notes. Further, whilst the Regulations refer to those incidents resulting in exposures much greater than intended, it is recognised that in certain situations e.g. radiotherapy, exposures much lower than intended can also have serious consequences. Whilst not notifiable under these Regulations, as a matter of good practice, the employer may wish to carry out his own investigations in such circumstances.

Reg 4

(6) The employer shall undertake appropriate reviews whenever diagnostic reference levels are consistently exceeded and ensure that corrective action is taken where appropriate.

NoGP

6.9.1. The review required by this regulation is intended to provide an opportunity at a local level to evaluate the reasons why diagnostic reference levels have been exceeded. Corrective action might include setting new values for diagnostic reference levels (see regulation 4(3)(c) and notes thereon). Corrective action may also include retraining an individual. This might not be restricted to techniques directly involving ionising radiation.

6.9.2. It is not intended that this regulation should replace or diminish the need for regular reviews of diagnostic reference levels.

Duties of the Practitioner, Operator and Referrer

NoGP

7.1. Regulation 5 sets out the respective responsibilities of practitioner, operators and referrers and makes clear that where the employer also acts in one or more of these roles concurrently, he is responsible accordingly. Points to note are as follows:

Reg 5

5. - (1) The practitioner and the operator shall comply with the employer's procedures.

NoGP

7.2.1. The practitioner and the operator must comply with the employer's procedures and where these include detailed standard operating procedures, they must be followed explicitly e.g. patient identification and checking procedures. All those matters required by the Regulations to be in employers' procedures (Schedule 1) are binding.

Reg 5

(2) The practitioner shall be responsible for the justification of a medical exposure and such other aspects of a medical exposure as is provided for in these Regulations.

(3) Practical aspects of a medical exposure or part of it may be allocated in accordance with the employer's procedures by the employer or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

NoGP

7.3.1. This regulation deals with the allocation of responsibility for practical aspects of a medical exposure to specific individuals. The employer must set out in his procedures who

will be entitled to act in this capacity. In doing so he should have due regard to professional roles and appropriate training. The person to whom a practical aspect has been allocated is responsible for that aspect (regulation 5(4)).

Reg 5 (4) *The operator shall be responsible for each and every practical aspect which he carries out as well as for any authorisation given pursuant to regulation 6(5) where such authorisation is not made in accordance with the guidelines referred to in regulation 6(5).*

NoGP 7.4.1. Those persons undertaking practical aspects (operators) are responsible under the Regulations for their functions. No overarching responsibility is held by another person.

Reg 5 (5) *The referrer shall supply the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the medical exposure requested by the referrer to enable the practitioner to decide on whether there is a sufficient net benefit as required by regulation 6(1)(a).*
(6) *The practitioner and the operator shall cooperate, regarding practical aspects, with other specialists and staff involved in a medical exposure, as appropriate.*
(7) *For the avoidance of doubt, where a person acts as employer, referrer, practitioner and operator concurrently (or in any combination of these roles) he shall comply with all the duties placed on employers, referrers, practitioners or operators under these Regulations accordingly.*

Justification of Individual Medical Exposures

NoGP 8.1. This regulation deals with the justification and authorisation of individual medical exposures and provides that no one may carry out a medical exposure unless the matters set out in regulation 4(1)(a)-(e), where applicable, have been complied with. Points to draw attention to under this regulation are as follows:

Reg 6 6. - (1) *No person shall carry out a medical exposure unless -*

NoGP 8.2.1. In this regulation, the phrase "carry out a medical exposure" refers to the actual process of exposure to ionising radiation itself, and not to other practical aspects of the exposure, such as calibration, which can be carried out irrespective of the justification of individual exposures.

Reg 6(1) (a) *it has been justified by the practitioner as showing a sufficient net benefit giving appropriate weight to the matters set out in paragraph (2); and*

NoGP 8.3.1. The practitioner is responsible for the justification of each individual medical exposure. This should be based on his knowledge of the hazard associated with the exposure and the clinical information supplied by the referrer. Authorisation is a separate process and is the means by which it can be demonstrated that justification has been carried out. The method of authorisation may depend on local circumstances and may include a signature on the request card, addition of an electronic signature etc. It is recommended that the employer specify a method of authorisation to be used locally to ensure a consistent approach.
8.3.2. In cases where the referrer is the same person as the practitioner and/or the operator (e.g. some dental practitioners), justification and authorisation still must be carried out, but

this may be done by the same person.

8.3.3. In nuclear medicine, the ARSAC certificate holder will be the practitioner, although the authorisation of the procedure may be undertaken by an operator under guidelines (see regulation 6(5)).

Reg
6(1)

(b) it has been authorised by the practitioner or, where paragraph (5) applies, the operator;^k and

Reg
6(1)

*(c) in the case of a medical or biomedical exposure as referred to in regulation 3(d)^l, it has been approved by ~~a Local Research Ethics Committee^m~~ *an ethics committee*; and*

NoGP

8.4.1. Guidance on the establishment, composition and functions of Local Research Ethics Committees (LRECs) is provided by the Health Departments. The guidance states that all research in the UK should be approved by a LREC, whether or not it has been submitted also to a Multi-centre Research Ethics Committee (MREC). The LREC can recommend that research is undertaken with a proviso that a certain dose is not exceeded.

Reg 6

(d) in the case of an exposure falling within regulation 3(e)ⁿ, it complies with the employer's procedures for such exposures; and

(e) in the case of a female of childbearing age, he has enquired whether she is pregnant or breastfeeding, if relevant.

(2) The matters referred to in paragraph (1)(a) are -

NoGP

8.5.1. The process of justification must give appropriate weight to the factors specified in regulation 6(2) and in doing so pay special attention to the matters set out in regulation 6(3).

Reg
6(2)

(a) the specific objectives of the exposure and the characteristics of the individual involved;

(b) the total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure;

(c) the individual detriment that the exposure may cause; and

(d) the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

NoGP

8.5.2. The criteria referred to in regulation 6(2)(d) highlight the need, where practicable, to choose techniques involving the minimum necessary amount of exposure to ionising radiation. These are to be preferred where they have the same objective. In practice, use of such techniques will be influenced by availability. The implications of delaying diagnosis or

^k The authoriser must be identified - e.g. by signing request card as approved. A practitioner can authorise any examination or treatment that they are entitled to do in the Trust's procedures. Where operators are to be allowed to authorised exposures, guidelines must written, signed and dated by a practitioner.

^l Research volunteers, patients or others

^m As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, coming into force on 1/11/06

ⁿ Medico-legal exposures

treatment in order to provide the preferred method should be weighed against the potential detriment associated with an increased radiation dose of other techniques.

Reg 6

(3) In considering the weight to be given to the matters referred to in paragraph (2), the practitioner justifying an exposure pursuant to paragraph (1)(a) shall pay special attention to -

(a) exposures on medico-legal grounds;

(b) exposures that have no direct health benefit for the individuals undergoing the exposure; and

(c) the urgency of the exposure, where appropriate, in cases involving -

(i) a female where pregnancy cannot be excluded, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the expectant mother and the unborn child; and

(ii) a female who is breastfeeding and who undergoes a nuclear medicine exposure, taking into account the exposure of both the female and the child.

(4) In deciding whether to justify an exposure under paragraph (1)(a) the practitioner shall take account of any data supplied by the referrer pursuant to regulation 5(5) and shall consider such data in order to avoid unnecessary exposure.

NoGP

8.6.1. Regulation 5(5) requires the referrer to supply the practitioner with sufficient medical data relevant to the medical exposure requested to enable the practitioner to decide whether the exposure can be justified. Regulation 6(4) requires the practitioner to consider the data provided by the referrer before justifying a medical exposure. In order for the data to be sufficient for the purposes of justification it may need to include previous diagnostic information or medical records. However, the Regulations do not require the medical records to be provided for every procedure.

Reg 6

(5) Where it is not practicable for the practitioner to authorise an exposure as required by paragraph (1)(b), the operator shall do so in accordance with guidelines issued by the practitioner.

NoGP

8.7.1. The Regulations recognise that it may not be practicable for a practitioner to consider every request for a medical exposure. Regulation 6(5) requires practitioners to produce guidelines which must be followed by operators when it falls to them to authorise an individual exposure. It must be borne in mind that any person who authorises an exposure becomes an operator by virtue of doing so. The guidelines may be written to allow flexibility e.g. in radiology an agreed range of projections which may be taken to provide the necessary clinical information. This will allow the operator the appropriate freedom to exercise professional judgment.

8.7.2. If the operator authorises an exposure which does not accord with the guidelines, he will be in breach of the regulation and will be responsible accordingly. In these circumstances, the operator's actions in themselves do not change the status of the operator to one of a practitioner in respect of that exposure.

Optimisation

NoGP 9.1. Regulation 7 provides for the optimisation process which involves ensuring that doses arising from exposures are kept as low as reasonably practicable. Optimisation is a process which relies heavily on professional competence and skill. While employer's standard operating procedures can provide a framework within which the health professional is to work, they will not generally prescribe the manner in which the functions specified therein are to be carried out. This is left to the health professionals to effect in a manner commensurate with their professional status.

9.2. Points to highlight in relation to optimisation are as follows:

Reg 7 7. - (1) *In relation to all medical exposures to which these Regulations apply except radiotherapeutic procedures, the practitioner and the operator, to the extent of their respective involvement in a medical exposure, shall ensure that doses arising from the exposure are kept as low as reasonably practicable consistent with the intended purpose.*

(2) *In relation to all medical exposures for radiotherapeutic purposes the practitioner shall ensure that exposures of target volumes are individually planned, taking into account that doses of non-target volumes and tissues shall be as low as reasonably practicable and consistent with the intended radiotherapeutic purpose of the exposure.*

NoGP 9.3.1. This regulation requires individual planning of target volumes for all radiotherapeutic exposures. It also applies to therapeutic research exposures therefore.

9.3.2. In complying with this regulation, the practitioner should use the best means available to him. However, in order to comply with the regulation it will not be necessary, for example, in external beam radiotherapy, that all patients be planned for treatments using therapy machines equipped with multi-leaf collimators. In practice, decisions on the use of such devices will rest with the practitioner and may depend on availability, clinical circumstance etc. Equally, for therapy with unsealed sources, the requirement for individual planning will be satisfied by carrying out an assessment of the individual patient. However, recommended standard activities of radiopharmaceuticals can still be used.

Reg 7 (3) *Without prejudice to paragraphs (1) and (2), the operator shall select equipment and methods to ensure that for each medical exposure the dose of ionising radiation to the individual undergoing the exposure is as low as reasonably practicable and consistent with the intended diagnostic or therapeutic purpose and in doing so shall pay special attention to -*

(a) *quality assurance;*

(b) *assessment of patient dose or administered activity; and*

(c) *adherence to diagnostic reference levels for radiodiagnostic examinations falling within regulation 3(a), (b), (c) and (e) as set out in the employer's procedures.*

(4) *For each medical or biomedical research programme falling within regulation 3(d), the employer's procedures shall provide that -*

NoGP 9.4.1. This regulation requires the employer's procedures to provide safeguards for medical and biomedical research programmes and to specify how and by whom these shall be effected. The research co-ordinator may be the person best placed to carry out some of these tasks and, where he does so, he will be the operator for those purposes.

9.4.2. All research programmes should be submitted to a Local Research Ethics Committee for approval before commencing.

Reg 7(4) (a) *the individuals concerned participate voluntarily in the research programme;*
(b) *the individuals concerned are informed in advance about the risks of the exposure;*
(c) *the dose constraint set down in the employer's procedures for individuals for whom no direct medical benefit is expected from the exposure is adhered to; and*

NoGP 9.5.1. This regulation requires dose constraints to be applied where no direct medical benefit for the individual is expected from the exposure. The constraint must be set by the employer in his procedures and must not be exceeded. The constraint should be set at a level to facilitate the research, and be deemed appropriate by the practitioner and agreed by the LREC.

Reg 7(4) (d) *individual target levels of doses are planned by the practitioner for patients who voluntarily undergo an experimental diagnostic or therapeutic practice from which the patients are expected to receive a diagnostic or therapeutic benefit.*

9.6.1. This regulation requires the planning of individual target levels of doses for patients who voluntarily undergo experimental diagnostic or therapeutic practices in cases where some benefit to the patient is expected. The practitioner is identified as the person who is most able to set these target levels, due to his knowledge of ionising radiation and its potential risks. The practitioner may seek advice from others to clarify the doses involved.
9.6.2. In separating these cases from the situation in (c) above, the Regulations recognise that where there is potential benefit for patients from exposures as part of research, setting a constraint is inappropriate. However, regulation 7(4)(d) requires that some target level of dose is set before the exposure begins, for which the benefit still outweighs the detriment. In this way, excessive doses should be avoided. For example, in routine interventional techniques, the radiation dose from screening should not be so great as to produce unacceptable levels of skin damage and a target level should ensure that this will not happen.

Reg 7 (5) *In the case of patients undergoing treatment or diagnosis with radioactive medicinal products, the employer's procedures shall provide that, where appropriate, written instructions and information are provided to -*
(a) *the patient, where he has capacity to consent to the treatment or diagnostic procedure; or*
(b) *where the patient is a child who lacks capacity so to consent, the person with parental responsibility for the child; or*
(c) *where the patient is an adult who lacks capacity so to consent, the person who appears to the practitioner to be the most appropriate person.*

NoGP 9.7.1. This regulation requires the employer's procedures to provide for the giving of instructions and information in appropriate cases where radioactive medicinal products are administered. The regulation sets out the persons to whom such instructions and information should be given.
9.7.2. Regulation 7(5)(a) refers to the patients themselves where they are adults or children who have capacity to consent to the treatment or diagnostic procedure. A child is a person under the age of 18 in England and Wales or 16 in Scotland. The regulation recognises that many "children" are mature enough to consent to treatment etc. and to understand what is

involved and that such children should be given the information/advice themselves. However, in such cases, it will usually be appropriate to give the information/advice to the person(s) with parental responsibility (generally the parent or parents) as well.

9.7.3. Regulation 7(5)(b) deals with where the patient is a child who lacks capacity to consent. The regulation requires that the information be given to the person(s) with parental responsibility.

9.7.4. Regulation 7(5)(c) deals with mentally incapable adults. In some cases there may be a court appointed receiver (or, in Scotland, a tutor dative or curator) or person with an enduring power of attorney who can deal with their affairs. However, such persons do not necessarily have any rights in relation to the individual's health care. Therefore the most appropriate person to whom to give the information in practice is likely to be a relative taking care of the patient or, for example, the manager of a care home. The position in Scotland will change when the Adults with Incapacity (Scotland) Act is implemented. This is expected to be from the summer of 2001 onwards.

Reg 7 *(6) The instructions and information referred to in paragraph (5) shall -*

(a) specify how doses resulting from the patient's exposure can be restricted as far as reasonably possible so as to protect persons in contact with the patient;

(b) set out the risks associated with ionising radiation; and

(c) be provided to the patient or other person specified in paragraph (5) as appropriate prior to the patient leaving the hospital or other place where the medical exposure was carried out.

NoGP

9.8.1. This regulation sets out some of the matters to be addressed in the information/instructions to be provided pursuant to regulation 7(5) and when they should be given. In practice, the level of administered activity and resulting dose to others will determine what, if any, advice needs to be given. For example, it will usually be appropriate to give advice in most therapy exposures. A small number of diagnostic exposures also may be of sufficient activity to require advice etc to be given eg scanning for metastases after thyroid ablation.

Reg 7

(7) In complying with the obligations under this regulation, the practitioner and the operator shall pay special attention to -

(a) the need to keep doses arising from medico-legal exposures as low as reasonably practicable;

(b) medical exposures of children;

(c) medical exposures as part of a health screening programme;

(d) medical exposures involving high doses to the patient;

(e) where appropriate, females in whom pregnancy cannot be excluded and who are undergoing a medical exposure, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the expectant mother and the unborn child; and

(f) where appropriate, females who are breastfeeding and who are undergoing exposures in nuclear medicine, taking into account the exposure of both the female and the child.

NoGP

9.9.1. This regulation requires the practitioner/and the operator to pay special attention to certain factors in the optimisation process. One such factor is high doses to the patient. This will be relevant to procedures, such as interventional radiology, radiotherapy and some CT scanning, which deliver an increased radiation dose compared to most routine diagnostic

examinations.

9.9.2. Another factor is potential pregnancy in particular if abdominal and pelvic regions are involved. In practice, the dose to the uterus, and, where pregnancy is confirmed, to the unborn child, is likely to vary with the anatomical site and magnitude of the exposure in radiology and with the administered activity and radiopharmaceutical in nuclear medicine. Where practicable, the scheduling of the exposure should be influenced by the date of the last menstrual period.

9.9.3. In nuclear medicine, females who are breast feeding must also be paid special attention. In practice, depending on the administered activity and radiopharmaceutical used, it may be necessary to advise the patient temporarily to cease breast feeding.

Reg 7

(8) The employer shall take steps to ensure that a clinical evaluation of the outcome of each medical exposure, is recorded in accordance with the employer's procedures or, where the employer is concurrently practitioner or operator, shall so record a clinical evaluation, including, where appropriate, factors relevant to patient dose.

NoGP

9.10.1. This regulation requires the employer to ensure that a clinical evaluation of the outcome of each medical exposure is recorded and to set out in his procedures how and when this is to be done. This evaluation should detail the resulting diagnostic findings or therapeutic implications. If it is known prior to the exposure taking place that no clinical evaluation will occur, then the exposure would not be justified and could not lawfully take place.

9.10.2. Where the employer is concurrently the practitioner/operator, he must still make the appropriate record. Where the evaluation of a medical exposure is not done by an operator engaged by the employer, that employer must take steps to ensure that it is carried out by a third party in accordance with the employer's procedures

9.10.3. Factors relevant to the patient dose should be included in the record where appropriate, in order that, if necessary, at a later date an estimation of the effective dose to the patient can be made.

Reg 7

(9) In the case of fluoroscopy -

(a) the operator shall ensure that examinations without devices to control the dose rate are limited to justified circumstances; and

NoGP

9.11.1. This regulation requires the operator to ensure that, in fluoroscopy, examinations without devices to control the dose rate are limited to justified circumstances. An example of when such justification may exist is in paediatric radiology where devices designed to control the dose rate can result in doses greater than necessary.

Reg
7(9)

(b) no person shall carry out an examination without an image intensification or equivalent technique.

Clinical Audit

Reg 8

8. The employer's procedures shall include provision for the carrying out of clinical audit as appropriate.

NoGP

10. Clinical Audit - Regulation 8

10.1. This regulation requires the employer's procedures to provide for the carrying out of clinical audit as appropriate. In doing so, the employer may wish to take account of existing guidance, for example in England and Wales: "Clinical Governance: Quality in the new NHS" (March 1999). Similar Guidance exists in Scotland.

Reg 9

Expert advice

9. - (1) *The employer shall ensure that a medical physics expert shall be involved in every medical exposure to which these Regulations apply in accordance with paragraph (2).*

(2) *A medical physics expert shall be -*

(a) *closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;*

(b) *available in standardised therapeutic nuclear medicine practices and in diagnostic nuclear medicine practices;*

(c) *involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other radiological practices.*

NoGP

11.1. This regulation requires the employer to ensure that a medical physics expert (MPE) is involved, to varying degrees, in every medical exposure. In practice, the level of involvement of the MPE should be determined by the level of hazard and risk associated with the exposure and the amount of benefit expected from their advice. For most radiotherapy, MPEs are likely to be full-time contracted members of staff and will be available on site. For nuclear medicine imaging, the number of sessions per week that the MPE will be on site is likely to vary with the complexity of the service offered.

11.2. In all other radiological practices it is recommended that a MPE's availability be secured under contract although, depending on the rate of introduction of new techniques, the amount of time spent on site in fact may be limited (although for dental radiology it is unlikely that a MPE will need to be contracted on a permanent basis). In practice, it may be appropriate only to seek advice as and when new techniques are introduced.

Reg 10

Equipment

10. - (1) *The employer shall draw up, keep up-to-date and preserve at each radiological installation an inventory of equipment at that installation and, when so requested, shall furnish it to the appropriate authority.*

(2) *The inventory referred to in paragraph (1) shall contain the following information -*

(a) *name of manufacturer,*

(b) *model number,*

(c) *serial number or other unique identifier,*

(d) year of manufacture, and
(e) year of installation.

(3) *The employer shall ensure that equipment at each radiological installation is limited to the amount necessary for the proper carrying out of medical exposures at that installation.*

NoGP

12.1. Regulation 10 sets out some requirements in respect of equipment. However, most of the requirements of the Directive are addressed in IRR 1999 and reference to those Regulations should be made accordingly.

12.2. The regulation requires the employer to keep and make available for inspection an inventory of equipment and specifies what information the inventory must contain.

12.3. The inventory should be preserved for periods consistent with Health Departments' guidance on retention of records.

12.4. The inventory must be made available, on request, to officials acting on behalf of the appropriate authority, normally inspectors appointed for the purposes of the Regulations.

Training

Reg 11

11. - (1) *Subject to the following provisions of this regulation no practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained.*

(2) *A certificate issued by an institute or person competent to award degrees or diplomas or to provide other evidence of training shall, if such certificate so attests, be sufficient proof that the person to whom it has been issued has been adequately trained.*

(3) *Nothing in paragraph (1) above shall prevent a person from participating in practical aspects of the procedure as part of practical training if this is done under the supervision of a person who himself is adequately trained.*

(4) *The employer shall keep and have available for inspection by the appropriate authority an up-to-date record of **all training undertaken by**^o all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposures or, where the employer is concurrently practitioner or operator, of his own training, showing the date or dates on which training qualifying as adequate training was completed and the nature of the training.*

(5) *Where the employer enters into a contract with another to engage a practitioner or operator otherwise employed by that other, the latter shall be responsible for keeping the records required by paragraph (4) and shall supply such records to the employer forthwith upon request.*

NoGP

13.1. This regulation prohibits any practitioner or operator from carrying out a medical exposure or any practical aspect without having been adequately trained. An exception is made for trainees where they participate in practical aspects under the supervision of someone who is adequately trained. Adequate training is training that satisfies the requirements of Schedule 2.

13.2. The regulation also requires the employer to keep and have available for inspection an

^o As amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, coming into force on 1/11/06

up-to-date record of all practitioners and operators engaged by him showing the date on which training was completed and the nature of the training. Where the employer is concurrently practitioner or operator, he must keep a record of his own training,

13.3. Training records should be available separately from general personal records and preserved for periods consistent with Health Departments' guidance on retention of records.

13.4. Regulation 11(5) makes clear that, where an employer engages individuals to act as practitioners or operators but those individuals remain employed by another body, e.g. agency staff, then the second party i.e. the agency are responsible for keeping and maintaining the training records. These must be made available to the first employer upon request so that he can make them available to officials acting on behalf of the appropriate authority as the Regulations require.

Enforcement

Reg 12

12. - (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 and, except as provided in paragraph (2), 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 these Regulations shall be the appropriate authority.

NoGP

14.1. This regulation provides for the Regulations to be enforced as if they were made under section 15 of the Health and Safety at Work etc. Act 1974 save that the enforcing authority is the appropriate authority. As explained in the definitions (see notes on section 2) the enforcing authority for is specific to each of the Home Countries. The provisions of the 1974 Act regarding offences also apply.

Defence of due diligence

Reg 13

13. In any proceedings against any person for an offence consisting of the contravention 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.

Revocation

Reg 14

14. The Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988 are hereby revoked.

Alan Milburn, One of Her Majesty's Principal Secretaries of State, 13th April 2000

Sch 1

SCHEDULE 1 - Regulation 4(1) Employer's Procedures

The written procedures for medical exposures shall include –

- (a) procedures to identify correctly the individual to be exposed to ionising radiation;*
- (b) procedures to identify individuals entitled to act as referrer or practitioner or operator;*
- (c) procedures to be observed in the case of medico-legal exposures;*
- (d) procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;*
- (e) procedures to ensure that quality assurance programmes are followed;*
- (f) procedures for the assessment of patient dose and administered activity;*
- (g) procedures for the use of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within regulation 3(a), (b), (c) and (e)^p, specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;*
- (h) procedures for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 7(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(d) where no direct medical benefit for the individual is expected from the exposure;*
- (i) procedures for the giving of information and written instructions as referred to in regulation 7(5);^q*
- (j) procedures for the carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose;*
- (k) procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.*

NoGP

15. Employer's procedures - Schedule 1

15.1. Schedule 1 sets out a list of matters that must be covered in the employer's procedures. The list is not exhaustive but all those matters identified in Schedule 1 will be binding as a result of having to be included in the procedures. Employers are recommended to take care in wording the procedures as any additional matters which the employer wishes to provide for but intends not to be binding must take a different form and be easily identified as such.

15.2. Some of the matters listed in Schedule 1 require further comment. These are as follows:

15.3. "Procedures to correctly identify individuals to be exposed to ionising radiation"

15.3.1. The patient identification procedure must specify how a patient is to be identified before a medical exposure is made. The procedure should be positive and active e.g. "What is your name?" etc.

15.3.2. The procedure should state by whom the patient should be identified e.g. by the operator carrying out the exposure. The person with responsibility for identifying the patient will be considered as an operator by this function, and as such subject to the Regulations.

15.4. "Procedures for making enquiries of females of child-bearing age to establish whether the individual is or may be pregnant or breast feeding"

15.4.1. It is recommended that such procedures include the age range of individuals who should be asked about pregnancy or breast feeding. In setting this age range, consideration should be given to the increased period of reproductive capacity due to earlier maturity and advances in technology.

15.5. "Procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable"

15.5.1. The employer should include within standard operating procedures a requirement that all practical aspects should be conducted with due regard to minimising unintended doses to patients. This is particularly relevant in radiotherapy e.g. treatment plans should be produced with due regard to the most effective treatment delivery and the potential for error.

^p Regulation 3(a), (b), (c) and (e) cover diagnosis, occupational health surveillance, health screening programmes and medico-legal procedures (but not research).

^q Regulation 7(5) refers to written instructions to nuclear medicine patients or guardians

Practitioners and operators shall have successfully completed training, including theoretical knowledge and practical experience, in -

- (i) such of the subjects detailed in section A as are relevant to their functions as practitioner or operator; and
- (ii) such of the subjects detailed in section B as are relevant to their specific area of practice.

A. Radiation production, radiation protection and statutory obligations relating to ionising radiations

1. Fundamental Physics of Radiation

1.1 Properties of Radiation

Attenuation of ionising radiation
Scattering and absorption

1.2 Radiation Hazards and Dosimetry

Biological effects of radiation
Risks/benefits of radiation
Dose optimisation
Absorbed dose, dose equivalent, effective dose and their units

1.3 Special Attention Areas

Pregnancy and potential pregnancy
Infants and children
Medical and biomedical research
Health screening
High dose techniques

2. Management and Radiation Protection of the Patient

2.1 Patient Selection

Justification of the individual exposure
Patient identification and consent
Use of existing appropriate radiological information
Alternative techniques
Clinical evaluation of outcome
Medico-legal issues

2.2 Radiation Protection

General radiation protection
Use of radiation protection devices
- patient
- personal
Procedures for untoward incidents involving overexposure to ionising radiation

3. Statutory Requirements and Advisory Aspects

3.1 Statutory Requirements and Non-Statutory Recommendations

Regulations

Local rules and procedures

Individual responsibilities relating to medical exposures

Responsibility for radiation safety

Routine inspection and testing of equipment

Notification of faults and Health Department hazard warnings

Clinical audit

B. Diagnostic radiology, radiotherapy and nuclear medicine

4. Diagnostic Radiology

4.1 General

Fundamentals of radiological anatomy

Fundamentals of radiological techniques

Production of X-rays

Equipment selection and use

Factors affecting radiation dose

Dosimetry

Quality assurance and quality control

4.2 Specialised Techniques

Image intensification/fluoroscopy

Digital Fluoroscopy

Computed Tomography Scanning

Interventional procedures

Vascular imaging

4.3 Fundamentals of Image Acquisition etc.

Image quality v. radiation dose

Conventional film processing

Additional image formats, acquisition, storage and display

4.4 Contrast Media

Non-ionic and ionic

Use and preparation

Contra-indications to the use of contrast media

Use of automatic injection devices

5. Radiotherapy

5.1 General

Production of ionising radiations

Use of radiotherapy

- benign disease

- malignant disease

- external beam

- brachytherapy

5.2 Radiobiological Aspects for Radiotherapy

Fractionation

Dose rate

Radiosensitisation

Target volumes

5.3 Practical Aspects for Radiotherapy

Equipment

Treatment planning

5.4 Radiation Protection Specific to Radiotherapy

Side effects - early and late

Toxicity

Assessment of efficacy

6. Nuclear Medicine

6.1 General

Atomic structure and radioactivity

Radioactive decay

The tracer principle

Fundamentals of diagnostic use

Fundamentals of therapeutic use

- dose rate

- fractionation

- radiobiology aspects

6.2 Principles of Radiation Detection, Instrumentation and Equipment

Types of systems

Image acquisition, storage and display

Quality assurance and quality control

6.3 Radiopharmaceuticals

Calibration

Working practices in the radiopharmacy

Preparation of individual doses

Documentation

6.4 Radiation Protection Specific to Nuclear Medicine

Conception, pregnancy and breastfeeding

Arrangements for radioactive patients

Disposal procedures for radioactive waste

NoGP

16.1. Schedule 2 sets out details of the training which a practitioner or operator must have successfully completed in order to be permitted to carry out medical exposures or practical aspects under the Regulations. The Schedule is divided into two sections. Section A sets out subjects relevant to an individual's functions as practitioner or operator. Section B details subjects relevant to specific areas of practice. Not all the subjects listed in Schedule 2 have to be covered. The subjects of Schedule 2 that would need to be covered will depend on the range of exposures the practitioner or operator intends carrying out.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, together with the Ionising Radiations Regulations 1999 (S.I. 1999/3232) partially implement, as respects Great Britain, Council Directive 97/43/Euratom (OJ No. L180, 9.7.97, p.22) laying down basic measures for the health protection of individuals against dangers of ionising radiation in relation to medical exposure. The Regulations impose duties on those responsible for administering ionising radiation to protect persons undergoing medical exposure whether as part of their own medical diagnosis or treatment or as part of occupational health surveillance, health screening, voluntary participation in research or medico-legal procedures.

Regulation 2 is an interpretation provision. Amongst other definitions, there is a definition of adequate training, a concept which is defined with reference to the matters set out in Schedule 2 to the Regulations, and a definition of employer which goes beyond the term as conventionally understood and includes the self-employed, partners in a partnership and contractual relationships.

Regulation 3 sets out the medical exposures to which the Regulations apply.

Regulation 4 requires the employer to provide a framework of procedures for medical exposures. A sole practitioner is required to establish and follow his own procedures. The employer's procedures must cover the matters set out in Schedule 1 as a minimum. **Regulation 4** also requires the employer to establish written protocols for standard radiological practices, recommendations concerning referral criteria, quality assurance programmes for standard operating procedures, diagnostic reference levels, and dose constraints and to carry out investigations of incidents and appropriate reviews. Other regulations require the employer to take steps to ensure that a clinical evaluation is recorded of each medical exposure (**regulation 7**); to ensure that clinical audit is carried out (**regulation 8**) and that a medical physics expert is involved in every medical exposure as appropriate (**regulation 9**); to keep an inventory of equipment and to ensure that equipment is limited to a necessary amount (**regulation 10**).

Regulation 5 sets out the respective responsibilities of practitioners, operators and referrers and makes clear that where the employer also acts in one or more of these roles concurrently he is responsible accordingly. Practitioners and operators are required to follow the framework of procedures provided by the employer and to be adequately trained. The practitioner is responsible for the justification of a medical exposure and for authorisation save where this is carried out by the operator. The operator is responsible for each practical aspect he carries out as well as any authorisation given by him. The referrer must provide medical data as required by the practitioner.

Regulation 6 prohibits any medical exposure from being carried out which has not been justified and authorised and sets out matters to be taken into account for justification.

Regulation 7 provides for the optimisation process, which involves ensuring that doses arising from exposures are kept as low as reasonably practicable. The practitioner and the operator are responsible for elements of the optimisation of medical exposures as specified in **regulation 7**. **Regulations 6 and 7** provide that special attention be given to exposures in medico-legal procedures, health screening or voluntary participation in research, where no direct medical benefit is expected from the exposure or where exposure involves high doses, pregnant or potentially pregnant or breastfeeding females and children. **Regulation 7** also provides that certain information and instructions be given where radioactive medicinal products are administered.

Regulation 8 provides for clinical audit to be carried out and **regulation 9** for medical physics experts to be consulted where appropriate. **Regulation 10** requires the employer to maintain an inventory of equipment and to ensure that the amount of equipment is limited to what is necessary.

Regulation 11 prohibits a practitioner or operator from carrying out a medical exposure without having been adequately trained and requires the employer to keep a record of training qualifications of all practitioners and operators engaged by him. In addition, the employer is under an obligation to take steps to ensure compliance with the training requirements including continuing education after qualification (**regulation 4**). Again, sole practitioners and partners must keep records about their own training and comply with the requirements themselves. Proof of adequate training is provided by way of a certificate or other evidence attesting to a person's training.

Regulation 12 provides that the Regulations are made enforceable as health and safety regulations under the Health and Safety at Work etc. Act 1974, except that the enforcing authority is the Secretary of State in England, the National Assembly in Wales and the Scottish Ministers in Scotland. **Regulation 13** provides that it is a defence to proceedings for an offence under the Regulations that all reasonable steps were taken and due diligence exercised.

Regulation 14 revokes the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988 (S.I. 1988/778).

Notes:

- [1] S.I. 1977/1718.
- [2] 1972 c. 68.
- [3] OJ No. L180, 9.7.97, p.22.
- [4] S.I. 1978/1006.
- [5] 1974 c. 37.
- [6] S.I. 1988/778.

ISBN 0 11 099131 1

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Prepared 26 April 2000