

### Image Diagnostic Technology Ltd

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# Radiography and Radiation Protection

### Anthony Reynolds BA MSc PhD Registered Clinical Scientist CS03469

## Image Diagnostic Technology Ltd.

# Who or what is IDT?

Image Diagnostic Technology Ltd aka "IDT Scans"



#### **Specialises in:**

- arranging dental CT/CBCT scans
- 3D processing
- radiology reports
- implant simulation
- 3D models
- surgical drill guides

#### 32,300 scans processed since 1991

# What can IDT do with my images

- Prepare datasets for planning implants
- Radiology Reports
- Treatment Plans
- 3D Models
- Surgical Drill Guides



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#### Get the most out of your dental CT/CBCT scans



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#### www.idtscans.com



#### www.idtscans.com



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# **Outline of Lecture**

## Introduction / Disclosures

- Diagnostic Imaging in Dentistry
  - Conventional Radiography
  - CT / CBCT Scans
- Radiation Dose and Risk
- Compliance with the Legislation

## What do dentists use x-ray imaging for?

### **Review patient anatomy and pathology**

- diagnostic quality images
- at a low radiation dose

### **Answer specific clinical questions**

- is caries present
- how many teeth are present
- quality and quantity of bone
- radio-lucencies or radio-opacities

# Imaging for specific dental applications

**Planning dental implants** 

Orthodontics

**Endodontics** 

**Surgical Planning** 

# What Imaging Modalities are available?

- Intra-oral radiography
  - Periapicals, bitewings, occlusal views

## Extra-oral radiography

- AP and Lateral cephs
- Dental Panoramic Tomography (DPT or OPG)

Cone Beam computed tomography (CBCT)

# **Intra-oral Imaging**







- + Very high resolution (20 lp/mm)
- + Fast, convenient, low dose
- Magnification / Distortion
- No (quantitative) bone quality
- Distance measurements not reliable



# **Distortion in intra-orals**



X

## **Solutions:**

- bisecting angle
- paralleling technique

# **Extra-oral: Lateral Cephs**





- + Good overview
- + Useful for orthodontics
- Magnification / Distortion
- Distance measurements not reliable

# **Conventional Tomography**

#### (tomography by blurring)



## **Dental Panoramic Tomography (DPT)**



## Dental Panoramic Tomography (DPT, OPG, OPT)



- + Very good overview
  - + Mandibular fractures, unerupted teeth
- + Sufficient detail for caries diagnosis
- Variable Magnification / Distortion
- Patient positioning is crucial

# **Cross-Sectional Imaging**



- Linear Tomography
- Complex Motion Tomography (CMT)
- Ultrasound
- Magnetic Resonance Imaging (MRI)
- Computed Tomography (CT or CBCT)

## Computed Tomography (tomography by computation)



The dentoalveolar region has high natural contrast

So we can get away with

- high resolution
- low radiation dose



We can reduce the dose and get away with images that would not be acceptable for a medical CT scan.



### • CBCT is useful for:

- > planning dental implants
- maxillofacial surgery
- >cleft palate assessment
- TMJ and airway analysis
- >impacted, supernumerary and abnormal teeth
- ➢root canals, root fractures etc
- ➢ periapical disease
- CBCT is not good for:
  - dental caries
  - Soft tissue tumours

# Systematic Review of Indications for CBCT



# The SEDENTEXCT project (2008-2011)

4.18: Where CBCT images include the teeth, care should be taken to check for periapical disease when performing a clinical evaluation (report).

#### GP

4.19: CBCT is not indicated as a standard method for demonstration of root canal anatomy.

#### GP

4.20: Limited volume, high resolution CBCT may be indicated, for selected cases where conventional intraoral radiographs provide information on root canal anatomy which is equivocal or inadequate for planning treatment, most probably in multi-rooted teeth.

#### GP

4.21: Limited volume, high resolution CBCT may be indicated for selected cases when planning surgical endodontic procedures. The decision should be based upon potential complicating factors, such as the proximity of important anatomical structures.

#### GP

4.22: Limited volume, high resolution CBCT may be indicated in selected cases of suspected, or established, inflammatory root recorption or internal recorption, where threedimensional information is likely to alter the management or prognosis of the tooth.

#### D

4.33: Limited volume, high resolution CBCT may be justifiable for selected cases, where endodontic treatment is complicated by concurrent factors, such as resorption lesions, combined periodontal/endodontic lesions, perforations and atypical pulp anatomy.

#### 0

4.34: Limited volume, high resolution CBCT is indicated in the assessment of dental trauma (suspected root fracture) in selected cases, where conventional intraoral radiographs provide inadequate information for treatment planning.

в

#### **Prof Keith Horner**

## Grading systems used for levels of evidence [adapted from Scottish Intercollegiate Guidelines Network (SIGN), 2008].

Grade		
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results	
В	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+	
с	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++	
D	Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+	
GP	Good Practice (based on clinical expertise of the guideline group and Consensus of stakeholders)	

## Cone Beam CT (CBCT) Scanner



GXCB-500<sup>™</sup> is a trademark of Gendex Dental Systems of Lake Zurich, USA



#### (Review Paper)

THE DENTAL CLINICS OF NORTH AMERICA

Dent Clin N Am 52 (2008) 707–730

# What is Cone-Beam CT and How Does it Work? William C. Scarfe, BDS, FRACDS, MS<sup>a,\*</sup>, Allan G. Farman, BDS, PhD, DSc, MBA<sup>b</sup>

<sup>a</sup>Department of Surgical/Hospital Dentistry, University of Louisville School of Dentistry, Room 222G, 501 South Preston Street, Louisville, KY 40292, USA <sup>b</sup>Department of Surgical/Hospital Dentistry, University of Louisville School of Dentistry, Room 222C, 501 South Preston Street, Louisville, KY 40292, USA Int. J. Oral Maxillofac. Surg. 2009; 38: 609-625 doi:10.1016/j.ijom.2009.02.028, available online at http://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

## Invited Review Paper Imaging

# Cone-beam computerized tomography (CBCT) imaging of the oral and maxillofacial region: A systematic review of the literature

### W. De Vos<sup>1</sup>, J. Casselman<sup>2,3</sup>, G. R. J. Swennen<sup>1,3</sup>

<sup>1</sup>Division of Maxillo-Facial Surgery, Department of Surgery, General Hospital St-Jan Bruges, Ruddershove 10, 8000 Bruges, Belgium; <sup>2</sup>Department of Radiology and Medical Imaging, General Hospital St-Jan Bruges, Ruddershove 10, 8000 Bruges, Belgium; <sup>3</sup>3-D Facial Imaging Research Group, (3-D FIRG), GH St-Jan, Bruges and Radboud University, Nijmegen, 3-D FIRG, Ruddershove 10, 8000 Bruges, Belgium



## DentoMaxilloFacial Radiology



## **CBCT Special Issue**

## how CT works...



Godfrey Hounsfield

Allan Cormack

Nobel prize in Medicine, 1979



Animation courtesy of Demetrios J. Halazonetis www.dhal.com



## acquisition



## acquisition



## acquisition



## reconstruction








### Voxels (Volume elements)



### Voxels (Volume elements)



512 x 512 x  $\frac{400}{\text{slices}} \approx 100 \text{ million voxels (200 Mb)}$ 

### cone-beam CT (CBCT)



### cone-beam CT (CBCT)



### cone-beam CT (CBCT)





Notes e.g. specific imaging parameters / protocols / concerns..... PLEASE AUUID SCANING THE SPINE

"Sorry mate – no can do!"



The Absorbed Dose to the left side of the patient is not zero (maybe around 50% of the Absorbed Dose to the right side).

# **Outline of Lecture**

# Introduction / Disclosures Diagnostic Imaging in Dentistry

- Conventional Radiography
- CT / CBCT Scans
- Radiation Dose and Risk
- Compliance with the Legislation





26 April 1986



#### 14 June 2017



### **Dose Rate at Chernobyl (2017)**

- 200m from the reactor
- 1.35 microSievert per hour

### Background Dose Rate in the UK (Average)

• 0.25 microSievert per hour

### Flight from the UK to Chernobyl

• 3 hours x 5 μSv/hr = 15 μSv

### **Dental x-ray (intraoral)**

1 microSievert

### **CBCT scan (both jaws)**

100 microSievert

# **Topics**

- What is radiation?
- Sources of radiation
- Is radiation harmful?
- How can I estimate the risk?

# What is Radiation?

- Energy travelling through space
- Sunshine is a familiar example
  - A small amount is beneficial
  - Too much can be harmful

# The Electro-Magnetic Spectrum



from http://www.yorku.ca/eye/spectru.htm

Energy depends on the frequency  $\mathbf{E} = \mathbf{h}\mathbf{v}$ 

### **Gamma Rays and X-Rays**

- Referred to as "lonising Radiation"
- Can disrupt atoms and turn them into positive and negative ions
- This can cause damage at molecular level.



# **Sources of Ionising Radiation**

- 1. Environmental (e.g. Radon)
- 2. Cosmic Rays
- 3. Radioactive Isotopes
  - inside or outside the body
  - natural or man-made
- 4. Medical and Dental x-rays

The first 3 make up "Background Radiation" The first 4 make up "Per-Capita Dose".

### **Per-Capita Dose in the UK**

Natural, 84%





Background Radiation Medical and Dental Average Per-Capita Dose 2.2mSv0.5mSv2.7mSv per person per year

# **Topics**

- What is radiation?
- Sources of radiation
- Is radiation harmful?
- How can I estimate the risk?

### **Deterministic and Stochastic effects**

#### **Deterministic Effects are reproducible**

- severity of the effect increases with the dose
- not observed below a threshold dose of about 500mSv

#### **Stochastic Effects are random**

- the risk (not the severity) increases with the dose
- known to occur above 20mSv or so
- below about 20mSv we don't know if they occur or not

# Hereditary Effects are random (stochastic) but the incidence in humans is very low.

### **Deterministic Effects**

For a high dose of radiation received over a short period of time, we know that the following effects will occur:

- radiation sickness: 1-2Gy (whole body dose)
- skin erythema: 2-5Gy (local dose)
- sterility: 2-3Gy (local dose)
- hair loss: 2-5Gy (local dose)
- death: 3-5Gy (whole body dose)

We should never see any of these effects in a dental practice!

### **Stochastic Effects**

- For a high dose of radiation received over a short period of time, it is very likely (but not certain) that cancer will be induced.
- For a low dose of radiation, we think that cancer may be induced (maybe many years after exposure) but we don't know for sure.

#### Deterministic Effects



# **Effects of Chernobyl Disaster**

- 28 workers known to have died from Radiation Sickness (deterministic effect)
- 15 children known to have died from thyroid cancer (stochastic effect)

Population (years exposed)	Number	Average total in 20 years (mSv) <sup>1</sup>
Liquidators (1986–1987) (high exposed)	240 000	>100
Evacuees (1986)	116 000	>33
Residents SCZs (>555 kBq/m2) (1986–2005)	270 000	>50
Residents low contam. (37 kBq/m2) (1986–2005)	5 000 000	10–20
Natural background	2.4 mSv/year (typical range 1–10. max >20)	48

 An additional 4000 may have died from stochastic effects – we don't know for sure.

http://www.who.int/ionizing\_radiation/ chernobyl/backgrounder/en/



### Cancer risks attributable to low doses of ionizing radiation: Assessing what we really know

David J. Brenner<sup>a,b</sup>, Richard Doll<sup>c</sup>, Dudley T. Goodhead<sup>d</sup>, Eric J. Hall<sup>a</sup>, Charles E. Land<sup>e</sup>, John B. Little<sup>f</sup>, Jay H. Lubin<sup>g</sup>, Dale L. Preston<sup>h</sup>, R. Julian Preston<sup>i</sup>, Jerome S. Puskin<sup>j</sup>, Elaine Ron<sup>e</sup>, Rainer K. Sachs<sup>k</sup>, Jonathan M. Samet<sup>l</sup>, Richard B. Setlow<sup>m</sup>, and Marco Zaider<sup>n</sup>

Contributed by Richard Doll, August 29, 2003

Estimated excess relative risk (±1 SE) of mortality (1950–1997) from solid cancers among groups of survivors in the LSS cohort of atomic bomb survivors, who were exposed to low doses (<500 mSv) of radiation (2).



Brenner D J et al. PNAS 2003;100:13761-13766

# The Linear No-Threshold (LNT) Model

Assumes that the risk of producing cancer is proportional to the dose (no safety threshold)

Assumes that cellular damage does not accumulate from one x-ray exposure to the next

Assumes that the risk for a given exposure depends only on the dose for that x-ray exposure and not on the patient's previous dose history

Assumes that x-ray exposures are independent events.

# **Criticism of the LNT Model**

Doesn't take dose rate into account

Implies that cells do not have a repair mechanism (if they did, the curve would be less than linear and maybe have a threshold)

Implies that cellular damage does not accumulate from one x-ray exposure to the next (if it did, the curve would be greater than linear)

There is no proof that the LNT model is correct – but it is prudent to use it for Radiation Protection.

# The concept of Effective Dose

We know the risks from high doses of radiation

- e.g. Atom Bomb survivors
- Atom Bomb survivors received whole body doses
- Dental patients receive doses to a very small region
- How can we relate the risks?

**Effective Dose** is a way of describing the dose to a limited region in terms of the whole body dose that would result in the same risk to the patient

**Effective Dose is a measure of risk!** 

# **Dose Terminology**

#### **Absorbed Dose**

Energy absorbed by tissue (Gray, Gy) 1 Gray (Gy) = 1 Joule per Kilogram (J/Kg)

#### Equivalent Dose H<sub>T</sub>

(Sievert, Sv)

Multiply the Absorbed Dose by the Radiation Weighting factor  $W_R$  (= 1 for x-rays) to get  $H_T$ "Local Dose"

### Effective Dose E

(Sievert, Sv)

Multiply the Equivalent Dose  $H_T$  by the Tissue Weighting factor ( $W_T$ ) for each organ, and add them up to get the Effective Dose E "Whole Body Dose"

# Annals of the ICRP

**PUBLICATION 103** 

The 2007 Recommendations of the International Commission on Radiological Protection

> Editor J. VALENTIN

#### PUBLISHED FOR

The International Commission on Radiological Protection

by





### **Tissue Weighting Factors from ICRP 103**

### More about Effective Dose

• The Effective Dose calculation takes the size of the region and the body parts irradiated into account

 It's tempting to say "My CBCT scanner might deliver a high Effective Dose, but it's only to a very small region" but this argument is not valid. SEDENTEXCT measured Effective Doses for common CBCT scanners and found they were in the range

**20 microSieverts to 370 microSieverts**
#### **Effective dose for large field CBCTs**



Prof. Ria Bogaerts, Katholieke Universiteit Leuven, March 2011



#### Workshop on dental Cone Beam CT

#### Effective dose for medium field CBCTs



Prof. Ria Bogaerts, Katholieke Universiteit Leuven, March 2011



Workshop on dental Cone Beam CT

#### **Effective dose for small field CBCTs**



Prof. Ria Bogaerts, Katholieke Universiteit Leuven, March 2011



Workshop on dental Cone Beam CT

Review

#### E.A.O. guidelines for the use of diagnostic imaging in implant dentistry 2011. A consensus workshop organized by the European Association for Osseointegration at the Medical University of Warsaw

David Harris<sup>1,\*</sup>, Keith Horner<sup>2</sup>, Kerstin Gröndahl<sup>3</sup>, Reinhilde Jacobs<sup>4</sup>, Ebba Helmrot<sup>3</sup>, Goran I. Benic<sup>5</sup>, Michael M. Bornstein<sup>6</sup>, Andrew Dawood<sup>7</sup> and Marc Quirynen<sup>8</sup>

Article first published online: 20 MAR 2012 DOI: 10.1111/j.1600-0501.2012.02441.x

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Issue



Clinical Oral Implants Research

Volume 23, Issue 11, pages 1243–1253, November 2012



Fig. 1. Ranges of effective dose for the imaging modalities used in implant dentistry.

#### How to estimate the Risk

ICRP 103:

"Effective dose is not recommended for epidemiological evaluations, nor should it be used for detailed specific retrospective investigations of individual exposure and risk."

- But we use it anyway!

### What is the Risk from an Intraoral x-ray?

- Assume adult patient, F speed, rectangular collimation
- Effective Dose might be 2 microSieverts (worst case)
- Risk that patient might develop fatal cancer in 20 years time

= 5% (1 in 20) per Sievert (from ICRP103)

- = 1 in 20 million for 1 microSievert
- = 2 in 20 million for 2 microSieverts
- = 1 in 10 million for 2 microSieverts

Health & Safety people would call this a "Negligible Risk"

#### Cancer: science and society and the communication of risk

Kenneth C Calman

BMJ VOLUME 313 28 SEPTEMBER 1996

This article is based on the Calum Muir lecture, delivered in Edinburgh in September 1996.

**Table 2**—Descriptions of risk in relation to the risk of an individual dying (D) in any one year or developing an adverse response (A)

Term used	Risk range	Example	Risk estimate
High	≥1:100	(A) Transmission to susceptible household contacts of measles and chickenpox <sup>6</sup>	1:1-1:2
		(A) Transmission of HIV from mother to child (Europe) <sup>7</sup>	1:6
		(A) Gastrointestinal effects of antibiotics <sup>8</sup>	1:10-1:20
Moderate	1:100-1:1000	(D) Smoking 10 cigarettes a day <sup>9</sup>	1:200
		(D) All natural causes, age 40 <sup>9</sup>	1:850
Low	1:1000-1:10 000	(D) All kinds of violence and poisoning <sup>9</sup>	1:3300
		(D) Influenza <sup>10</sup>	1:5000
		(D) Accident on road <sup>9</sup>	1:8000
Very low	1:10 000- 1:100 000	(D) Leukaemia <sup>9</sup>	1:12 000
		(D) Playing soccer <sup>9</sup>	1:25 000
		(D) Accident at home <sup>9</sup>	1:26 000
		(D) Accident at work <sup>9</sup>	1:43 000
		(D) Homicide <sup>9</sup>	1:100 000
Minimal	1:100 000- 1:1 000 000	(D) Accident on railway <sup>9</sup>	1:500 000
		(A) Vaccination associated polio <sup>10</sup>	1:1 000 000
Negligible	≤1:1 000 000 <	(D) Hit by lightning <sup>9</sup>	1:10 000 000
		(D) Release of radiation by nuclear power station <sup>9</sup>	1:10 000 000

## What is the Risk from a CBCT scan?

- Assume adult patient, dento-alveolar scan, both jaws
- Effective Dose might be 100 microSieverts (worst case)
- Risk that patient might develop fatal cancer in 20 years time

= 5% (1 in 20) per Sievert (from ICRP103)

- = 1 in 20 million for 1 microSv
- = 100 in 20 million for 100 microSv
- = 1 in 200,000 (roughly) for CBCT scan

Health & Safety people would call this a "Minimal Risk"

\* If your patient is a child the risk is 3x more

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	1.100 000	(D) Playing soccer <sup>9</sup>	1:25 000
		(D) Accident at home <sup>9</sup>	1:26 000
		(D) Accident at work <sup>9</sup>	1:43 000
	/	(D) Homicide <sup>9</sup>	1:100 000
Minimal	1:100 000-	(D) Accident on railway <sup>9</sup>	1:500 000
		(A) Vaccination associated polio <sup>10</sup>	1:1 000 000
Negligible	≤1:1 000 000	(D) Hit by lightning <sup>9</sup>	1:10 000 000
		<ul> <li>(D) Release of radiation by nuclear power station<sup>9</sup></li> </ul>	1:10 000 000

## **Typical Doses from Dental X-Rays**

	Effective Dose (µSv)	Risk
Intraoral (F speed, rect coll)	2	
Intraoral (E speed, round coll)	6	
Lateral Ceph	10	
Panoramic	3 to 24	
Cone Beam CT	19 to 1073	
Medical CT (using dental protocol)	280 to 1410	

## **Typical Doses from Dental X-Rays**

	<b>Effective Dose</b>	<b>;</b>	
	(µSv)	Risk	
Intraoral (F speed, rect coll)	2	1 in 10 million	Negligible
Intraoral (E speed, round coll)	6	1 in 3.3 million	Negligible
Lateral Ceph	10	1 in 2 million	Negligible
Panoramic	3 to 24	1 in 6.7 million to 833 thousand	Negligible to Minimal
Cone Beam CT	19 to 1073	1 in 1.05 million to 1 in 19 thousand	Mimimal to Very Low
Medical CT (using dental protocol)	280 to 1410	1 in 71 thousand to 1 in 14 thousand	Very Low

### **Risk varies with Age**

Age group (years)	Multiplication factor for risk	
<10	х 3	
10-20	x 2	
20-30	x 1.5	E <sup>0</sup> / per Sigvert et ego 20
30-50	x 0.5	5% per Sievert at age 30
50-80	x 0.3	
80+	Negligible risk	

RADIATION PROTECTION N° 172 A report prepared by the SEDENTEXCT project 2011
<u>www.sedentexct.eu</u>

## **CBCT Scans**

#### **Risk**

- Exposure to ionising radiation
- Might induce a cancer
- Might induce a hereditary defect

Clinical

#### **Benefit**

- Accurately pre-plan dental implant treatment
- Less risk of damaging a critical structure
- Reduce operating time
- Improved aesthetic results



#### Decision

#### Implant Surgery Complications: Etiology and Treatment

Kelly Misch, DDS,\* and Hom-Lay Wang, DDS, MSD, PhD†

ISSN 1056-6163/08/01702-159 Implant Dentistry Volume 17 • Number 2 Copyright © 2008 by Lippincott Williams & Wilkins



#### The Risk of Not Having a CBCT Scan



Take the CT Scan first, do the surgery second (not the other way around)!

# If everyone in the UK had a dental CBCT scan every year ...

- There might be 160 extra cancer deaths per year (if LNT is correct)
- Compared to 155,000 cancer deaths from other causes

UK Mortality 2002: Cancers which contribute one per cent or more to total cancer mortality

	Lung	33,600	(22%)
Bowel		16,220	(10%)
Breast		12,930	(8%)
Prostate		9,940	(6%)
Oesophagus		7,250	(5%)
Pancreas		6,880	(4%)
Stomach		6,360	(4%)
Bladder		4,910	(3%)
Non-Hodgkin's lymphoma		4,750	(3%)
Ovary		4,690	(3%)
Leukaemia		4,310	(3%)
Brain and CNS		3,370	(2%)
Kidney		3,360	(2%)
Head and neck		3,000	(2%)
Multiple myeloma		2,600	(2%)
Liver		2,510	(2%)
Mesothelioma		1,760	(1%)
Malignant melanoma		1,640	(1%)
Cervix		1,120	(1%)
Body of Uterus		1,070	(1%)
Other		22,910	(15%)
Persons: all malignant neoplasms		155,180	(100%)

http://www.cancerresearchuk.org/aboutcancer/statistics/mortality

## **Outline of Lecture**

# Introduction / Disclosures Diagnostic Imaging in Dentistry

- Conventional Radiography
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## European Directives for Radiation Safety

- Basic Safety Standards Directive
  - 96/29/Euratom of 13 May 1996
- Medical Exposure Directive
  - 97/43/Euratom of 30 June 1997

#### **Both Replaced by**

- Basic Safety Standards Directive (revised)
  - 2013/59/Euratom of 5 December 2013
  - National legislation to be enacted by 5 February 2018

## **Transposition into National Law**

Two separate bodies of legislation:

- Radiation Safety for Workers and the Public
  - based on 96/29/Euratom of 13 May 1996
  - revised by 2013/59/Euratom of 5 December 2013
- Radiation Safety for Patients
  - based on 97/43/Euratom of 30 June 1997
  - revised by 2013/59/Euratom of 5 December 2013
- New legislation has come into force in Great Britain and Northern Ireland but not in the Republic of Ireland yet.

## In the UK

#### **Radiation Safety for Workers and the Public**

- Ionisation Radiations Regulations 1999 "IRR99"
- Enforced by Health and Safety Executive
- Revised legislation "IRR 2017" came into force on 6 February 2018.

#### **Radiation Safety for Patients**

- Ionising Radiation (Medical Exposure) Regulations 2000 (amended in 2006 and 2011) – "IR(ME)R 2000"
- Enforced by Care Quality Commission (CQC)
- Revised legislation "IR(ME)R 2017" came into force on 6 February 2018.

# Legislation versus Guidelines – what's the Difference?

- "Legislation" refers to Criminal Law
- Example: it is an offence not to register with HSE if you own an x-ray machine

"Guidelines" refer to Best Practice and are often relevant in Civil Law

- Can I defend myself if a patient sues me?
- What if I'm investigated by the GDC?

You won't go to jail for not complying with the Guidelines, but compliance puts you in a stronger position.

## Ionising Radiation Regulations 2017 (IRR 2017)

- Regulates all use of radiation in the workplace (industry as well as medicine and dentistry)
- Not directly concerned with patient exposures (unless accidental)
- Regulated by Health and Safety Executive (HSE) not Department of Health or Care Quality Commission.

## **IRR 2017 - New System of Authorisation**

- Under IRR99 employers had to notify HSE 28 days in advance of commencing work with ionising radiation.
- Under IRR 2017 you just have to register in advance (doesn't specify how much in advance).
- Graded system under IRR2017 (based on level of risk):
  - Notification: work with radionuclides only
  - Registration: work with radiation generators including x-ray tubes.
     Costs £25 to register (for all sites under one Employer).
  - Consent: administering radiopharmaceuticals to patients (costs £25 per Employer)
- Must re-register (and pay a new fee) after a material change (such as change of Employer's name or address)

## **IRR 2017 - New System of Authorisation**

- Employers (e.g. dental practice owners) had to register and pay £25 fee by 5 February 2018.
- Associates (working at someone else's practice and following the owner's rules and regulations) do not have to register.
- If you should have registered but haven't already done so you can register online here: https://services.hse.gov.uk/bssd/

## **Risk Assessment**

A Risk Assessment is required before commencing new activities involving ionising radiation.

- 1. Look for the hazards (sources of radiation)
- 2. Decide who may be harmed and how (staff, public)
- 3. Decide if existing control measures (shielding, warning signs) are adequate or if more are needed
- 4. Record the findings of the Risk Assessment
- 5. Review the Assessment periodically (e.g. once per year) and revise if necessary.

## **Sources of Radiation**

#### Primary Beam

only the patient should be exposed to the primary beam.

#### Tube Leakage

must be less than 1mGy/hour at 1 meter

- tests are performed to ensure this.

#### Scattered Radiation

- radiation scattered from the patient
- staff can protect themselves through Distance, Shielding, Time.

## **Hierarchy of Control Measures**

**Control Measures should be considered in this order:** 

- **1. Engineering Controls** 
  - Beam collimation, shielding, warning devices

#### 2. Systems of Work

- Controlled Areas
- Local Rules

3. Personal Protective Equipment (should be a last resort)

Lead aprons

## **Staff Protection**

#### **Based on 3 principles:**

#### Distance

- the further you are from the source the less radiation you receive
- follows Inverse Square Law (1/d<sup>2</sup>)

#### Shielding

- fixed (built into the walls)
- a mobile shield
- Protective equipment (e.g. lead apron for staff)

#### • Time

- shorter exposure to radiation results in less dose.

Staff are present 8 hours a day so it is vital to protect them.

## **Protecting Members of the Public**

- Adequate shielding needs to be built into the walls, ceilings, floors, doors, windows of rooms containing x-ray equipment
  - if you have windows in the doors make sure they contain lead
- Think carefully about the best locations for waiting rooms, toilets etc
- Think how to prevent members of the public from walking into a Controlled Area
  - warning signs
  - radiographer stands at the door
  - good building design ensuring the public have no reason to walk past a Controlled Area.

## Dose Limits for Workers and the Public

Annual Dose limits (mSv)					
	Adults	Trainee	Other		
	(over 18 yrs)	(under 18 yrs)	persons		
Whole body	20	6	1		
Lens of the	150	50	15		
eye					
Skin	500	150	50		
Hands etc.	500	150	50		
Women of reproductive capacity 13 mSv averaged over the					
abdomen in any consecutive 3 months					

IRR 2017: Dose Limit to Lens of Eye is now 20mSv/year for Adults and 15mSv/year for Trainees/Other Persons

## **Classified Persons**

Employees must be "classified" if they are likely to receive:

- An Effective Dose of more than 6mSv per year, or
- An Equivalent Dose to lens of eye of more than 15mSv per year, or
- An Equivalent Dose to extremities of more than 150mSv per year (skin, hands, forearms, feet or ankles)

#### If they are Classified they must have

- An appointed doctor
- A passbook if they work in another Employer's controlled environment.

## **People who work in dental practices** are not normally "Classified"!

## **Controlled Areas**

# An area is **Controlled** if "special procedures designed to restrict significant exposure" are necessary.

#### Workloads up to 100 intra-orals or 50 DPTs:

- Within the primary x-ray beam until sufficiently attenuated
- Within 1.5m of the x-ray tube and patient in any other direction.

#### **Dental CBCT:**

Usually the entire room is a Controlled Area while the power is on.



## **Local Rules**

Work in a Controlled Area must be carried out according to Local Rules

Local Rules should be on display in each room where x-ray equipment is used

Employees must read Local Rules and sign an undertaking that they have been read.

Some dental practices put the Local Rules on their website.



### **Radiation Protection Advisor**

- Dental Practices must appoint a suitable RPA
- Must consult RPA to ensure observance of IRR 2017
- RPA should review radiation safety for each new x-ray installation and at least every 3 years for existing installations
  - e.g. adequate shielding
  - designation of controlled areas
  - training of operators
  - local rules / written procedures

### **Radiation Protection Advisor**

- RPA is generally a physicist with certification from HSE-approved Assessing Body
- Usually an outside consultant
- Should be available for consultation (otherwise, get a different one)
- A list of RPAs is available at www.rpa2000.org.uk

## **Radiation Protection Supervisor (RPS)**

- Where work is subject to Local Rules, employer must appoint a Radiation Protection Supervisor (RPS)
- Usually a member of staff who can command authority (e.g. a dentist)
- Should be trained to have knowledge of the Regulations and understand the precautions to be taken
- Legal responsibility remains with the employer.


An Outside Worker is someone who carries out work in the Controlled Area of an Employer other than their own

- Now includes both Classified and Non-Classified workers (used to be just Classified workers)
- May include Agency Staff e.g. radiographers
- Includes service engineers, contractors etc
- You are responsible for their safety
- In the case of an engineer you can hand responsibility over temporarily through a Handover Procedure.

#### RADIATION CONTROLLED AREA AND EQUIPMENT HANDOVER FORM



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Hazard Notice response										
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	ications for radiation safety									
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Version 4, 03 April 2018

*Ionising Radiation (Medical Exposure) Regulations 2017* 

### Ionising Radiation (Medical Exposure) Regulations 2000 (amended in 2006 and 2011) – "IR(ME)R 2000"

- Medical exposures (e.g. patients)
- Enforced by Care Quality Commission www.cqc.org.uk
- In Northern Ireland: enforced by Regulation and Quality Improvement Authority www.rqia.org.uk

## IR(ME)R 2000 was replaced by IR(ME)R 2017.

## **Principles of Patient Protection**

Justification

(benefits must outweigh the risks)

- Optimisation (keep doses As Low As Reasonably Practicable) (consistent with the intended diagnostic purpose)
- Dose Constraints

   (20 mSv per year for Classified Persons)
   (1 mSv per year for members of the public)
   (no dose limits for medical exposures)
   (must set limits for research programs)
   (must set limits for carers and comforters)

# **Duty Holders under IR(ME)R 2000**

## **The Employer**

• provides a framework of policies and procedures

**The Referrer** ("Prescriber" in most EU countries)

 must supply sufficient clinical information to allow the exposure to be justified

## **The Practitioner**

 is responsible for justifying the exposure in terms of benefits versus risks

## **The Operator**

• is responsible for carrying it out safely.

# **Employer**

The **Employer** is the legal person responsible for compliance with IRR 2017 and IR(ME)R 2017.

The Employer could be:

- An NHS Trust
- The owner of a dental practice
- The owner of an x-ray repair and servicing company
- etc.

The Employer must create a framework for Radiation Protection through written policies and procedures.

## **Practitioner**

- Practitioner must decide if the exposure is justified (i.e. the benefits must outweigh the risks)
- Must take into account the objectives of the exposure and the characteristics of the patient
- Is there another way to obtain the required information?
- What do the Referral Guidelines say?
- Urgency of the procedure (e.g. pregnant women may prefer to postpone it).

## Justifying the Exposure

- There must be procedures to ensure that a clinical evaluation of the outcome of the exposure is carried out and recorded
- If it is known, prior to the exposure, that no clinical evaluation will occur then the procedure cannot be justified and the exposure must not take place
- If exposure will not change the patient's management it cannot be justified and must not take place.

## **Informed Consent**

Wherever practical and prior to an exposure, the patient must be provided with information relating to benefits and risks.

• For dental radiography, leaflets in the waiting room would meet this requirement in practice.

# Referrer

- **Referrers** may prescribe (request) x-ray examinations.
- They must be registered health care professionals.
- They must provide sufficient clinical information to substantiate the need for an x-ray examination.
- A history and clinical examination of the patient is essential prior to any request for an exposure.
- Previous x-ray examinations should also be investigated
- "Routine" x-rays are not allowed.



- Operators are responsible for carrying out the exposure safely.
- They should ensure the dose from the exposure is as low as reasonably practicable and consistent with the intended diagnostic purpose
  - dose should not be so low as to give non-diagnostic images
- There should be written protocols in place for each type of examination
- If the dose is above the Diagnostic Reference Levels (DRL) the reason should be recorded.

# Medical Physics Expert (MPE)

Under IRR 2017 dental practices have to appoint an RPA

Under IR(ME)R 2017 they have to appoint an MPE (who will often be the same person):

- MPE to be available for consultation on Optimisation
- Give advice on radiological equipment
- Setting of local DRLs
- Establish and maintain QA programme

A list of RPAs and MPEs is available at www.rpa2000.org.uk

## **Automated Dose Reporting**

CT/CBCT equipment installed after 5 Feb 2018 must have the capacity to transfer all dose related parameters to the patient's exposure record.

## **Dose Reference Levels**

- Local DRLs should be set for each type of x-ray procedure
- Local DRLs should not normally exceed National DRLs
- For intra-orals the National DRL is 1.7 mGy in the UK (entrance dose) 4 mGy in Ireland
- For DPTs the National DRL is 67 mGy.cm<sup>2</sup> for children and 93 mGy.cm<sup>2</sup> for adults (Dose Area Product, DAP)
- We don't have a DRL for CBCT yet.

## **Accidental or Unintended Exposures**

- "Significant events" (not defined) must be analysed, recorded and reported (including near misses)
- Includes equipment or procedural failures
- Duty of candour to disclose "clinically significant" (not defined) events to patient, referrer, practitioner "professionals involved with the care of the patient"
- If not in patient's best interests to inform patient then representatives must be informed instead.

## Guidance on investigation and notification of medical exposures much greater than intended.

16 January 2017

All Modalities	When to notify (what constitutes an exposure much greater than intended)		
Wrong patient exposed	All cases – regardless of dose		
Wrong examination including incorrect body part or modality.			
Low dose examinations, where the intended dose is less than 0.5mSv, to include DEXA, skull, dentition, chest, in-vitro nuclear medicine	When the total exposure is at least 20 times greater than the intended dose.		

Table 1 - Examples of unintended medical exposures that require notification

#### https://www.cqc.org.uk/guidance-providers/ionising-radiation/reporting-irmer-incidents

# Summary of Changes in IR(ME)R 2017

- Evolution of IR(ME)R 2000, not revolution
- Now covers non-medical imaging using medical radiological equipment (replaces "medico-legal exposures")
- Doses to "comforters and carers" must be justified and optimised and are subject to constraints
- "Outside Workers" now includes non-classified workers
- Clarification of Medical Physics Expert (MPE) role
- Equipment QA is now addressed in IR(ME)R instead of IRR.

# Training Requirements – IRR 2017 and IR(ME)R 2017

 Employers must maintain an up-to-date record of training, available for inspection, with date and nature of training recorded.

## **Practitioner Training**

**Practitioners** must have received adequate training both in radiation safety and clinical aspects (e.g. selection criteria)

- for dentists this would normally be a degree course
- must keep up to date with CPD

# **Operator Training**

# **Operators** must have received adequate training specific to the tasks that they undertake

- dental nurses, hygienists, therapists etc required to take x-rays would normally require the Certificate in Dental Radiography or equivalent
- must receive training on practical aspects of operating the equipment
- must keep up to date with CPD

## **Referrer Training**

There are no specific requirements in IR(ME)R 2017 for Referrer training, however, many people believe that training of Referrers would be beneficial, especially for Dental CBCT.

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<sup>1</sup>, R Jacobs<sup>2</sup>, E Levring Jäghagen<sup>3</sup>, C Lindh<sup>4</sup>, G Baksi<sup>5</sup>, D Schulze<sup>6</sup> and R Schulze<sup>7</sup>

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https://www.rcseng.ac.uk/education-and-exams/courses/

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## Friday 15 March 2019 £300 Dental CBCT Course for Referrers

Cone Beam Computed Tomography (CBCT) is increasingly common in hospital and general dental practice. This course is based on the Level 1 training criteria published in the latest European EADMFR guidelines. Upon completion participants will have fulfilled their legal and ethical responsibilities.

The course is hosted by the RCS and the British Society of Dental and Maxillofacial Radiology and is delivered by experienced consultant dental maxillofacial radiologists.





https://www.rcseng.ac.uk/education-and-exams/courses/



## Friday 19 October 2018 £400 Basics of Dentoalveolar CBCT Interpretation

This hands-on course is designed to train dentists to interpret and write reports on CBCT scans limited to dento-alveolar regions. The course content is modified from the "Level 2" training criteria published in the latest European guidelines.

This course is jointly hosted by the British Society of Dental and Maxillofacial Radiology (BSDMFR) and the Royal College of Surgeons of England and is delivered by experienced consultant dental maxillofacial radiologists.





## Dental Cone Beam CT Radiological Interpretation PG Cert Online Course

https://www.kcl.ac.uk/study/postgraduate/taught-courses/ dental-cone-beam-ct-radiological-interpretation-pg-cert.aspx

# **Radiology Reports**

- IR(ME)R 2017 requires a *clinical evaluation* of the outcome of each exposure (other than for carers and comforters) and that this must be *recorded*.
- There is no legal requirement to send the images to a Radiologist for reporting
- If you have received sufficient training, it is good practice to report on the images yourself
- If you haven't received sufficient training, or if you suspect pathology may be present, it is good practice to send the images to a Specialist in Dental and Maxillofacial Radiology for a Report.

# Due Diligence

- "In any proceedings against any person for an offence consisting of the contravention of these Regulations it is a defence for that person to show that the person took all reasonable steps and exercised all due diligence to avoid committing the offence"
- Document everything!

# **Guidance Documents**

- New Approved Code of Practice L121 (costs £27) <u>www.hse.gov.uk/pubns/priced/l121.pdf</u>
- Revised Medical and Dental Guidance Notes to be published.
- Guidance Notes for Dental Practitioners on the Safe Use of X-Ray Equipment – updates planned by Public Health England (PHE).
- IR(ME)R Companion Guide to be published.
- IR(ME)R 2017 legislation is available here: www.legislation.gov.uk/uksi/2017/1322/contents/made



L121 (Second edition) Published 2018

## **Medical and Dental Guidance Notes**

- Provide general guidance on good practice
- Not an attempt to interpret legal requirements
- Following the guidance is not compulsory but should be sufficient to comply with the law
- Covers IR99, IR(ME)R 2000, equipment
- To be revised for IRR 2017 and IR(ME)R 2017



A good practice guide on all aspects of ionising radiation protection in the clinical environment

Prepared by Institute of Physics and Engineering in Medicine

with the support of National Radiological Protection Board Health and Safety Executive The Health Departments The Environment Agencies



IPEM 2002 Costs £20

# **Guidance Documents (Europe)**





http://europa.eu.int/comm/energy/nuclear/radioprotection/publication/doc/136\_en.pdf