Combined Practice Inspection Requirements for Ionising Radiation in Dental Practice

Guidance for Dental Practices

January 2016

1. Purpose

The purpose of this document is to help dental practices better understand what evidence practice inspectors require to satisfy the questions included in the Combined Practice Inspection Document (2015 version) on compliance with the Ionising Radiations Regulations (IRR- for the protection of staff) and the Ionising Radiation (Medical Exposure) Regulations (IRMER- for the protection of patients).

2. Duty Holders

The regulations impose a range of legal duties on defined 'duty holders'. The main duty holders are:

1. the employer (IRMER and IRR)
2. referrers (IRMER)
3. practitioners (IRMER)
4. operators (IRMER)
5. the Radiation Protection Adviser (RPA) (IRR)
6. the Medical Physics Expert (MPE) (IRMER)

The nature of these duties is described in *(IR(ME)R) - An Explanation Guide for Dental Practices*[1] and in *Work with ionising radiation Ionising Radiations Regulations 1999 Approved Code of Practice and guidance*[2].

Responsibility for the requirements addressed by most of the questions in the CPI document lies with **the employer**. You should state clearly in writing the identity of the employer and ensure that all staff know the identity of this individual. It is likely that the inspector will ask the employer to accompany them as they conduct this part of the inspection. If the employer role is performed by a body corporate, and therefore the employer is not available at inspection, the Radiation Protection Supervisor is a suitable replacement.

3. Quality Controlled Documents

You should ensure that the documents required to show compliance with IRR and IR(ME)R are up-to-date quality controlled documents. This means is that there should be a clear definition of:

- The document title and (where appropriate) number;
- The maximum period between regular document reviews;
- The date of the last review;
- A version number;
- A 'Page of pages' definition.

It should also be clear who is responsible (to the employer) for producing the document and keeping it up-to-date.

[1] See www.scottishdental.org/professionals/ionising-radiation-irmer/
[2] See www.hse.gov.uk/pubns/priced/l121.pdf

With particular regard to Question 10 of the CPI document, there is a duty on the employer to define how this document quality control shall be implemented for the written procedures and protocols required under IRMER. (See Procedure EP12 in www.scottishdental.org/professionals/ionising-radiation-irmer/ from the Scottish Dental website).

An example of such a quality controlled document is appended as Annex 1.

4. What Will Inspectors Expect to See?

A copy of the relevant sections from the CPI document is appended as Annex 2.

This section of the guidance considers each of the questions in turn, and explains what evidence the inspector will expect to see.

Section 2F: Radiation Protection.

Questions 1 to 3: Appointments. The employer is responsible for appointing a Radiation Protection Supervisor (RPS), an external Radiation Protection Advisor (RPA) and an external Medical Physics Expert. There should be written evidence (such as a letter of appointment) that persons suitable to hold these roles have been appointed.

Your RPA must be on the list of *Current holders of the RPA 2000 Certificate of Competence to Act as a Radiation Protection Adviser under IRR99*[3].

Currently there are no similar statutory requirements for the MPE, and, in most cases, the MPE will be the same person who acts as your RPA.

The RPS is a member of staff appointed by the employer whose main function is to oversee implementation of the 'Local Rules' (see Question 4) within your practice.

Question 4: Local Rules. The main purpose of the 'Local Rules', as required by Regulation 17 of IRR, is to set out the key arrangements for restricting exposure to controlled areas (and, where appropriate, supervised areas).

You should ensure that Local Rules are in place and that you can show to the inspector an up-to-date document that:

- identifies and describes the controlled areas and includes a summary of the arrangements to restrict access;
- identifies the RPS who is responsible to the employer for overseeing implementation of the Local Rules;
- defines the arrangements for testing and maintenance of equipment, including engineering controls and design features, safety features and warning devices;
- summarises the particular steps to be taken to control exposure in the event of a reasonably foreseeable radiation accident.

It is also advisable to include details of the following:

[3] See www.rpa2000.org.uk/wp-content/uploads/2014/06/Holders-RPA-at-1-June-2015.pdf

- arrangements for radiation monitoring and personal dosimetry, including examination and testing of radiation monitoring equipment;
- arrangements for protection of pregnant staff.

Question 5: Risk Assessment. All employers in the UK are required under the management of Health and Safety at Work Regulations to undertake risk assessments and, if there are 5 or more employees, to record the findings.

Ensure that you can show the inspector an up-to-date risk assessment that identifies the risks due to radiation and the measures put in place to manage them. An example of the content of a radiation risk assessment is appended as Annex 3, which is taken from the SDCEP Practice Support Manual (www.psm.sdcep.org.uk).

Question 6: Equipment Quality Assurance. There is a statutory duty on the manufacturers and installers of equipment used for medical exposures to provide the user with adequate information about any necessary maintenance. You should ensure that the installer provides information on the proper use, testing and maintenance of the radiation equipment and you should also ensure that you are able to show this information to the inspector.

The information provided by the installer should be used to define a written system and schedule for equipment maintenance, and for recording that this maintenance has been carried out. You should be able to show the inspector evidence that this is in place.

Question 7: Radiation Safety Assessment. As stated above, manufacturers and installers of equipment used for medical exposures should provide the user with adequate information about how the safety performance of this equipment should be periodically tested.

Use this information, along with advice from your RPA, to define a written system for testing of the performance of the radiation equipment at appropriate intervals, and after any major maintenance procedure, and for recording the results of this testing.

This should include measurement of the dose to the patient for a range of representative equipment settings, and the testing of any control measures to restrict the exposure of staff and members of the public.

Ensure that you can provide the inspector with evidence that this system is in place and operating as stated.

Question 8: Employer's Written Procedures. Employer's Written Procedures under IRMER are instructions from the employer on how the various aspects of radiation exposure of the patient will be managed. Duty holders are legally obliged to follow these instructions without deviation.

You should ensure that a set of Employer's Written Procedures, in a similar (quality controlled) format to that shown in Annex 1, is available for the inspector to view.

Annex 4 (from www.scottishdental.org/professionals/ionising-radiation-irmer/ on the Scottish Dental website) lists the Employer's Written Procedures that an inspector will expect to see. The procedures in bold letters are those that are specifically required by the Regulations. If, for example, no research exposures are carried out, the relevant Employer's Written Procedures should simply state this.

Question 9: Employer's Written Protocols. Employer's Written Protocols under IRMER differ from Employer's Written Procedures in that duty holders are not legally obliged to follow these instructions without deviation. They allow for professional latitude in approach, for example, in adjustment of X-ray machine settings to suit a particular patient.

You should ensure that a set of Employer's Written Protocols, covering every type of standard radiological practice for each piece of equipment, is available for the inspector to view. As with the Employer's Written Procedures, these documents should be quality controlled and in a similar format to that shown in Annex 5.

Question 10: Quality Assurance System for Employer's Written Procedures and Protocols. The set of Employer's Written Procedures must include a procedure giving instructions from the employer on how these documents are to be provided and maintained. This should specify, for example, the information to be included in the document header and footer. For more information see Section 3 on page 2 of this document.

Question 11: Entitlement of Duty Holders. The duty holders under IRMER are:

The **'Referrer'** who requests the exposure.

The **'Practitioner'** who decides whether the exposure can be justified as doing more good for the patient than harm.

The **'Operator'** who carries out the various 'practical aspects' of the exposure, including the 'clinical evaluation' of the images produced.

The '**Medical Physics Expert'** who advises on all aspects of measurement and optimisation of patient doses.

Anyone who fulfils any of these roles must be entitled by the employer to do so, on the basis that the employer is satisfied that the duty holder is sufficiently well qualified, experienced and trained for the role. Ensure that a written procedure saying how this entitlement will be carried out and recorded is in place and available for the inspector to view.

The inspector will also want to view an example of how duty holders' scope of entitlement is documented in your practice. This will normally be a document that lists the tasks ('competencies') relevant to the type of exposures (X-rays, OPTs etc) carried out in the practice, with the tasks at which each duty holder is considered competent be 'signed –off' by, or on behalf of, the employer. An example of such a document is appended here as Annex 6.

'Signing-off' of each of these competencies should, where appropriate, be backed by a documented training record for each duty holder. The inspector may ask to view this.

Question 12: Diagnostic Reference Levels (DRLs). The set of Employer's Written Procedures must include one giving the DRLs adopted by the employer for the practice. These are dose levels that would not normally be exceeded, for example in a carrying out an intra-oral X-ray for an adult. Examples of suggested DRL's are at Annex 7.

You should also make arrangements to record the actual doses to patients and compare these doses to the defined DRL for the exposure in question. If these recorded doses regularly exceed the DRL, you should investigate why this is the case and address the problem. The inspector may ask you to provide information on how this is done in your practice.

Question 13: Dose Assessment and Recording. The set of Employer's Written Procedures must include one that states how the dose to the patient will be measured and recorded. The inspector will ask you how this is done in your practice.

If your X-ray or OPT machine etc. displays the dose for each exposure, then you should put in place a procedure for recording this figure. If this never varies, e.g. for all adult exposures, then it is sufficient for the procedure to state what this routine dose is and to note that recording of patient dose for individual exposures will be confined to those involving any deviations from the norm. Ensure that any dose to the patient that is used routinely does not exceed the DRL.

If, on the other hand, your machine only displays 'exposure factors' (kV, mAs, etc) then the only practical means of assessing patient dose is to record these settings and to assess the dose on the basis of previous equipment assessment and calibration carried out by your RPA on a 3 yearly basis. Your procedure for dose assessment and recording should state how this will be done in your practice. If the exposure factors used never vary, e.g. for all adult exposures, then it is sufficient for the procedure to state what this routine dose is (as assessed from the exposure factors used) and to note that recording of exposure factors for individual exposures will be confined to those involving any deviations from the norm. Ensure that any dose to the patient that is used routinely does not exceed the DRL.

An example of how exposure factors and related doses might be recorded and compared with DRLs is in Annex 8.

If any additional checks, such as the use of a stepwedge, are carried out regularly then the written procedure should say so.

Question 14: Pregnancy Checking. While it is the case that dental radiographic imaging is, by general professional consensus, not damaging to a developing foetus, it remains the case that the Regulations require that an Employer's Written Procedure must be in place. This might simply state, for example, that '*Within this Dental Practice, we currently do not undertake any radiographic examinations where the foetus will be exposed to the primary beam of radiation. Consequently we do not ask the patient if she might be pregnant. Any concerns raised by pregnant patients will be dealt with sympathetically. This might mean a deferral of treatment.*' The inspector will ask to see this procedure.

Question 15: Radiology Audit. Clinical audit is a review of dental radiological practices which seeks to improve the quality and outcome of patient care. Ensure that an Employer's Written Procedure stating how this will be done (usually on an annual basis) is available for the inspector to view. (See Procedure EP13 in www.scottishdental.org/professionals/ionising-radiation-irmer/ from the Scottish Dental website). The inspector may also ask to see the recorded results of your latest audits; these should clearly indicate when they were carried out and by whom.

Examples of audit might include:

- Review of image quality;
- Dose audit to ensure compliance with DRLs;
- An audit of dental records to ensure that each dental exposure has been referred, authorised and clinically evaluated in line with the written procedures and that the duty holders are identifiable;
- An audit to check that entitlement of staff has taken place and that it is supported by appropriate training and CPD when necessary;
- Audit of the patient identification process to ensure that each operator is following the correct procedure.

Annexes

Annex 1: Example of a quality controlled document.

Employer's Written Procedure Number EP 8	**Clinical Evaluation**	**Big Town Dental Practice**

Objectives

To ensure every dental exposure undertaken within Big Town Dental Practice has a recorded clinical evaluation

Responsibilities

A dentist, as an entitled operator, is responsible for ensuring that a clinical evaluation is recorded in the patient's dental record.

The Process of recording a clinical evaluation

Following a dental exposure each image must be clinically evaluated by the dentist and the findings documented in the patient's dental record.

This evaluation of the whole image shall include:

- The identity, either signature or initials of the operator undertaking the evaluation.
- The details of all findings including:
    - Charting of caries;
    - Findings relevant to the patients management or prognosis;
    - In the case of a pre-extraction radiograph, it may be sufficient to record either 'root form simple' or 'nothing abnormal diagnosed'.

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Annex 2: The relevant sections from the CPI document.

		2F. Radiation Protection See also Section 3D Radiation (Processes) and Part 4 Section G Radiology	**Yes**	**No**	**Information Source**
1	A	Radiation Protection Adviser appointed* Name: _____			
2	A	Radiation Protection Supervisor appointed* Name: _____			
3	A	Medical Physics Expert appointed** Name: _____			
4	A	Up to date 'local rules' in place and subject to document quality assurance* (*Evidence required*).....			
5	A	Risk assessment for radiation work*. *(Evidence required if there are 5 or more employees*).....			
6	A	Documented quality assurance system for radiation equipment in place* *(Evidence required of proper documentation and of implementation)*.....			PSM Radiation Protection
7	A	Radiation safety assessment carried out for each machine (every 1-3 years)***			
8	A	Set of Employer's Written Procedures in accordance with **IR(ME)R 2000**** in place and up to date.....			Scottish Dental Website (IR[ME]R Information)
9	A	Employer's Written Protocol for each type of exposure in place and up to date.....			
10	A	Documented quality assurance system for Employer's Written Procedures and Protocols in place and up to date.....			
11	A	All duty holders (Referrers, Practitioners and Operators) identified and properly entitled by the Employer.....			
12	A	Appropriate Diagnostic Reference Levels (DRLs) in place.....			
13	A	Procedure for dose assessment and recording in place and being implemented.....			
14	A	Documented procedure for pregnancy checking in place and up to date.....			
15	A	Radiology audit undertaken in accordance with Employer's Written Procedures.....			

*** The Ionising Radiations Regulations 1999, enforced by HSE & HSE(NI)**

**** The Ionising Radiation (Medical Exposure) Regulations 2000 (as amended)**

***** According to manufacturer's instruction**

Annex 3: Example of the content of a radiation risk assessment (from SDCEP Practice Support Manual, www.psm.sdcep.org.uk)

What are the hazards?	Who might be harmed and how?	What are you already doing?	What further action is necessary / recommended?	Action by whom	Action by when	Done
Over-exposure to radiation	Patients and staff. Overexposure during radiographic examination due to equipment failure or staff error.	Equipment subject to regular testing and maintenance. Equipment is of suitable quality to ensure radiation doses are as low as reasonably practicable. Collimation and fast film speeds used. Diagnostic reference levels in accordance with national DRLs in place and adhered to. Contingency plans in place. Only entitled staff may carry out tasks related to radiography. Staff training and CPD.				
Total yearly exposure exceeds practice dose investigation level.	Staff. Exposure greater than dose investigation level due to large volume of examinations carried out.	Dose investigation level set. Personal dosimetry will be carried out if estimated annual dose exceeds 1 mSv. A. Number of films per week B. Number of work weeks/year C. Estimated max dose per radiograph to staff at 2m from tube and patient outside main beam = 0.125 µSv Estimated max annual dose A x B x C =	A formal review of working conditions will be undertaken if results of personal dosimetry suggest annual dose exceeds the dose investigation level to ensure that exposure to radiation is restricted as far as reasonably practicable.			

Accidental exposure to radiation	Staff, patients and members of the public. Unintended exposure to radiation due to mis-identification, equipment failure, staff error or inadequate shielding.	Patient identification procedure in place. Controlled area defined. Only patient allowed in controlled area when x-ray beam is activated. If parent or carer is required to stay in controlled area during exposure, they will be informed of the risks and issued with a lead apron.				
Additional exposure to radiation	Patients. Poor image quality or processing resulting in clinically unacceptable x-ray images and retakes are required.	Regular maintenance and testing of processing equipment. Quality assurance programme monitors image and processing quality. Clinical audit and peer review.				
Unnecessary exposure to radiation	Patients. Radiographic examination undertaken unnecessarily i.e. previous radiographs were sufficient for patient's treatment	Full clinical history and exam required before referral for radiography. Justification and authorisation required before exposure.				
Other comments						

Annex 4: List of the Employer's Written Procedures

Title of Procedure
Entitlement of Duty Holders
Referrals for Dental Examinations
Justification and Authorisation
Patient Identification
Pregnancy Enquiries
Assessment of Patient Dose
Diagnostic Reference Levels
Clinical Evaluation
Training and Education
Incident Reporting
Reducing the Probability and Magnitude of Unintentional Exposures
Document Quality Assurance
Audit
Research Exposures
Medico-Legal and Occupational Exposures

Annex 5: Example of a Dental Written Protocol

PRO1	Protocols for dental radiographs	Big Town Dental Practice

Adults (over 16 years of age)

Type of dental exposure	Clinical indication	Comments
OPG	Unusual eruption patterns Unusual morphology Extensive and general periodontal breakdown	Whole mouth is required
	Impacted teeth on one side	Select setting that includes the side required only
	Delayed eruption Unexplained missing teeth	Limit the area of the jaw imaged to the minimum area required
	Assessment of wisdom teeth prior to planned surgical intervention	Select setting to cover the wisdom teeth and not the whole mouth, unless specifically requested

Children (up to the age of 16 years)

Type of dental exposure	Clinical indication	Comments
OPG	Unusual eruption patterns Unusual morphology	Limit the area of the jaw imaged to the minimum area required
	Delayed eruption Unexplained missing teeth	Limit the area of the jaw imaged to the minimum area required
	Prior to orthodontic treatment for assessment of developing dentition when patient is aged 12-13 years	Image dentition image only – no condyles

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Annex 6: Duty Holder Scope of Entitlement

Name of Duty Holder | Job Title

Qualification(s) and date obtained

Registration Number | Date last checked

Referrer competencies	**Assigned as competent** **Date & signature/initials of duty holder**
Refer for all dental examinations (excluding CBCT)	
Refer for Cone Beam CT dental examinations	

Practitioner competencies	**Assigned as competent** **Date & signature/initials of duty holder**
Competent to justify requests for all dental examinations	
Competent to justify requests for cone Beam CT dental examinations	

Operator competencies	**In training** **Date & signature/initials of duty holder and assessor**	**Assigned as competent** **Date & signature/initials of duty holder and assessor**
Competent to carry out patient identification		
Competent to undertake all dental X-rays		
Competent to undertake OPT/Lat Ceph exposures		
Competent to undertake cone beam CT exposures		
Competent to process dental films		
Competent to process digital images		
Competent to change chemicals in a dental processor		
Competent to clinically evaluate all dental examinations undertaken at practice		
Competent to clinically evaluate all dental examinations undertaken outwith the practice		
Competent to clinically evaluate cone beam CT dental examinations		
Competent to carry out quality assurance on equipment		

Entitled by | Date

Name of Entitler | Date

Signature of Duty Holder (DH) | Date

IR(ME)R procedures read by DH | Date

Annex 7: Diagnostic Reference Levels

The following table lists the agreed national DRLs from the Scottish Warranted Inspector for Medical Exposure Regulations and the Chief Dental Officer (Scotland) (see www.sehd.scot.nhs.uk/publications/CDO(2012)01.pdf).

Radiograph	Patient entrance dose (PED) per radiograph (mGy)
Adult mandibular molar (film)	2.0
Adult mandibular molar (digital)	1.0
Child mandibular molar (film)	1.2
Child mandibular molar (digital)	0.7

The following table gives recent recommendations on other DRLs that might be adopted by dental practices (see www.scottishdental.org/professionals/ionising-radiation-irmer/).

Radiograph	Dose Width Product (DWP) per radiograph (mGy mm)
Panoramic (adult and child)	60
	Dose Area Product (DAP) per radiograph (mGy cm^2)
Panoramic (adult and child)	82
Cephalometric (adult)	40
Cephalometric (child)	25
Cone Beam CT (adult)	250

Regulation 4(6) of IRMER requires that the employer must undertake an appropriate review whenever the defined DRLs are consistently exceeded. To establish whether this is the case, the employer must therefore, in accordance with Schedule 1(g), have a written procedure 'for the assessment of patient dose'.

Annex 8: Dose recording and comparison to DRLs.

Example of an adult exposure chart that should be completed each time that the machine in question is calibrated by the RPA service.

Film speed setting (or equivalent) _____

Examination	X-ray Machine Settings	kV	mAs	mA	sec	FSD or FFD cms	Ref. Dose	Local DRL	Specific Comments
Upper 1-3 **4-5** **6-8**	Adult and incisor Adult & premolar Adult and molar	70	1.4 1.75 2.8	7	0.2 0.25 0.4	20	1.4 mGy 1.9 mGy 2.0 mGy	2.1 mGy	Rectangular collimation should be used whenever clinically possible
Lower 1-3 **4-5** **6-8**	Adult and incisor Adult & premolar Adult and molar	70	1.12 1.4 2.24	7	0.16 0.2 0.32	20	1.1 mGy 1.4 mGy 1.6 mGy	1.7 mGy	Rectangular collimation should be used whenever clinically possible
Bitewing	Adult and appropriate tooth	70	2.24	7	0.32	20	1.6 mGy		Rectangular collimation should be used whenever clinically possible
Occlusals	Adult and occlusal	70	2.24	7	0.32	20	1.6 mGy		Rectangular collimation should be used if clinically possible
Lat Ceph	Standard	90	-	20	0.3	150	40mGy cm^2	40mGy cm^2	If possible, limit field to area of interest
Panoramic	Standard jaw	73	-	8	10	-	80mGy cm^2	82mGy cm^2	If possible, limit field to area of interest in line with written protocols