Regulations relating to Cone Beam CT use in Northern Ireland

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Learning Objectives

- to be aware of legislation applicable to the use of cone beam CT (CBCT) in Northern Ireland
  - Ionising Radiation Regulations (Northern Ireland) 2017
  - Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018
- to be aware of sources of guidance in adhering to relevant radiation legislation

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STATUTORY RULES OF NORTHERN IRELAND

2017 No. 229

HEALTH AND SAFETY

The Ionising Radiations Regulations (Northern Ireland) 2017

Made - - - - 5th December 2017
Coming into operation 1st January 2018

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Ionising Radiation Regulations (Northern Ireland) 2017 (IRR(NI)17)

- enforced by **Health & Safety Executive Northern Ireland (HSENI)**

applies to:

- **staff** who carry out ionising medical exposures
- other persons, such as members of the **public**, who may be incidentally exposed

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Application to HSENI for work with Ionising Radiation

- every employer is required to inform HSENI of work that they carry out with ionising radiation or in an atmosphere containing radon above a certain level
- authorised employee familiar with work carried out by employer should submit this information (typically radiation protection supervisor (RPS) or radiation protection advisor (RPA))
- done using RADAN online platform on hse.gov.uk website

Overview - Notification, registration or consent for work with ionising radiation | Health and Safety Executive for Northern Ireland, controlling risk together

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Applications to HSENI

three tiers:

- notification
- registration
- consent

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Notification

- need to notify HSENI if you work in an atmosphere containing radon above an annual concentration of 300 Bq m^{-3}
- most common reason for employers being required to notify HSENI
- radon - naturally occurring radioactive gas that seeps into building from ground with long term exposure estimated 1,000 radon linked lung cancer deaths in the UK annually

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Welcome to UKradon

Three steps to manage radon in buildings - check, measure, act

Every building has radon and in most areas the levels are low. Some buildings in "radon Affected Areas" have higher levels. Buildings in these areas should be tested for radon. High levels can be reduced by simple building works. There are three simple steps you can follow:





1. Check
Is your property in a radon Affected Area?
Find out more

2. Measure
If you are in a radon Affected Area you should order a radon measurement pack for your home or workplace
Find out more

3. Act
If the radon level is high you should reduce it using simple building works
Find out more

ukradon.org

UKradon - Home

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Registration

- required for any medium-risk work with ionising radiation including **work with a radiation generator (i.e. x-ray tube)**
- **currently no fees** associated with registration for work within Northern Ireland (£25 - £27 in England, Scotland and Wales) – "however, please be aware that this position will remain under review and may change in the future" *HSENI*
- must inform HSENI if **"material change"** e.g. name or address of practice changes, increase in number of radiation generators or type/maximum output energies of X-ray devices being used

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Consent

- relates high-risk work with ionising radiation e.g. radioactive material / industrial radiography
- not relevant to dental radiography

If you are a dentist or dental practice using X-rays you require REGISTRATION for radiation generators, NOT consent.

Notify, registration or consent for work with ionising radiation: How to notify or apply - HSE

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Radiation Protection Advisor (RPA)

- individual or body competent to advise on radiation protection in relation to occupational and public exposures with specific knowledge and adequate experience of radiation protection in field of dental diagnostic radiology
- must be appointed in writing and in an ongoing basis by employer with appointment specifying scope of advice RPA will be expected to provide
- must be registered and demonstrate compliance with HSE's current criteria of core competence

https://www.rpa2000.org.uk

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Prior Assessment of Installation Plans

consult RPA about layout and construction of new dental radiography facilities

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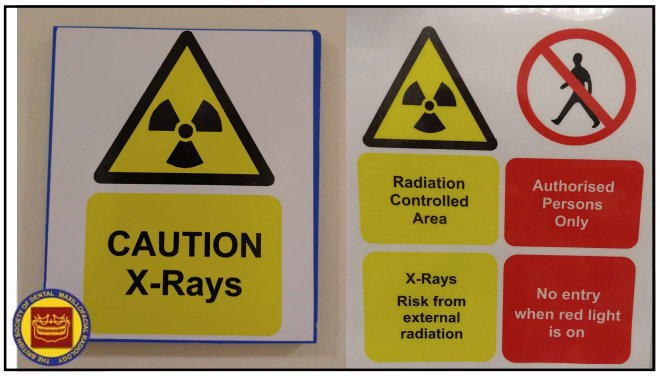
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Critical Examination

- **responsibility of installer**
- ensure safety features and warning devices operate correctly - adequate protection for employees and other persons from exposure to ionising radiation
- provide employer with adequate information about proper use, testing and maintenance

- carried out as soon as possible after installation - **equipment not to be used until performed** and any deficiencies identified in report discussed with RPA regarding remedial measures to be taken before equipment enters clinical use

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Radiation Risk Assessment

- must be carried out in consultation with RPA before any **new activity e.g. CBCT** involving ionising radiation commences

aims to:

- evaluate nature and level of risks to employees and other persons (other than patients), during both reasonably foreseeable accident situations & routine work
- identify means necessary to ensure that doses to employees and other people are restricted, so far as reasonably practicable

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Local Rules

essential contents:

- summary of contingency plans e.g. what to do if:
  - failure of timer to terminate exposure
  - failure of rotation of dental CBCT equipment during exposure
  - loss of shielding or damage to x-ray tube

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Local Rules

essential contents:

- summary of contingency plans
- name of appointed Radiation Protection Supervisor (RPS)

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Radiation Protection Supervisor (RPS)

- employer must appoint one or more suitable persons as RPS whenever controlled area designated
- role – supervise daily work with ionising radiation ensuring employees adhere to local rules

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(typically team manager or superintendent radiographer)

← Suitably scary person

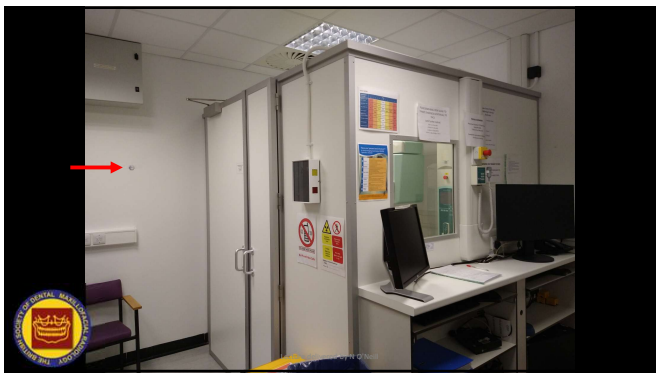
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Local Rules

essential contents:

- contingency plan
- RPS
- identification & description of controlled area(s) – typically "whole room" for cone beam CT
- dose monitoring

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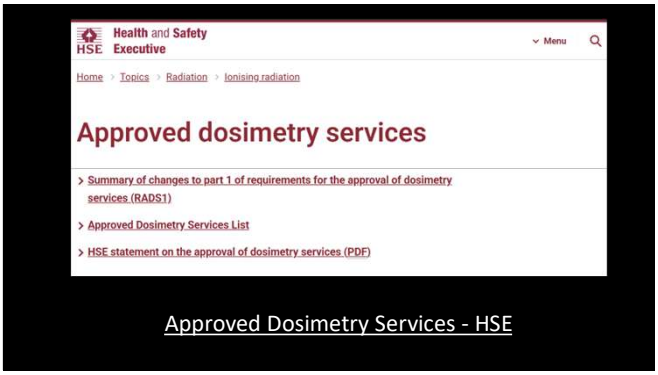


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initial period of personal monitoring for six months following installation of new equipment and then discuss with RPA if ongoing monitoring indicated

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Approved Dosimetry Services - HSE

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Maintenance and Examination of Engineering Controls

- part of quality assurance programme (every six months)
- covers recommendations of manufacturer

examples include:

- visual inspection of the X-ray tube (including check for signs of oil leakage)
- smoothness of rotational or scanning motion of dental CBCT equipment
- operation of equipment warning lights and sounds
- operation of mains on/off switches and/or emergency stops
- adequacy of exposure control, including security against unauthorised use
- condition of cabling and connections including power leads and plugs

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Dentomaxillofacial Radiology (2014) 43, 20130291
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http://dmfr.birjournals.org

SHORT COMMUNICATION

Basic training requirements for the use of dental CBCT by dentists: a position paper prepared by the European Academy of DentoMaxilloFacial Radiology

J Brown[1], R Jacobs[2], E Levring Jäghagen[3], C Lindh[4], G Baksi[5], D Schulze[6] and R Schulze[7]

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Level 1 (Core) Training in Dental Cone Beam CT

- intended for dentists, dental nurses with the NEDBN Certificate in Dental Radiography (CDR), dental hygienists & therapists who are already adequately trained to take conventional radiographs
- limited to cone beam CT imaging of the dento-alveolar region
- period of 12 hours recommended (part of which can be provided by up to five hours of verifiable CPD in radiography and radiation protection)

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Level 2 / Further Training for Operators **Performing** Cone Beam CT Imaging

- intended for dentists, dental nurses with the NEBDN Certificate in Dental Radiography, dental hygienists & dental therapists who act as operators undertaking dental CBCT examinations
- training covers practical aspects using dental CBCT equipment
- should be **provided by manufacturer / installer** of CBCT equipment as it is specific to each particular unit
- initial period of 6 hours training recommended
- further 6 hours training provided short time after initial period of use of equipment to provide further detailed training on patient positioning, dose & image optimisation, further machine options, answer queries & address any problems

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Level 2 / Further Training in Dental Cone Beam CT **Justification & Image Interpretation**

- further training in interpretation to extend knowledge of dentist undertaking justification & interpretation of CBCT imaging in the dento-alveolar region
- must follow successful completion of Level 1 (core) course
- combination of didactic teaching, hands-on training in use of imaging software & case-based interpretation exercises over initial period of at least 6 hours
- recommended further 6 hours self-study & small group-study

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Refresher Training in Dental CBCT

- employer must take steps to ensure that IRMER practitioners & operators undertake continuing education and training after qualification
- for those involved with dental CBCT suggested minimum of one of recommended five hours of verifiable CPD in radiology and radiation protection should be specific to dental CBCT

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Training Requirements within IRR(NI)17 - Staff **not** Directly Involved in Radiography

non-clinical staff such as receptionists & cleaners should be provided with information sufficient to enable them to work safely within their role

should include:

- awareness X-rays are used – benefits, risks & need to avoid any personal exposure
- significance of any room warning notices, lights & restrictions
- name & contact details of RPS (in case of emergency)

N.B. training of this nature typically provided in-house

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Summary – IRR(NI)17 and Cone Beam CT

- register with HSENI (& notify if appropriate)
- appoint registered RPA – help with installation plans, critical examination, risk assessments, local rules, controlled areas, dosimetry…
- appoint RPS to enforce the rules
- ensure employees undergo appropriate training

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STATUTORY RULES OF NORTHERN IRELAND

2018 No. 17

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

Made - - - - *1st February 2018*

Coming into operation *6th February 2018*

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SCHEDULE 3 Regulation 17

Adequate Training

1. Practitioners and operators must have successfully completed training, including theoretical knowledge and practical experience, in—

(a) such of the subjects detailed in Table 1 as are relevant to their functions as practitioner or operator; and

(b) such of the subjects detailed in Table 2 as are relevant to their specific area of practice.

All Modalities	
	Equipment selection and use
Specialised Techniques	Computed Tomography: advanced applications
	Interventional procedures
	Cone Beam Computed Tomography
	Hybrid imaging

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STATUTORY INSTRUMENTS

2024 No. 896

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024

Made *2nd September 2024*

Laid before Parliament *3rd September 2024*

Coming into force *1st October 2024*

Within the UK, responsibility for healthcare is devolved and different approaches may be taken in each of the four nations. The amendments to IR(ME)R 2017 (Great Britain) came into effect in 2024, applicable within England, Wales and Scotland. At the time of publication, the amendments are under review and have not been adopted by Northern Ireland. The amendments reflect good practice and learning from the clinical implementation and enforcement of the Regulations.

Royal College of Radiologists, August 2026

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The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 – IR(ME)R(NI)18

enforced by:

- the **Regulation & Quality Improvement Authority (RQIA)**

applies to:

- **patients** undergoing exposure
- **comforters & carers**

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Employer

- position of legal responsibility under IR(ME)R for providing the framework to ensure safe clinical practice when using ionising radiation (in consultation with medical physics expert)
- typically practice owner, CEO of corporate body, NHS Trusts in community / hospital typically designate accountable representative e.g Chief Executive

main responsibility under IR(ME)R:

- provide 'Employer's Procedures'

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Employer's Procedures

- identification of individuals entitled to act as referrer, IR(ME)R practitioner or operator **within their specified scope of practice**

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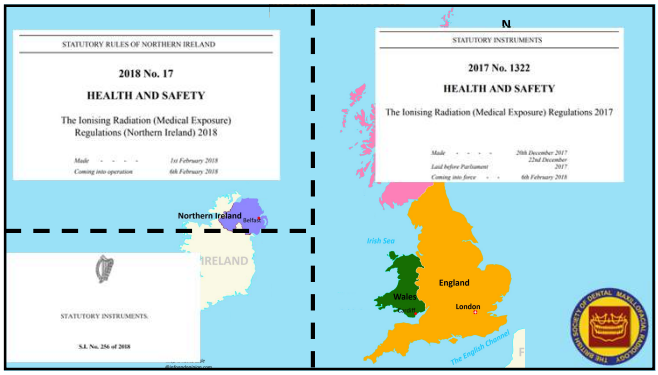
Referrer

- **registered** medical practitioner, dental practitioner or other registered healthcare professional
- entitled to refer individuals to IRMER practitioner for medical (or non-medical e.g. research, medico-legal) exposure

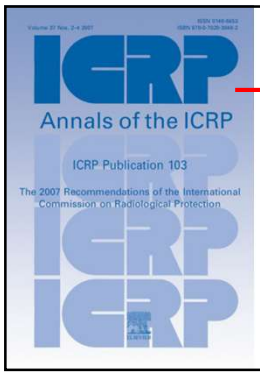
responsibilities under IR(ME)R:

- ensuring sufficient clinical information and context for requesting radiographic examination provided to enable IR(ME)R practitioner to determine whether exposure can be justified

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all member states must comply with Basic Safety Standards Directive & transpose into legislation by 6th February 2018

included UK regardless of outcome of EU membership referendum

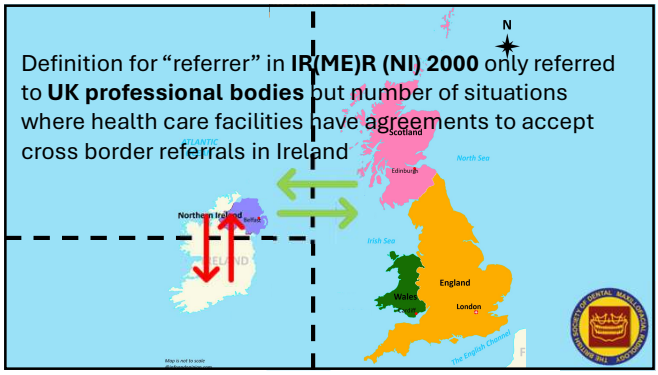
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Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Consultation on the transposition of European Council Directive 2013/59/Euratom (Medical Exposures) in Northern Ireland

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Definition for "referrer" in **IR(ME)R (NI) 2000** only referred to **UK professional bodies** but number of situations where health care facilities have agreements to accept cross border referrals in Ireland



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STATUTORY RULES OF NORTHERN IRELAND

2018 No. 17

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

Made - - - - *1st February 2018*
Coming into operation *6th February 2018*

"referrer" means a registered health care professional, or a medical practitioner registered with the Medical Council of Ireland, who is entitled in accordance with the employer's procedures to refer individuals for exposure to a practitioner;

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STATUTORY INSTRUMENTS.

S.I. No. 256 of 2018

EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO IONISING RADIATION) REGULATIONS 2018

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Referrers

4. (1) A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is—

(*a*) a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,

(*b*) a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),

(*c*) a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007),

(*d*) a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or

(*e*) a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland.

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Number 9 *of* 1985

DENTISTS ACT, 1985

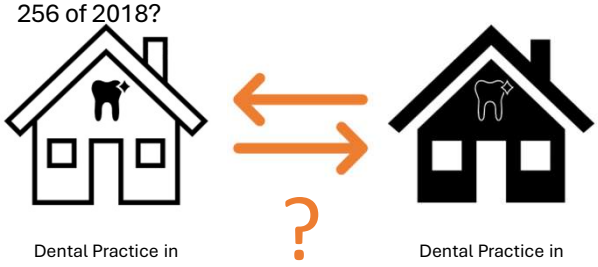
AN ACT TO PROVIDE FOR THE ESTABLISHMENT OF A COUNCIL TO BE KNOWN AS AN CHOMHAIRLE FIACLÓIREACHTA OR IN THE ENGLISH LANGUAGE THE DENTAL COUNCIL WHICH SHALL PROVIDE FOR THE REGISTRATION AND CONTROL OF PERSONS ENGAGED IN THE PRACTICE OF DENTISTRY AND TO PROVIDE FOR OTHER MATTERS RELATING TO THE PRACTICE OF DENTISTRY AND THE PERSONS ENGAGED IN SUCH PRACTICE AND TO PROVIDE FOR THE REPEAL OF THE DENTISTS ACT, 1928 , AND THE DENTISTS (AMENDMENT) ACT, 1983 , AND TO PROVIDE FOR OTHER MATTERS CONNECTED WITH THE MATTERS AFORESAID. [11*th May,* 1985]

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

Lecture delivered by N O'Neill

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Can registered **dental** professionals act as cross border **referrers** under IR(ME)R (NI) 2018 / SI No. 256 of 2018?



Dental Practice in Dundalk

Dental Practice in Belfast

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IR(ME)R Practitioner

- registered healthcare professional entitled to **take responsibility** for an individual medical exposure

responsibilities under IR(ME)R:

- **justification** and authorisation (written record of justification decision) of individual exposures

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Operator(s)

- any person trained and entitled to carry out any part of **practical aspects** associated with radiographic examination

responsibilities under IR(ME)R NI:
- positive identification of patient
- positioning of patient in cone beam CT scanner
- setting exposure parameters
- pressing exposure button
- post processing CBCT scans (e.g. adjusting brightness/contrast)
- **clinical evaluation (interpretation and reporting) of CBCTs**
- exposing test objects as part of CBCT quality assurance (QA)

N.B. there may be multiple persons acting in different aspects of operator role

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Operator(s)

- operators who carry out 'clinical evaluation' **must have appropriate training in interpretation of that particular imaging modality**
- non-clinical staff may undertake certain operator duties (e.g. confirming patient details) but only where they have been appropriately trained

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FGDP Caveats on Scope of Practice

- hygienist and therapists not normally expected to refer, justify or act as operator in a reporting role for CBCT
- suitably qualified dental nurses, hygienists and therapists may, however, be entitled to act as operator in an imaging acquisition role for any form of dental X-ray equipment including CBCT, subject to them having appropriate theoretical & practical training
- no UK undergraduate dental courses currently provide adequate training in CBCT therefore additional training required to act as referrer, IR(ME)R practitioner or operator (including reporting) for this particular imaging modality

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Medical Physics Expert (MPE)

- individual or group having knowledge, training and experience to act or give advice on matters relating to physics applied to exposures
- **definition of operator includes MPE** therefore their scope of practice should be defined in employer's procedures e.g. exposure of test objects during QA

IR(ME)R responsibilities:
- providing employer with advice on compliance with IR(ME)R NI

N.B. functions of Medical Physics Expert (MPE) role differ to that of Radiation Protection Adviser (RPA) therefore may be different person/organisation

RPA 2000 – Certifying Competence for Radiation Protection Professionals

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Employer's Procedures

- identification of individuals entitled to act as referrer, IR(ME)R practitioner or operator
- identification of individuals to be exposed

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Positive Patient Identification

- name
- 1st line of address
- date of birth
- *area* / tooth to be imaged and why



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Employer's Procedures

- identification of individuals entitled to act as referrer, IR(ME)R practitioner or operator
- identification of individuals to be exposed
- pregnancy inquiry

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Pregnancy Inquiry

- not typically relevant in dental radiography given path of primary x-ray beam not involving pelvic region and relatively low ionising radiation dose associated with dental radiography including dental CBCT
- if pregnant patient remains concerned about potential risks, then may consider delaying imaging if appropriate and in best interests of patient with this **decision documented in patient's dental record**



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Employer's Procedures

- identification of individuals entitled to act as referrer, IR(ME)R practitioner or operator
- identification of individuals to be exposed
- pregnancy inquiry
- information on benefits and risks of exposure

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Information on Benefits vs Risks of Exposure

- patient or patient's representative should be provided with adequate information relating to benefits of having exposure and risks associated with radiation dose
- must be provided **prior** to exposure taking place though could be in waiting room

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Typical Effective Doses from X-ray Examinations involving Head & Neck

TABLE 1 Typical patient doses from x-ray examinations of the head

Examination	Effective dose (μSv)[1]	Dose as a multiple of the dose from a typical panoramic exam
Panoramic	24	1
Small FOV* CBCT	48 – 652	2 - 27
Large FOV* CBCT	68 – 1073	3 - 45
CT scan (dental programme)	534 – 2100	22 - 88

* FOV = Field of view

Guidance on Safe Use of Dental Cone Beam CT (Computed Tomography Equipment), Health Protection Agency, October 2010

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Typical doses in dental radiography relative to background radiation

- UK average annual background radiation dose ~ 2.7 mSv or 2700 µSv = approx. 7 µSv/day

Imaging	Dose (µSv)	Equivalent background radiation

UKHSA: Ionising Radiation Dose Comparisons, March 2011
International Atomic Energy Agency, Radiation Doses in Dental Radiology

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Employer's Procedures

- identification of IR(ME)R duty holders
- identification of individuals to be exposed
- pregnancy inquiry
- information on benefits and risks of exposure
- comforters and carers

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Comforters & Carers

- individuals, who are **not employees**, who knowingly and willingly incur exposure to ionising radiation whilst supporting individual undergoing exposure
- every exposure of carer or comforter must be justified and authorised by IR(ME)R practitioner **separately** to justification and authorisation of patient's exposure

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Employer's Procedures

- identification of IR(ME)R duty holders
- identification of individuals to be exposed
- pregnancy inquiry
- information on benefits and risks of exposure
- comforters and carers
- clinical evaluation

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Clinical Evaluation

- refers to interpretation and documentation of findings i.e. reporting (not image quality rating) of each exposure by suitably trained operator(s)
- clinical evaluation must cover whole image, including regions outside area of interest, using appropriate viewing facilities
- employer must take steps to ensure clinical evaluation of outcome of each exposure is recorded (even if just to confirm non-diagnostic and why) including factors relevant to patient dose

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Clinical Evaluation and CBCT

- for CBCT the imaging practice is responsible for establishing that the referring dentist (or whoever referring dentist has named as person to undertake clinical evaluation) has received adequate training and therefore entitled to act as operator for purpose of clinical evaluation with decision documented as part of service level agreement (SLA)
- exposures should not be justified or authorised if not clear to IR(ME)R practitioner who will complete clinical evaluation (report)

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Service Level Agreement

REFERRING practice				RECEIVING practice	
Referral criteria					
Entitlement of people					
Enter below the details of all people at the referring practice who will refer patients for radiographic examinations and/or report on dental images. Evidence of suitable training must be provided.					
For completion by REFERRING practice				For completion by RECEIVING practice	
Names	GDC/GMC Registration Number	IRMER17 roles (tick) Referrer	Operator (reporting)	Training OK?	Registration OK?
Signatures of agreement					

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Employer's Procedures

- identification of IR(ME)R duty holders
- identification of individuals to be exposed
- pregnancy inquiry
- information on benefits and risks of exposure
- comforters and carers
- clinical evaluation
- assessment of patient dose

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Assessment of Patient Dose

- operator undertaking exposure will ensure data required to assess patient dose is recorded
- if dental X-ray equipment provides read-out of dose delivered then operator should record this
- equipment installed on or after 6th February 2018 must provide information relating to relevant parameters for assessing patient dose (including CBCT)
- employer must collect dose estimates from exposures as requested to provide these to Department of Health to aid in calculating national dose reference levels

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Employer's Procedures

- identification of IR(ME)R duty holders
- identification of individuals to be exposed
- pregnancy inquiry
- information on benefits and risks of exposure
- comforters and carers
- clinical evaluation
- assessment of patient dose
- diagnostic reference levels
- accidental or unintended exposures

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Accidental or Unintended Exposure

- **accidental exposure:** an individual has received an exposure in error, when no exposure of any kind was intended e.g. wrong patient imaged
- **unintended exposure:** although exposure of individual was intended, exposure received was different than that intended e.g. significantly greater dose, unintended modality / technique, incorrect laterality i.e. wrong site, timing of exposure
- may be due to procedural, systematic, human error or equipment malfunction (including software faults)
- does not include non-diagnostic images due to technical / patient factor e.g. patient movement, jewellery not removed

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Notification of Accidental or Unintended Exposure

Notification Code	Exposure Category	Criteria for Notification
Accidental Exposure		
1 (England only)	All modalities (including therapy)	Adult - 3 mSv effective dose or above Child – 1 mSv effective dose or above
1 (Northern Ireland, Scotland & Wales)	All modalities (including therapy)	**All**, regardless of dose

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The Regulation and Quality Improvement Authority

Statutory Notification of Accidental and Unintended Exposures

Guidance for Providers of IR(ME)R Regulated Services

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The Regulation and Quality Improvement Authority

Form (1a) - Notification of accidental or unintended exposure form

(Please complete all relevant sections)

Part 1: Service Details

Name of organisation/hospital/site:	
Modality Type:	
Local incident reference number:	

Part 2: Details of Service Users affected

Unique Identifier *(Please Do Not Use Name)*	Year of Birth *(yyyy)*	Gender *(male/female)*

(If more than 2 service users are affected please list details of remaining individuals in Part 4 of this form)

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Part 3: Information about the Event

Date: *(dd/mm/yyy)* **Time:** *(24 hour clock)*

Please select one of the following:

- ☐ Wrong patient exposed
- ☐ Wrong radioactive substance administered(NM)
- ☐ Unintended planning or verification exposure (RT)
- ☐ Wrong examination including body part or modality
- ☐ Failure to follow procedure regarding pregnancy or breast feeding enquiries
- ☐ Timing errors when an additional unintended exposure is undertaken
- ☐ Incident involving several individuals to an extent significantly greater or lower than considered proportionate (but less then the guidance factors)
- ☐ Equipment malfunction
- ☐ Unintended foetal exposure where there was no failure to follow procedures
- ☐ All other cases at the Employer's discretion

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Part 4 Concise description of surrounding circumstances

Details of the event *(Provide details of what happened, anatomical site or system affected, known contributory factors leading to the incident)*	
Any immediate action taken following the event	
Any action taken to minimise recurrence and lessons learnt *(where appropriate)*	

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Any duty holder/relevant parties informed:

Duty holder	**Date** *(dd/mm/yy)*
• Referrer	
• Practitioner	
• Employer	
• Patient/patient representative	
• Medical physics expert	
Others: *(e.g. NIAIC)*	

Duty of Candour

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Please submit the medical physics expert (MPE) report of this incident with the notification form (or immediately when available)

- ☐ MPE report attached
- ☐ MPE report to be forwarded when available

Part 5: Form Completed by:

Name	***Job Role***	**Date** *(dd/mm/yy)*

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The Regulation and Quality Improvement Authority

Form (2) - Notification of accidental or unintended exposure form

(Please complete all relevant sections)

Part 1: Service Details

Name of organisation/hospital/site:
Modality Type:
Local incident reference number:

Part 2: Details of Service User affected

Unique Identifier *(Please Do Not Use Name)*	Year of Birth *(yyyy)*	Gender *(male/female)*	Date of Admission *(dd/mm/yy)*

Part 3: Information about the Event

	Date *(dd/mm/yy)*	Time *(hh:mm)*	
Timing of Event:			*(Insert original date of event when reported)*

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Part 4: Detail of Follow up action:

Summary of incident follow up	
Lessons learned	
Training needs identified	

Part 5: Form Completed by:

Name	Job Role	Date

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Unintended Exposures Below Notification Threshold

- **unintended exposures** that do not meet dose threshold for notification criteria, including near misses, still need to be investigated and analysed locally e.g. IR-1 / DATIX / radiation incident form
- employer must record analyses of such events as RQIA may review these as part of an IR(ME)R inspection

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Equipment Fault

- for incidents involving equipment failures, regardless of whether anyone received accidental or unintended exposure, equipment manufacturer &, in Northern Ireland, **Adverse Incident Centre (NIAIC)** must be informed
- includes software faults resulting in loss of images
- helps identify wider trends such as certain manufacturers with greater incidence of faults

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Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Northern Ireland Adverse Incident Centre (NIAIC)

Reporting Adverse Incidents and disseminating Safety Information

Apr 2021

Annex 1

Examples of medical devices

Anaesthetic equipment
Blood warming cabinets
Catheters (e.g. urinary, cardiac)
Chiropody equipment
Dental equipment and materials
Dressings
Endoscopes
Examination gloves
Hospital beds
Implants – powered (e.g. implantable defibrillators, pacemakers) and non-powered (e.g. heart valves, orthopaedic implants, bone cements)
Incontinence products
IV administration sets and pumps
Ophthalmic equipment
Patient monitoring equipment (e.g. cardiac monitors)
Physiotherapy equipment
Radiotherapy equipment (brachytherapy, external beam)
Sphygmomanometers
Surgical instruments and equipment
Syringes and needles
Thermometers
Urine drainage systems
Vaginal specula
X-ray systems, ultrasound imagers and CT/MR scanners

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Department of Health
An Roinn Sláinte
Männystrie O Poustie

NIAIC ADVERSE INCIDENT REPORT FORM

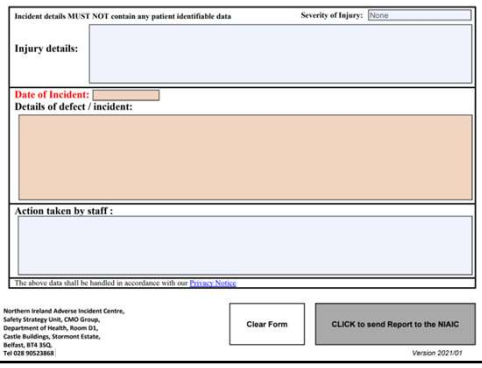
Details of the report:	**Location of the incident:**
Reporting Body: Other Address : Post Code : Reporter : Position : Tel No : Email : Date : Trust / Datix Ref:	As Reporter : Facility/Building: Ward/Dept : Local Contact for Further Details: Position : Email : Tel No :

Details of device:

Manufacturer	Catalogue No
Type of Product	Serial No
Model	
Supplier	
Batch / Lot No	Date of mfr
Quantity Defective	Expiry date
CURRENT LOCATION OF DEVICE	Other (Supply Details)

Has the manufacturer already collected the device? YES ☐ NO ☐ If yes please supply their contact details:

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Incident details MUST NOT contain any patient identifiable data

Severity of Injury: None

Injury details:

Date of Incident:

Details of defect / incident:

Action taken by staff :

The above data shall be handled in accordance with our Privacy Notice

Northern Ireland Adverse Incident Centre,
Safety Strategy Unit, CMO Group,
Department of Health, Room D1,
Castle Buildings, Stormont Estate,
Belfast, BT4 3SQ.
Tel 028 90523868

Clear Form

CLICK to send Report to the NIAIC

Version 2021/01

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Selection of X-ray Equipment

- responsibility for '**optimisation**' of patient doses through appropriate selection of equipment and methods by IRMER practitioner and operator by keeping patient dose "as low as reasonably practicable" while producing images of adequate diagnostic quality

when purchasing new equipment:

- must be designed, constructed and installed in compliance with recognised British, European or international standards
- compliant with UK medical devices regulations
- capable of producing clinically acceptable images using patient doses that are below any relevant national diagnostic reference levels

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Selection of CBCT Equipment

- MPE must be consulted for advice on preparation of technical specifications for equipment

especially important for dental CBCT

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Selection of CBCT Equipment

- MPE must be consulted for advice on preparation of technical specifications for equipment

especially important for dental CBCT:

- operating potential = 60 - 120 kV
- range of field of view (FOV) options matched to range of diagnostic tasks equipment to be used for (e.g. endo, orthognathics)
- collimation adjusted automatically depending on FOV selected
- light beam or other alignment aids available to assist with patient positioning

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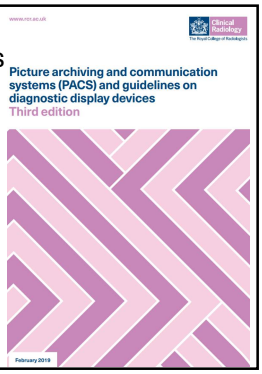
Selection of Ancillary Equipment

- essential to have dedicated and well-maintained viewing facilities to get most benefit from exposure and avoid unnecessary repeats
- digital images always viewed and interpreted on suitable display device under ideal lighting conditions to extract maximum diagnostic benefit from each image
- MPE should be consulted as necessary on selection of suitable display screen equipment and appropriate viewing conditions

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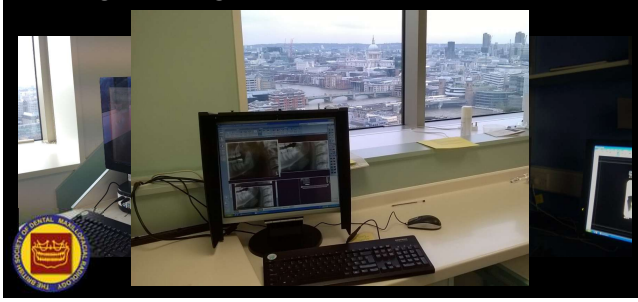
Digital Display Requirements

- minimum requirements for quality of display for review and reporting of radiographic images
- quality of display may degrade with time therefore need for regular QA to monitor image quality



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Image Viewing Conditions



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Summary of IR(ME)R(NI)18 and Cone Beam CT

- Appoint Medical Physics Expert (MPE)
- Draft Employers Procedures in consultation with MPE (entitlement of duty holders, QA etc.)
- Consult MPE regarding selection of cone beam CT scanner and ancillary equipment i.e. viewing screen

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Sources of Guidance on Ionising Radiation Legislation

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G4 DENTAL CBCT IMAGING

The practice should complete the relevant sections, following consultation with their medical physics expert (MPE).

Manufacturer and model:
Serial number/identifier:
Details of image receptors:

Radiographic technique	Voltage (kV)	Current (mA)	Exposure time(s)	Field of view (cm x cm)	Voxel size (mm3)	Rotation angle (°)
EXAMPLE Placement of a single maxillary implant, standard adult male	90	5	10	5 x 5	0.2	360

Radiographic technique and other comments:

Date of preparation:

Guidance Notes for Dental Practitioners on the Safe Use of X-Ray Equipment, 2nd Edition

www.cgdent.uk/safe-use-of-x-ray-equipment

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IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine, second edition | The Royal College of Radiologists



14 Communicating benefits and risks

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