

Guide to Radiation Protection Documentation for the Combined Practice Inspection

February 2020



Version 1.0	Feb 2020	First version of SDCEP Guide to Radiation Protection
		Documentation, for CPI Checklist v4, February 2020.

Acknowledgements

This guide has been informed by guidance for practices and inspectors previously published on the Scottish Dental website by the former warranted Scottish IR(ME)R Inspector, Arthur Johnston, and by CPI guidance developed within NHS Lothian.

SDCEP acknowledges the contribution of reviewers Mark Worrell and Andrew Hince of the Scottish Radiation Protection Advisers group and Mark McCutcheon and Jonathon Turnbull of the Dental Practice Advisers group.

Scottish Dental Clinical Effectiveness Programme

Dundee Dental Education Centre, Frankland Building, Small's Wynd, Dundee DD1 4HN

Email: scottishdental.cep@nes.scot.nhs.uk

Tel: 01382 425751/425771 **Website:** <u>www.sdcep.org.uk</u>

Contents

Introduction	2
The Combined Practice Inspection	2
Aims of this Guide	2
CPI Radiation Protection Requirements	3
2F.1 Registration with HSE	3
2F.2, 3 & 4 Formal Appointments of Personnel	4
2F.5 Local Rules	5
2F.6 Radiation Risk Assessment	6
2F.7 & 8 Equipment Inventory, Quality Assurance and Safety Assessment	7
2F.9 Employer's Procedures	9
2F.10 Employer's Protocols	10
2F.11 Entitlement of Duty Holders	11
2F.12 Exposure Charts & Diagnostic Reference Levels	12
2F.13 Dose Assessment and Recording	13
2F.14 Pregnancy Enquiries	14
2F.15 Information on Benefits and Risks	15
2F.16 Radiology Audit	16

Introduction

The Combined Practice Inspection

All NHS general dental practices in Scotland are subject to a Combined Practice Inspection (CPI) by their Health Board every 3 years. The current version of the CPI checklist can be downloaded from the <u>Scottish Dental website</u>.

Part of the inspection assesses compliance with the requirements of the Ionising Radiations Regulations 2017 (IRR) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R). As such, the CPI checklist (Section 2F) includes a number of items relating to documentation for work with dental x-rays.

The legislation regulating the use of radiation is complex and, in order to evidence compliance, some of the items in the CPI checklist require multiple documents, that may originate from a variety of sources.

Aims of this Guide

This guide aims to explain the CPI requirements for radiation protection and indicate what is expected by inspectors for each of the items in Section 2F of the checklist. It signposts to further information, advice, templates and examples of documents and records that may be adapted for use by practices to meet the requirements. CPI checklist items relating to practices' x-ray facilities (Sections 3D & 4G of the checklist) involve physical inspection rather than documentation and are not included in this guide.

The Scottish Dental Clinical Effectiveness Programme (SDCEP) <u>Practice Support Manual</u> (PSM) provides information, advice and key actions on a variety of topics, including radiation protection, to help practices carry out best practice and comply with regulations. This guide provides links to the relevant sections of the PSM radiation protection topic and to specific PSM templates for each checklist item, where available. Additional templates and example documents that may help practices meet the inspection requirements are also identified and can be downloaded from the <u>SDCEP website</u>.

Practices may use templates from other sources to develop their radiation protection documentation, as long as they fulfil the requirements of the regulations and the inspection items. When using templates or examples from any source these must be adapted to be specific to the actual circumstances in the practice.

Please note: This document presents an interpretation of the relevant legislation and CPI requirements. Consequently, it should not be regarded as definitive and is intended as a guide only. Assessment of compliance with CPI checklist items is at the discretion of the inspector.

This guide is not intended as a substitute for the information provided in the PSM on radiation protection, and it is recommended that practices refer to the PSM or other relevant sources for more comprehensive advice. Users can register for login details via the <u>PSM website</u>.

CPI Radiation Protection Requirements

The following sections of this guide list CPI radiation protection items, together with examples of documentation and processes to demonstrate compliance with the requirements of national radiation protection legislation. Explanatory notes are included in each section, below the item and requirements.

It is recommended that the documentation required to demonstrate compliance is kept in the practice's Radiation Protection File (see **PSM Radiation Protection File**).

2F.1 Registration with HSE

CPI Item	Requirements
2F.1 Health and Safety Executive registration for use of x-ray equipment	Copy of HSE registration certificate

Explanation

Employers must apply online to the Health and Safety Executive (HSE) for registration for the use of x-ray machines before beginning work with ionising radiation. See **PSM Specification** and **Use of X-ray Equipment** for more information.

2F.2, 3 & 4 Formal Appointments of Personnel

Decree and decreed of any sinder and
 Documented record of appointment, including the scope of advice the RPA is required to give (e.g. appointment letter)
 Documented record of appointment, including responsibilities (e.g. appointment letter) Name(s) of RPS stated in the Local Rules
Documented record of appointment (e.g. appointment letter)

Explanation

The Employer is responsible for appointing a suitable Radiation Protection Supervisor (RPS), Radiation Protection Adviser (RPA) and Medical Physics Expert (MPE). For more information on these appointments see **PSM Formal Appointments and Entitlement of Personnel**.

If the RPA and MPE are provided through external radiation protection services, ensure that you have confirmation in writing that they will act on your behalf as the RPA and MPE. The appointment of the RPS, including their responsibilities, should be confirmed in writing. An **RPS Appointment Letter template** can be downloaded from the PSM website.

The appointed personnel should be named in the Radiation Protection File (e.g. see Radiation Protection File Overview template in 2F.11).

Templates

PSM RPS Appointment Letter template

2F.5 Local Rules

CPI Item	Requirements
2F.5 Up to date 'local rules' in place and subject to document control (Evidence required)	 Current version of Local Rules, specific to the practice and with document control (i.e. practice name, date, version, authorisation, review date and page numbering) Local Rules readily available to all relevant personnel

Explanation

The Employer is responsible, under IRR17, for providing Local Rules that are specific to the Controlled Areas in the practice, to set out the key arrangements for restricting exposure to radiation. The Local Rules should be developed in consultation with the Radiation Protection Adviser (RPA). For more information on the Local Rules, including the minimum requirements, see **PSM Local Rules**.

A **Local Rules template** is also available to download from the PSM website. If using a template, it must be adapted to be specific to the working environment in the practice. The practice's Local Rules must be regularly reviewed and subject to document control.

Templates

PSM Local Rules template

2F.6 Radiation Risk Assessment

CPI Item	Requirements
2F.6 Risk Assessment for Radiation Work	Current radiation risk assessment specific to the practice

Explanation

The radiation risk assessment identifies the risks due to radiation and the measures put in place to manage them, and the assessment should be discussed with workers and others who could be affected. The radiation risk assessment should be developed with the practice's RPA and must be specific to the practice, regularly reviewed and kept up to date.

Further information on radiation risk assessment is provided in the **PSM Controlling Exposure of Staff and Other People** section.

2F.7 & 8 Equipment Inventory, Quality Assurance and Safety Assessment

CPI Item	Requirements
2F.7 Documented inventory and quality assurance system for radiation equipment in place (Evidence required of proper documentation and of implementation)	 Up-to-date inventory of x-ray equipment (including the type of machine, manufacturer, model and serial numbers, year of manufacture, year of installation, location and date of acceptance test) Employer's Procedure on equipment quality assurance Records of routine testing and maintenance (including schedule for checks) Record of routine surveillance Reports from engineers, MPE, RPA regarding testing, maintenance and repairs
2F.8 Radiation safety assessment carried out for each machine (every 1-3 years)	Records of safety assessment tests (may be carried out as part of routine tests)
Evalanation	

Explanation

An **example Employer's Procedure for Equipment Inventory and Quality Assurance (EP18)** is available on the SDCEP website for adapting to describe the practice's approach to these items (see 2F.9 on Employer's Procedures). An **X-ray Machine Inventory template** can be downloaded from the PSM.

The aim of the quality assurance programme is to ensure that the equipment is fit for use and maintained effectively so that radiation doses are kept as low as reasonably practicable. X-ray equipment should be subject to critical examination and acceptance testing at installation followed by maintenance, routine performance and safety testing and visual checks (routine surveillance), at intervals recommended by the manufacturer, installer, MPE or RPA. The radiation safety assessment includes 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. Safety testing may be carried out as part of the routine testing. See PSM Testing and Maintenance of X-ray Equipment and PSM Quality Assurance of Patient Dose and Equipment for further information and advice on equipment tests and quality assurance.

An X-ray Machine Routine Testing and Maintenance Record template to record the tests carried out and the schedule for future tests, and an X-ray Machine Routine Surveillance Record template to record in-house checks can be downloaded from the PSM website.

Quality assurance of image production (including phosphor screens and digital sensors) and image quality is addressed under radiology audit (see 2F.16).

Templates

<u>Example Employer's Procedure EP18, within Employer's Procedures</u>

PSM X-ray Machine Inventory template

PSM X-ray Machine Routine Testing and Maintenance Record template

PSM X-ray Machine Routine Surveillance Record template

2F.9 Employer's Procedures

CPI Item	Requirements
2F.9 Up to date Employer's Procedures in accordance with IR(ME)R, in place and subject to document control	 Current version of Employer's Procedures, specific to the practice and with document control (i.e. practice name, date, version, authorisation, review date and page numbering) Employer's Procedures available to all relevant personnel

Explanation

Employer's Procedures, under IR(ME)R, are written instructions from the Employer on how the various aspects of radiation exposure of the patient will be managed. For further information on the content of Employer's Procedures, see **PSM Written Procedures and Protocols**.

A document containing a suite of **example Employer's Procedures** (EP1-18) can be downloaded from the SDCEP website. If using these, each of the procedures must be tailored to be specific to your local circumstances. Some of the examples might not be applicable to the practice, for example if no research exposures are carried out. If so, the relevant Employer's Procedure should simply state that this is the case.

Example Employer's Procedures EP18, EP1, EP7, EP6, EP5, EP17 and EP13 also relate directly to CPI items 2F.7, 2F.11, 2F.12, 2F.13, 2F.14, 2F.15 and 2F.16, respectively.

Employer's Procedures must be regularly reviewed, subject to document control and the current version made available to all duty holders. The example Employer's Procedure EP12 (Document Control) describes measures (e.g. version number, authoriser, review date etc.) that can be adopted to ensure document control.

Other versions of Employer's Procedures that fulfil the requirements of the regulations may be used or developed by the practice. Refer to your Medical Physics Expert for advice on your Employer's Procedures.

Templates

Example Employer's Procedures

2F.10 Employer's Protocols

CPI Item	Requirements
2F.10 Up to date Employer's Protocol for each type of exposure, in place and subject to document control	 Current versions of Employer's Protocols for each type of exposure, specific to the practice and with document control (i.e. practice name, date, version, authorisation, review date and page numbering) Employer's Protocols available to all relevant personnel

Explanation

Written protocols are required under IR(ME)R, to provide guidance on the details of each type of dental exposure carried out in the practice. These should include recommended exposure settings for each x-ray machine, for adults and children, and other information relating to the exposures, such as any special techniques, recommended views and specific dose reduction comments. **Example Employer's Protocols for Exposures** for specifying the exposure settings and other relevant information can be downloaded from the SDCEP website. Practices may also have protocols for selection criteria for exposures and these may be informed by professional guidelines. See **PSM Written Procedures and Protocols** for more information on protocols.

As with the Employer's Procedures, the Protocols must be regularly reviewed, subject to document control and the current version made available to all relevant duty holders. The example Employer's Procedure EP12 (Document Control) describes measures (e.g. version number, authoriser, review date etc) that can be adopted to ensure document control.

Other versions of Employer's Protocols that fulfil the requirements of the regulations may be used or developed by the practice.

Templates

Example Employer's Protocol for Intra-oral Exposures
Example Employer's Protocol for Cephalometric Exposures
Example Employer's Protocol for Panoramic Exposures

2F.11 Entitlement of Duty Holders

CPI Item	Requirements
2F.11 All duty holders (Referrers, Practitioners and Operators) identified and properly entitled by the Employer	 Employer's Procedure on entitlement of duty holders A record of named individuals, their entitlements and scope of duties* Records of competencies for each duty holder assessed against their duties

Explanation

All IR(ME)R duty holders (Referrers, Practitioners, and Operators (including MPEs)) must be formally entitled by the Employer, or by the person to whom the task of entitlement has been delegated. See **PSM Formal Appointments and Entitlement of Personnel** for information on the duty holders' roles and entitlement.

As part of the Employer's Procedures requirement described in 2F.9, practices should have a procedure on entitlement. The **example Employer's Procedure EP1** (Entitlement of Duty Holders) can be adapted to describe how entitlement is carried out in the practice and outlines qualifications and training required for each role. The **Radiation Protection File Overview template** available from PSM website includes a table (in Appendix 1) that may be used for recording a summary of staff entitlements and the scope of their duties. Example Employer's Procedure EP1 provides an example template (in EP1 Appendix 2) for recording a duty holder's competencies (**Example Competencies for Entitlement as a Duty Holder**). This template is also available separately on the SDCEP website so a record can be completed for each duty holder. 'Signing-off' of each of the competencies should, where appropriate, be backed by documented training records for each duty holder.

Templates

Employer's Procedure EP1, within example Employer's Procedures

PSM Radiation Protection File Overview template (Appendix 1)

Example Competencies for Entitlement as a Duty Holder (EP1 Appendix 2)

^{*} This information can be recorded in a summary or within the individual records for each duty holder.

2F.12 Exposure Charts & Diagnostic Reference Levels

CPI Item	Requirements
2F.12 Appropriate exposure charts and diagnostic reference levels (DRLs) readily available	 Employer's Procedure on DRLs Exposure charts for each type of exposure for each x-ray machine, readily available to all Operators in the practice Local DRLs for each type of exposure, readily available to all Operators in the practice (these may be included in the exposure charts)

Explanation

IR(ME)R requires that practices have a written Employer's Procedure to ensure that local Diagnostic Reference Levels (DRLs) for the different types of dental exposures performed are in place, regularly reviewed and made available to the Operators. It is expected that DRLs would not usually be exceeded without good reason and if consistently exceeded, an investigation should be carried out so that corrective action can be taken. The Employer's Procedures described in 2F.9, include an **example Employer's Procedure on DRLs (EP7)** that may be adapted for use.

The appointed Medical Physics Expert (MPE) should advise on appropriate local DRLs for the practice, taking into consideration national DRLs (see **PSM Optimisation of Dose**).

Exposure charts to indicate the settings for each type of exposure for a specific x-ray machine should be available near the relevant machine. To evidence that patient doses are assessed against the local DRLs, the exposure charts could also include the representative patient doses for each setting (from the most recent routine testing of equipment; see 2F.7&8), and the local DRLs for comparison. Alternatively, these may be documented separately. **Example Exposure Charts** can be downloaded from the SDCEP website and populated with the current exposure settings, representative patient doses and local DRLs for the practice, with advice from your MPE. Any changes to these settings should be reported to the MPE.

Templates

Employer's Procedure EP7, within example Employer's Procedures
Example Exposure Charts

2F.13 Dose Assessment and Recording

CPI Item	Requirements
2F.13 Procedure for dose assessment and recording in place and being implemented.	Employer's Procedure on assessment of patient dose

Explanation

The Employer's Procedures (see 2F.9) must include a procedure to describe how patient doses will be measured and recorded, so that the doses can be assessed to confirm that the local DRLs are not being consistently exceeded. The procedure should include details of the exposure factors or dose indicators that the practice will record, which will depend on the x-ray machine(s) used.

If the x-ray machine displays a Dose Area Product (DAP) value or other indicator of actual dose delivered, this can be recorded as a direct measure. If the x-ray machine only displays the exposure factors (e.g. kV, mAs, time etc.) then these settings can be recorded, and the patient dose assessed on the basis of the most recent routine equipment testing and calibration for that machine (e.g. see Example Exposure Charts in 2F.12).

Where the standard settings specified in the practice's exposure protocols for a particular type of exposure (e.g. adult bitewing) are always used, it is not necessary to record the details of the dose or exposure factors for each exposure.

The Employer's Procedures described in 2F.9, include an **example Employer's Procedure for Assessment of Patient Dose (EP6)** that may be adapted for use to specify how patient dose assessment and recording is carried out in the practice.

Templates

Employer's Procedure EP6, within example Employer's Procedures

2F.14 Pregnancy Enquiries

CPI Item	Requirements
2F.14 Documented procedure relating to pregnancy enquiries in place	Employer's Procedure on pregnancy enquiries

Explanation

Since the foetus will not be exposed to the primary beam of radiation, dental radiographic imaging is, by general professional consensus, not damaging to a developing baby. However, IR(ME)R requires that a written Employer's Procedure must be in place to describe the practice's approach to pregnancy enquiries for dental exposures. See **PSM Controlling Exposure of Patients** for further information.

The Employer's Procedures described in 2F.9, include an **example Employer's Procedure EP5** (Pregnancy Enquiries) that may be adapted to outline the practice's approach.

Templates

Employer's Procedure EP5, within example Employer's Procedures

2F.15 Information on Benefits and Risks

CPI Item	Requirements
2F.15 Documented procedure for providing information on benefits and risks of dental radiographic exposure	Employer's Procedure on providing information on benefits and risks

Explanation

Under IR(ME)R, practices must have in place a written Employer's Procedure describing the practice's approach to providing patients, or their representatives if appropriate, adequate information relating to the benefits and risks of the exposure (see **PSM Written Procedures and Protocols**).

The Employer's Procedures described in 2F.9, include an **example Employer's Procedure EP17** (Provision of Information Relating to the Benefits and Risks of an Exposure) can be adapted to outline the practice's approach.

Templates

Employer's Procedures EP17, within example Employer's Procedures

2F.16 Radiology Audit

CPI Item	Requirements
2F.16 Radiology audit undertaken in accordance with Employers Written Procedures	 Employer's Procedure on radiology audit Records of radiology audits carried out

Explanation

The purpose of radiology audit is to ensure that the practice's quality assurance programmes for radiology are being followed, the procedures and protocols adhered to and to identify any areas for improvement (see **PSM Quality Assurance**). Essentially this involves reviewing all the various documents, records and processes relating to dental radiology on a regular basis.

While audit of quality assurance programmes and clinical audit may be considered distinct, in practical terms the approaches to these for radiological practice are likely to overlap. Some aspects of radiology audit will involve simply checking whether documents and records are in place and up to date (e.g. audit of equipment inventory), while for others a more in-depth review of patient records, evaluation of compliance across procedures and implementation of improvements might be required (e.g. audit of dental records to ensure that each exposure has been referred, justified, authorised and clinically evaluated in line with the written procedures).

An **example Radiology Quality Assurance and Audit Programme template**, with the processes involved, quality assurance records that might be kept and aspects to consider for auditing is available to download from the PSM website.

The Employer's Procedures described in 2F.9, include **example Employer's Procedure (EP13)** that may be adapted for use to describe the practice's approach to radiology audit. EP13 includes a suggested list of radiology audits that a dental practice could carry out. Additional or alternative audits that ensure that the practice's quality assurance programme is being followed effectively and the procedures and protocols implemented may be outlined in this procedure.

Practices will be expected to have records of the audits carried out, including details of the audit activity, who carried it out and when it was done. A **Record of Audit template** can be downloaded from the PSM website.

Templates

Employer's Procedures EP13, within example Employer's Procedures

PSM Example Radiology Quality Assurance and Audit Programme template

PSM Record of Audit template