

**THE IONISING RADIATION (MEDICAL  
EXPOSURE) REGULATIONS 2000**

**(together with notes on good practice)**

## 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.

## 4. **Application - Regulation 3**

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.

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.

## 5. **Interpretation - Regulation 2**

5.1. This regulation defines a number of terms used in the Regulations. Certain key definitions are discussed below.

## 5.2. *“appropriate authority”*

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.

## 5.3. *“diagnostic reference level”*

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)).

## 5.4. *“employer”*

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.

## 5.5. *“equipment”*

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.

## 5.6. *“medico-legal procedure”*

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.

## 5.7. *“medical physics expert”*

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.

#### 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.

#### 5.9. *"practical aspects"*

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.

#### 5.10. *"practitioner"*

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

#### 5.11. *"radiological"*

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.

## 5.12. "referrer"

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.

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.

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.

## 6. Duties of the Employer - Regulation 4

### 6.1. Regulation 4(1)

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.

### 6.2. Regulation 4(2)

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.

### 6.3. ***Regulation 4(3)(a)***

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.

### 6.4. ***Regulation 4(3)(b)***

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.

### 6.5. ***Regulation 4(3)(c)***

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.

### 6.6. ***Regulation 4(3)(d)***

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.

### 6.7. ***Regulation 4(4)***

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.

#### 6.8. ***Regulation 4(5)***

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.

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.

#### 6.9. ***Regulation 4(6)***

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.

## **7. Duties of the Practitioner, Operator and Referrer - Regulation 5**

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:

### **7.2. Regulation 5(1).**

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.

### **7.3. Regulation 5(3).**

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)).

### **7.4. Regulation 5(4)**

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.

## **8. Justification of Individual Medical Exposures - Regulation 6**

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:

### **8.2. Regulation 6(1)**

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.

### **8.3. Regulation 6(1)(a)**

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)).

#### 8.4. ***Regulation 6(1)(c)***

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.

#### 8.5. ***Regulation 6(2)***

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).

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

#### 8.6. ***Regulation 6(4)***

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.

#### 8.7. ***Regulation 6(5)***

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.

## 9. **Optimisation - Regulation 7**

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:

### 9.3. ***Regulation 7(2)***

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.

### 9.4. ***Regulation 7(4)***

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.

### 9.5. ***Regulation 7(4)(c)***

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.

### 9.6. ***Regulation 7(4)(d)***

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.

#### 9.7. **Regulation 7(5)**

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.

#### 9.8. **Regulation 7(6)**

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.

#### 9.9. **Regulation 7(7)**

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.

#### 9.10. **Regulation 7(8)**

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.

#### 9.11. **Regulation 7(9)(a)**

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.

### 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.

### 11. **Expert Advice - Regulation 9**

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.

## **12. Equipment - Regulation 10**

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.

## **13. Training - Regulation 11**

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 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.

## **14. Enforcement and Offences - Regulation 12**

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.

## **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.

16. **Adequate Training - Schedule 2**

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.