SUMMARY OF CURRENT UK LEGISLATION AND GUIDELINES

Legislation

There are two sets of regulations in the UK governing the use of ionizing radiation. They both form part of The Health and Safety at Work Act 1974 and comply with the provision of the European Council Directives 96/29/Euratom and 97/43//Euratom:

- ***The Ionising Radiations Regulations 1999 (SI 1999 No. 3232***) (IRR99) which replace the Ionising Radiations Regulations 1985 (SI 1985 No. 1333).

- ***The Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000 No. 1059)*** (IR(ME)R 2000) which replace the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988 (SI 1988 No. 778), to which additional amendments were made in 2006 and 2011- ***The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 (SI 2006 No.2523)*** and ***The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011 (SI 2011 No.1567).***

General points regarding the Ionising Radiations Regulations 1999:

- Concerned principally with the safety of workers and the general public but also address the equipment aspects of patient protection
- Came into force on 1st January 2000
- Replaced the Ionising Radiations Regulations 1985
- Enforced by the Health and Safety Executive (HSE).

General points regarding Ionising Radiation (Medical Exposure) Regulations 2000:

- Concerned with the safety of patients
- Came into force on 13th May 2000
- Replaced the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988
- Defined new positions of responsibility, namely:
  - the *employer*
  - the *referrer*
  - the *practitioner*
  - the *operator*
- Enforced in the UK by:
  - the Care Quality Commission (CQC) in England
  - the Healthcare Inspectorate Wales (HIW) in Wales
  - the Scottish Executive (SE) in Scotland
  - the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland.

Guidelines

In the last 20 years, four major sets of UK guidelines have been published, namely:

- *Guidelines on Radiological Standards in Primary Dental Care* published in 1994 by the National Radiological Protection Board (NRPB) and the Royal College of Radiologists. These guidelines and their recommendations covered all aspects of dental radiology and set out the principles of *good practice* - much of what was recommended in 1994 is still relevant today.

- *Selection Criteria for Dental Radiography 1st Edn 1998, 2nd Edn 2004, 3rd Edn 2013* published by the Faculty of General Dental Practice (UK) of the Royal College of Surgeons of England. These booklets reviewed the evidence for, and provide guidance on, which radiographs are appropriate for different clinical conditions and how frequently they should be taken. Several of the recommendations in the 2013 3rd Edn are reproduced in appropriate chapters in *Essentials of Dental Radiography and Radiology* 5th Edn 2013 with kind permission of the Faculty of General Dental Practice (UK).

- *Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment* published by the Department of Health in 2001 which brought together the requirements of IRR99 and IR(ME)R 2000 as they relate to dentists and included the principles of *good practice* established in the 1994 Guidelines. The main points and various extracts from these 2001 Guidance Notes are reproduced below with kind permission from the Radiation Protection Division of the Health Protection Agency (formerly the National Radiological Protection Board (NRPB).

- *Guidance on the Safe Use of Dental Cone Beam CT (Computed Tomography) Equipment* published by the Health Protection Agency in 2010. This document specifically covered the radiation protection requirements for CBCT, as this was not included within the 2001 Guidance Notes. The main points and various extracts from the 2010 CBCT Guidance are also reproduced below with kind permission from the Radiation Protection Division of the Health Protection Agency.

NOTE: The summaries below are **not** intended to cover all aspects of the various guidance notes and legislation. The various publications mentioned above, particularly the *2001 Guidance Notes* and the *2013 Selection Criteria*, should be regarded as essential reading for all members of the dental profession, whether in general practice, dental hospitals or community clinics. The *2010 CBCT Guidance* should be regarded as essential reading for all members of the dental profession involved with CBCT equipment. The Health Protection Agency will become part of Public Health England on 1st April 2013 and it is anticipated that their guidance documents will be available on-line from Public Health England via GOV.UK.

Summary of the legislation and extracts from the *2001 Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment*

Essential legal requirements of IRR99

- *Authorization*. Use of dental X-ray equipment for research purposes should be in accordance with a generic authorizations granted by the Health and Safety Executive (HSE).

- *Notification*. The HSE must be notified of the routine use of dental X-ray equipment and of any material changes to a notification including a change in ownership of the practice of a move to new premises.

- *Prior risk assessment.* This must be undertaken before work commences and be subject to regular review. All employers are recommended to record the findings of their risk assessment, but it is a requirement for employers with five or more employees. A five-step approach is recommended by the HSE:
  1. Identify the hazards (i.e. routine and accidental exposure to X-rays).
  2. Decide who might be harmed and how they might be affected.
  3. Evaluate the risks and decide whether existing precautions are adequate or whether more precautions need to be taken. Implement additional precautions, if needed.
  4. Record the findings of the risk assessment.
  5. Review the risk assessment and revise it, if necessary.

- *Restriction of exposure*. There is an over-riding requirement to restrict radiation doses to staff and other persons to as low as reasonably practicable (ALARP) (see later).

- *Maintenance and examination of engineering controls*. Applies particularly to safety and warning features of dental X-ray equipment.

- *Contingency plans*. These should arise out of the risk assessment and be provided within the Local Rules (see later).

- *Radiation Protection Adviser (RPA).* A suitably trained RPA must be appointed in writing and consulted with to give advice on IRR99. The RPA should be an expert in radiation protection and will be able to advise on compliance with the Regulations and all aspects of radiation protection, including advice on:
  - controlled and designated areas for all radiation equipment
  - installation of new or modified X-ray equipment
  - periodic examination and testing of engineering controls, safety features and warning signals
  - systems of work
  - risk assessment

- contingency plans
- staff training
- assessment and recording of doses received by patients
- quality assurance (QA) programmes.

- *Information, instruction and training*. Must be provided, as appropriate, for all persons associated with dental radiology.

- *Designated areas*. During an exposure, *a controlled area* will normally be designated around the X-ray set as an aid to the effective control of exposures. The controlled area may be defined within the primary X-ray beam until it has been sufficiently attenuated by distance or shielding and within 1.5m of the X-ray tube and the patient. Normally, only the patient is allowed in this area. This can be facilitated by the use of appropriate signs.

- *Radiation Protection Supervisor (RPS).* An RPS - usually a dentist or senior member of staff in the practice – should be appointed to ensure compliance with IRR99 and with the Local Rules. The RPS must be adequately trained, should be closely involved with the radiography and have the authority to adequately implement their responsibilities.

- *Local Rules*. All practices should have a written set of Local Rules relating to radiation protection measures within that practice and applying to all employees. Information should include:
  - the name of the RPS
  - identification and description of the controlled area
  - summary of working instructions including the names of staff qualified to use the X-ray equipment and details of their training as well as instructions on the use of equipment
  - contingency arrangement in the event of equipment malfunction and /or accidental exposure to radiation.
  - name of the person with legal responsibility of compliance with the regulations.
  - details and results of dose-investigation levels (Note: A dose constraint of no higher than 1mSv per year is recommended as generally appropriate for practice staff from dental radiography)
  - name and contact details of the RPA
  - arrangements for pregnant staff
  - reminder to employees of their legal responsibilities under IRR99.

- *Classified persons*. Division of staff into classified and non-classified workers and the dose limits that apply to each group are discussed later. In dental practice, most staff are non-classified unless their radiography workload is very high.

- *Duties of manufacturers*. The installer is responsible for the critical examination and report of all new or significantly modified X-ray equipment, which should include:
  - a clear and unambiguous description of the equipment and its locations.

- an evaluation of the acceptability of the equipment's warning signals.
- an evaluation of the acceptability of the exposure control
- confirmation that the equipment's safety features are in place and operating correctly (e.g. beam dimensions and alignment, beam filtration and timer operation)
- an overall conclusion as to whether or not the equipment's safety features are operating correctly, the installation is providing sufficient protection for persons from exposure to X-rays and whether the user has been provided with 'adequate information about proper use, testing and maintenance of equipment'.

- *X-ray equipment*. All equipment must be critically examined and acceptable tested before being put into clinical use and then routinely tested as part of a QA programme. The acceptance test, in addition to the features covered in the critical examination outlined above, should include:
  - measurements to determine whether the equipment is operating within agreed performance parameters (e.g. operating potential (kV), X-ray output (mA) and timer accuracy (s)
  - an assessment of the typical patient dose for comparison with national Diagnostic Reference Levels (DRLs)
  - a review and record of film, film/screen combinations and processing details and an evaluation of the adequacy of processing
  - a review and record of digital imaging systems.

A permanent record should be made of the results and conclusions of all tests and this should be retained as part of the QA programme and all deficiencies should be rectified.

All equipment (X-ray generating and image receptors) should comply with the general requirements in the regulations namely:

***Intraoral radiography**

- Tube voltage should not be lower than 50kV. New equipment should operate within the range 60-70kV.
- All equipment should operate within 10% of the stated or selected kV setting.
- Beam diameter should not exceed 60mm at the patient end of the spacer cone or beam indicating device.
- Rectangular collimation should be provided on new equipment and fitted to existing equipment at the earliest opportunity and the beam size should not exceed 40 by 50mm.
- Total beam filtration (inherent and added) should be 1.5mm of aluminium for sets operating below 70kV and 2.5mm of aluminium for sets operating above 70kV and should be marked on the tube housing.
- The focal spot position should be marked on the outer casing of the tubehead.
- Focal spots to skin distance (fsd) should be at least 100mm for sets operating below 60kV and 200mm for sets operating above 60kV
- Film speed controls and finely adjustable exposure time settings

should be provided. The fastest film available (E or F speed) that will produce satisfactory diagnostic images should be used.

Panoramic radiography

- Equipment should have a range of tube potential settings, preferably from 60 to 90kV.
- The beam height at the receiving slit of cassette holder should not be greater than the film in use (normally 125mm or 150mm). The width of the beam should not be greater than 5mm.
- Equipment should be provided with adequate patient-positioning aids incorporating light beam markers.
- New equipment should provide facilities for field-limitation techniques.

Cephalometric radiography

- Equipment must be able to ensure the precise alignment of X-ray beam, cassette and patient.
- The beam should be collimated to include only the diagnostically relevant area.
- To facilitate the imaging of the soft tissues, an aluminium wedge filter should be provided at the X-ray tubehead, in preference to one at the cassette.

All equipment:

- Should have a light on the control panel to show that the mains supply is switched on.
- Should be fitted with a light that gives a clear and visible indication to the operator that an exposure is taking place and audible warnings should also provide the operator with the same information.
- Exposure switches (timers) should only function while continuous pressure is maintained on the switch and terminate if pressure is released.
- Exposure switches (timers) should be positioned so that the operator can remain outside the controlled area and at least 2 m from the X-ray tubehead and patient.
- Exposure times should be terminated automatically.

- *Duties of employees*. Notwithstanding the many and varied responsibilities placed on the person legally responsible, the so-called legal person, IRR99 places over-riding responsibilities on employees which include:
  - to not knowingly expose themselves or any other person to X-rays to an extent greater than is reasonably necessary for the purposes of their work
  - to exercise reasonable care when working on any aspect of dental radiology
  - to immediately report to the legal person whenever they have reasonable cause to believe that an incident or accident has occurred with the X-ray equipment and that they or some other person have received an overexposure.

Essential legal requirements of IR(ME)R 2000

- *Duties of employers*. The employer (legal person) is the person or body corporate with natural or legal responsibility for a radiological installation. He/she is responsible for providing the overall safety of the practice and for ensuring that staff and procedures conform with the regulations. In addition, the legal person must provide a framework of *written procedures* for medical exposures which should include information on:
    - procedures for correctly identifying patients before radiography
    - identification of referrers, practitioners and operators
    - authorization and justification of all clinical exposures to ensure that the justification process has taken place
    - justification of medico-legal exposures
    - identification of pregnant patients
    - compliance with and details of QA programmes
    - assessment of patient dose
    - use of diagnostic reference levels (DRLs) –defined as 'dose levels in medical radiodiagnostic practices for typical examinations for group of standard-sized patients or standard phantoms for broadly defined types of equipment'. As such, they should not normally be exceeded without good reason. In 2012, the HPA recommended DRLs of 1.7mGy for an adult mandibular molar periapical radiograph and 93mGy cm^2 for an adult panoramic radiograph
    - carrying out and recording a clinical evaluation of the outcome of each exposure
    - ensuring that the probability and magnitude of accidental or unintended doses to patients are reduced as low as reasonably practicable
    - provision for carrying out clinical audits
    - guidelines for referral criteria for radiographic examinations
    - written protocols (guideline exposure settings) for every type of standard projection for each item of equipment
    - procedures to follow if a patient is suspected of having received an excessive exposure as a result of any occurrence other than equipment malfunction.

It is recommended that these employers' *written proced*ures and the *Local Rules* (see earlier) are kept together as a *Radiation Protection File* and that all staff are made aware of the contents.

- *Duties of the IR(ME)R Referrer, Practitioner and Operator.*

The IR(ME)R referrer: a registered doctor or dentist or other health professional entitled to refer a patient to a *practitioner* for a medical exposure. The *referrer* is responsible for supplying the *practitioner* with sufficient information to justify an appropriate exposure.

The IR(ME)R practitioner: a registered doctor or dentist or other health professional entitled to take responsibility for a medical exposure. The *practitioner* must be adequately trained (see later) to take decisions and the responsibility for the justification of every exposure.

The IR(ME)R operator: the person conducting any practical aspect of a medical exposure. *The operator* must be adequately trained (see later) for his/her role in the exposure. Practical aspects include:

- patient identification
- positioning the image receptor, patient or X-ray tubehead
- setting the exposure parameters
- pressing the exposure switch to initiate the exposure
- processing films or reading phosphor plates
- clinical evaluation (reporting) of radiographs
- exposing test objects as part of the QA programme.

- *Justification of individual medical exposures.* Before an exposure can take place, it must be justified (i.e. assessed to ensure that it will lead to a change in the patient's management and prognosis) by an *IR(ME)R practitioner* and authorized as the means of demonstrating that it has been justified. Every exposure should be justified on the grounds of:
  - the availability and/or findings of previous radiographs
  - the specific objectives of the exposure in relation to the history and examination of the patient
  - the total potential diagnostic benefit to the patient
  - the radiation risk associated with the radiographic examination
  - the efficacy, benefits and risks of alternative techniques having the same objective but involving no or less exposure to ionizing radiation.

Note: The 2013 *Selection Criteria in Dental Radiography* states that there can be no possible justification for routine radiography of 'new' patients prior to clinical examination. A history and clinical examination are the only acceptable means of determining that the most appropriate, or necessary radiographic views are requested.

- *Optimization*. All doses must be kept as low as reasonably practicable (ALARP) consistent with the intended purpose. This includes the need to apply QA procedures to the optimization of patient dose.

- *Clinical audit.* Provisions must be made for clinical audit. Suitable topics could include the various aspects of the QA programme, the appropriateness of radiographic requests and the clinical evaluation of radiographs.

- *Expert Advice.* The regulations lay down the need for, and involvement of a Medical Physics Expert (MPE) who would give advice on such matters as the measurement and optimization of patient dose. However, the need for the medical physics support in dental practice is fairly limited and in most cases the RPA should be able to act as the MPE.

- *Equipment.* The keeping and maintenance of an up-to-date inventory of each item of equipment is required and should include:
  - name of manufacturer
  - model number
  - serial number or other unique identifier
  - year of manufacture
  - year of installation.

- *Adequate training of IR(ME)R operators* and *practitioners.* Both groups must have received *adequate training*, the nature of which is specified in the 2001 Guidance Notes as:

  - ***Adequate training for UK graduated IR(ME)R practitioners:***

  An undergraduate degree conforming to the requirements of the undergraduate curriculum in dental radiology and imaging as specified by the General Dental Council and including the latest core curriculum in dental radiography and radiology published by the British Society of Dental and Maxillofacial Radiology.

  - ***Adequate training for IR(ME)R operators involved in selecting exposure settings and/or positioning the patient, image receptor or X-ray tubehead:***

  - *Dentists – practitioner* training (as above)

  - *Dental Nurses* – should possess a recognised post qualification Certificate in Dental Radiography awarded by a reputable body such as the National Examining Board for Dental Nurses (NEBDN) or the British Dental Association (BDA).

  - *Dental hygienists and therapists* – should have received an equivalent level of training to that for dental nurses.

  - ***Adequate training for other IR(ME)R operators not directly involved with X-raying patients:***

  Dental nurses and other such *operators* should preferably possess the Certificate in Dental Nursing or they must have received adequate and documented training specific to the tasks that they undertake. Dental nurses (or other staff), who simply 'press the exposure button' after the patient has been prepared by another adequately trained *operator*, may only do so in the continued presence and under the direct supervision of the operator.

- *Continuing education and training of IR(ME)R operators* and *practitioners.* In addition to *adequate training* both groups must undertake *continuing education and training* after qualification in all aspects of dental radiology as part of *practitioners'* and *operators'* life-long learning. In 2006 the General Dental Council (GDC) recommended *Radiography and Radiation Protection* as one of their core subjects of Continuing Professional Development (CPD) for dentists and this recommendation was extended to all Dental Care Professionals (DCPs) in 2008. To this end, it is recommended that *IR(ME)R practitioners* and *operators* attend a formal course (equivalent to 5 hours of verifiable continuing education) every 5 years covering all aspects of radiation protection. The content of the courses are specified in the 2001 Guidance Notes:

  - ***Continuing education courses for practitioners*** should include:

    - principles of radiation physics
    - risks of ionizing radiation
    - radiation doses in dental radiography factors affecting doses in dental radiography
    - principles of radiation protection
    - statutory requirements
    - selection criteria
    - quality assurance.

- Continuing education for courses operators involved in X-raying patients should include:

- principles of radiation physics
- risks of ionizing radiation
- radiation doses in dental radiography factors affecting doses in dental radiography
- principles of radiation protection
- statutory requirements
- quality assurance.