

Code of Practice on the application of Ionising Radiation Regulations for Dentistry in Ireland

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New System of Regulatory Control in Ireland

The **Environmental Protection Agency** (EPA) is the Competent Authority for implementing and enforcing the provisions of IRR19 (S.I. 30 of 2019)

The **Health Information and Quality Authority** (HIQA) is the Competent Authority for implementing and enforcing the provisions of S.I. 256 of 2018

To legally carry out oral radiology in Ireland, it is necessary for Undertakings to comply with the provisions of both IRR19 and S.I. 256 of 2018

[Undertaking means a natural or legal person with legal responsibility for carrying out the practice of oral radiology ie the operation of x-ray equipment for the purposes of oral radiology]

Summary of Regulatory System

Protection Remit	Regulations	Competent Authority/Regulator
Workers and Members of the Public	IRR 19	EPA
Patients	S.I. No. 256 2018	HIQA

New System of Regulatory Control in Ireland

- Regulation should be risk-based, with the greatest regulatory effort being directed towards higher risk activities.
- Under the new system higher risk activities will be subject to a more rigorous form of Authorisation; will be inspected more frequently and will be subject to greater enforcement focus
- Introduces a Graded Authorisation System of Radiological Control into Ireland

Graded Authorisation System of Regulatory Control – Oral Radiology

Depending on the nature of the radiological practice an Authorisation may be in the form of Registration or Licensing

- *Registration* is appropriate for lower risk oral radiology procedures carried out using:
 - *Intraoral Equipment* or
 - *Extraoral Equipment (including Panoramic and Cephalometry)* or
 - *Cone Beam Computed Tomography (CBCT) in a Dental Clinic.*
- *Licensing* is appropriate where oral radiology procedures are undertaken using Hand-Held Equipment

Irrespective of the form of Authorisation, all Undertakings/Dentists carrying out oral radiology must fully comply with the relevant provisions of IRR19

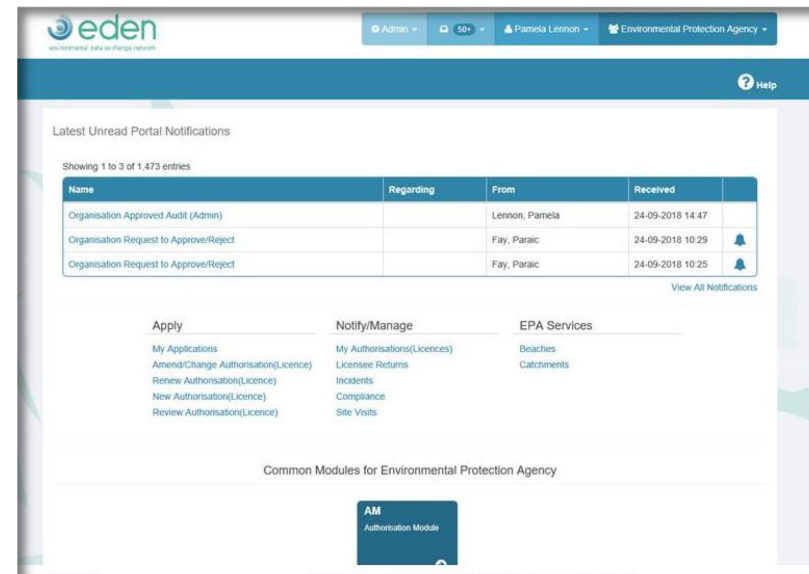
Significant Differences between the Forms of Authorisation

	Registration	Licensing
Duration	Indefinite <i>(unless surrendered or revoked)</i>	10 years (Renewable)
Documentation to be submitted With Applications	Self-Declaration <i>[Confirming Compliance with the requirements for Registration]</i>	- Risk Assessment - Additional Radiation Safety Procedures - Other information as specified by the EPA

Only dental practices with hand held dental x-ray units will be subject to Licensing

Application Process

- Applications through EDEN
- User guided through Registration or Licencing process depending on the nature of the radiology procedures
- For Registration the process can be completed entirely Online
- Registration includes Self Declaration and is based on assumption of Compliance



Registration: Self-Declaration by Registrants

Undertaking/Dentist must self-declare that they have:

- *Completed a Risk Assessment in consultation with an RPA to identify any necessary protective measures (No longer appoint in writing)*
- *Implemented the Dental Code of Practice and any additional measures identified in the Risk Assessment*
- *Designated a Radiation Protection Officer (RPO)*
- *Provided staff with the appropriate training in Radiation Protection*
- *Developed procedures to be followed in the event of an Incident liable to have radiation safety implications for Workers and Members of the Public*

The Undertaking

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.

The Undertaking/Dentist's responsibilities shall include but not be exclusive to the following:

- *Ensuring that risks to staff and members of the public from all activities involving the use of ionising radiation are adequately assessed*
- *Implementation of arrangements for the radiation protection of all staff and members of the public*
- *Designation of an RPO, who shall report directly to the Undertaking/Dentist*

Governance and Responsibilities

- Governance arrangements associated with radiation protection must be clearly defined and have been notified to Staff, as appropriate

In the case of large institutions these arrangements may include a Radiation Safety Committee

- All Staff have an obligation to comply with the requirements outlined in the Dental Code and any additional Safety Procedures

Undertaking; Radiation Protection Adviser (RPA); Radiation Protection Officer (RPO)

Undertaking - Condt

- Provision of appropriate resources and training to the RPO to effectively carry out their responsibilities as specified in Dental Code
- Seeking advice from an RPA to ensure compliance with IRR19
- Providing the RPA with access, adequate information and facilities for the discharge of his/her functions
- Ensuring that X-Ray equipment is operated only by appropriately trained staff and under the supervision of a Dental Practitioner

Undertaking - Condt

- Ensuring that X-Ray equipment is appropriately Installed, Commissioned and subject to Quality Assurance
- Ensuring, where the Authorisation covers multiple premises, that local governance arrangements are in place
- Ensuring that Documentation relevant to compliance with IRR19 is maintained and accessible as required by the EPA.

Radiation Protection Adviser (RPA)

In accordance with the Regulations, the Undertaking/Dentist shall seek advice from an RPA on a range of matters including but not limited to:

- Preparation or update of Risk Assessments and Additional Safety Procedures where relevant
- Estimation of doses to Workers and Members of the Public
- Classification of Areas and Categorisation of Workers
- Quality Assurance Measures
- Radiation Protection training of relevant Staff
- Dose Monitoring where appropriate

Radiation Protection Adviser (RPA) - Cond

- Safety aspects associated with the acquisition of any new X-Ray equipment
- Commissioning and Acceptance into service of new X-Ray equipment;
- Preparation and submission of Incident Reports;
- Design (including shielding specifications) of any new Buildings or Facilities;
- Modifications to any existing X-Ray equipment or Facilities;
- Changes to the use of any Buildings or adjoining Buildings where X-Ray equipment is in use

Radiation Protection Officer (RPO)

The RPO shall be designated by the Undertaking/Dentist to supervise or implement the radiation protection arrangements and shall report directly to the Undertaking/Dentist.

The RPO's responsibilities shall include but not be exclusive to the following:

- Liaise with the RPA, as required, to comply with IRR19
- Ensure that adequate Records are maintained to provide assurance that the Dental Facility complies with the requirements outlined in the Dental Code
- Oversee the ongoing safe operation of X-Ray equipment
- Monitor implementation of the Dental Code and additional Safety Procedures where applicable

Radiation Protection Officer (RPO) - Cond

- *Facilitate and/or provide Training to Staff, as appropriate*
- *Maintain an adequate record of all X-ray units associated with the Authorisation*
- *Maintain relevant documentation in a manner that is accessible by the EPA*
- *Consult and liaise with the EPA as the Regulatory Authority*
- *Supervise radiation protection arrangements in order to minimise personal radiation doses*
- *In cases of multiple premises - the Governance Arrangements must ensure that the RPO functions are appropriately carried out at each location.*

This may necessitate the nomination of additional RPOs and/or named Member(s) of Staff with relevant experience to support the RPO(s).

Risk Assessment

- Prior to acquiring X-Ray equipment, the Undertaking/Dentist must make an assessment of the nature and magnitude of the risks of exposure to ionising radiation for workers and members of the public
- The Risk Assessment must take account of the nature and magnitude of the risks of exposure to radiation for staff and members of the public from normal operation as well as from reasonably foreseeable incidents (such as equipment failure or operator errors)
- Must be Reviewed in all circumstances where it reasonable to believe that the risk assessment is no longer appropriate.

General Room Design Considerations

- Operator must be able to observe the patient
- Operator must be able to control access to the room
- Exposure isolation switches must be located at a point more than 2m from the patients head
- It shall be ensured that measures are in place to prevent unauthorised exposures
- If more than one x-ray unit is in the room it must not be possible to inadvertently energise the wrong x-ray unit.

General Room Design Considerations

- No structural shielding is required if the workload is fewer than 20 intraoral exposures per week and the distance between the patient and the wall or other boundary is at least 2 metres
- For all other circumstances the requirement for shielding should be determined from the Risk Assessment.

New Equipment

In Specifying and Acquiring new Dental X-Ray equipment, the Undertaking/Dentist must have regard to the following:

- All equipment must be CE marked and be approved for use under the Medical Devices Regulations
- Account must be taken of any relevant advice or guidance issued by HIQA, the Health Products Regulatory Authority (HPRA), the Dental Council, the European Commission or other Relevant Authorities

Installation of Equipment

- X-Ray Equipment must be installed by suitably Competent and Qualified Installers *(Now subject to Registration)*
- The Installer shall provide a written Installation Report, which should include details of the safety checks carried out
- This Installation Report should be retained and be available to your RPA and to an EPA Inspector on request.
- These provisions also apply to X-Ray Equipment which is being Relocated.

Commissioning

Dental X-Ray Equipment shall not be used on Patients until it has been Commissioned

Commissioning is a set of Acceptance Tests carried out, independent of the Installer, by a suitably qualified person on behalf of the Undertaking/Dentist in consultation with an RPA.

These tests are designed to ensure that the equipment is safe to use and to establish baseline values against which the results of routine Quality Assurance Tests can be compared. Commissioning reports must be retained and must include:

- *The results of performance tests against the parameters listed in the Dental Code*
- *A Statement as to whether each Test Result falls within the Acceptable Criteria*
- *The Standards (EU, international, etc.) against which these Results have been assessed*

These provisions also apply to X-Ray equipment which is being relocated or has undergone major modifications affecting radiation output eg the fitting of a new X-ray tube.

Maintenance and Servicing of Equipment

- All X-Ray units shall be maintained in good working condition and serviced as per Manufacturer's instructions and any defects in their performance or safety shall be corrected as soon as possible by a suitably qualified and Competent Person
- Equipment deemed to have a fault that may impact on radiation protection and safety must be taken out of service until the fault is rectified.
- Maintenance Reports must be retained
- The advice of an RPA shall be sought on an appropriate Preventive Maintenance Schedule taking account of the Manufacturer's Recommendations, Workload, Age of the equipment and other relevant factors.

Quality Assurance (QA)

- All X-Ray units must be subject to Quality Assurance assessment every two years
- The parameters to be assessed and the acceptable tolerances should be determined by the RPA considering International guidance, the Manufacturer's recommendations and any relevant factors arising from the Risk Assessment
- In general, the parameters assessed as part of the Quality Assurance Testing will be similar to those assessed during Commissioning. Quality Assurance Reports must be retained

Operating Procedures General

- Operator must stand at least 2m from x-ray tube head and control access to the area
- Operator or other staff must not be exposed to the primary beam during radiography
- The primary beam shall not be directed through unshielded doors, floors windows or ceilings behind which a person may be situated
- During radiography the operator must position themselves so that they can observe the patient and the x-ray exposure indicator
- Handheld equipment shall only be used with the x-ray beam in the horizontal plane and with the back scatter shield in place

Training General

- Undertaking must provide training on the following
 - Code of Practice
 - The safety features of x-ray equipment
 - Procedures to be followed for the safe operation of the equipment
 - Procedures to be followed following an equipment malfunction
 - General principles of radiation protection
 - Health risks of exposure to ionising radiation
 - The importance of the risk assessment and the operators input into this document
 - Legal responsibilities and duties of an RPO
 - Understanding of relevant legislation and the Code
 - Understanding of the conditions attached to an authorisation