Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Joint Webinar for Dental Practices using X-ray and Cone Beam Computed Tomography (CBCT) units

Frequently Asked Questions (FAQs)

Introduction

This document serves as a resource for dental practices to ensure compliance with the regulatory requirements for the use of X-ray and Cone Beam Computed Tomography (CBCT) units in Ireland. It provides clear and practical answers to frequently asked questions (FAQs) that were raised during a webinar jointly hosted by the Environmental Protection Agency (EPA) and the Health Information and Quality Authority (HIQA) on 17 October 2024. The content is tailored to support dental professionals, practice owners, and undertakings in understanding their responsibilities and implementing best practices for radiation protection and compliance.

The FAQs address key areas, including the declaration process for undertakings, responsibilities related to radiation safety, the use and authorisation of handheld X-ray units, and the introduction of new equipment. Additional topics such as clinical audit requirements, training standards for staff, and guidance on Diagnostic Reference Levels (DRLs) are also covered. Each section is designed to clarify the expectations of both the EPA and HIQA while aligning with current legislation, including S.I. 256 of 2018 and the Ionising Radiation Regulations (IRR19).

This resource aims to enhance awareness of the regulatory framework, promote patient and operator safety, and provide practical steps for compliance. While it is not exhaustive, the document references additional tools, templates, and guidance available from the EPA and HIQA to further assist undertakings. By following the guidance outlined here, dental practices can ensure they meet the required standards for providing safe and effective radiological services.

About this document

This document comprises a compilation of questions submitted by attendees of a webinar held jointly by HIQA and EPA on 17 October 2024.

The submitted questions were collated, grouped and organised thematically. The content of this document is not intended to be a comprehensive summary of every aspect of the regulations.

Questions are addressed by either the relevant regulator or both regulators where applicable. Answers addressed by HIQA are in **blue** and answers addressed by the EPA are in **green**. The different regulators can be further identified by their logos at the start of each question.

Please note that these responses only apply to compliance with:

- S.I. 256 of 2018 (as amended),
- the Radiological Protection Act 1991 (as amended)
- S.I. 30 of 2019 (also known as Ionising Radiation Regulations 2019 or IRR19)

The responses do not cover any other legislation relevant to dentistry.

While the undertaking has overall statutory responsibility to ensure that they comply with the regulations, all personnel who are conducting medical exposures in dental services should be aware of their role in terms of regulatory compliance.

HIQA has a dedicated page on its website for Ionising Radiation which provides specific information about the regulation of medical exposures. This can be accessed by clicking here.

The EPA also has relevant information on its website, available here. The EPA's Code of Practice on the Application of the IRR19 in Dentistry is available here.

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Responsibility for Radiation Safety

Q. Do all associate dentists need to declare to HIQA as an undertaking?

A. No. In most cases, the principal dentist, practice owner, or company owner is the undertaking responsible for radiation protection of service users. Staff conducting dental exposures to ionising radiation operate under the governance and oversight of the principal dentist or owner of the practice, who is the undertaking.

This means that associate dentists agree to adhere to the undertaking's local procedures, protocols and rules and contribute to the clinical audit programme set by the undertaking. For more information, please see the *Regulatory Notice* and *Undertaking Information Handbook* which explains how such a relationship might work.

In these circumstances it is important that:

- The undertaking clearly allocates responsibility for the radiation protection of service users.
- This allocation is documented, communicated and understood by all relevant staff, including associate dentists.

If, as an associate dentist, you do not think that you meet these criteria, you may need to declare to HIQA as a separate undertaking. If you are unsure, please contact radiationprotection@hiqa.ie and we will discuss your individual circumstances with you.

Please note: A dentist working at a practice independently (for example, leasing a room or not under the oversight of the principle dentist or practice owner) may be considered a separate undertaking.

Each individual undertaking must ensure compliance with the regulatory requirements and be able to provide evidence of compliance. If an undertaking is found to be non-compliant, they are responsible for taking action to come into compliance and may be subject to enforcement by HIQA if they fail to do so.

Q. What if I work in many different dental practices?

A. Associate dentists working at one or several practices should identify the undertaking for each practice. They must fully understand

their roles and responsibilities in relation to patient radiation protection and regulatory compliance, as highlighted by the undertaking for each practice they work in.

There may be different arrangements in place in each practice. While you may not need to declare as an undertaking for one practice, circumstances in another practice require you to declare.

Further details about undertakings are outlined in the *Undertaking Information Handbook*.

If you have any queries about your individual circumstances, please contact radiationprotection@hiqa.ie and we will discuss the requirements with you.

Q. Do all associate dentists need to declare to the EPA as an undertaking?

A. No. The undertaking is the person with primary legal responsibility for compliance with the regulations and the conditions of their authorisation. In dentistry, this is usually —but not always —the principal dentist or practice owner.

If you are self-employed and working in a dental practice using the undertaking's X-ray equipment, there must be a clear division of responsibilities between yourself and the undertaking. Responsibilities for the protection of workers may fall to the undertaking, the self-employed worker, or both depending on specific circumstances.

It is vital that contractual agreements between undertakings and employers clearly specify the responsibilities for radiation protection at each step of a planned exposure.

For further information see Sections 3.4 and 3.6 of the EPA's *Guidance for undertakings on the application of the Ionising Radiation Regulations (IRR19)*.

Q. What if I work in many different dental practices?

A. Dose limits apply to the **sum of all occupational exposures** received by an individual across all planned exposure situations. If a worker may be exposed to radiation in multiple workplaces under the control of different undertakings, the risk assessment and categorisation of the worker, must take into account all work performed by the individual, including work performed in other workplaces.

Exposed workers are required, under the regulations, to disclose to the undertaking any details of other undertakings under whose control they may be exposed.

Handheld Devices

Q. For undertakings already licensed for a handheld unit, will the justification issue be raised when the licence is renewed?

A. Justification will be sought for any replacement or additional unit(s). Please ensure that your authorisation has the correct serial number for your current handheld unit.

Q. What is the cost of an EPA authorisation?

A. The fees are publicly available on the EPA website. The registration fee is a once-off payment of €300, and the registration is valid indefinitely. If an undertaking is carrying out registered dental radiology practices at multiple premises, an additional fee of €75 will apply for each premise added to the registration.

The application fee for a licence to use a handheld unit is currently €1000. A licence is valid for 10 years, with a renewal fee of €250. Annual enforcement fees also apply to a licence, which in 2024 was €581, but is subject to review.

Q. Why must a handheld unit be licensed if it is operated with all the safety features in place?

A. Handheld intraoral X-ray equipment has the potential to result in exposure of higher doses to the operator and members of the public in comparison to conventional dental systems mounted on a wall or stand. As a result, the use of handheld intra-oral X-ray equipment is subject to licensing, even if operated with all the safety features in place.

Q. How can I get more information about authorisation of handheld X-ray units and what is needed for the EPA to grant a licence?

A. The use of handheld X-ray units is discouraged except in special circumstances. This aligns with European guidance which recommends that generally the use of

handheld equipment should be limited to situations where the use of a fixed or semi-mobile units is impractical and should not be considered as a replacement for fixed or semi-mobile units. Justification for the use of handheld X-ray units is assessed on a case-by-case basis, considering factors specific to each individual application.

As in other EU member states, justification must be robust, with stringent safety measures in place to protect both operators and patients from potential radiation hazards.

Q. How do I protect myself while operating a handheld X-ray system in the dental practice?

A.

- Ensure that you have received both basic radiation protection training and training on how to use the handheld unit – and that training is repeated at appropriate intervals.
- As per one of the licence conditions, the handheld unit should always be operated with an appropriate backscatter shield, positioned at the outer end of the collimator cone. It should be noted that, for the backscatter shield to offer maximum protection for the operator, the X-ray beam must be confined to the horizontal plane.
- The risk assessment will identify any additional control measures required for safe working practices.
- If the risk assessment has concluded that you should wear a dosimetry badge, ensure that it is worn correctly each time you take an X-ray; stored correctly when not in use; and returned promptly at the end of each wear period.
- Be familiar with the emergency procedures to follow in the event of an accident or incident such as:
  - damage to the equipment affecting the shielding,
  - accidental exposure of a person (other than the patient) to the X-ray beam,
  - failure of the timer to terminate the exposure after the pre-set time has elapsed,
  - loss or theft of the equipment.
- Ensure that quality assurance (QA) and maintenance are carried out on the unit at the frequency indicated in the *EPA's Code of Practice on the Application of the Ionising Radiation Regulations (IRR19) in Dentistry 2019* (EPA-Ionising-Radiation-Dentistry.pdf) and as per manufacturer's instructions, respectively.

New Equipment

Q. Do I need to inform HIQA when I purchase new equipment?

A. For existing undertakings adding new equipment, the following should be taken into account:

- An existing undertaking only needs to update HIQA about the purchase of new equipment if the new equipment changes the service type of the practice.
- Undertakings who carry out only intra-oral or orthopantomography (OPG) X-rays have the service type 'dental'.
- If an undertaking adds a new intra-oral or OPG unit, they do not need to inform HIQA.
- If this undertaking purchases a CBCT, this is considered as a different service type. One month before using the CBCT equipment, an ***NF201C*** notification form must be submitted to HIQA with both service types ticked, namely 'dental' and 'computed tomography'.
- An undertaking who previously informed HIQA of its 'computed tomography' service type does not need to inform HIQA if they buy a new CBCT unit.
- Undertakings should ensure that HIQA has the most up-to-date contact details for them. If you change your email address or the staff details previously provided, for example the designated manager, submit the relevant form to HIQA as soon as possible.
- All notification forms are available here.

For new undertakings, the following should be taken into account:

- All undertakings must declare all dental practices for which they are responsible to HIQA one month prior to starting to carry out X-rays.
- This must be done using an ***NF200 Declaration of Undertaking*** form available here.
- Please see the *Undertaking Information Handbook* for guidance on how to fill out this form.
- Some key tips are as follows:
    - The undertaking name and details refer to the legal entity.
    - If you are a sole trader, use your name and information. If you are a company, use the company's name and information.
    - The undertaking representative is a member of the legal entity. This means the sole trader, a partner in a partnership or a director of a company.

- Medical radiological installation is the legal term used for the **location** where the X-rays are to be carried out. This is usually the name of the dental practice. If more than one dental practice is being declared, these should be listed, along with the relevant service types.
- The designated manager is responsible for the day-to-day operation of the dental practice. This can be the practice manager or a senior dentist. They must be allocated this responsibility by the undertaking. The email provided for the designated manager is the **main email HIQA will use to contact the practice**. It is important that contact with this **email address is regularly monitored**.

Q. Do I need to inform the EPA if I purchase new equipment?

A. All equipment must be CE marked and be approved for use under the medical devices regulations.

For registered practices with the correct authorisation in place, it is not necessary to inform the EPA about new equipment. However, it is important to retain the commissioning report on file. The EPA may request copies of supporting documents at any stage following registration or during a compliance assessment, to verify the self-declaration.

For a licensed practice, the EPA must be informed of any proposals to amend schedules 2 or 3 of the licence before these changes take effect. Licensed items may not be relocated or replaced, nor may new licensable items be acquired without securing approval from the EPA. Licensing is a two-step process which includes the following:

1. Undertaking (or their representative) submits a licence amendment request via Environmental Data Exchange Network (EDEN) to add the new equipment and its serial number as well as a risk assessment and additional safety procedures, where relevant.
2. The EPA reviews the request and associated documents prior to authorising the equipment for use with a licensing restriction of “for commissioning purposes only.” Equipment shall not be used on patients until it has been successfully commissioned. Commissioning is a set of acceptance tests conducted, independent of the installer, by a suitably qualified person on behalf of the undertaking and or dentist in consultation with a Radiation Protection Adviser (RPA).
3. When the new equipment has been commissioned, the undertaking (or their representative) submits a licence change request via EDEN to remove the “for

commissioning purposes only" licensing restriction and uploads the commissioning report to EDEN as evidence.

4. The EPA reviews the request and documentation prior to authorising the equipment for clinical use, and an amended licence schedule is issued via EDEN with the licensing restriction removed.

Compliance - Help and Checklists

Q. Where can I find a checklist for meeting HIQA's regulatory requirements?

A. A useful aid to check that you have addressed important aspects required for different regulations can be found in **Appendix C** of HIQA's A Guide to the inspection of dental services providing medical exposure to ionising radiation. Appendix C provides examples of regulatory considerations. This is a good starting point to determine your own level of compliance with the regulations.

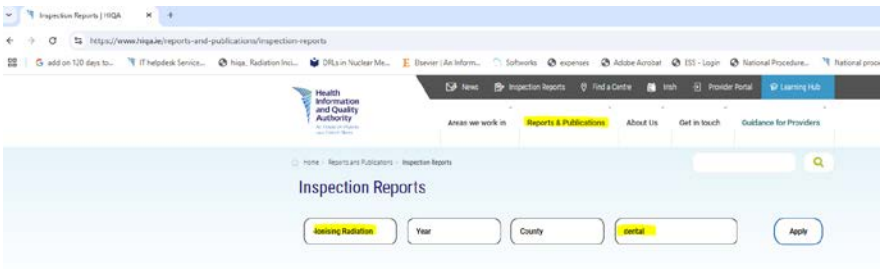
Appendix B provides a sample of documentation types that may be requested before the inspection. These and any additional documents that can provide evidence of the undertaking's compliance with the regulations should be accessible, maintained and kept up-to-date at each facility.

For more comprehensive details about each regulation, the following documents are also available on our website:

- Guidance on the assessment of compliance in undertakings
- Assessment judgment framework for ionising radiation

The assessment judgment framework outlines the questions that inspectors use to assess compliance. The guidance on the assessment of compliance explains what compliance with these questions entails.

Reviewing previously published inspection reports, available here, may also provide useful insights into what is assessed during inspections and how compliance is evaluated. These reports can serve as a valuable resource for individual practices. Please select 'ionising radiation' from the 'report type' menu and add 'dental' in the 'search' text box and click 'apply', as shown below. This should filter your view to published dental inspection reports.



Regarding clinical audit, Appendix 6 of the *National Procedures for Clinical Audit* is specific for dental services. Resources for clinical audit, such as the webinar recording, are available here.

This document and the recorded webinar can help to explain the regulatory requirements.

Q. What records will the EPA ask for?

A. To demonstrate compliance with *IRR19*, the onus is on the undertaking to compile and fully maintain relevant records. These records include but are not limited to, those listed in section 7 of the EPA's *Code of Practice in Dentistry*.

Q. Can the EPA provide a checklist to allow a dentist to self-assess their compliance?

A. For those with a registration, an undertaking must complete a self-declaration form through EDEN confirming that several steps have been performed. Undertakings with an EPA registration must retain documentary evidence supporting the self-declaration on file. In addition, an inventory of equipment used for authorised practices must be maintained.

For those with a licence, additional information must be provided at the time of application, which is available on the EPA website in Section 2.2.2 of the EPA's Guidance for undertakings on the application of the Ionising Radiation Regulations (IRR19).

Some recommended starting points for a compliance self-assessment are:

- Check that the correct authorisation is in place (registration or licence) and that the correct practices are listed in table 1 of the authorisation.
- Review the authorisation conditions and identify any areas of non-compliance.
- Make the EPA's *Code of Practice in Dentistry* available to all staff who are directly involved in work with ionising radiation.

- Ensure that the practice(s) authorised in table 1 are carried out in accordance with the provisions of the EPA's *Code of Practice in Dentistry.*

Justification of X-rays and Record-keeping

Q. What should I record for each X-ray that I take?

A. As part of an inspection, HIQA reviews the records of referral and justification. These records must be retained for **five years** from the date the X-ray was taken. The record of each dental X-ray taken in a facility is important, as it demonstrates that an undertaking is compliant with a number of regulations during an inspection.

These records must show that:

- there is a referral by a referrer for each X-ray carried out,
- that the X-ray was justified in advance by a practitioner,
- information about the dose is included in the report which should also show that the clinical evaluation of the X-ray was completed by a practitioner.

Allocation of referral and practitioner roles and responsibilities and delegation of the practical aspects of dental X-rays must be clearly documented in local procedures.

In most dental settings the same dentist will carry out all the different steps and roles (referrer and practitioner) in relation to dental X-rays. Therefore, evidence of compliance with one step may also serve as evidence of compliance with another step. Evidence of each of these steps is often recorded in the patient's notes by the dentist treating the patient. Where it is the same dentist completing all steps, duplication of information in the patient's notes is not necessary and each dentist should decide how to best record the information required under the regulations, to streamline their own practice.

Dentists must be able to identify all patients who have had X-rays in their practice and retain their X-ray records for the last five years, to ensure compliance with S.I. 256 of 2018 (as amended).

Example of requirements in dental X-ray records by a dentist working alone.

A dentist working alone is the referrer and practitioner for all dental X-rays in the practice.

- The dentist may make one entry into the patient's notes to record that they plan to conduct an intra-oral X-ray to look for caries, after conducting their clinical examination of a patient.
- The dentist should ensure that they are clearly identifiable in this record which may be considered as evidence of the referral, justification and conduct for this dental X-ray.
- The dentist should ensure that the record shows that the clinical evaluation of the X-ray's outcome is available and contains information relating to the patient dose.

Example of additional steps to be taken by a dentist performing a dental X-ray, based on a referral received from another dentist (this could be an external dentist).

1. Check for a written referral signed by a dentist with current Dental Council registration.
2. Check if the referral states the type of X-ray required, the reason for the X-ray and sufficient data to allow you as the practitioner, to justify the X-ray.
3. Review the information to perform justification in advance.
4. Record that the procedure is justified, in addition to the name of the person who carried out the X-ray.
5. Ensure that the appropriately trained individual with responsibility for the clinical evaluation is clearly identifiable in the record.
6. Where the external referrer or another dentist is taking responsibility for the clinical evaluation (where no report is issued by the undertaking or practitioner conducting the X-ray), this must be clearly understood by all parties and documented.

Medical Physics Expert

Q. Does HIQA have a register of medical physics experts (MPEs)?

A. No. The regulations state that responsibility for establishing and maintaining a register of MPEs is allocated to the Minister for Health.

Until such time as this Register of Medical Physics Experts is established, MPEs acting or giving advice on matters relating to radiation physics should be on the voluntary register of medical physics experts maintained by the Irish College of Physicists in Medicine.

Equipment Quality Assurance

Q. How often should my equipment be serviced by an MPE or manufacturer?

A. Regulation 14: equipment; requires that dental X-ray equipment is kept under strict surveillance. The undertaking must ensure that the following arrangements are in place:

- On purchase of new equipment, or moving of equipment to a new location, **acceptance testing** (also known as commissioning) must be carried out by an MPE before it is used for the first time on a patient to ensure that the equipment is safe for clinical use.
- A **quality assurance (QA) programme** must be established and maintained. This programme must be defined and documented by the undertaking in consultation with an MPE, to ensure that the equipment is kept in safe and good working order.
- This QA programme will typically need to include:
    - QA testing every two years by an MPE
    - Regular preventative maintenance and servicing by:
        1. the vendor or manufacturer, as per their guidelines. This is usually required annually but may differ between manufacturers.
        2. the dental team. Some equipment may require more regular quality control testing, for example, quarterly checks on the radiation output. If these are required, they must be carried out and must be documented.

- Records of each test carried out that identifies the type of test and date completed, who was involved, the outcomes and any corrective measures taken must be retained for five years.

Q. What equipment tests are recommended by HIQA?

A. The undertaking has a responsibility to ensure that an MPE is involved in the design and implementation of the QA programme and is best placed to provide advice on the testing requirements for individual equipment. Therefore, the MPE's contribution should determine the types and frequency of testing and this must also adhere to the criteria for acceptability of equipment, as adopted by HIQA.

For more information, please see HIQA's *Guidance on Criteria for the Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy*, available here.

Q. What service records will HIQA ask for?

A. The information HIQA typically seeks on inspection is outlined in the appendices of the *Dental Guide to Inspection*. **Appendix B** of this guide outlines the documentation which HIQA requires dentists to submit prior to the inspection. The following documentation is required in relation to equipment:

- the policy on quality assurance and quality control of the radiological equipment,
- records of acceptance testing of each item of radiological equipment installed after 8 January 2019,
- records of regular performance testing, from 8 January 2019, for all radiological equipment,
- a summary of the annual or periodic quality assurance or performance testing for all radiological equipment,
- an inventory of all radiological equipment using the template provided in the announcement letter. This template includes the following:
    - name of equipment
    - location of equipment
    - manufacturer and or model serial number
    - date of installation of equipment
    - date of initial acceptance testing
    - date of most recent QA testing performed by an MPE
    - nominal replacement date

- record of the decision to use the equipment beyond the nominal replacement date (if applicable).

Q. What frequency of dental X-ray equipment servicing is expected by the EPA?

A. All X-ray equipment must be maintained in good working condition and serviced as per the manufacturer's instructions. 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.

Q. What is the recommended frequency for conducting quality assurance on dental X-ray equipment?

A. As per the authorisation conditions and EPA's Code of Practice in Dentistry (EPA-Ionising-Radiation-Dentistry.pdf), the undertaking shall ensure that all X-ray equipment used in the practice of dental radiography is subject to a quality assurance assessment every two years.

Q. Does the EPA need to be informed if I plan to dispose of my handheld unit?

A. Yes, you would need to inform the EPA by submitting a licence amendment request via EDEN to update schedule 2 of the licence. If you have removed all handheld units and now only require to be authorised for the practice of dental radiography using an intra/extra oral unit (except handheld) and/or dental cone beam CT, then you may downgrade your authorisation to a registration from a licence and annual enforcement fees will no longer apply. Prior to disposal, X-ray equipment must be rendered permanently incapable of producing ionising radiation. A record shall be maintained of all X-ray equipment disposed of.

If you are closing or selling your dental practice, it is your responsibility to inform the EPA and close the licence via EDEN. Transfer of a licence is prohibited. You will still be liable for the annual enforcement fees associated with the licence until it has been successfully closed.

Diagnostic Reference Levels

Q. **What are DRLs and why are they important?**

A. Diagnostic Reference Levels (DRLs) are dose levels set to aid optimisation of diagnostic exposures. In Ireland, there are national DRLs set by HIQA for a number of standard dental X-rays. The doses set out in these DRLs can be compared to doses delivered to patients during routine dental X-rays to indicate if the dose to the patient is unusually high or unusually low for that procedure. The comparison of doses by those conducting X-rays can help to identify a potential issue with the equipment or protocols being used, for example where there is a trend of too much or too little radiation being delivered. This is particularly important in higher-dose modalities such as CBCT.

Please see HIQA's, *Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation* available here.

This document must be made available to all personnel involved in conducting X-rays and includes information about:

- how to establish and use DRLs,
- current national DRLs.

Tip: While we advise reading the whole document as all the information applies to all undertakings, search for the word 'dental' on the PDF version to navigate quickly to the specific dental-related items.

Q. What must I do in my practice?

A. Each dental practice must have established DRLs locally for all:

- standard examinations they carry out,
- pieces of equipment,
- categories of patients (for example, paediatric and adult).

Even if a national DRL hasn't been established, the dental practice must still establish local facility DRLs for each type of examination they perform.

These should be reviewed regularly. For a dental facility, this means at least every two years or after the introduction of new equipment or techniques.

Once reviewed, the values must be made known to all staff involved in the conduct of X-rays. Staff should be aware of these values and know how these values should be used and referred to when carrying out X-rays to ensure each examination is

optimised. This is especially important in higher-dose and more complex imaging, such as CBCT.

Q. How do I use DRLs once they are established?

A. Where the typical dose for a dental X-ray procedure within a practice is consistently different from either the local facility DRL or the equivalent national DRL, an undertaking must investigate the cause. This is what is meant by using DRLs. Where a national (or other European value if no national values) is available, the local facility DRLs should be compared to this value and if found to exceed this value, a review and corrective actions should be carried out. Similarly, doses identified to be well below local or national DRLs should also be reviewed to ensure the image is of sufficient diagnostic quality to achieve the objective of the X-ray (allow diagnosis).

Q. What role dose the MPE have in DRLs?

A. An MPE must be involved in the establishment and use of DRLs in each practice. They have an important role to play in providing advice and contributing to optimisation.

Clinical Audit

Q. What do I need to have in place for clinical audits?

A. The undertaking must ensure that clinical audits are carried out in accordance with HIQA's *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* (national procedures) published in November 2023, available here.

Appendix 6 of this document gives information specific to dental settings and provides undertakings with examples of types and topics for clinical audit, along with descriptions.

Useful templates and other resources are also included in the guidance document and are available to download here.

To comply with clinical audit requirements, what do undertakings need to do?

Undertakings must:

- have a clinical audit strategy in place that includes the nine principles and essential criteria set by the *National procedures* (a clinical audit strategy template is available in Appendix 3 of the *National procedures*),
- consider the risks associated with the dental X-ray service they provide and develop audit topics based on the needs of their practice (see Appendix 6 of the *National procedures*),
- use clinical audit to improve the quality and safety of patient care and dental X-rays,
- use the clinical audit findings to provide assurances of the quality and safety of patient care and services they provide,
- make this document available to all staff involved in medical radiological procedures (dental X-rays), so that staff are aware of their role in relation to clinical audit.

Q. What does the EPA expect from a dentist in relation to audit?

A. Undertakings must ensure that all required control measures identified in the risk assessment(s) are fully implemented and should verify this through regular audits. The adequacy of radiation protection training should also be audited from time to time.

Use of cone beam computed tomography (CBCT)

Q. What should I do if I think routine CBCT is being conducted in dental imaging?

A. HIQA's monitoring and inspection programme assesses if all exposures are justified and optimised and if referral criteria (selection criteria) have been used to guide the dentist in determining the **most appropriate type of image required for the clinical indication**.

For example, the *European Commission Radiation Protection N° 172 Cone Beam CT For Dental And Maxillofacial Radiology Evidence-Based Guidelines* states that the evidence currently does not support the clinical use of CBCT for caries detection and diagnosis.

Examples of international bodies who provide selection criteria are provided in Appendix C of our guide to the inspection of dental services, available here.

If it is known that patients are being exposed to unnecessary or increased levels of radiation, or potentially could be, then these **concerns can be raised with us** through our dedicated **Concerns team** at 021 240 9646 or by email to Concerns@hiqa.ie. For more information, please click here.

An information booklet which provides information about HIQA's actions in response to concerns or feedback is available here.

Additionally, HIQA has a mechanism in place to receive **protected disclosures** about services within HIQA's statutory remit. You can do so in writing, by phone, by email or in person. For more information, please see our webpage here. To contact the dedicated protected disclosure team by phone or email please use 01 814 7635 or protecteddisclosures@hiqa.ie.

The Dental Council also has a mechanism in place to receive information on concerns about professional standards.

CBCT and Training

Q. What does HIQA require in relation to CBCT specific training?

A. It is the responsibility of the undertaking to ensure that staff using CBCT are appropriately qualified and trained.

Training requirements in relation to CBCT are prescribed by the **Dental Council of Ireland**, and it is imperative that the undertaking, and those involved in the conduct of CBCTs, are familiar with these training requirements.

CBCTs should only be conducted by personnel with the relevant training, as prescribed by the Dental Council.

The key points to note are:

- You can find Dental Council training requirements at https://www.dentalcouncil.ie/code-of-practice/ionising-radiation. For CBCT requirements please see section called '**CBCT Training**'.

- In order to refer for, take responsibility for and conduct CBCT examinations, those registered with the Dental Council must complete the following training requirements outlined in the ***Basic training requirements for the use of dental CBCT by dentists: a position paper prepared by the European Academy of DentoMaxilloFacial Radiology.***
- There are different levels of training required to refer (Level 1) and act as a practitioner and or conduct the practical aspects (Level 2). Dentists and undertakings should be familiar with the different roles and levels.
- On inspection, HIQA seeks:
    - appropriate professional registration,
    - training records associated with each staff member that demonstrate compliance with the requirements specified in the ***Basic training requirements for the use of dental CBCT by dentists: a position paper prepared by the European Academy of DentoMaxilloFacial Radiology***,
    - evidence of how the undertaking is assured that the completed courses meet all the requirements outlined in this document, including learning outcomes, course delivery and time requirements.

Examples of evidence may include records of communication with training providers outlining the course content and how it meets the requirements.

The Dental Council is currently developing a template to support undertakings and staff involved in CBCT, to record such training and check that it meets the requirements of the regulations. The Dental Council has consulted HIQA on this matter and hopes to make this template available by the end of 2024.

Q. Where can I access such training?

A. HIQA cannot be prescriptive in sources of training. Undertakings and relevant staff should review and inquire with training organisers about training content to ensure specified training requirements are met, in line with those prescribed by the Dental Council. Multiple training activities may be necessary to fully meet all the requirements, as outlined above.

Q. I am a dental nurse taking X-rays, what training requirements does HIQA expect from me and my associated undertaking?

A. It is the responsibility of the undertaking to ensure that staff delegated the practical aspects of dental exposures, are appropriately qualified and trained.

The practitioner with overall clinical responsibility will also need to have the appropriate level of training.

The following are the some of the main requirements that should be in place for a dental nurse taking X-rays:

- registration with the Dental Council of Ireland,
- written delegation of responsibility for the practical aspects of dental radiological procedures by the practitioner or the undertaking, which must be available and maintained,
- associated radiation safety training as prescribed or approved by the Dental Council must be completed by the dental nurse or dental hygienist taking X-rays.

Dental Council training requirements can be found at:
https://www.dentalcouncil.ie/code-of-practice/ionising-radiation.

Note that the training courses and requirements in place for dental nurses and auxiliary dental workers to conduct intra-dental X-rays do not meet the requirements for being delegated the practical aspects of CBCT.

Training records must be maintained by the undertaking and available to HIQA on request to demonstrate that staff training requirements have been completed and to demonstrate the undertaking's compliance with the regulations.

Q. Are there any regulatory requirements for undertakings to be able to train staff to perform CBCT?

A. From an EPA perspective, all relevant training as set out in section 5 of the EPA's Code of Practice in Dentistry (EPA-Ionising-Radiation-Dentistry.pdf) must be completed prior to a staff member using any dental X-ray equipment. There is no requirement for this training to be delivered by the undertaking, so long as staff have been provided the training by a suitably qualified and competent person. A record of this training to include the date of training; name of person who attended; who provided the training; and topics covered by training shall be maintained.

Clinical Evaluation of the Outcome and or Report

Q. Who is responsible for the report of dental X-rays and CBCT images?

A. For all dental radiological procedures, the undertaking must ensure that a practitioner (usually a dentist) takes responsibility for the clinical evaluation of the outcome.

In the case of clinical evaluation of the outcome of CBCT procedures, it is the responsibility of the undertaking to ensure that the practitioners providing the clinical evaluation of the outcome of CBCT procedures are appropriately qualified and trained as outlined above.

Therefore, for every dental X-ray and CBCT, HIQA require a record of the clinical evaluation of the outcome, where the practitioner with responsibility for this task is clearly identifiable.

Where the dentist is the referrer and practitioner for an intra-oral X-ray the report (record of the clinical evaluation of the outcome) may be recorded in the patient's clinical notes by the dentist.

Where a CBCT is being performed for external referrers/dentists, a more formalised record authored by an appropriately trained individual may be needed. This is in line with recommendations from the *European Commission Radiation Protection no. 172 Cone Beam CT For Dental And Maxillofacial Radiology Evidence-Based Guidelines,* which state that 'CBCT images must undergo a thorough clinical evaluation ('radiological report') of the entire image dataset'.

Use of patient lead shielding during dental X-ray procedures

Q. Does HIQA require the lead shielding of patients during dental X-ray procedures?

A. The undertaking must be assured that they have appropriate measures in place for patient radiation protection. HIQA is not prescriptive on the use of lead shielding. It is important for those taking X-rays to keep up-to-date on any new and important information in relation to patient radiation protection and ensure practices are continuously optimised and evidence-based.

Any questions in relation to the use of collars or aprons must be addressed by the undertaking, after full consideration of best practice guidance, equipment specifications and MPE advice.

Regulatory Updates and Terminology

Q. Why is the naming of the people taking X-rays so complicated?

A. All guidance documentation produced by HIQA aims to ensure that plain English is used as much as possible. However, when discussing the regulations and legal requirements, HIQA aligns language with that of the regulations to reduce the potential for misinterpretation by readers. As a result, terms such as undertaking, practitioner and persons delegated practical aspects are used consistently, for clarity, as the regulations apply across a wide range of sectors.

HIQA has published some dental specific guidance and this aims to explain the different terms as they relate to dentistry, specifically.

Q. Have there been any recent changes to the law we should be aware of?

A. It is important for undertakings and those involved in carrying out X-rays to keep up-to-date on all existing and any new and important information in relation to regulatory updates or requirements. An up-to-date copy of the regulations with recent amendments is available here.

Major changes or important information in relation to the regulations is communicated by email to the Designated Manager. It is therefore important to ensure that the contact details you have provided to HIQA are kept up-to-date. Notification forms to update any details which have changed are available here.

Published information is available on HIQA's website (www.hiqa.ie). A webpage dedicated to information on the regulation of medical exposure to ionising radiation is available here.

HIQA recommends using only the digital copy of documents available, as these are updated to reflect any changes when they occur.

Pregnant Staff

Q. Is it safe for a pregnant staff member to continue to take X-rays and should a lead apron be worn by the pregnant staff member?

A. In the case of exposed workers who are pregnant, the undertaking must ensure that the work practices are reviewed in consultation with a Radiation Protection

Advisor (RPA) to determine whether specific safety procedures or additional dosimetry is required to ensure that adequate protection is afforded to the foetus. In accordance with Regulation 24 of IRR19, once a worker informs the undertaking that they are pregnant, the undertaking must ensure that the worker's employment conditions are such that the dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv.

The relevant risk assessment(s) including the expected and potential doses for the pregnant worker must also be reviewed and revised, if necessary, in consultation with the RPA, to determine whether any additional protective measures such as use of a lead apron or changes to work practices are required.

Continuous Professional Development (CPD)

Q. Are CPD points awarded for this content?

A. This webinar was not intended as a CPD activity but as an aid for dentists regarding compliance with regulations relating to radiation protection. Therefore, no CPD certificates were provided.

Please note that the Dental Council no longer directly approves CPD activities. However, the Dental Council does provide details about how to record CPD. Those who wish use this webinar as CPD can find information about how to do this at: https://www.dentalcouncil.ie/code-of-practice/competence-cpd.