General Chiropractic Council

Ionising Radiation (Medical Exposure) Regulations 2000 (as amended) Ionising (Medical Exposure Regulations (Northern Ireland) 2000 (as amended)

(IR(ME)R)

An Explanation Guide for Chiropractors

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1. Introduction

The Ionising Radiation (Medical Exposure) Regulations 2000[1] (as amended[2, 3]) and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000[4] (as amended[5)]) governs the use of Ionising radiation, including radiographs, in healthcare. For the purpose of this document, these regulations will be referred as IR (ME) R. They apply to any facility that carries out medical exposures involving the use of ionising radiation, whether in the NHS or independent sector. This includes therefore any chiropractic practice that undertakes radiographic examinations.

The purpose of IR (ME) R is to minimize the risk to patients undergoing medical exposures. The legal requirements for the protection of employees who are involved in the use of ionising radiation are addressed by the Ionising Radiations Regulations (IRR 1999)[6] and IRR (Northern Ireland) 2000[7]. These are not covered in this document.

The requirements of IR (ME) R apply regardless of the size of the chiropractic practice, number of chiropractors employed or number of radiographic exposures carried out, and the aim of this document is to assist chiropractic practices with their compliance with IR (ME) R through explanation and advice.

The use of ionising radiation within chiropractic practices falls largely into 3 categories:

1. Where only chiropractors undertake their own radiographs
2. Where, as well as chiropractors undertaking their own radiographs, other staff groups such as radiographers may take radiographs
3. Where chiropractors refer patients to local hospitals or nearby Chiropractic Practice, where there are radiography facilities.

These procedures and their appendices are intended as a guide only, and, whilst attempts have been made to ensure they are comprehensive, there will always be local variations which must be taken into account. Therefore, all the suggested text and examples must be carefully adapted to ensure they match local practice. Any text displayed in red will need to be carefully considered to demonstrate local ownership and practice.

It is important to note that, as definitive interpretation of law can only be established in the courts, the advice given here should be regarded as an expression of professional opinion rather than an absolute statement on the legal position.

Within IR (ME) R the term “medical exposure” is used to describe any exposure of an individual to ionising radiation but unless quoting directly from IR (ME) R the term chiropractic exposure will be used in this document.

IR (ME) R is regulated and enforced by different organisations within each of the four home nations. These are known within the regulations as the ‘appropriate authorities’.

<u>England</u>
Care Quality Commission

<u>Scotland</u>
The Scottish Ministers

<u>Wales</u>
Healthcare Inspectorate Wales,

<u>Northern Ireland</u>
The Regulation and Quality Improvement Authority

2. Duty Holders and their responsibilities

There are 4 classes of 'duty holder' defined within IR (ME) R, and the legal obligation associated with each role is detailed below. These responsibilities apply even when the same person is acting as the employer, referrer, practitioner and operator.

2.1 Employer

As defined within IR(ME)R Regulation 2, the employer is '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'.

The employer is sometimes known as the 'legal person'. The employer as defined within IR (ME) R is not necessarily the same as that defined in employment law. It should be the most appropriate person to take the responsibilities of this role. The employer is required to provide a framework under which duty holders carry out their functions.

It may not be practicable for the employer to personally carry out all the duties required of the employer by IR (ME) R. While the task of carrying out these duties may be delegated to others, the legal responsibility will always remain with the employer. Therefore, any such delegation should be properly documented, along with arrangements by the employer to oversee implementation of these duties by the delegated person.

The duties of the employer are –

a) To ensure that appropriate written procedures are in place (Regulation 4(1)) and are subject to a quality assurance programme for document maintenance (Regulation 4(3) (b)). These written procedures shall include those defined in Schedule 1 of IR (ME) R, for example, procedures for entitlement of all duty holders, clinical evaluation and audit. A comprehensive list of Schedule 1 procedures may be found in Appendix 2. **Ensuring written procedures are in place is the most important duty of an employer.**

b) To ensure that the procedures are complied with by practitioners and operators (Regulation 4(1)(a))

c) To ensure that the training needs of practitioners and operators are met and that there is continuing education for these duty holders (Regulation 4(4)). See Section 4

d) To ensure there is an up to date training record for all practitioners and operators, including where the employer is concurrently the practitioner or operator (Regulation 11(4))

e) To establish recommendations on referral criteria for chiropractic exposures and make these available to all entitled referrers (Regulation 4(3) (a)). See Section 2.2

f) To ensure that appropriate written protocols are in place for every type of standard radiological practice and each piece of equipment (Regulation 4(2)). See Section 15

g) To establish diagnostic reference levels (DRLs) for standard radio-diagnostic examinations and ensure that there is a mechanism for assessment of compliance with these DRLs. If it is known that the DRLs are consistently exceeded, the employer shall set up a review and shall ensure that corrective action is taken (Regulation 4(3) (c) and (Regulation 4(6)). See Section 10

h) If research is carried out at the practice, to establish 'dose constraints' for biomedical and medical research programmes where there is no direct medical benefit to the individual (Regulation 4(3) (d)). See Section 7

i) To establish a process for the investigation of incidents resulting in exposures much greater than intended and for reporting such incidents to the appropriate authority (Regulation 4(5)). See Section 12

j) To ensure that a medical physics expert is retained and provides advice on matters relating to radiation protection concerning chiropractic exposures (Regulation 9(1)). See Section 2.4.1

k) To keep an inventory of equipment and ensure that this equipment is limited to the amount necessary (Regulation 10(1) and Regulation 10(3)). See Section 16

2.2 Referrer

A referrer is defined within IR (ME) R Regulation 2 as a **REGISTERED** healthcare professional who is entitled in accordance with the employer's procedures to refer individuals to a practitioner for chiropractic exposure.

The referrer is responsible for supplying the practitioner with sufficient medical data (such as previous diagnostic information or medical information) relevant to the chiropractic exposure to enable the practitioner to decide on whether there is a sufficient net benefit (Regulation 5(5)). The referrer should take a history and perform a relevant assessment of the patient's clinical information prior to requesting the radiograph, and document this information in the patient's chiropractic records.

The referrer is expected to consider the specific 'Referral Criteria' provided by the employer when making a referral. Referral criteria should include the clinical problem or diagnosis, the type of radiograph required an indication of the radiation dose to the patient, and any additional relevant comments such as the recommended interval between radiographs. The referrer is usually a chiropractor, but potentially could also be an appropriate registered healthcare professional

Where it is necessary for a chiropractor to refer a patient for a chiropractic exposure (such as a cervical or lumbar spine) that cannot be undertaken within the chiropractic practice itself, e.g. hospital radiology department or separate Chiropractic practice, then the chiropractor remains the referrer, but must be so entitled by the employer at the site where the exposure is undertaken.

It is for the employer where the radiograph is taken to ensure that all such 'external' referrers are properly entitled.

2.3 Practitioner

IR (ME) R Regulation 2 defines a practitioner as a **REGISTERED** healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual chiropractic exposure. This is a different definition to that of a 'chiropractic practitioner' and care should be taken not to confuse the two.

Whilst the main duty of the IR (ME) R practitioner is the justification of individual medical exposures; the practitioner must also:

- **a)** Comply with the employer's procedures (Regulation 5(1))
- **b)** Cooperate with the operator regarding practical aspects, with other specialists and staff involved in a chiropractic exposure, as appropriate (Regulation 5(6))
- **c)** Provide guidelines if they require entitled operators to authorise against them (Regulation 6(5)). See Section 5
- **d)** Ensure, to the extent of their involvement with the exposure, that the dose arising from the exposure is kept as low as reasonably practicable (Regulation 7(1))
- **e)** Only carry out a duty if they are trained to do so (Regulation 11(1))

Normally the role of the practitioner is carried out by a chiropractor

2.4 Operator

Under IR(ME)R Regulation 2 an operator is 'any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects of medical exposures, except where they do so as a trainee under the direct supervision of a person who is adequately trained'.

The operator's duties are to take responsibility for each and every practical aspect which he/she undertakes. These duties may be carried out by a chiropractor or appropriate trained person involved in the process of taking a radiograph. Operators DO NOT need to be Registered Health professionals. Examples of practical aspects might be:

- Identification of the patient
- Carry out medical exposures
- Processing of radiographic film or CR plates
- Clinical evaluation of chiropractic exposures

- Undertake QA of equipment

The range of duties for some operators may be fairly limited e.g. process radiographic film, but still must be specified. For this, it is recommended that employers establish a list of competences against which each operator may be entitled. (See Employer's Procedure EP1 Appendix 2)

It is important to note that an X-ray Engineer is not entitled as an IR(ME)R Operator and simple performance /safety checks must be made on equipment AFTER a repair by IR(ME)R Operators employed by the practice before equipment is used on patients

Consideration should be given to the training requirements appropriate to each of the operator's defined competences. (See Employer's Procedure EP1 Appendix 1)

Whilst the primary role of the operator is to carry out the practical aspects of an exposure, an operator must also:

a) Comply with the employer's procedures (Regulation 5(1))
b) Cooperate with the practitioner, regarding practical aspects, with other specialists and staff involved in a chiropractic exposure, as appropriate (Regulation 5(6))
c) Ensure, to the extent of their involvement with the exposure, that the dose to the patient arising from the exposure is kept as low as reasonably practicable (Regulation 7(1))
d) Only carry out a duty if they are trained to do so (Regulation 11(1))

2.4.1 Medical Physics Expert

The medical physics expert (MPE) should not be confused with the radiation protection adviser (RPA) which is identified in IRR99 and IRR (NI) 2000. The functions are different although, in practice, the same person may undertake both roles if suitably qualified.

The MPE must hold a science degree or its equivalent which is relevant to the use of ionising radiation as applied to chiropractic exposures. The MPE is required to have been adequately trained, for their involvement in chiropractic exposures under the Regulation 11(1) as this role is considered to be an operator function.

The MPE must be entitled by the employer as an operator, on appointment, and their roles and functions (their 'scope of entitlement' (SoE)) defined. Evidence of this appointment and definition of SoE might be included in the Radiation Protection File (see section 17).

Within a chiropractic practice, the MPE would be expected to undertake tasks such as giving advice on patient dose, development and use of new and/or complex techniques, as well as other matters related to radiation protection concerning medical exposures, when necessary (Regulation 9(2)(c)).

3. Entitlement

All referrers, practitioners, and operators (including MPEs) must be entitled by the employer, or by the person to whom the task of entitlement has been delegated. If the task of entitlement of duty holders is delegated, then the allocation of this duty should be clearly documented by the employer.

A prerequisite for entitlement as a referrer or practitioner within chiropractic practice is registration as a healthcare professional.

There is no requirement for operators to be registered. So, for example, an employer could, if they so wish, entitle an appropriately trained Receptionist or Practice Manager for the operator function of film processing.

Practitioners and operators must be adequately trained for the tasks they are entitled to perform (Regulation 11(1)), and the Regulations require that the employer shall keep an up-to-date record of such training which shall be available for inspection (Regulation 11(4)). More information on adequate training is covered in Section 4 of this guidance, and within Employer's Written Procedures EP1.

The Regulations do not require that employers keep training records for their entitled referrers.

Each duty holder should have an associated scope of entitlement which outlines the duties they are entitled to undertake. This scope of entitlement might change over time for a number of reasons; a person might develop further skills, undertake additional training, or the practice might install new equipment. If the needs of a chiropractic practice change, then competences might need to be added or removed as appropriate.

3.1 Scope of entitlement

Entitlement as a practitioner or operator must be restricted to those functions for which the duty holder is properly trained and experienced. To achieve this, employers should define a set of 'competences' which are applicable for the various staff groups (registered chiropractors, radiographers etc.), then, for each staff member, assess and assign the appropriate range of duties according to training and competence.

Appropriate assessment of competence might include:

For referrers: Competent to refer for all chiropractic exposures within the practice

For practitioners: Competent to justify all chiropractic exposures within the practice

For operators:

i Competent to identify the patient prior to a chiropractic exposure in accordance With Employer's Procedure EP4

ii Competent to carry out all chiropractic exposures within the practice

iii Competent for clinical evaluation of all chiropractic exposure carried out within the practice

iv Competent to process films/CR plates

v Competent to change chemicals in an x-ray processor

vi Competent to carry out quality assurance on equipment

The employer may nominate specific individuals as competence assessors where it is impractical for them to personally assess all duty holders. A competence assessor should be entitled and experienced in the duties they are assessing.

For staff members that have been working within a practice for some time, and are known by the competence assessor to be competent to undertake certain duties, it is not expected that they be reassessed and asked to demonstrate competence. They may be deemed competent by their experience. A competence assessor may assess their own competence.

Each practice owner must also appoint a Medical Physics Expert, the scope of entitlement for whom should be to provide any necessary expert advice for all types of medical exposure carried out within the practice.

The provisions described above are reflected in the sample Employer's Written Procedure EP1 and its appendices, which accompany this explanation guide. This also includes examples of required qualifications, training, and experience.

4. Training and Education

Under IR (ME) R Regulation 11(1), no operator or practitioner shall carry out a chiropractic exposure or any practical aspect without first having been adequately trained. Under IR (ME) R referrers do not need additional training on radiation protection, however there may be merit in having up to date training on new techniques and technologies relevant to chiropractic radiography. (Full IRMER Training is NOT legally required for Referrers but an awareness of the hazards of radiation is advised

IR (ME) R also requires (Regulation 4(4) (a)) that the employer take steps to ensure that every practitioner or operator engaged by them is adequately trained to undertake all of their duties. This includes undertaking continuing education and training after qualification (Regulation 4(4) (b)). For example, in the case of clinical use of new techniques, this might include training related to these techniques and the relevant radiation protection requirements.

It is important that practitioners and operators maintain their competence for each duty for which they are entitled. If competence cannot be maintained for any reason, consideration should be given to either

undertaking further training or removing the task from their scope of entitlement. Where appropriate, a review of scope of entitlement could form part of an appraisal process.

The employer is responsible for ensuring an up to date record is kept of training and must make it available to an inspector if requested (Regulation 11(4)). The training record should contain, as a minimum, any relevant dates on which training was completed and the nature of the training. Whilst the employer is responsible for this record, it is often the duty holder themselves who maintains their own personal continuing professional development folder which contains a more detailed record. For clarity this could be laid out within an employer's written procedure, though this is not required by the legislation. (See Employers Procedures, EP1) For an example of a training record, see Appendix 6.

When the employer is concurrently the practitioner and operator, he/she is required keep a record of their own training.

Regulation 11(5) says that when the employer enters into a contract with another employer to engage a practitioner or operator, the 'supplying' employer must provide the training records for each of these individuals to the chiropractic practice employer. E.g. in the case of an MPE, the MPE employer is responsible for keeping the MPE training records. This requirement should be specified in the contract between the employer and third party.

Where a duty holder is "in training" for a particular competence, that function may only be carried out under the supervision of a duty holder who is 'assigned as competent' for that function. The level of supervision shall be appropriate to the function in question, and the supervisor shall be responsible for carrying out that function in accordance with employer's written procedures and protocols.

5. Justification and Authorisation

Justification is the intellectual process of weighing up the expected benefit of an exposure against the possible detriment of the associated radiation dose. Authorisation is the documentation that this justification has been carried out, and must occur prior to the exposure. This record is usually a signature or unique electronic entry either in the patient's chiropractic notes against the referral for radiography, or on the referral form/letter.

Justification is the primary role of the practitioner. However, if it is not practicable for a practitioner to justify a chiropractic exposure, then an appropriately entitled operator may authorise an exposure using guidelines issued by a practitioner (Regulation 6(5)).

These are sometimes known as justification or authorisation guidelines. It should be noted that these guidelines are <u>not</u> required if chiropractic exposures are always justified and authorised by a practitioner.

These guidelines must be comprehensive and written by a chiropractor who is entitled as a practitioner for all the chiropractic exposures it contains. They should be explicit as to the age of patient they refer to e.g. adult or child. The guidelines must be verified by the practitioner to display ownership and demonstrate suitable document control.

When justifying an exposure appropriate weight must be given to the following

IR(ME)R - Regulation 6(2)		Consider
a	The specific objectives of the exposure	What is to be gained by carrying out the exposure? How will it change the management of the patient?
b	The characteristics of the individual involved	Such as age or individual medical history of the patient
c	The potential diagnostic benefits to the individual from the exposure	What is the expected benefit of the chiropractic exposure? Have they already had a radiograph which could provide the required information?
d	The detriment the exposure may cause	What is the possible detriment from the associated radiation dose?
e	The efficacy, benefits and risk of available alternative techniques having the same object but involving no or less exposure to radiation	What other examinations are available that could answer the diagnostic question but involve no or less exposure to radiation?

IR(ME)R requires special attention to be given during the justification of any chiropractic exposure that is undertaken for either medico-legal reasons (Regulation 6(3)(a)) or for research when there is no direct benefit to the patient (Regulation 6(3)(b)and (c)).

Suggested chiropractic provisions for justification and authorisation have been outlined in Employer's Written Procedure EP3.

6. Optimisation

Every chiropractic exposure must be optimised to ensure that the radiation dose arising from the exposure is kept as low as reasonably practicable (Regulation 7(1)). This is the responsibility of both the practitioner and operator in their respective roles.

Matters which may help ensure optimisation include the following; however this list is not exhaustive:

a) When purchasing new equipment or introducing new techniques, consideration should be given to the resultant dose to the patient
b) If using film, ensure that a fast film screen combination is utilised when applicable e.g. >/= 400 speed for spinal images
c) All practitioners and operators are adequately trained to perform the tasks for which they are entitled
d) Practitioners and operators undertake regular and relevant CPD and training after qualification
e) Protocols are written to ensure that the minimum number of exposures are taken to answer the clinical question
f) The correct settings are used to ensure that the dose is as low as reasonably practicable
g) The correct collimation used to ensure that the dose is as low as reasonably practicable
h) Images should be scored using the 1, 2, 3 system or poor, satisfactory, good system to monitor image quality. This may highlight any issues.
i) Audit of image quality
j) Implementing DRLs and preferably specific chiropractic DRLs where possible.
k) Quality assurance required by IR(ME)R 2000 and IRR99 aids optimisation

Critical examination of newly installed equipment, acceptance testing and regular equipment quality assurance is also ways to ensure that examinations are optimised; these are covered under IRR 1999 or IRR (NI) 2000.

IR (ME) R also calls for special attention for optimisation to be given to any medico-legal exposure (Regulation 7(7) a) and to exposures to children (Regulation 7(7) (b)). Although not defined in law, an example of special

attention may be having specific protocols in place for paediatric and medico-legal chiropractic exposures. X-rays on children should only be justified/authorised by Health Professionals and performed by Operators that have experience in this field. This should be considered before a Chiropractor justifies such exposures.

7. Research

Although not common within chiropractic practices, IR (ME) R places additional obligations relating to research exposures. These are listed below and, if research is undertaken within a chiropractic practice, must be addressed within the employer's procedures. (See Employers Procedures EP12)

a) All research must have been approved by an ethics committee (Regulation 6(1)(c))
b) All individuals must participate voluntarily (Regulation 7(4)(a))
c) Individuals must be informed of the risks of the radiation exposure in advance (Regulation 7(4)(b))
d) Dose constraints must be set down in the employers procedures for individuals whom no direct medical benefit is expected (Regulation 7(4)(c))
e) Individual dose targets are planned when the individual is expected to receive a diagnostic benefit (Regulation 7(4)(d))

All X-ray images of the volunteer obtained during the research project MUST be reported and acted on as if they are non research Clinical images

A dose constraint is a restriction on the total dose of a research study that is not expected to be exceeded. The constraint is based on the total dose from all radio-diagnostic procedures included in the research protocol. A dose target is target level of dose set before research exposures begin, in this way, excessive doses should be avoided.

8. Medico-Legal

Medico-legal exposures are defined in Regulation 2 as an examination performed for insurance or legal purposes without a medical indication. An example of this may be a radiograph following an assault where compensation is being claimed and the radiograph is not required as part of the persons diagnosis or treatment.

IR (ME) R has additional obligations associated with medico-legal exposures which are listed below. If medico-legal exposures are undertaken within a chiropractic practice, an employer's written procedure is required (See Employer's Procedure EP13).

a) The practitioner when justifying the exposure shall pay special attention to medico legal exposures (Regulation 6(3)(a))
b) The practitioner and operator shall pay special attention to the need to keep doses arising from medico legal exposures as low as reasonably practicable. (Regulation 7(7)(a))

9. Diagnostic Reference Levels

Diagnostic Reference Levels (DRLs) are dose levels for typical examinations for standard sized patients that are not expected to be exceeded when good and normal technique is used (Schedule 1(g)).

The employer must establish DRLs (Regulation 4(3) (c)) and must undertake an appropriate review if they are consistently exceeded (Regulation 4(6)).

National and European DRLs (see for example Table 1 below) are available and should be considered when setting local values (Regulation 4(3) (c)). Local DRLs reflect local practice and could be calculated and provided to the employer by the MPE following a dose survey. Local DRLs set higher than the national ones would need to be explained. Further information on DRLs can be found on the Department of Health website[8].

Radiograph	National DRL, ESD per radiograph (mGy)
Lumbar spine AP	14

DRLs, once established, should be made available and for awareness may be displayed next to the x-ray machine. It is considered good practice to have an understanding of the doses that result from local standard exposure factors. It must be noted that DRLs relate to mean doses for groups of patients and so apply to typical practice rather than individual exposures.

If a dose value, e.g. a 'Dose Area Product (DAP), for a radiographic view, is displayed by the x-ray equipment, consideration of this information will give an indication of whether the corresponding local DRL has been exceeded.

Where the equipment does not provide a dose value after an exposure then regular quality assurance of the equipment should give reassurance that the intended exposure factors and dose are being delivered by the x-ray machine.

If a step-wedge test is carried out regularly and is within tolerance then it can be assumed that the x-ray machine and processor are both working correctly. If the step-wedge test is out of tolerance and the chemistry is proven to be correct, then consideration should be given to carrying out further tests on the x-ray equipment.

For CR/DR the resultant image may include a Sensitivity/Exposure Index or graph. This information can be compared the manufacturers recommendations which will give an indication of how much radiation has reached the detector. If the information displayed on the image is higher or lower than recommended, too much or too little radiation is being used. If no index/graph is displayed then care must be taken as the image will appear diagnostic even when too much radiation is used.
If it can be demonstrated that a DRL has been unexpectedly exceeded, it should be documented along with any extenuating circumstances. Where DRLs are consistently exceeded it should be reported to the employer for investigation. Once an investigation has taken place any necessary corrective action must be implemented.

The procedure for establishing and using DRLs, along with the process of investigation needs to be documented (See Employer's Procedure EP7).

10. Clinical Evaluation

Every exposure, including those taken as part of a clinical trial, must have a documented report or clinical evaluation. If it is known prior to the exposure that no clinical evaluation will occur, the exposure cannot be justified and cannot lawfully take place (IR (ME) R Notes for Guidance[9] paragraph 9.10.1)

Clinical evaluation is considered to be one of the practical aspects of an exposure, and is therefore an operator function. The employer's written procedures must make it clear where this evaluation is to be recorded e.g. in the patients chiropractic record, and how the entitled operator undertaking this task can be identified. (See Employer's Procedure EP8)

In most cases the chiropractor will be the operator for clinical evaluation.

11. Incidents and near misses involving ionising radiation

It is a requirement of the legislation that when an employer knows or has reason to believe that the radiation dose given to a patient is 'much greater than intended' (MGTI), it must be investigated and if necessary be reported to the appropriate authority (Regulation 4(5)).

Incidents involving chiropractic radiation exposures can occur for several reasons. They may be due to an equipment fault, human error or a procedural failure. Incidents should be internally reported and investigated. Following a preliminary investigation, if it is found that a given exposure was MGTI then this would require external reporting to the appropriate authority. The MPE and RPA should be asked for advice prior to the reporting of any such incident. The authority will vary depending on the cause of the incident
External reporting could be to either-

- The relevant national 'appropriate authority', for all incidents (see Section 1), excluding those due to equipment malfunctions.
  These include when the wrong patient is x-rayed or there has been a failure to follow Employer's Written Procedures.
- HSE, for incidents caused by equipment malfunctions (IRR 99/IRR(NI) 2000)

"Near miss" incidents do not need to be reported, but, ideally, should be similarly investigated, as any leassons learnt can be applied and have the potential to prevent an actual incident from occurring. The process of investigation of incidents and near misses, including responsibilities and timescales may be laid out within employer's written procedure, although this is not required under legislation. Then should a radiation incident occur the process of investigation will be standardised. (See Employer's Procedure EP10) Further information can be obtained from either the Department of Health website or the Health and Safety executive Guidance document PM77"Equipment used in medical exposure".

12. Clinical Audit

Clinical audit is a requirement under IR (ME) R Regulation 8. It includes a review of chiropractic radiological practices which seeks to improve the quality and outcome of patient care. This can be done through a structured review which might lead to a modification of practice or the application of new practices where necessary. The employer's written procedures should include provision for carrying out clinical audit as appropriate. (See Employer's Procedure EP12)

Clinical audit might include:

a) Review of image quality monitoring (1, 2, 3 or poor, satisfactory, good). These should be reviewed to see if there are any issues which may highlight training requirements
b) Review of images, by multiple persons where possible, to agree levels of quality
c) Dose audit
d) An audit of chiropractic records to ensure that each chiropractic exposure has been referred, authorised, clinically evaluated and a written record made of the clinical evaluation in line with the written procedures and that the duty holders are identifiable
e) An audit to check that entitlement of staff has taken place and that it is supported by appropriate training and CPD when necessary
f) Audit of the patient identification process to ensure that each operator is following the correct procedure

13. Quality Assurance

Quality assurance (QA) as defined in IR (ME) R Regulation 2 refers to the provision and maintenance of the employer's written procedures and protocols (see Employer's Procedure EP11). It does not refer to equipment QA which is covered by IRR 99/IRR (NI) 2000.

Document QA entails ensuring that the employer's written procedures and protocols comply with a document control system where the document author, version number, issue date, review date etc. are clearly identified, and that the documents are reviewed by the review date.

Schedule 1(e) requires that there shall be employer's written procedures outlining what QA under IR (ME) R is to take place, who is responsible for carrying it out, how often documentation is reviewed, usually on an annual basis, and, importantly, how the employer knows this has taken place.

14. Written Protocols

The employer must ensure that written protocols are in place for every type of standard radiological practice for each piece of equipment (Regulation 4(2)).

Written protocols describe which exposures/projections should be done in most circumstances and should include matters such as whether it is an adult or paediatric exposure, routine and additional views, anatomy to be included on the image, +/- grid, +/- compensatory filtration, source to receptor distance, the machine settings or exposure factors, and the expected dose or DRL if available. Protocols may be displayed next to the each x-ray machine. For an example of a written protocol and exposure chart see Appendix 4 and 5.

Written protocols are subject to the document quality assurance provisions referred to in Section 13 of this guidance (and see Employer's Procedure EP11).

15. Equipment

The employer is responsible for keeping an up-to date inventory of equipment and ensuring it is available to an IR(ME)R inspector if requested (Regulation 10(1)).

The inventory must contain the following information (Regulation 10(2))

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

The inventory must include all equipment that has the potential to impact patient dose e.g. processor, CR reader and each digital detector. It could also include information such as location and servicing arrangements if not covered elsewhere.

The employer must also ensure that the amount of equipment at an installation is limited to the amount necessary (Regulation 10(3)). This implies that any superseded equipment must be decommissioned.

16. IR (ME) R within the existing Radiation Protection File

Most chiropractic practices will already have a (paper or electronic) Radiation Protection File, and this could contain a number of statements which outline the key requirements of IR (ME) R (See Appendix 1).

These might include:

- Clarification over who is the IR(ME)R 'employer' for the organisation
- Radiation doses to patients are kept as low as reasonably practicable consistent with the clinical purpose
- Clear framework of delegation if persons are to carry out duties on the employers behalf (if appropriate)
- That the required IR(ME)R procedures are in place
- A statement that all duty holders must comply with IR(ME)R procedures
- Appointment and entitlement of a Medical Physics Expert

This file should also include copies of the employer's written procedures and protocols, and records to demonstrate that they have been read by the appropriate staff members.

17. References

1. Ionising Radiation (Medical Exposure) Regulations 2000
   http://www.legislation.gov.uk/uksi/2000/1059/contents/made

2. Ionising Radiation (Medical Exposure) Regulations (Amendments) 2006
   http://www.legislation.gov.uk/uksi/2006/2523/contents/made

3. Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011
   http://www.legislation.gov.uk/uksi/2011/1567/made

4. Ionising Radiation (Medical Exposure) Regulations (NI) 2000
   http://www.opsi.gov.uk/sr/sr2000/20000375.htm

5. Ionising Radiation (Medical Exposure) Regulations (NI) (Amendments) 2010
   http://www.opsi.gov.uk/sr/sr2010/plain/nisr_20100029_en_1
6. Ionising Radiation Regulations 1999
   http://www.legislation.gov.uk/uksi/1999/3232/contents/made

7. Ionising Radiations Regulations (NI) 2000
   http://www.opsi.gov.uk/sr/sr2000/20000375.htm

8. Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010
   http://www.opsi.gov.uk/sr/sr2010/plain/nisr

9. Guidance on the establishment and use of "Diagnostic Reference Levels" (DRLs) as the term is applied in the Ionising Radiation (Medical Exposure) Regulations 2000
.http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074067

10. Guidance and good practice notes for IR (ME) R
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007957

Appendix 1

The following statements describe some key requirements of IR (ME) R that could be considered for inclusion in the Radiation Protection File, if they are relevant and reflect local practice.

IR(ME)R statements
For the XXXXX Practice, *(named person)* is the employer for the purposes of IR(ME)R
The employer will ensure that all of the Employer's Written Procedures and protocols required for compliance with IR(ME)R are provided and are authorised by *(named person)* on behalf of the employer, and are subject to a written procedure for document quality control.
Entitlement of duty holders at XXXXX Chiropractic Practice, will be carried out by *(named person),* on behalf of the employer *(if a different person)*
The employer will ensure that all referrers to the XXXXX Chiropractic Practice are provided with appropriate referral criteria
Responsibility for the task of maintaining a record of training of duty holders under IR(ME)R (including other staff carrying out procedures within the chiropractic practice's premises) will lie with *(named person(s))*
A Medical Physics Expert shall be appointed and entitled to be involved as required for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning chiropractic exposures
The employer shall establish 'diagnostic reference levels' (DRLs) for chiropractic examinations and ensure that there is a mechanism for assessment of compliance with these DRLs. Where it is known that DRLs are consistently exceeded, the employer shall set up a review, and shall ensure the corrective action is taken
The employer shall establish a procedure for the investigation of incidents which may have resulted in an overexposure of patients and for reporting such incidents to the appropriate authority for IR(ME)R and HSE or for incidents due to equipment malfunction the HSE (for IRR 99)/MHRA
Entitled practitioners and operators must comply with the employer's procedures. 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
All practitioners and operators, to the extent of their respective involvement in a chiropractic exposure, shall ensure that doses arising from the exposure are kept as low as reasonably practicable consistent with the intended purpose
Responsibility for maintaining an inventory of all radiation equipment used at the XXXXX Chiropractic Practice lies with *(named person)*
The document authoriser is responsible for ensuring that the document is reviewed within the required period and for recording completion of each review (irrespective of whether the document is amended or not)

Appendix 2

IR (ME) R Schedule 1

The whole of Schedule 1 is included below for completeness. However Procedure (f) '…and administered activity' and all of Procedure (i) refers to nuclear medicine examinations so are not applicable to chiropractic exposures.

Schedule 1

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), 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); (applies to use of radioactive materials only)
j) procedures for the carrying out and recording of an evaluation for each chiropractic exposure including, where appropriate, factors relevant to patient dose;

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.

Appendix 3 Example of Chiropractic Written Protocols

PRO1	**Example** Protocols for chiropractic radiographs	XXXXX Practice

Cervical Spine (Adult)

Routine Views	SID cms	GRID	Collimation to visualise	Comments
AP	100	yes	C3 –T2 Soft tissue of neck laterally	
APOM	100	yes	C1 and C2 Mandibular- rami laterally	
LATERAL	180	yes	Sella- tursica - superior border T1 All spinous processes and anterior soft tissue	Compensatory filter may be used if patient unable to depress shoulders , exposure to be adjusted appropriately
Additional Views				
Swimmers	180	yes	To include part of Cervical spine not visualised on lateral view.	
Oblique	180	yes	C1 – T1 Soft tissue of neck	To assess IVF

Appendix 5 – Example of Chiropractic Exposure Settings

PRO2	**Example** Exposure Settings for chiropractic radiographs	XXXXX Practice

The information within the columns with red headings may not be available for all types of exposure or machine. They are all shown here for demonstration purposes to provide examples of the type of information that may be available.

This protocol information may be displayed in a different format and limited to the exposure settings available.

Adult Exposures for film

Examination	Source To Receptor distance	kV	mAs	mA	sec	Local DRLs	Specific comments
AP cervical spine	100	75	4.8			15	
Lat cervical spine	180	80	10.5			11	
AP knee	100	60	5			5	
Lat knee	100	60	5			5	

The information within the columns with red headings may not be available for all types of exposure or machine. They are all shown here for demonstration purposes to provide examples of the type of information that may be available.
Factors for differing sizes of patients must be included.

This protocol information may be displayed in a different format and limited to the exposure settings available.

Exposure protocols specifically for children must be included if paediatric radiographs are taken at a Chiropractic practice

Appendix 6

Examples of Training records

Name				
Job title	**e.g. chiropractor, chiropractic assistant, etc.**			
Site/Room/Equipment	**e.g. XXXX Practice, Exam room 2, X-ray machine**			
Task		**✓**	**Trainer initials**	**Date**
Switch x-ray equipment on and off				
Aware of exposure charts and protocols				
Can select appropriate exposure factors				
Undertake an exposure				
Use collimation				
Complete room log including exposure factors/dose when appropriate				
This person has received training on the above tasks				**Date**
Signature of trainer				
Name of Trainer				
Signature of duty holder				

Name				
Job title	**e.g. chiropractor, chiropractic assistant, etc.**			
Site/Room/Equipment	**e.g. XXXX Practice, Exam room 2, Desktop processor**			
Task		**✓**	**Trainer initials**	**Date**
Switch x-ray equipment on and off				
Process a film				
Clean processor				
Change chemicals in processor				
Processor QA				
This person has received training on the above tasks				**Date**
Signature of trainer				
Name of Trainer				
Signature of duty holder				

Name				
Job title	**e.g. Chiropractor, chiropractic assistant, etc.**			
Site/Room/Equipment	**e.g. XXXXX Practice, Exam room 2, X-ray machine + desktop processor**			
Task		**✓**	**Trainer initials**	**Date**
Use of x-ray machines				
How to process a film				
This person has received training on the above tasks				**Date**
Signature of trainer				
Name of Trainer				
Signature of duty holder				