

SUMMARY AND EXTRACTS FROM THE 2010 GUIDANCE ON THE SAFE USE OF DENTAL CONE BEAM CT (COMPUTED TOMOGRAPHY) EQUIPMENT

The use of dental CBCT equipment must comply with all the regulations (IRR99 and IR(ME)R2000) outlined in the 2001 Guidance Notes for conventional dental X-ray equipment [see *Summary of Current UK Legislation and Guidelines*, neighbouring Tab]. However, additional radiation safety requirements apply to the use of these more complex machines as they deliver higher doses of radiation to patients and result in higher levels of scattered radiation. The 2010 CBCT guidance addresses two main issues:

- Radiation protection
- Equipment standards and testing

Essential requirements of IRR99 for Dental CBCT

- *Notification.* The Health and Safety Executive (HSE) must be notified when it is intended to use ionising radiation for the first time, or a ‘material change’ is going to be made to an existing use. Provided the HSE have already been informed of the use of conventional X-ray equipment in a dental practice/clinic, the addition of dental CBCT does not constitute a ‘material change’ and further notification is not required. If dental CBCT is installed in a new practice/clinic, the HSE must be informed.
- *Radiation Protection Adviser (RPA).* A suitably trained RPA must be consulted with and appropriate advice obtained, particularly on the following matters:
 - CBCT equipment selection
 - prior assessment of installation plans
 - review of risk assessment, local rules and contingency plans
 - designation of areas and subsequent requirements
 - personal dosimetry
 - QA programme, including adequate testing and routine testing
 - periodic testing of engineering controls, design features, safety and warning devices etc
- *Equipment selection.* As with other types of X-ray equipment, dental CBCT equipment should be capable of providing images of adequate diagnostic quality while restricting patient exposures as far as reasonably practicable (ALARP). The equipment should be provided with the following features:
 - safety and warning features including:
 - two-stage automatic warning lights outside the room entrance(s) to indicate when the unit is switched ON and when X-rays are being generated
 - the operator should not normally need to enter the room to initiate exposures or to disconnect the equipment from the power supply in the event of an incident

- a suitable emergency off/stop switch or mains isolator should be provided within easy reach of the operator if the exposure is initiated from a computer keyboard
 - equipment kept in a password protected, locked state when not in use to ensure it cannot be operated by unauthorised personnel.
 - imaging software that allows the manipulation and clinical evaluation of patient images
 - approved display screen (monitor) equipment conforming to the minimum requirements specified by the Royal College of Radiologists for CT and CBCT equipment
 - quality assurance software and test objects to allow monthly in-house checks
 - CE marking in accordance with the European Medical Devices Directive
- *Design of facilities.* Dental CBCT equipment should be installed in a dedicated room used solely for radiography. Particular attention to be paid to:
 - the position and construction of the walls, windows, floor and ceiling
 - and the use and occupancy of the surrounding areas
 - the maximum weekly workload and the need for shielding of the room
 - positioning of the operator and controls (normally they should be outside the room because of the generally higher levels of scattered radiation from CBCT machines but the operator should be able to observe the patient throughout the exposure)
 - the need for warning lights outside the room (see above)
 - provision of a lead apron (at least 0.25mm lead equivalent) for any individual who remains within the room to provide assistance/reassurance to a patient.
- *Critical examination.* The installer should, in consultation with the RPA determine the scope and conduct of the critical examination but should ensure all radiation safety aspects of the equipment are covered and tested, including the radiation safety of the patient. It is recommended that the following are included:
 - equipment warning lights indicating 'mains on' and 'X-rays'
 - equipment audible warning of X-ray emission
 - warning lights and signs outside all entrances to the room
 - presence and operation of mains isolation switches and/or emergency stops
 - adequacy of the exposure control, including security against unauthorized use
 - adequacy of the shielding provided for the operator and other persons, including suitable measurements of radiation levels in adjacent areas
 - adequacy of the general layout of the room with respect to radiation protection
 - patient safety features such as filtration and tubehead leakage.

- *Prior risk assessment.* The legal person should, in consultation with the RPA, ensure that a suitable and sufficient risk assessment is carried out. The aims of the risk assessment are to:
 - evaluate the nature and magnitude of risks to employees and other persons during both accident situations and routine work
 - identify the means necessary to ensure that doses to employees and others are restricted
 - identify all hazards with the potential to cause a radiation accident
 - prevent any such accidents
 - limit the consequences of any accidents that do occur.

- *Personal protective equipment (PPE).* Lead aprons should not be necessary for employees who stand outside the room or behind protective lead shields/screens during an exposure as annual effective doses should not exceed 1mSv. Lead aprons are required for other persons inside the *controlled area* (see below) supporting or reassuring patients.

- *Designation of controlled areas.* For dental CBCT equipment the designation of the *controlled area* is more important and relevant than for conventional dental X-ray equipment. It is recommended that the *controlled area*:
 - includes the entire CBCT room because of the high levels of scattered radiation within the room during exposures
 - applies during installation, maintenance, testing and routine clinical use
 - exists whenever the equipment is switched on and the exposure controls enabled (as CBCT equipment needs to be left switched on, the controlled area exists throughout the working day)
 - access is restricted and staff aware of the meaning of the warning lights and notices at the room entrance(s).

- *Classified persons and personal dosimetry.* As with conventional dental X-ray equipment operators of CBCT equipment are usually designated as *non-classified* workers following the risk assessment. As such, personal dosimetry is not mandatory but it is recommended, at least for a minimal trial period, to ensure that the radiation safety precautions in place are effective. No special protection measures are usually necessary for pregnant employees.

- *Dose investigation level.* As with conventional dental X-ray equipment, 1mSv per annum is regarded as an appropriate dose investigation level for CBCT equipment.

- *Local Rules.* As with conventional dental radiography Local Rules are required and need to reflect the different and specific requirement of CBCT and must include:
 - the description and extent of the *controlled area* and the exact conditions under which it exists
 - the means of restricting access to the *controlled area*
 - the name of the RPS

- the means of preventing operation of the equipment by unauthorised persons
 - the 'key working instructions' setting out the safety precautions that staff must follow
 - written arrangements governing access to the *controlled area* especially for persons supporting or reassuring patients during an exposure
 - the dose investigation level (1mSv)
 - arrangements for personal dosimetry
 - contingency arrangements to be followed in the event of accidents including:
 - switching off CBCT power supply
 - not approaching the tubehead
 - informing the RPS
 - prohibiting further use pending investigation.
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- *Monitoring of designated areas.* Levels of ionizing radiation are required to be adequately monitored to ensure that any *controlled* and *supervised areas* remain correctly designated over time. Appropriate measurements should be agreed with the installer and RPA and made at installation and checked during the annual routine tests and at least once every three years.

 - *QA programme for equipment.* IRR99 require a QA programme to be established, in consultation with the RPA, to ensure the equipment remains capable of the adequate restriction of patient dose and must include:
 - adequate testing before first clinical use (commonly known as *acceptance testing*) to establish baseline values for image noise, image density, image uniformity, spatial resolution, reconstructed image measurement, radiation output, radiation field size X-ray tubehead leakage, beam filtration and dose measurements for comparative purposes during later testing
 - routine retesting (including monthly in-house QA checks) at appropriate intervals (yearly) and following any major maintenance
 - representative measurements of *achievable patient dose* which is currently defined as the dose-area product (DAP) for the clinical protocol that would normally be used for imaging the upper first molar region prior to implant placement in a standard male patient ie 250 mGy cm^2
 - remedial and suspension levels for action, typically set at 20% more than the established local diagnostic reference level
 - preventative maintenance and inspections in accordance with the manufacturer's instructions including in-house checks on:
 - equipment warning lights indicating 'mains on' and X-rays'
 - equipment audible warning of 'X-rays'
 - warning lights and signs outside all entrances
 - emergency stops and/or mains switches

- adequacy of the exposure control, including security against unauthorised use.
- *Information, instruction and training.* This must be provided for all staff involved with dental CBCT particularly in relation to CBCT *Local Rules* and the importance of the CBCT *controlled area*, warning lights and signs. The *Radiation Protection Supervisor (RPS)* must be aware of the differences in the magnitude of the hazard presented by dental CBCT equipment, compared to conventional dental X-ray equipment and may require formal training in radiation safety. Manufacturers and suppliers have a duty to pass on adequate information to the user of CBCT equipment in respect of its proper use, testing and maintenance.
- *Patient doses much greater than intended.* Patient doses that would need to be notified to the Health and Safety Executive (HSE) as ‘much greater than intended’ as a result of equipment failure are those that are 10 times greater than intended. (for conventional dental imaging the figure is 20 times greater than intended).

Essential requirements of IR(ME)R 2000 for Dental CBCT – Administrative aspects

- *Duties of employer (legal person).* The legal person must ensure that suitable persons are identified and entitled to act in their roles of responsibility, including persons at other dental practices, if appropriate, including:
 - IR(ME)R *referrer(s)* (including persons at other practices if appropriate)
 - IR(ME)R *practitioner(s)*
 - IR(ME)R *operator(s)* involved in taking the CBCT scans and X-raying patients
 - Other IR(ME)R *operator(s)* in other practical aspects including the reporting of the CBCT images (including persons at other practices).

Unlike conventional dental X-ray equipment which may be installed in every dental surgery, CBCT equipment is likely to have several dentists within one practice making use of the same piece of equipment, with a limited number of staff trained and competent to use the equipment. In addition, it is likely that referrals will be accepted from other dental practices. As such, robust management systems need to be in place to ensure that the CBCT equipment is used correctly, without incident and in line with the IR(ME)R requirements. As with conventional dental X-ray equipment the *legal person* must provide a framework of *written procedures* specific for CBCT exposures which should include information on:

- procedures for correctly identifying patients before radiography
- identification and training of *referrers, practitioners* and *operators* (as above)
- referral criteria
- 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 ensuring all doses are kept as low as reasonably achievable
 - use of diagnostic reference levels (DRLs)
 - clinical audit
- *CBCT referrals.* Referrals to a dental practice where CBCT equipment has been installed (the *CBCT practice*) should only be accepted from IR(ME)R *referrers* entitled to refer and who have provided the following information in their referral:
 - patient unique identifier information
 - the clinical context for requesting the dental CBCT examination
 - the question which the referrer would like the dental CBCT examination to answer
 - a clear indication of the area(s) for which dental imaging is requested.
 - *Referral criteria.* IR(ME)R2000 requires *referrers* have access to suitable referral criteria to provide guidance on when it is appropriate to refer patients for CBCT examinations. Appropriate guidance is provided in the 2011 SEDENTEXCT publication *Radiation protection: Cone Beam CT for dental and maxillofacial radiology. Evidence based guidelines*, available from http://www.sedentexct.eu/files/guidelines_final.pdf and in the 2013 *Selection Criteria in Dental Radiography* 3rd edn available from the Faculty of Dental Practice (UK). In addition, all CBCT *referrers* and *practitioners* should be aware of the following seven basic principles relevant to the referral/justification of dental CBCT published in 2009 by the European Academy of Dental and Maxillofacial Radiology (EADMFR):
 1. Dental CBCT examinations must not be carried out unless a history and clinical examination have been performed and should not be performed 'routinely'
 2. Dental CBCT examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.
 3. Dental CBCT examinations should potentially add new information to aid the patient's management.
 4. Dental CBCT should not be repeated 'routinely' on a patient without a new risk/benefit assessment having been performed.
 5. When accepting referrals from other dentists for CBCT examinations, the referring dentist must supply sufficient clinical examination (results of a history and examination to allow the CBCT IR(ME)R *practitioner* to perform the *justification* process (see below).
 6. Dental CBCT should only be used when the question for which imaging is required cannot be answered adequately by lower dose conventional dental radiography.
 7. Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the appropriate imaging should be conventional medical CT or MR, rather than dental CBCT.

- *Justification of individual CBCT exposures.* Before any exposure (conventional or CBCT) 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 CBCT 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.
- *Documentation of CBCT exposures.* The typical information that should be recorded for each CBCT examination includes:
 - name of the patient
 - date of the examination
 - name of the *IR(ME)R referrer*
 - name of the *IR(ME)R practitioner*
 - name of the *IR(ME)R operator*
 - clinical reason for the examination
 - scanning exposure parameters and region of interest (to allow an estimate of patient dose)
 - QA rating of scan (acceptable or unacceptable)
 - cause of any errors
 - number of repeat scans.
- *Clinical evaluation of CBCT scans.* All CBCT images must be clinically evaluated and a written record (radiographic report) kept. Images must be viewed on an appropriate monitor using suitable software. Regions outside the specific area of interest that appear on the image must also be evaluated. This evaluation may require the services of a dental and maxillofacial radiologist or a clinical radiologist (particularly with large *field of view* (FOV) CBCT scans). CBCT exposures should not be authorized if it is not clear to the *IR(ME)R practitioner* **who** is to evaluate the image. A *written procedure* detailing the arrangements for the clinical evaluation of CBCT scans must be put in place by the *legal person* responsible for the CBCT equipment.
- *Adequate training and continuing education.* Under *IR(ME)R operators* and *practitioners* must have received adequate training and must undertake continuing education. The introduction of a new technique such as dental CBCT requires additional training and up to date records of appropriate training must be maintained by the *legal person*. In conjunction with the British Society for Dental and Maxillofacial Radiology (BSDMFR), the Health Protection Agency (HPA) have produced the following additional training requirements for the *referrer*, the *practitioner* and the *operator* that relate to CBCT examinations of the dento-alveolar region:

Theoretical training:

1. Radiation protection and radiological principles relevant to CBCT including:

- radiation physics in relation to CBCT equipment
- radiation protection in relation to CBCT examinations
- apparatus and equipment (including how exposure settings affect CBCT image quality)
- CBCT image acquisition and processing
- principles of CBCT imaging

2. Radiological interpretation in the dento-alveolar region including:

- principles and practice of interpretation of dento-alveolar 3D CBCT images
- CBCT anatomy of the teeth and jaws
- dental and maxillofacial pathology.

Practical instruction: An applications specialist from the CBCT manufacturer may best deliver this aspect of training and includes:

- practical techniques in acquiring, manipulating and storing the images
- quality assurance
- care of patients such as children, special care patients as well as infection control.

Essential requirements of IR(ME)R 2000 for Dental CBCT – Practical aspects

- **Optimization of patient dose – operation of CBCT equipment.** All CBCT scans need to be optimized i.e. doses kept as low as reasonably practicable (ALARP) whilst still ensuring that the images are of diagnostic quality. Basic requirements include:
 - the legal person must ensure *written protocols* are in place for all standard CBCT examinations which should include details of patient positioning as well as exposure parameters and volume size
 - patients should be accurately positioned using the light beam markers to ensure the region of interest is captured and their head immobilised using the chin cups and head straps
 - manufacturer's recommended exposure settings should be used and the following features adjusted:
 - Volume size (field of view (FOV)) - the smallest volume size needed to answer the clinical question should be used (using a smaller volume also reduces scatter and potentially improves image quality).
 - Exposure factors (kV, mAs) and voxel size - optimal exposure factors should be selected to satisfy the diagnostic requirements of the examination. Higher exposure factors may be chosen if a higher spatial resolution is required. The size of the reconstruction voxel can often be selected by the operator. If choosing a larger voxel size results in a reduced patient dose (due to lower exposure factors being used) then this should be considered as long as the lower resolution is compatible with the aims of the radiographic examination.

- Angle of rotation - some machines offer a 'quick scan' where the rotation arc is reduced. This feature reduces the number of projections taken and therefore reduces the dose. If the required diagnostic information can be obtained using this scan protocol then it should be selected.
 - images must be reconstructed using suitable software
 - images must be viewed on suitable display screens (monitors) under suitable conditions.

There is no need for the routine use of a protective lead apron or the routine use of a protective thyroid collar as the thyroid gland does not normally lie in the primary beam, however its use should be considered on a case by case basis.

- *Patient dose audit.* As with conventional dental imaging all CBCT exposures should be compared to *national diagnostic reference levels* (NDRLs), however these are not yet available. It is therefore recommended that base-line *local diagnostic reference levels* (LDRLs) are established along with representative measurements of *achievable patient dose* (see earlier) and reassessed every three years.
- *Image quality.* It is recommended that a two-point quality rating system is used for CBCT with images being either *diagnostically acceptable* or *diagnostically unacceptable*. As the radiation dose from CBCT investigations is generally higher than conventional dental radiography, and the digital capture of images is more reliable than using conventional film, the performance *targets* are set at *acceptable* – not less than 95% and *unacceptable* – not greater than 5%. Image quality should be monitored at regular intervals and may be carried out either prospectively (as the images are being produced) or retrospectively (as an audit) and an analysis of rejected images undertaken. Typical errors can include those related to:
 - patient preparation e.g. radiographic stent incorrectly positioned
 - inappropriate exposure factors
 - positioning e.g. inadequate immobilisation or incorrect patient positioning within the machine
 - inappropriate image reconstruction.