

# ***Guidelines and Regulations***

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# Annals of the ICRP

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Commission on Radiological Protection

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The International Commission on Radiological Protection

by



# ***Framework for Radiation Protection***

- **Based on the Recommendations of the International Commission for Radiation Protection (ICRP)**
  - an advisory body with no formal powers
- **European Directives for Radiation Safety**
- **National Legislation**
  - Ireland
  - Northern Ireland
  - England, Scotland, Wales
- **Local Rules / Written Procedures at each hospital or dental practice**
- **Each healthcare professional has an individual responsibility**

# *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
  - amended by 2013/59/Euratom of 5 December 2013
- **Radiation Safety for Patients**
  - based on 97/43/Euratom of 30 June 1997
  - amended by 2013/59/Euratom of 5 December 2013
- **Amended legislation came into force in Great Britain and Northern Ireland in 2018 and in the Republic of Ireland in 2019.**

# ***Legislation versus Guidelines – what's the Difference?***

**“Legislation” refers to Criminal Law**

- **Example: it is an offence to start taking x-rays in your dental practice without notifying both the EPA and HIQA**

**“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 Dental Council?**

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

# *Irish Legislation*

**Principal Act is the Radiological Protection Act 1991**

**Ministers can use Statutory Instruments (S.I.s) to create specific regulations under the Principal Act.**

# ***Ionising Radiation Regulations 2019***



STATUTORY INSTRUMENTS.

**S.I. No. 30 of 2019**

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RADIOLOGICAL PROTECTION ACT 1991 (IONISING RADIATION)  
REGULATIONS 2019

- **Protection of Workers and Members of the Public**
- **Enforced by the Environmental Protection Agency (EPA)**
- **Signed into law by Richard Bruton on 4 February 2019**



# *Medical Exposure Regulations 2018*



STATUTORY INSTRUMENTS.

S.I. No. 256 of 2018

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

- **Protection of Patients Undergoing Medical Exposures**
- **Enforced by the Health Information and Quality Authority (HIQA)**
- **Signed into law by Simon Harris on 8 January 2019**

# *Medical Exposure Regulations 2018*



STATUTORY INSTRUMENTS.

S.I. No. 332 of 2019

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EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION  
AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO  
IONISING RADIATION) (AMENDMENT) REGULATIONS 2019

- **First Amendment signed into law by Simon Harris on 3 July 2019**

# *Medical Exposure Regulations 2018*



STATUTORY INSTRUMENTS.

**S.I. No. 413 of 2019**

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EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION  
AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO  
IONISING RADIATION) (AMENDMENT) (NO. 2) REGULATIONS 2019

- **Second Amendment signed into law by Simon Harris on 2 August 2019**

# ***Irish Legislation***

- **Two bodies to notify – the EPA and HIQA**
- **Two sets of regulations to comply with**
- **Two different inspectors that could appear on your doorstep!**
- **The EPA and HIQA have agreed to work together to carry out their separate but parallel functions under the new legislation.**

# ***UK Legislation***

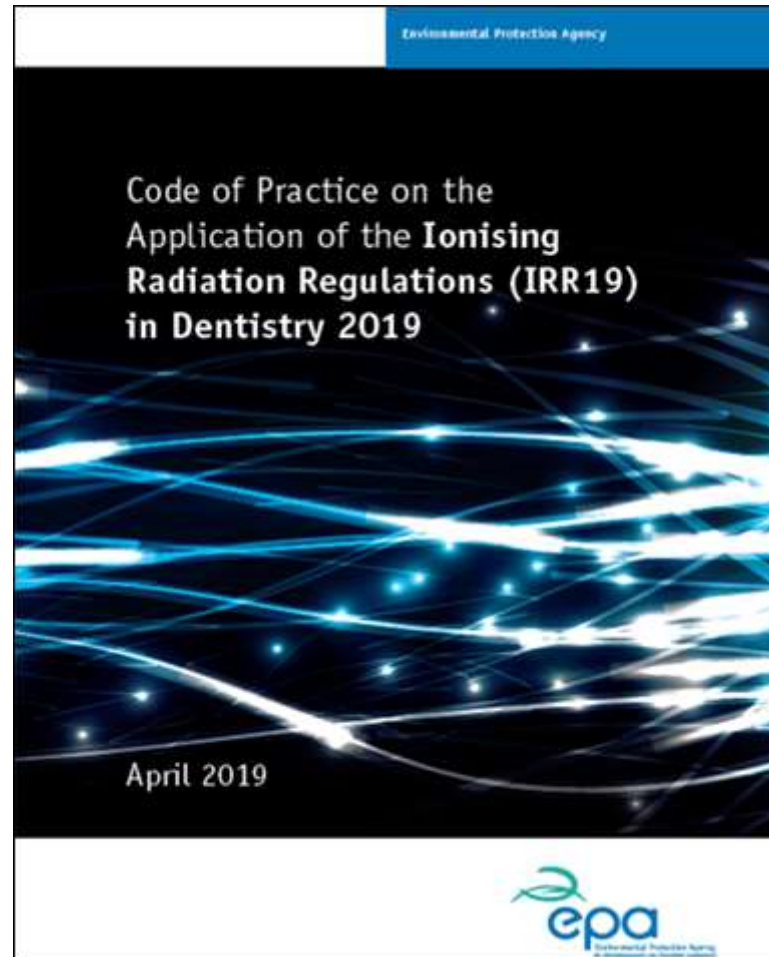
## **Radiation Safety for Workers and the Public**

- **Ionisation Radiations Regulations 1999 – “IRR99”**
- **Enforced by Health and Safety Executive**
  
- **Revised legislation “IRR 2017” came into force on 5 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) in GB**
- **Enforced by Regulation and Quality Improvement Authority (RQIA) in NI**
  
- **Revised legislation “IRMER 2017” came into force on 5 February 2018.**

# *Irish Ionising Radiation Regulations 2019*



**Guidance Document available at**  
<https://www.epa.ie/radiation/regulation/guidance/>

# ***Dose Limits for Workers and Members of the Public***

		<i><b>Exposed Workers</b></i>		<i><b>Public</b></i>
<i><b>Annual Dose limits (mSv)</b></i>				
	Adults (over 18 yrs)	Trainee (under 18 yrs)	Other persons	
<i>Whole body</i>	20	6	1	
<i>Lens of the eye</i>	<del>150</del> <b>20</b>	<del>50</del> <b>15</b>	15	
<i>Skin</i>	500	150	50	
<i>Hands etc.</i>	500	150	50	

***Category A      Category B***

***IRR 2019: Dose Limit to Lens of Eye is now 20mSv/year for Adults and 15mSv/year for Trainees/Other Persons***

# *Exposed Workers*

- If a person (either self-employed or working under an employer) is subject to exposure at work which makes them liable to receive doses exceeding one or other of the dose limits for public exposure they become an **exposed worker**
- Two categories of exposed workers: Category A and Category B
- Additional regulations apply to exposed workers
  - individual dose monitoring
  - training programmes
  - medical checks
- **Outside Workers** are exposed workers who perform duties in the **controlled or supervised areas** of undertakings other than their own employer
  - potentially includes Service Engineers but only if they are liable to exceed the dose limits for members of the public
  - they must follow your safety procedures.



# *Controlled and Supervised Areas*

An area is ***Controlled*** or ***Supervised*** (depending on the level of risk) if special procedures are needed to prevent significant exposure.

## **Intra-orals:**

- Within the primary x-ray beam until sufficiently attenuated
- Within 1.5m of the x-ray tube and patient in any other direction (operator should be at least 2m from the patient).

## **Dental CBCT:**

- Usually the entire room is a Controlled Area while the power is on.
- Two-stage warning lights are recommended.



# ***Undertakings***

- **The undertaking is the entity with primary legal responsibility for compliance with the Regulations**
- **In dentistry, this is usually, but not always, the principal dentist or practice owner.**
- **Does not include employees or associates (but they have to follow your safety procedures).**

# *Authorisation*

The use of oral radiology in Ireland must be authorised in advance by the EPA through either a registration or a licence.

- **Registration** is appropriate when using fixed X-ray equipment including intraoral, panoramic, cephalometric and **cone beam CT**
- Registration is indefinite unless surrendered or revoked
- Requires a self-declaration affirming compliance.
  
- **Licensing** is appropriate where oral radiology procedures are undertaken using **handheld equipment**
- Licence must be renewed every 10 years
- Risk Assessment and Safety Procedure documents must be submitted with the application
- Existing licences remain valid until they run out.

# *Handheld X-Ray Equipment*

- **European guidance recommends that handheld X-ray equipment should only be used when fixed or semi-mobile units are impractical**
- **Should not be used as a replacement for fixed or semi-mobile units**
- **Handheld X-ray equipment should always be used with arms fully extended (about 40cm) and in the horizontal plane**
- **All X-ray equipment must be CE marked.**



**Justification and good practice in using handheld portable dental X-ray equipment: a position paper prepared by the European Academy of DentoMaxilloFacial Radiology (EADMFR). Berkhout et al, DMFR 44, 6 (July 2015).**

# Fees

Sector	Practice	Fee to apply for new authorisation	Fee on Renewal
Dental	Dental radiography using an intra/extra oral unit (except handheld)	€300	NA
	Any use of dental X-ray equipment subject to licensing (including use of hand held X-ray equipment)	€1000	€250
	Dental radiography carried out at an additional risk assessed clinic under an existing registration	€75	NA

**Renewal fees for Licences apply after 10 years**

**In the case of Licences there is an additional “Enforcement Charge” of €450 p.a.**

# ***Application for Authorisation***

- **Must be done online using the EDEN system**
- **Must include the following:**
  - **The legal details of the undertaking/dentist**
  - **The address of the undertaking/dentist and of the premises at which oral radiology is to be carried out**
  - **The nature of the radiology activities (referred to as “practices” in EDEN)**
  - **The name of the Radiation Protection Adviser (RPA) who has been consulted.**

# *Self-Declaration*

- **The undertaking must declare that they have:**
  - Completed a **Risk Assessment** (RA) in consultation with an RPA
  - Implemented any Control Measures identified in the RA
  - Designated a Radiation Protection Officer (RPO)
  - Provided staff with the appropriate training
  - Developed procedures to be followed in the event of an **incident liable to have radiation safety implications** for workers and members of the public.
- **Undertakings must retain documentary evidence on file supporting the Self-Declaration and Risk Assessments**
- **An inventory of x-ray equipment must be retained.**

# Basic Risk Assessment

<b>Hazard</b>	<b>Control Measures</b>	<b>Residual Risk</b>
Member of Public might enter room while exposure is taking place	<ol style="list-style-type: none"><li>1. Two-stage warning light</li><li>2. Operator stands in front of door</li></ol>	Low
The wrong patient might be scanned	Always ask: Name, Address, Date of Birth	Low



# ***Reasonably Foreseeable Incidents***

<b>Incident</b>	<b>Response</b>
Exposure fails to terminate at end of scan	Operator activates emergency power off switch from outside the room
Damage to x-ray tube affecting the shielding	Take the equipment out of service

## ***What if an undertaking operates several clinics?***

- **Risk Assessment (and implementation of Control Measures) for each premises.**
- **Each individual premises must be listed in the registration/licence.**
- **When a certificate of registration or licence is granted this must be displayed publicly within each premises.**

# ***Changes to the Authorisation***

**Must apply for an amendment to the authorisation before:**

- **Adding or removing a dental premises**
- **Carrying out an additional oral radiology practice not covered by an existing licence or registration.**

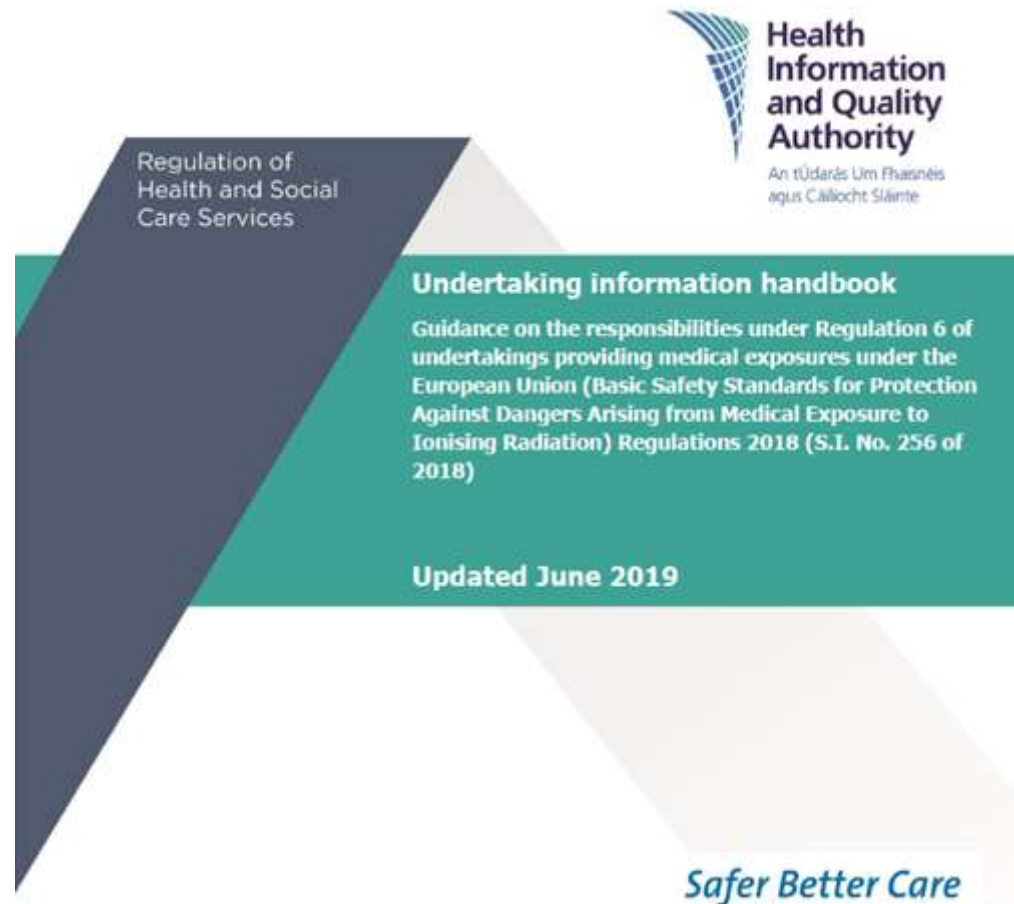
**An amendment would be necessary before introducing CBCT in a clinic already registered for the use of intraoral cephalometric or panoramic radiology.**

# ***Selling or Transferring a Dental Practice***

**Authorisations are non-transferable.**

**If a dental practice is sold or transferred, the new undertaking/dentist must apply for a registration or licence in their own name.**

# *Medical Exposure Regulations 2019*



Guidance Document available at  
<https://www.hiqa.ie/reports-and-publications/guide/guidance-providers-undertakings-medical-exposures>

# ***Duty Holders under SI 256***

## **The Undertaking** (used to be “Holder”)

- provides a framework of policies and procedures

## **The Referrer** (used to be “Prescriber”)

- prescribes an x-ray for their patient to answer a clinical question

## **The Practitioner**

- takes clinical responsibility for the exposure

## **Person carrying out practical aspects** (used to be “Operator”)

- is responsible for carrying it out safely.

# *Clinical Responsibility*

## **The Practitioner is responsible for:**

- **Justification** (benefits must outweigh the risks)
- **Optimisation** (keeping doses As Low As Reasonably Achievable)
- **Clinical evaluation of the outcome**
- **Cooperation with other specialists** (e.g. medical physicists) regarding practical aspects
- **Obtaining information on previous examinations**
- **Providing existing radiological information or records to other practitioners or the referrer**
- **Giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate.**

# Referrals

- In dental radiology, the **Practitioner** will usually be a dentist (maybe the owner of a practice with a CBCT scanner)
- In dental radiology, the **Referrer** will usually be another dentist (maybe a GDP who needs a CBCT scan for his or her patient)
- A Dentist working alone will often take on the role of **both Prescriber and Practitioner** (and Undertaking as well).
- **It is important to keep a record** (e.g. an entry in the patient's notes) demonstrating that the procedure was clinically indicated and the exposure was justified – and to make a second note saying what the outcome was.
- Where a dental practice accepts referrals for imaging from other dental practices, it should only do so on the basis of a **written prescription giving full clinical details**. Best Practice is to have a Service Level Agreement (SLA) between the two practices.



# ***Justification***

- **An x-ray exposure can only be Justified if the benefit (to the patient, or to society at large) outweighs the risk**
- **Both the Referrer and the Practitioner should be involved in the justification process**
- **When a Referrer sends a patient to a Practitioner for an x-ray procedure, both the Referrer and the Practitioner must consider if the procedure is justified.**

# ***Notifying HIQA***

- **Undertakings must notify both HIQA and the EPA of their intention to carry out medical radiological procedures.**
- **Notify HIQA using NF200 and NF200A forms:**
  - **NF200 – Declaration of Undertaking**
  - **NF200A – List of Practitioners**
- **Undertakings registered outside Ireland but carrying out medical radiological procedures within Ireland must also notify HIQA and comply with the regulations.**
- **Must be submitted by **8 April 2019** or one month before commencing practice.**

## ***Changes to the Notification***

- **Must notify HIQA of changes of details using form NF201, for example:**
  - **change in contact details**
  - **change in the services provided by the undertaking**
  - **change in the named representative or designated manager**
  - **change in the number or addresses of an undertaking's medical radiological installations**
  - **change in the members who make up an unincorporated body**
  - **change to the partners who make up a partnership.**

## Section A: Undertaking Information

Undertaking address — please enter the address and relevant Eircode of the principal place of business of the undertaking. If the undertaking has registered itself as a business (where applicable), please use the address associated with that registration ([www.cro.ie](http://www.cro.ie)).

The address submitted by the undertaking must be regularly monitored and should enable HIQA to readily communicate with the undertaking.

Section A: Undertaking Information			
A1. Undertaking details			For official use
Undertaking name	X-ray Ltd.		
Undertaking address	Address line 1	123 ABC Road	
	Address line 2	ABC Town	
	County	TOWN	
	Eircode	123 ABC	
Undertaking email address	X-ray@975.ie		
Undertaking contact number	123 456789		
Number of medical radiological installations for the undertaking's remit	3		

The **undertaking email address and contact number** must relate to the undertaking business type and be regularly monitored. It should not be an individual's personal email address.

This is referring to the **number of individual addresses, sites or geographical locations** where the undertaking carries out medical exposures to ionising radiation, and not the individual pieces of equipment.

Complete all fields in Section A2 **undertaking representative details.**

A2. Undertaking representative details						For official use
No.	Undertaking representative name	Undertaking representative type	Undertaking representative job title	Undertaking representative email address	Undertaking representative contact number	
1.	John Doe	Director	General Manager	j.doe@975.ie	123 456321	

Section A3 must be completed for **all** facilities under the undertakings remit. Please list **each** medical radiological installation (for example, the name of the dental practice, or the hospital's name) and complete all fields for each installation listed.

The medical radiological installation address is the address where **each** of the undertaking's facilities are located.

A3. Information on medical radiological installation – Undertaking service type									For official use
No.	Medical radiological installation name	Medical radiological installation address (include Eircode)	Medical radiological installation service type						
			Dental	General Radiography	Radiotherapy	Nuclear Medicine	Interventional Radiology	Computed Tomography	
1.	X-ray Ltd (Cork)	1 Street, Cork	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.	X-ray Ltd (Dublin)	1 Street, Dublin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	X-ray Ltd (Limerick)	1 Street, Limerick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Tick all medical **radiological procedure types** that apply. Please refer to guidance below when completing this section.

## HIQA Form NF200

**A5. Information per medical radiological installation – List of all persons for whom the undertaking takes responsibility for regulatory compliance as described in scenario 3 in the Regulatory Notice.** **For official use**

Please complete the medical radiological installation name and the names of **all persons** for whom the undertaking takes responsibility for regulatory compliance as described in scenario 3 in the Regulatory Notice.

1.										
Medical radiological installation <b>name</b> ( <b>service location</b> )										
No.	Practitioner <b>Name</b>	No.	Practitioner <b>Name</b>	No.	Practitioner <b>Name</b>	No.	Practitioner <b>Name</b>	No.	Practitioner <b>Name</b>	
1.		7.		13.		19.		25.		
2.		8.		14.		20.		26.		
3.		9.		15.		21.		27.		
4.		10.		16.		22.		28.		
5.		11.		17.		23.		29.		
6.		12.		18.		24.		30.		

2.										
Medical radiological installation <b>name</b> ( <b>service location</b> )										
No.	Practitioner <b>Name</b>	No.	Practitioner <b>Name</b>	No.	Practitioner <b>Name</b>	No.	Practitioner <b>Name</b>	No.	Practitioner <b>Name</b>	
1.		7.		13.		19.		25.		
2.		8.		14.		20.		26.		
3.		9.		15.		21.		27.		
4.		10.		16.		22.		28.		
5.		11.		17.		23.		29.		
6.		12.		18.		24.		30.		

# ***HIQA Notification Forms***

- **List each medical radiological installation (clinic) in Form NF200**
- **Tick **Dental** if the clinic only carries out dental radiological procedures.**
- **If the dental imaging includes CBCT, please also tick **Computed Tomography** in addition to **Dental**.**
- **List each Practitioner (dentist) in Form NF200A**
- **No mention of any Fees!**



# ***HIQA Stakeholder Forums***

**HIQA held a series of Stakeholder Forums in Dublin, Galway and Cork in June 2019. Take home messages:**

- **Dental practices should have **well-documented** governance structures setting out the different levels of authority and responsibility.**
- **All members of the dental team must be aware of their responsibilities.**
- **Dental premises where there is a CBCT unit will receive a radiation self-assessment questionnaire in September/October 2019.**
- **Based on the responses HIQA may request supporting evidence.**
- **HIQA intends to start inspecting dental premises with CBCT units by the end of 2019.**
- **Other dental practices will receive self-assessment questionnaires and inspections in 2020.**



# *Current Registration System (UK)*

- Under IRR99 employers had to notify the Health & Safety Executive 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:
  - 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)

# ***Frequently Asked Questions***

**What is the current Irish law?**

- **Radiation Safety for Workers and the Public**
  - S.I. 30 of 2019
- **Radiation Safety for Patients**
  - S.I. 256 of 2018 (as amended in 2019)
- **S.I. 125 of 2000 and S.I. 478 of 2002 have been revoked.**

# *Are Film Badges Required?*

- **Personal dosimeters** (sometimes known as personnel dosimeters, or film badges) are only required where a risk assessment indicates that staff are liable to receive doses in excess of 1 mSv per year.
- Where staff remain at a distance greater than 2 metres from the patient's head during exposure, and the workload is fewer than 100 intraoral or 50 extraoral per week (or some pro-rata combination), **personal dosimeters are not normally required**.
- If staff are likely to exceed the 1 mSv dose limit a risk assessment shall be undertaken to determine if they should be categorised as **exposed workers** and be subject to additional monitoring.

# ***What about Lead Aprons?***

- **There is no justification for the routine use of lead aprons in dental radiography.**
- **There is no requirement to provide a lead apron to a pregnant patient.**
- **Where *comforters, carers or staff* are involved in assisting or holding patients during radiographic procedures, a lead apron shall be provided for their protection.**

# ***What about Thyroid Collars?***

- **Thyroid collars should be used in the few examinations where the thyroid may be in the main primary beam and the collar will not interfere with the image (e.g. cephalometric radiography but not panoramic radiography or CBCT).**
- **In practice, it is usually better to collimate so that the thyroid is outside the primary beam.**
- **The use of thyroid collars should also be considered when intraoral radiographs are taken with **circular collimators** on patients under 30 years of age.**

# *Where can I find a Radiation Protection Advisor (RPA)?*

## **In Ireland:**

- The EPA maintains a list of registered RPAs here:  
<https://www.epa.ie/radiation/regulation/rpa/rparegister>
- RPAs must have Category I Registration to act as a Radiation Protection Advisor for Medical, Dental, or Veterinary practices.

## **In the UK:**

- A list of RPAs is available at  
<http://www.rpa2000.org.uk/list-of-certificate-holders/>

# ***What is the role of the Radiation Protection Officer (RPO)?***

- **The RPA is usually an outside consultant**
- **The RPO is a member of staff designated by the undertaking to supervise the radiation protection arrangements**  
(used to be called “Radiation Protection Supervisor”)
- **The RPO’s responsibilities include:**
  - **liaising with the RPA**
  - **ensuring that adequate records are maintained**
  - **overseeing the safe operation of X-ray equipment**
  - **facilitating and/or providing training**
  - **consulting and liaising with the EPA as the regulatory authority.**
  - **supervising radiation protection arrangements to minimise personal radiation doses**
- **Where an authorisation covers multiple premises, there must be an RPO for each premises.**

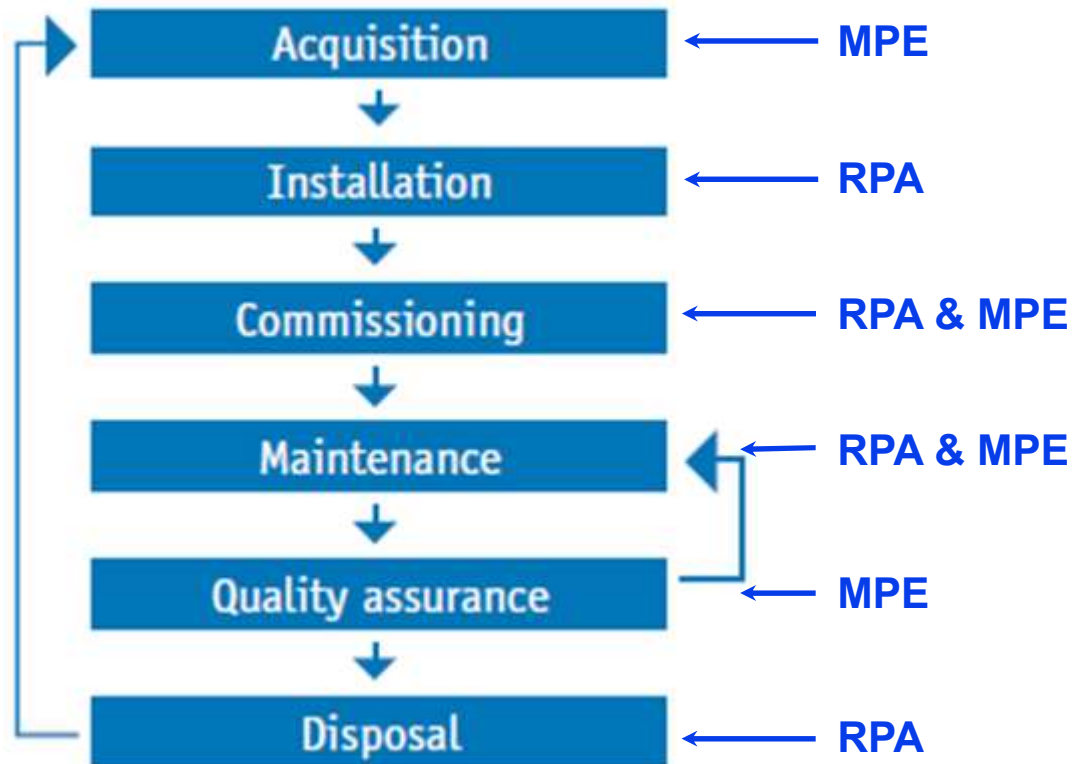
# ***What is the role of the Medical Physics Expert (MPE)?***

**S.I. 256 of 2018 defines Medical Physics Expert as:**

- **“An individual having the knowledge, training and experience to *act or give advice on matters relating to radiation physics applied to medical exposure*, whose competence in this respect is recognised by the Minister [for Health]”**
- **RPA's are concerned with *Radiation Safety for Workers and the Public***
- **MPE's are concerned with *Radiation Safety for Patients*, getting involved with Equipment Purchases, Quality Assurance and Optimisation**
- **At the moment, anyone on the Irish College of Physicists in Medicine (ICPM) register is entitled to act as an MPE**
- **In many cases, the RPA and the MPE will be one and the same person.**



# *Equipment Life Cycle*



- based on EPA Code of Practice Figure 2

# ***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.**

**Parameters such as kVp, mAs, DAP etc should be displayed to the operator and recorded in the patient's notes (preferably automatically).**

# ***Can my nurse take the CBCT scan?***

**The rules are the same for**

- **Intraoral radiographs**
- **Dental Panoramic Tomography (DPT)**
- **Cephalometric radiographs**
- **CBCT scans**
- **Any other type of dental X-ray**

**If your nurse is legally entitled to take intraorals or DPTs then he/she is entitled to take CBCT scans as well.**

# *How HIQA Inspectors Interpret the Regulations*

Regulation of  
Health and Social  
Care Services



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cailíocht Sláinte

Assessment-judgment framework  
for undertakings providing medical  
exposure to ionising radiation

Updated August 2019

*Safer Better Care*

# Who can be a Referrer?

Regulation 4	Referrers
Line of enquiry	<ol style="list-style-type: none"><li>1. Is the person making a referral for medical radiological procedures to a practitioner one of the following:<ol style="list-style-type: none"><li>a. <u>a registered nurse or registered midwife</u> 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</li><li>b. <u>a registered dentist</u> within the meaning of the Dentists Act 1985 (No. 9 of 1985)</li><li>c. <u>a registered medical practitioner</u> within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007)</li><li>d. a person whose name is entered in the register established and maintained by the <u>Radiographers Registration Board</u> pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or</li><li>e. a healthcare professional registered with the General Medical Council of the United Kingdom, and <u>practising medicine in Northern Ireland</u>, who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner?</li></ol></li><li>2. Does a person only carry out a medical radiological procedure on the basis of a referral from a referrer?</li></ol>

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# ***No-Deal Brexit***

**“In the event of the United Kingdom leaving the European Union without a withdrawal agreement, [the Dental Council](#) has agreed to continue to recognise UK qualifications obtained before 30 June 2021 as being equivalent to the minimum standards set out in the Professional Qualifications Directives.**

**This means applications for registration from holders of UK qualifications obtained before this date will be considered by the Dental Council in a manner similar to holders of other EU qualifications.”**

<http://www.dentalcouncil.ie/Dentist-application-details.php>

# Who can be a Practitioner?

Regulation 5	Practitioners
Line of enquiry	<p>1. Is the person who is taking clinical responsibility for an individual medical exposure one of the practitioners listed below:</p> <ul style="list-style-type: none"><li>a. a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985)</li><li>b. a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or</li><li>c. 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)?</li></ul>

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# Who can carry out Practical Aspects?

Regulation 10	Responsibilities
Line of enquiry	<p>4. Are practical aspects of a medical radiological procedure only delegated by:</p> <ul style="list-style-type: none"><li>a. <u>the undertaking</u>, or</li><li>b. <u>the practitioner</u></li></ul> <p>as appropriate, to one or more individuals, who are <u>registered or recognised by:</u></p> <ul style="list-style-type: none"><li>i. the Dental Council</li><li>ii. the Minister</li><li>iii. the Nursing and Midwifery Board of Ireland</li><li>iv. the Radiographers Registration Board or</li><li>v. the Medical Council</li></ul> <p>as appropriate, and that have <u>completed a course in radiation safety</u> as prescribed under Regulation 22(3) by the appropriate body?</p>

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# *So who can press the button?*

- The **Practitioner** can either perform the procedure, or delegate it to a person registered or recognised by the Dental Council, who has successfully completed a recognised course in radiation safety.
- **Registered dentists, registered dental nurses, registered dental hygienists, and registered clinical dental technicians** may perform x-ray procedures provided that:
  1. they have completed additional training in radiation safety
  2. the procedure has been authorised by a Practitioner.
- The Practitioner retains clinical responsibility for the exposure, even though the practical aspects have been delegated.

# *Courses in Radiation Safety*

**Dublin Dental Hospital Certificate in Dental Radiography:**  
<https://www.dentalhospital.ie/education/postgraduate-programmes/taught-postgraduate-programmes/certificate-in-dental-radiography>



**Cork Dental Hospital Online Dental Radiography Course**  
<https://www.ucc.ie/en/dentalschool/documents/>



# ***Are there Radiation Dose Limits for Patients?***

- **While there are no specified dose limits for patients, there is a responsibility to ensure that all exposures are **justified** and **optimised**.**
- **All exposures must have a net benefit, and must be kept as low as reasonably achievable consistent with obtaining the required diagnostic information.**

# ***What about Dose Constraints, are they Dose Limits?***

- **Yes – but they are not for Patients!**
- **Dose Constraints are a requirement of S.I. 256 in the context of **carers and comforters** and for **volunteers** participating in research programs.**
- **HIQA is responsible for setting dose constraints, after consultation with the Medical and Dental Councils.**
- **“Helpers” should be over 18 years old and must not be pregnant**
- **Staff members who assist the patient as part of their job are not considered “helpers” and therefore are subject to the Dose Limit of 1mSv per year for members of the public.**

# ***What About Diagnostic Reference Levels (DRLs), are they Dose Limits?***

- **They are not Dose Limits – they are guidelines!**
- **DRLs are dose levels which are not expected to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.**
- **HIQA is responsible for setting DRLs, after consultation with the Medical and Dental Councils.**
- **For intra-oral radiographs the National DRL in Ireland was set at 4 mGy (entrance dose) by the Dental Council.**
- **There are no National DRLs for DPTs or CBCT scans in Ireland at the present time (but each practice is responsible for setting its own Local DRLs).**

## ***Dose Reference Levels (UK)***

- For intra-orals the National DRL in the UK is **1.2 mGy** (entrance dose) for adults and **0.7 mGy** for children.
- For DPTs the National DRL in the UK is **81 mGy.cm<sup>2</sup>** (Dose Area Product, DAP) for adults and **60 mGy.cm<sup>2</sup>** for children.
- For CBCT the National DRL in the UK is **265 mGy.cm<sup>2</sup>** (DAP) for adults and **170 mGy.cm<sup>2</sup>** for children.  
This is for a single tooth implant or impacted canine (e.g. 5x5 field size).

# ***What about Pregnant Patients?***

**Regulation 16 of S.I. 256 relates to exposures of patients who are or may be pregnant.**

- **European Commission Guidance which has been adopted by the Medical Council indicates that *special precautions are not indicated for low dose procedures* or where the uterus is not in the primary beam (e.g. in dental radiography).**
- **There is a requirement in S.I. 256 to ask a female of childbearing age if she is pregnant, and record her reply.**
- **There is no requirement to use lead aprons for pregnant patients.**
- **Vertex occlusion projections (which might irradiate the foetus) are prohibited by the Dental Council.**

# ***Which Incidents need to be reported to the EPA?***

- Any incident involving the exposure of any person arising from a **design flaw** malfunction or incorrect operation of X-ray equipment
- Any incident involving a dose, or suspected dose, in excess of any dose limits for staff and members of the public  
(1mSv p.a. is the lowest dose limit)  
(a single exposure is very unlikely to exceed 1mSv in normal dental practice)
- The theft or loss of X-ray equipment
- Any inappropriate or unauthorised use of X-ray equipment.

Equipment related safety incidents should be notified to the Health Products Regulatory Authority (HPRA) [www.hpra.ie](http://www.hpra.ie)



# *Which Incidents need to be reported to HIQA?*



Regulation of  
Health and Social  
Care Services

## **Statutory notifications for accidental or unintended medical exposures to ionising radiation**

Guidance for undertakings carrying out medical exposures to ionising radiation on the statutory requirement to notify significant accidental or unintended exposure events to HIQA

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**Table 1. Significant events of accidental or unintended exposures that are notifiable to HIQA**

<b>1</b>	Administration of a Reference Point Air Kerma ( $K_{a,r}$ ) of 15 Gray (Gy) or greater as a result of a single interventional radiological procedure (including interventional cardiology) or a cumulative $K_{a,r}$ dose of 15 Gy arising from a series of interventional radiological procedures carried out over a six month period
<b>2</b>	Tissue reactions (deterministic effects) as a result of interventional radiology/cardiology
<b>3</b>	Diagnostic overexposure of an adult of more than twice the exposure intended that leads to a dose that is greater than 10 millisievert (mSv) or 20 times the dose intended
<b>4</b>	Diagnostic overexposure of a child of more than twice the exposure intended that leads to a dose that is greater than 3 millisievert (mSv) or 15 times the dose intended
<b>5</b>	Dose given to comforters and carers greater than 3 millisievert (mSv) for adults under 60 years of age and 15 millisievert (mSv) for those over 60 years of age
<b>6</b>	Dose to a breastfed child greater than 1 millisievert (mSv)
<b>7</b>	Inadvertent dose to a foetus greater than 1 milligray (mGy)
<b>8</b>	Incorrect anatomy greater than 1 millisievert (mSv)

**Almost impossible to exceed any of the above in a normal dental practice**

<b>9</b>	Incorrect procedure greater than 1 millisievert (mSv)
<b>10</b>	Incorrect radiopharmaceutical
<b>11</b>	Therapeutic dose given instead of diagnostic dose, for example, in the use of radioiodine
<b>12</b>	Administered activity variation of 20% from intended dose during use of therapeutic nuclear medicine
<b>13</b>	No dose intended/incorrect service user exposed to greater than 1 millisievert (mSv)
<b>14</b>	Radiotherapy dose or volume variation of 10% or greater from the total prescribed
<b>15</b>	Radiotherapy dose or volume variation of 20% or greater from the fraction prescribed
<b>16</b>	Unexpected tissue reactions (deterministic effects) as a result of radiotherapy treatment
<b>17</b>	Any other radiation exposure incident considered to have serious service user safety implications, for example, multiple non-notifiable incidents of a similar nature

**Almost impossible to exceed any of the above in a normal dental practice**

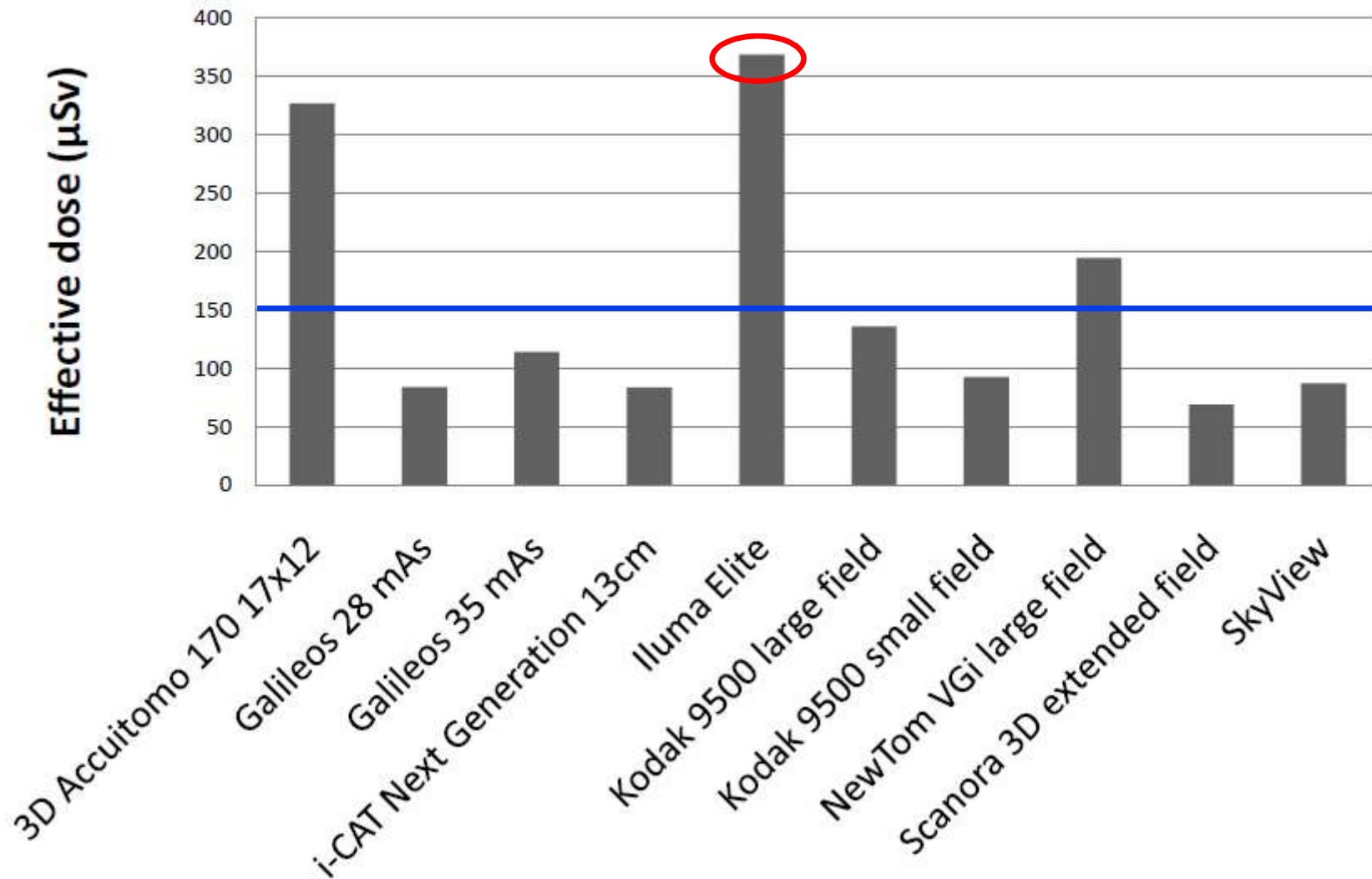
## Appendix B: Examples of notifiable, non-notifiable and near miss incidents

Type of event	Radiotherapy	Radiology	Nuclear Medicine	Dental
<b>Significant event (Notifiable)</b>	A service user receives a total dose or volume variation of greater than or less than 20% from the fraction prescribed.	A service user who had a chest X-ray ordered receives a computed tomography thoracic examination instead of the requested chest X-ray.	A service user presented for a technetium bone scan; however, the wrong radiopharmaceutical was administered and a diagnostic scan was not captured. This resulted in an effective dose of greater than 1mSv.	An incorrect service user receives a cone beam computed tomography examination. This resulted in an unintended dose greater than 1mSv.
<b>Non-notifiable</b>	A service user receives a minor tissue reaction which would be reasonably expected to occur in service users undergoing this treatment when national and international evidence-based best practice has been adhered to.	A service user request states that the service user is for an X-ray of the left hand for following a fall. The radiograph of the left hand is completed; however, after the exam, the service user queries why the right hand had been X-rayed instead of the left.	A service user presented for a diagnostic thyroid scan. During administration the injection activity differs by greater than 20% from the intended activity.	A radiograph was performed and it was noted that the incorrect body region had been imaged.
<b>Near Miss</b>	During identification check, service user A's date of birth differs from the request form, despite the name being correct. This is queried with the referrer, who notes that they have two service users of the same name and service user A was not meant to have the procedure. No inadvertent dose was received by the service user.			

**Very difficult to deliver 1mSv on any CBCT scanner currently on the market**



## Effective dose for large field CBCTs



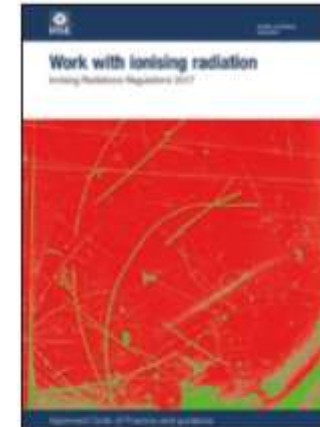
Prof. Ria Bogaerts, Katholieke Universiteit Leuven, March 2011

# ***Guidance Documents (Ireland)***

- **“The Dental Practice Radiation File” by Dr Andrew Bolas may be found at**  
<https://www.hse.ie/eng/about/qavd/meru/dental-practice-radiation-file.pdf>
- **EPA Guidance Documents are available at**  
<https://www.epa.ie/radiation/regulation/guidance/>
- **HIQA Guidance Documents are available at**  
<https://www.hiqa.ie/reports-and-publications/guide/guidance-providers-undertakings-medical-exposures>

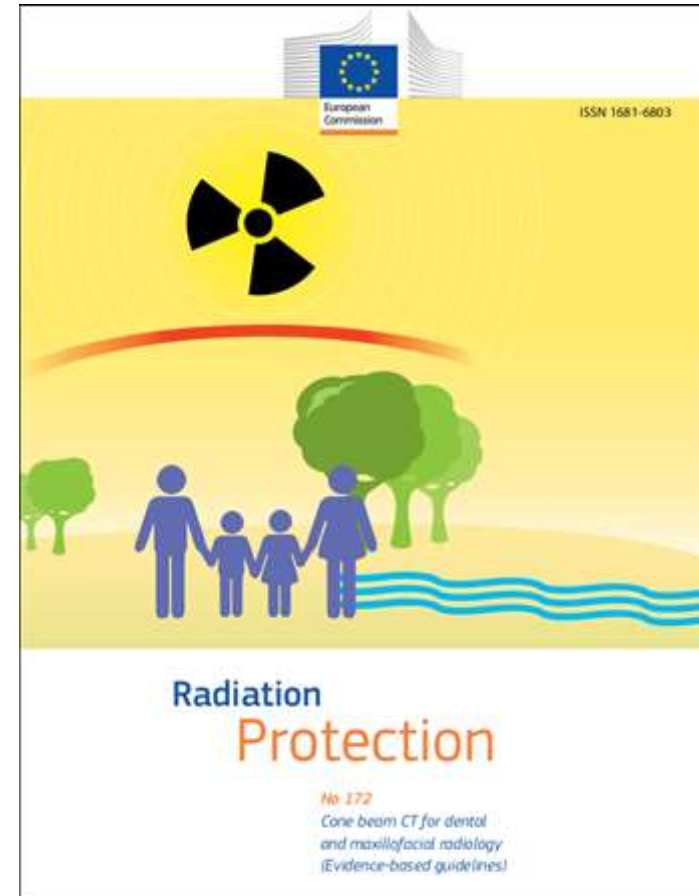
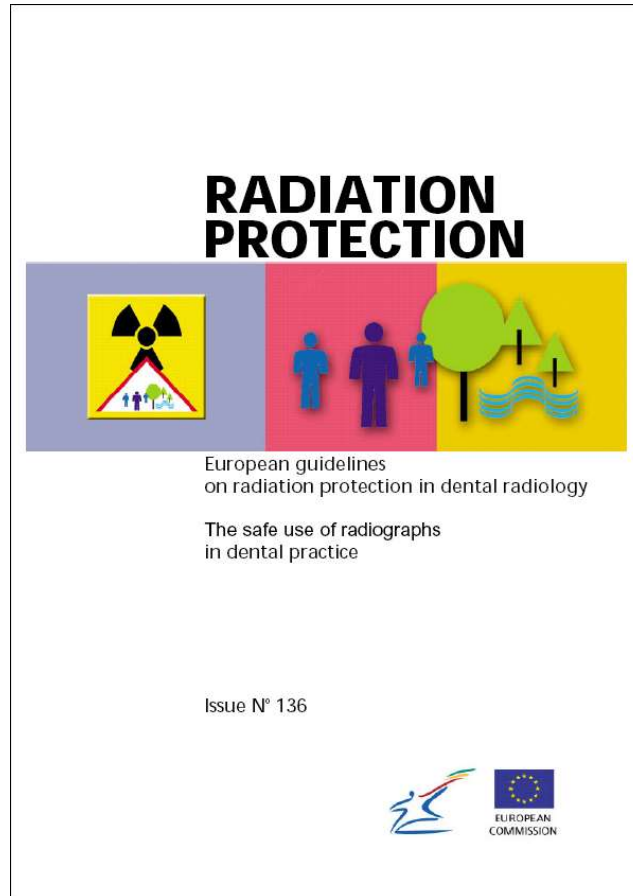
# *Guidance Documents (UK)*

- **New Approved Code of Practice L121 (costs £27)**  
[www.hse.gov.uk/pubns/priced/l121.pdf](http://www.hse.gov.uk/pubns/priced/l121.pdf)
- **Revised Medical and Dental Guidance Notes – to be published.**
- **Guidance Notes for Dental Practitioners on the Safe Use of X-Ray Equipment – PHE updates planned.**
- **IR(ME)R Companion Guide – to be published.**
- **IR(ME)R 2017 legislation is available here:**  
[www.legislation.gov.uk/ukxi/2017/1322/pdfs/ukxi\\_20171322\\_en.pdf](http://www.legislation.gov.uk/ukxi/2017/1322/pdfs/ukxi_20171322_en.pdf)



L121 (Second edition)  
Published 2018

# Guidance Documents (Europe)



<https://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/scientific-seminars-and-publications/radiation-protection-publications>





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# *Due Diligence*

**In proceedings for an offence under the Regulations, it is a defence to show that:**

- (a) commission of the offence was due to a **reasonable mistake****
- (b) the person charged with the offence exercised **due diligence** and took all reasonable precautions to avoid commission of the offence.**

**Document everything!**

***The End***

**Thank you for listening.**

## ***Current Registration System (UK) cont.***

- **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) don't 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/>**
- **Dental Practices also have to register with the Care Quality Commission (CQC).**

# ***Referral Criteria***

**S.I. 256 of 2018 Regulation 13 states:**

**“(1) An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.**

**(2) An undertaking shall ensure that **information relating to patient exposure forms part of the report** of the medical radiological procedure.**

**(3) An undertaking shall ensure that referral guidelines for medical imaging, **taking into account the radiation doses**, are available to referrers.**

**(4) An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Minister.”**

## ***Referral Criteria (2)***

- **In a dental practice, where a limited number of radiological procedures are performed, a written list of the clinical indications for each procedure (together with representative radiation doses) should be compiled and made available to Referrers.**
- **Alternatively, the practice could adopt a set of national or professional referral guidelines:**
  - **FGDP(UK) “Selection Criteria for Dental Radiography”**
  - **European Guidelines on Radiation Protection in Dental Radiography**
  - **American Dental Association “Dental Radiographic Examinations”**

# ***What about Dose Constraints, are they Dose Limits?***

- **Yes – but they are not for Patients!**
- **Dose Constraints are a requirement of S.I. 256 in the context of **carers and comforters** and for **volunteers** participating in research programs.**
- **HIQA is responsible for setting dose constraints, after consultation with the Medical and Dental Councils.**
- **The Dental Council has set the following dose constraints for the exposure of those individuals knowingly and willingly helping in the support and comfort of patients undergoing medical diagnosis or treatment (“helpers”, aka **carers and comforters**):**
  - **15mSv for those over 60 years old**
  - **3mSv for those less than 60 years old**
- **“Helpers” should be over 18 years old and must not be pregnant**
- **Staff members who assist the patient as part of their job are not considered “helpers” and therefore are subject to the Dose Limit of 1mSv per year for members of the public.**

**Figure 1. Example of an unintended medical exposure which may meet the criteria for mandatory notification to HIQA and the EPA**

Where a patient is incorrectly identified and receives an exposure that is not intended for them of over 1mSv of ionising radiation, this should be classified as both an unintended medical exposure under these regulations, and an exposure to ionising radiation of a member of the public under the parallel EPA legislation. Therefore, in this particular case, this incident is notifiable to both **HIQA** and the **EPA**.

**It is good practice to keep a local record of unintended exposures and near misses, even if you don't have to report them.**