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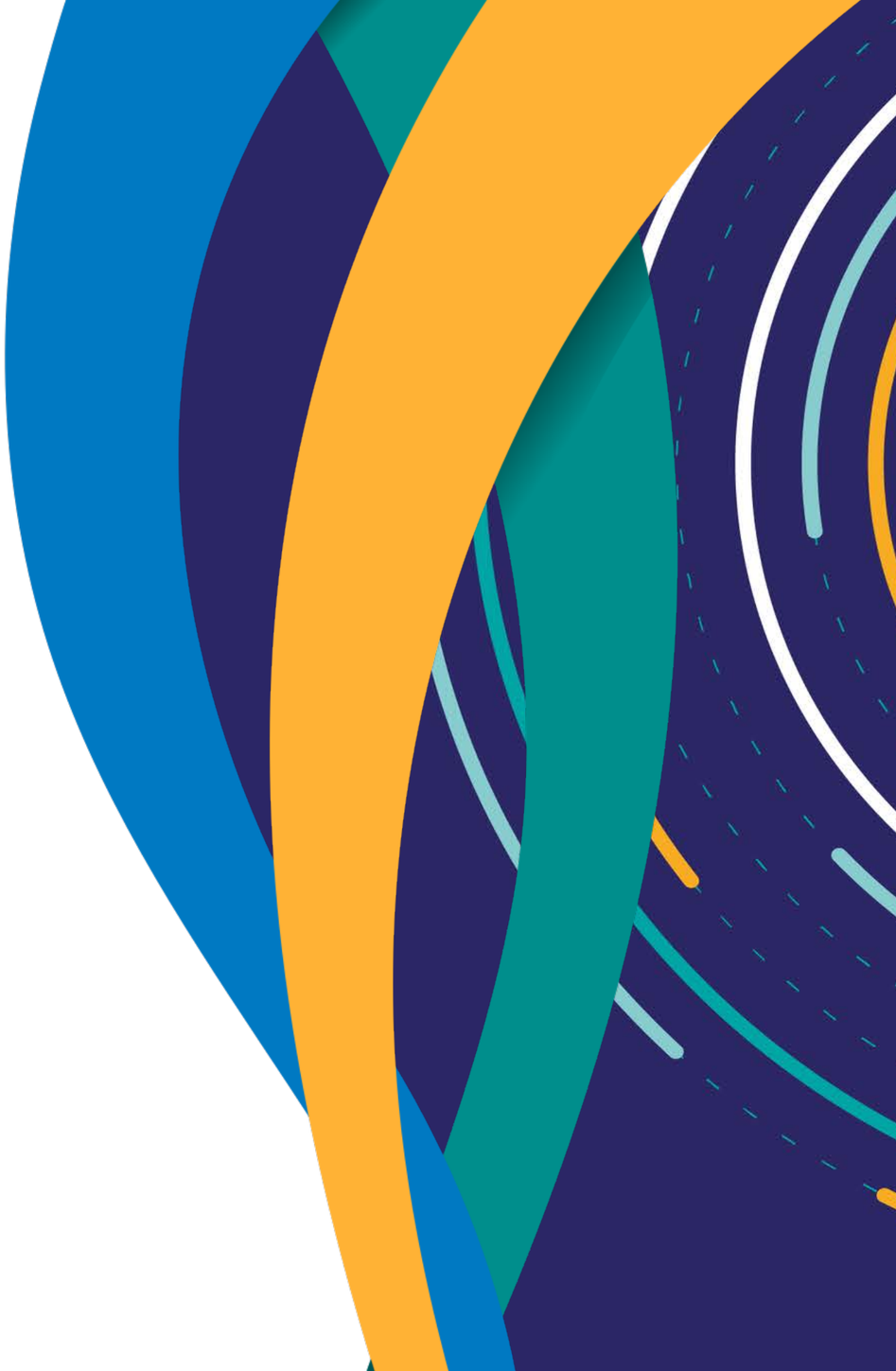
Joint webinar for dental practices using X-ray and CBCT units

17 October 2024



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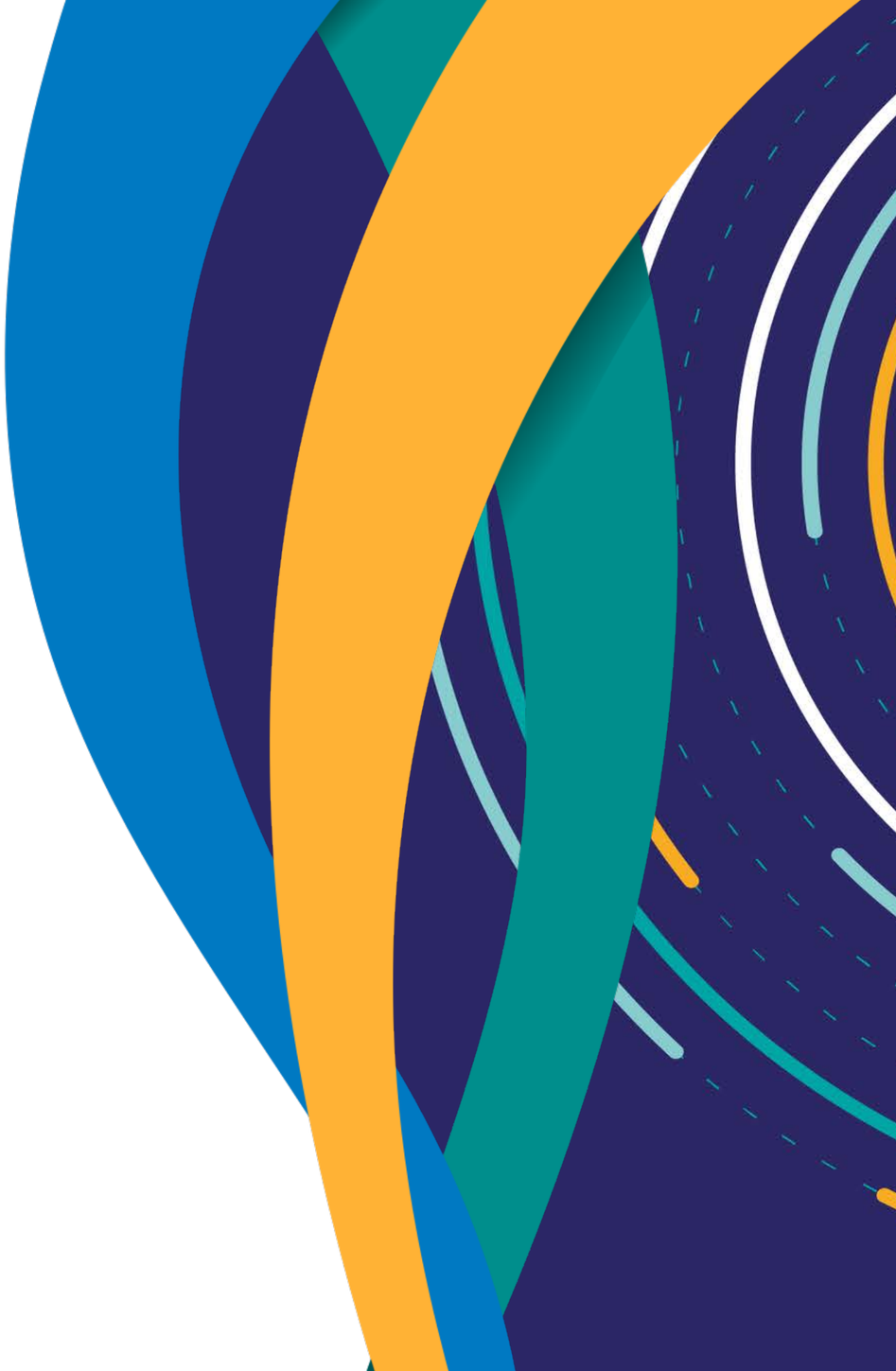


David Fenton,

Manager Radiation Regulation Section within the

Environmental Protection Agency (EPA)

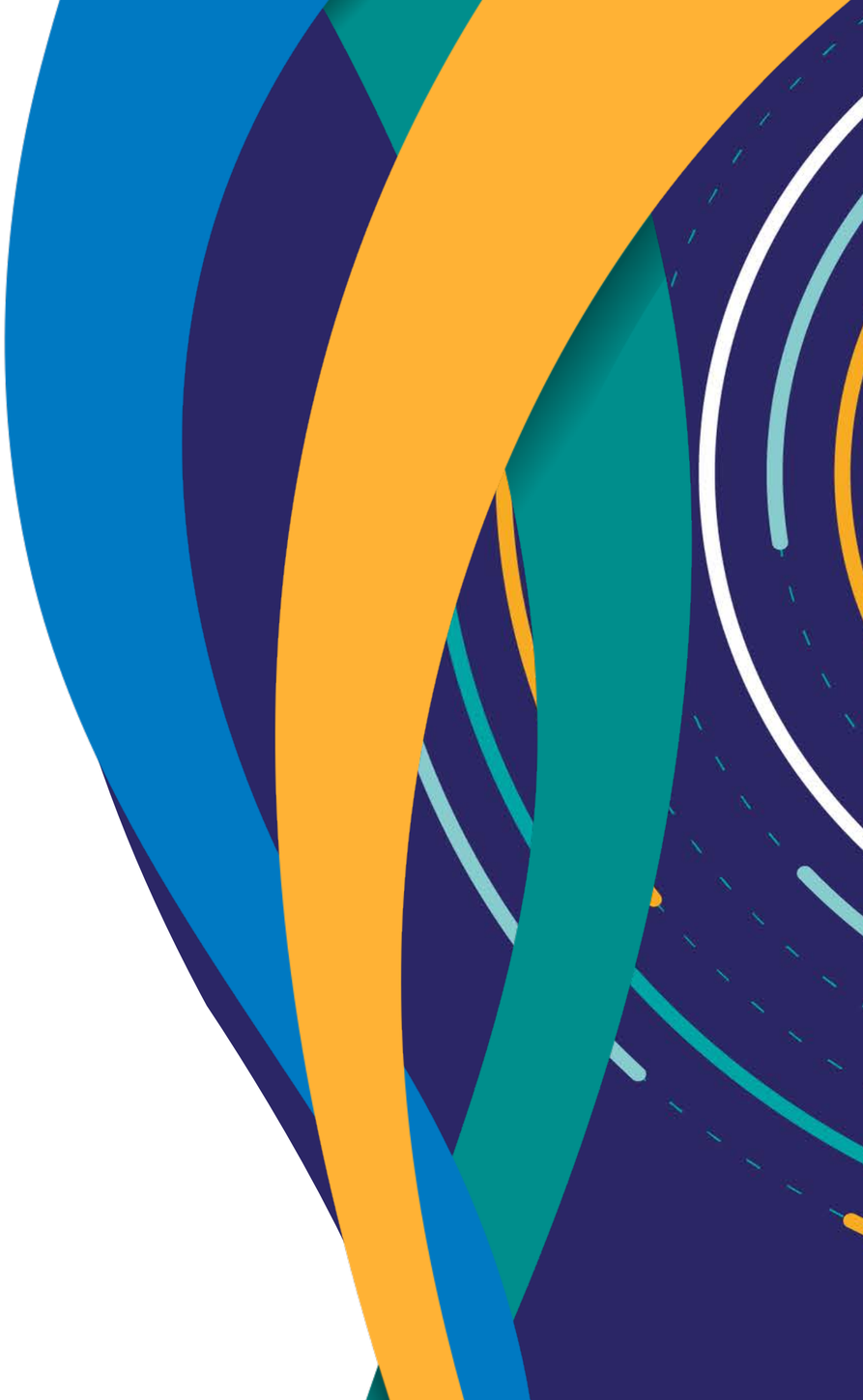
Agenda

19.05 - Welcome address - David Fenton

19.10 - Introduction to the legislation and regulators - Dr. Agnella Craig

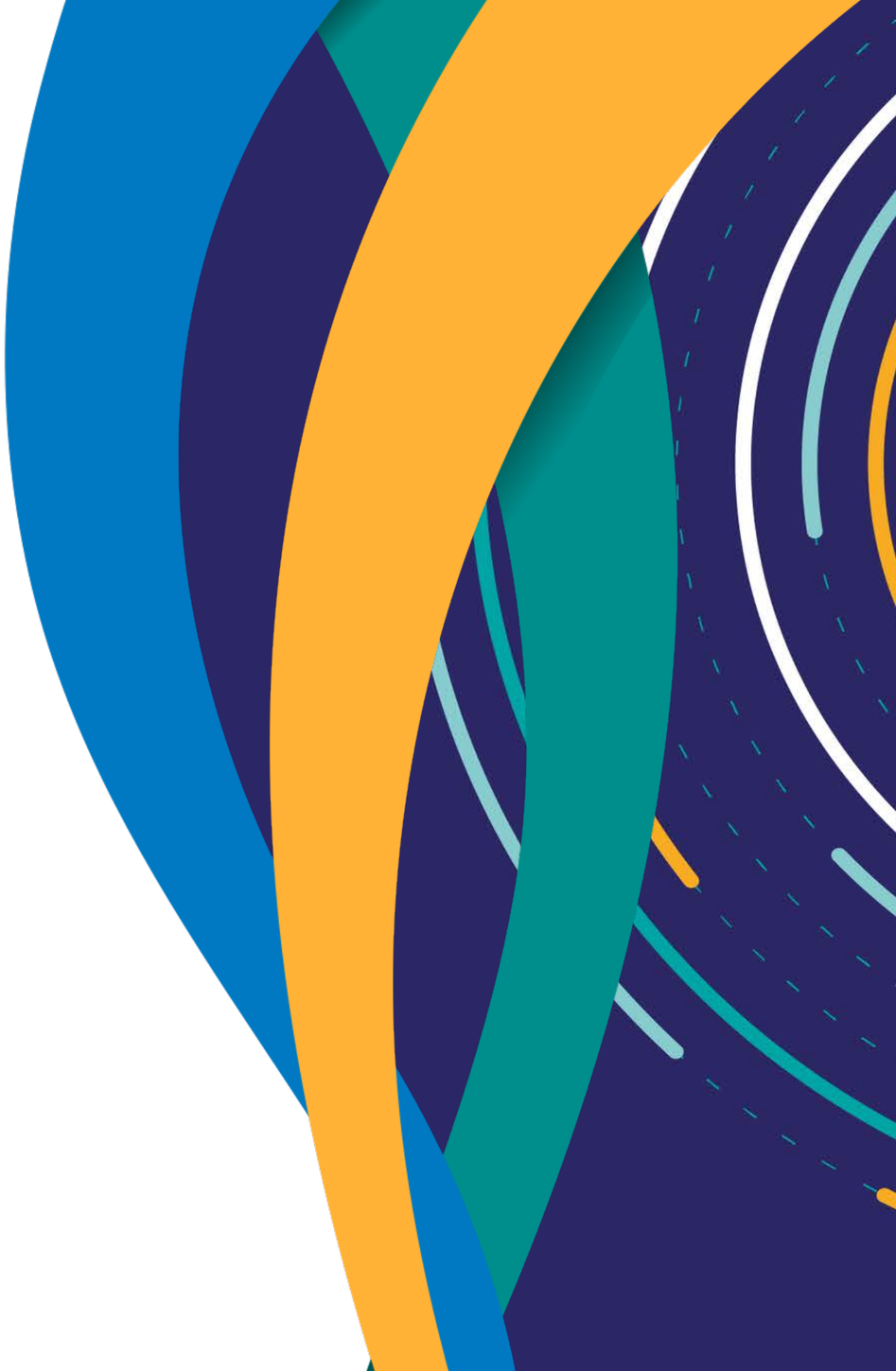
19.20 - Main content - Caitriona McCarthy/Lee O’Hora

19.55 - Questions and Answers



Legislative basis for the regulation of ionizing radiation in Ireland

Dr. Agnella Craig
Regional Manager
Ionising Radiation
Healthcare Regulation Directorate
HIQA



Legislative basis for regulation of medical exposure to ionising radiation

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European Commission

5 December 2013

Basic safety standards for protection against the dangers arising from exposure to ionising radiation (BSS)

Legislative basis for regulation of medical exposure to ionising radiation

European regulations are transposed into Irish laws in the form of statutory instruments (S.Is).

BSS - 2013/59/EURATOM

- In Ireland, the BSS was transposed into two documents
- Each new S.I. with different competent authorities

Legislative basis for regulation of medical exposure to ionising radiation

S.I. No. 256 of 2018
S.I. No. 332 of 2019
S.I. No. 413 of 2019
S.I. No. 528 of 2022
S.I. No 29 of 2023

Radiological Protection Act, 1991
S.I. No. 30 of 2019

Legislative basis for regulation of medical exposure to ionising radiation

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eISB

Service users

Staff & Public

In Summary

Any dentist using ionising radiation is subject to regulation and subsequent inspection from *BOTH* the EPA and HIQA

HIQA and the EPA are separate entities and inspect independently of each other

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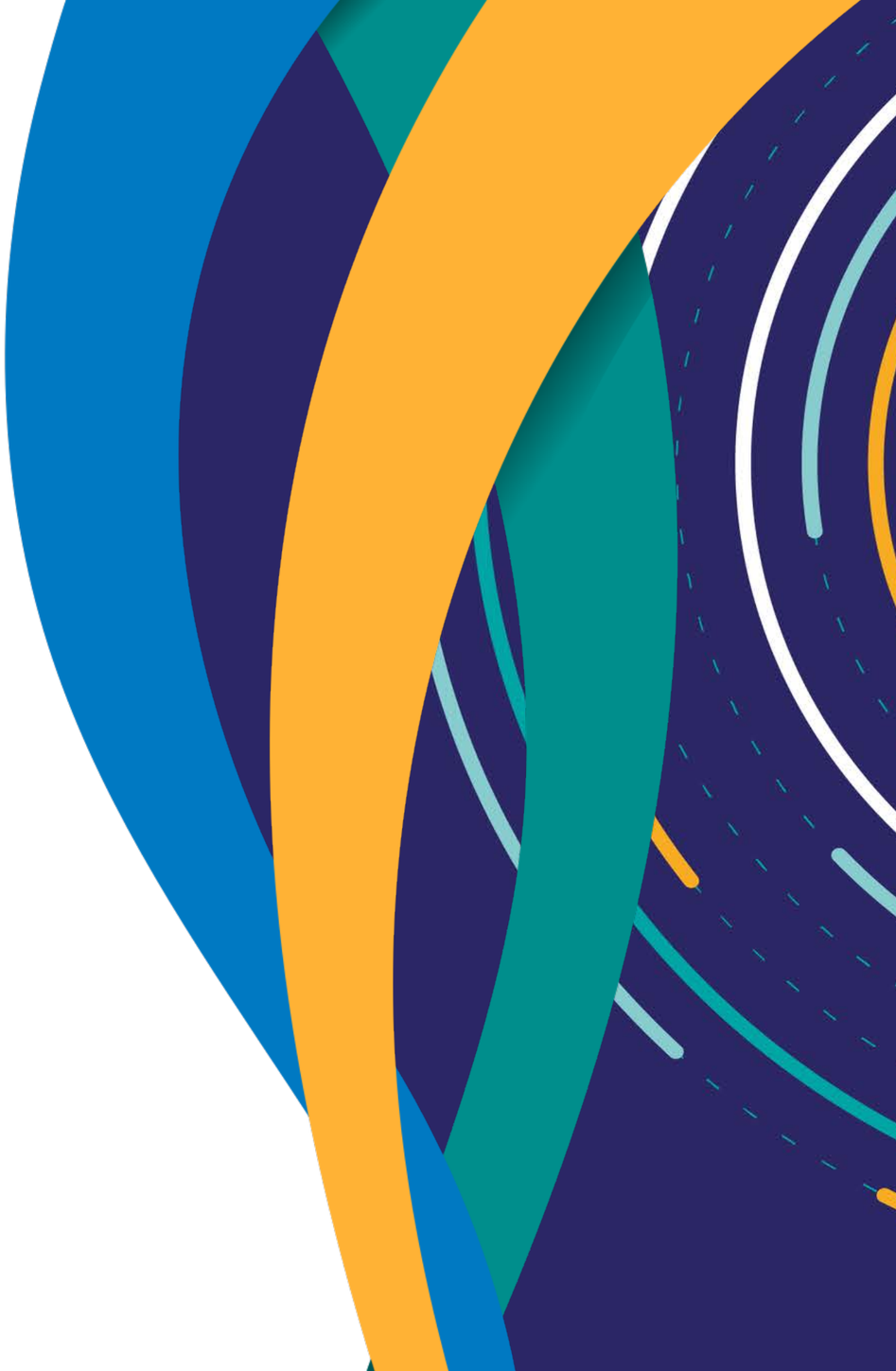
Thank You



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Joint Webinar for dental practices using X-ray and CBCT units

17 October 2024

Overview

Authorisation and Declaration

Roles and Responsibilities

Training

Equipment

Inspection

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Authorisation and Declaration

Authorisation

- Authorisation = consent to carry out a radiological practice.

- IRR19 provides for **Graded Authorisation** (two forms of authorisation commensurate with risk: registration and licensing).

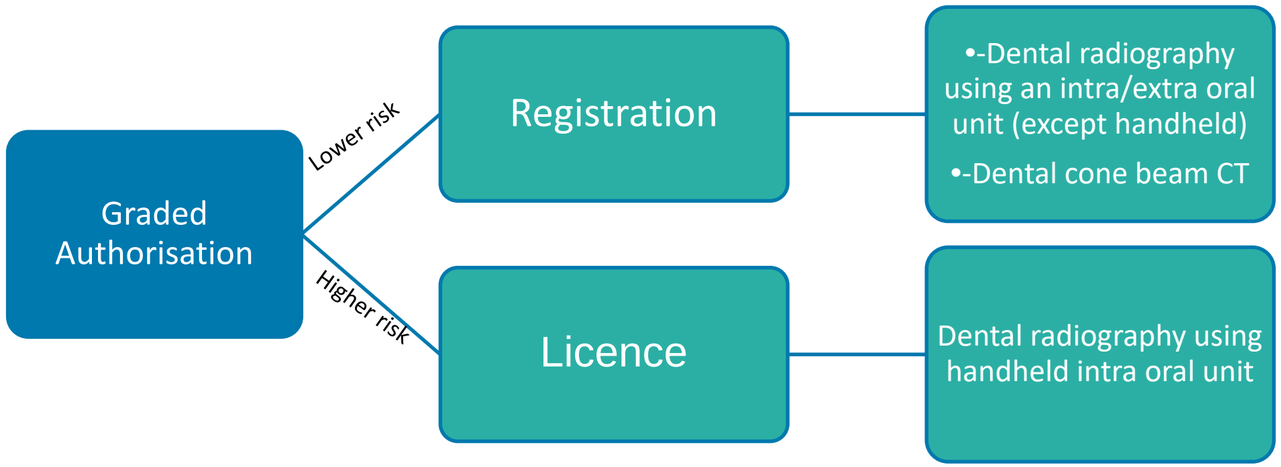


Table 1

Practice	Grade	Authorised From	Authorised To
Dental radiography using an intra/extra oral unit (except handheld)	Registered	28/11/2019	Indefinite
Dental radiography using handheld intra oral unit	Licensed	28/11/2019	27/11/2029
Dental cone beam CT	Registered	28/11/2019	Indefinite

Registration

Please complete all sections below

I confirm that, prior to the commencement of any registered practice, I have, in accordance with the provisions of Ionising Radiation Regulations 2019 (IRR19):

Completed a risk assessment to assess the nature and magnitude of the risks of exposure to ionising radiation arising from the practice or from potential exposures resulting from the practice for workers and members of the public who may be affected, and to identify the protective measures needed to restrict exposures to ionising radiation (regulation 31 and associated EPA guidance).	☐
Have implemented the protective measures identified in the radiation risk assessment that will restrict my employees' and other persons' exposure to ionising radiation (regulation 32 and associated EPA guidance)	☐
Will consult with a suitable Radiation Protection Adviser (RPA) as appropriate (regulation 33 and associated EPA guidance)	☐
Have designated a Radiation Protection Officer (RPO) to supervise or perform radiation protection tasks (regulations 34 and 80 and associated EPA guidance)	☐
Will provide appropriate training, information and instruction to any of my employees engaged in work with ionising radiation, and those likely to be affected by that work, and such training will be repeated at appropriate intervals (regulation 35 and associated EPA guidance)	☐
Have, where required, correctly classified and demarcated any controlled and/or supervised areas (regulations 36 and 37 and associated EPA guidance)	☐
Have drawn up procedures to be followed in the event of a reasonably foreseeable incident liable to have radiation safety implications as identified in the risk assessment (regulation 32 and associated EPA guidance)	☐

I declare that to the best of my knowledge the particulars given in this application for Registration are true, and that I am duly authorised to submit this application for Registration on behalf of the Undertaking.

Signature: _____ Print Name: _____

- ❑ Apply via EDEN portal
- ❑ Complete a self-declaration form
- ❑ Indefinite duration (unless surrendered or revoked)
- ❑ Do not need to submit inventory or documentation but these must be retained locally

Licensing

Dentists using handheld intra-oral units need a licence

- Apply via the EDEN portal.
- The information to be provided in an application includes but not limited to:
  - The nature of the radiology activities for which authorisation is sought
  - Details of the unit (s);
  - The legal details of the undertaking;
  - The name of the radiation protection officer;
  - The name of radiation protection advisor consulted.
- The documentation to be uploaded:
  - Risk Assessment with justification;
  - Commissioning report;
  - Radiation safety procedures;
  - Agreed arrangements with the radiation protection advisor.
- Licence valid for 10 years

Amendments to an Authorisation

- It is necessary to apply for an amendment to an authorisation when it intended to:
  - Change the Senior Management contact/ Contact for correspondence
  - Apply for authorisation of a new practice not covered by the existing registration or licence.
  - Add or remove a dental premises under an existing registration
  - Removal of an oral radiology practice under an existing registration.
  - Make any changes to the schedule of X-ray equipment used for licensed practices.

Applications to amend an existing registration or licence should be made before any changes are brought into effect

If a dental practice is sold or transferred, the new undertaking/dentist must apply for a registration or licence as appropriate in his or her own name, as authorisations are non-transferable.

Handheld X-ray Equipment

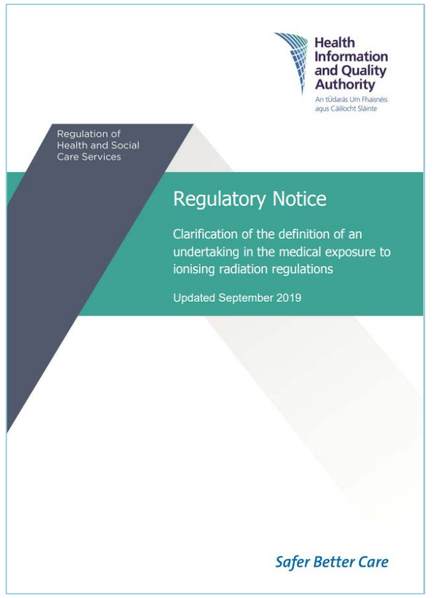
- The regulatory framework for the authorisation of the handheld dental X-ray units is set out in section 4.4.5 of the EPA's Dental Code of Practice, April 2019. This framework is in place to prevent unnecessary proliferation of such units and the associated radiation hazards that would bring.
- For those handheld dental units licensed prior to April 2019, these licences can remain in place as they met the criteria that were in place at the time.
- If there are units licenced after April 2019, then these licences can also remain in place. However, we would encourage such units to be replaced with a fixed or semi mobile X-ray unit and in no circumstances can a replacement unit (or second unit) be licensed without justification and risk assessment.
- In all cases the handheld X-ray unit should be rendered inoperable (e.g. battery removed) when not in use and locked away to prevent theft and/or inadvertent exposures.

- Clinic justification to be submitted via EDEN and is reviewed on a case-by-case basis:
  - Why is the handheld unit needed?
  - Why a fixed or semi mobile unit cannot be used?
  - Risk assessment and radiation safety procedures approved by the RPA.

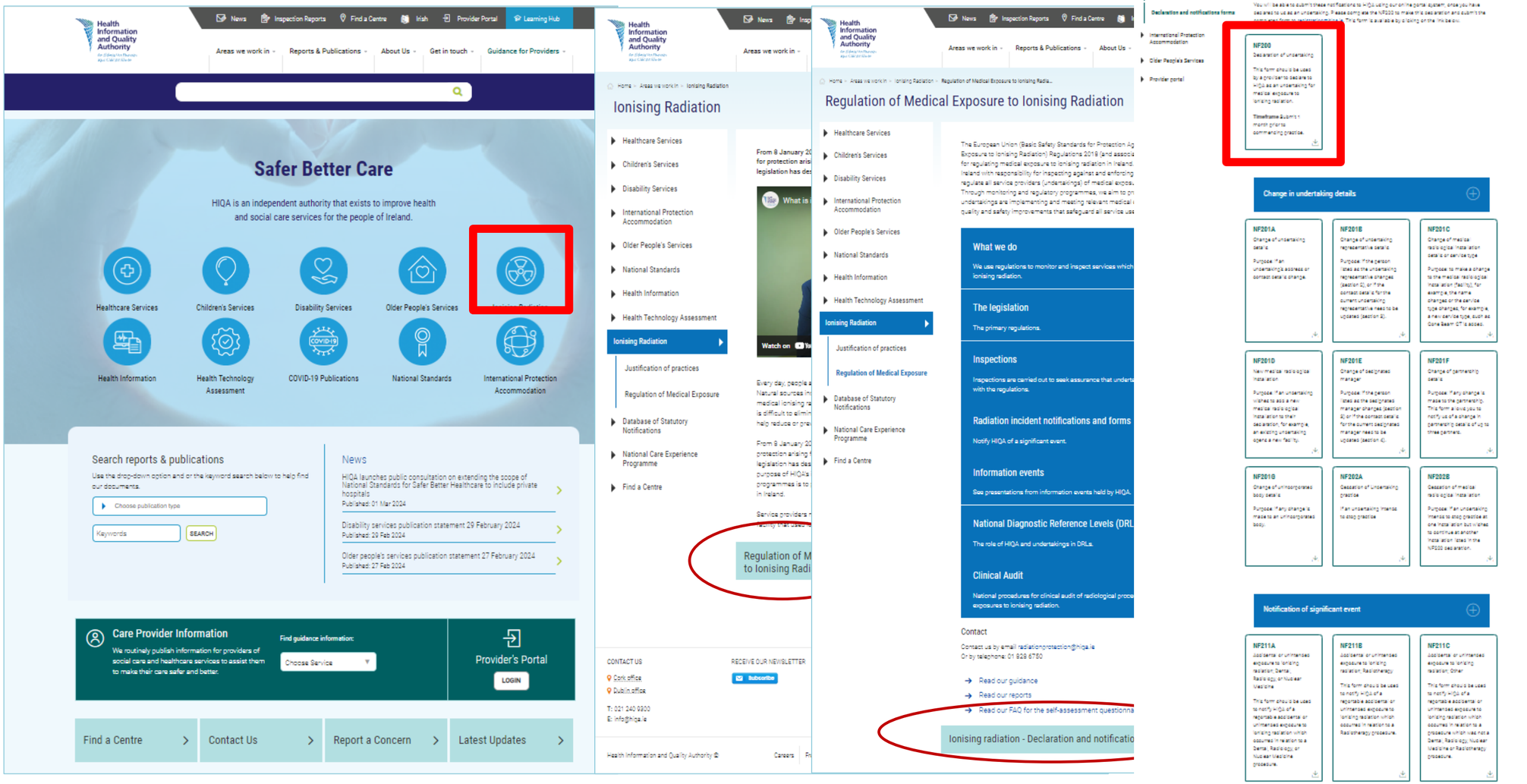
Declaration to HIQA

If it is a new undertaking, submit an **NF200** form as per guidance

If you are unsure if it is an new undertaking you may need to consult our Regulatory Notice



NF200 submission



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Roles and Responsibilities

Roles & Responsibilities – the Undertaking

- Who is 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.

Roles & Responsibilities – the Undertaking

Responsible for:

- 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;
- Provision of appropriate resources and training to the RPO (as outlined in Section 5 of this Code) to effectively carry out the responsibilities listed in Section 3.3 of this 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 (Section 5) and under the responsibility of a dental practitioner;
- 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

Roles & Responsibilities – Radiation Protection Adviser (RPA)

- Who is the RPA?

The RPA is a qualified expert approved by the EPA to provide radiological protection advice pursuant to IRR19.

Radiation Protection Adviser (RPA) Register

Roles & Responsibilities – 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:

Responsible for:

- 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;
- 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-rays are in use.

Roles & Responsibilities – Radiation Protection Officer (RPO)

- Who is the RPO?

The RPO shall be designated by the undertaking/dentist to supervise or implement the radiation protection arrangements. The RPO shall report directly to the undertaking/dentist.

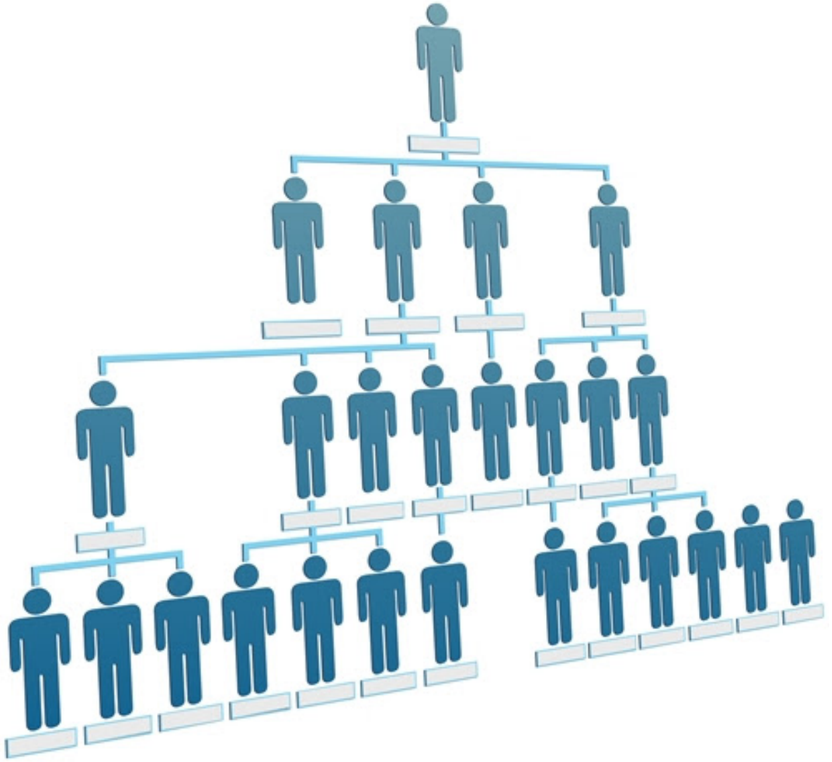
Roles & Responsibilities – Radiation Protection Officer (RPO)

Responsible for:

- 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 this Code;
- Oversee the ongoing safe operation of X-ray equipment;
- Monitor implementation of this Code and additional safety procedures where applicable;
- Facilitate and/or provide training, as appropriate;
- Maintain an adequate records of all X-ray equipment associated with the undertaking/dentist's 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.

The Undertaking

- Declaration NF200
- Clear allocation of responsibility for the radiation protection of service users
- Are the lines of communication and associated platforms documented, well articulated and understood



The Undertaking and associated designations

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HIQA must have **accurate and up-to-date** details of the undertaking, undertaking representative and designated manager.

"undertaking" means a person or body who, in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological procedure or the practical aspects of a medical radiological procedure.

LEGAL ENTITY

An undertaking representative is

the person authorised to communicate with HIQA on behalf of the undertaking. For sole traders, it is the sole trader themselves.

A designated manager

is nominated by an undertaking for each medical radiological installation for day-to-day management issues.

Regulatory recognised people

Referrers

Practitioner(s)

Person(s) delegated practical aspects

Medical Physics Expert(s) (MPE)

Referrers

- What are the processes employed to ensure that only appropriately qualified individuals refer service users for imaging

- Is there documentation outlining what referrer/referral sources your service accepts referrals from

- Is there documentation outlining what is needed on each referral for referrers

Practitioners

- What are the processes employed to ensure that only appropriately qualified individuals act as practitioners
- Are professional registration records maintained and available as required
- Do you have documentation outlining who or what professions are considered practitioners for your service
- Have you considered the Dental Council’s training requirements for staff involved in CBCT

Persons delegated the practical aspects

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- Is there a record of delegation by the undertaking or practitioner
- Are professional registration records maintained and available as required
- Are associated training records maintained and available as required

Medical physics experts (MPE)

- Is there a SLA or engagement documentation outlining the agreement which provides continuity of MPE expertise
- Are MPE responsibilities, advice and contributions defined
- Is professional registration available as required

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Training

Radiation Protection Training for all staff

RP training for all staff

- Operational protection measures set out in the EPA Code of Practice and those identified in the Risk Assessment(s)
- Safety features of the x-ray equipment in use
- Procedures to be followed in the event of an equipment malfunction liable to have radiation safety implications
- Possible risks to foetus and additional protective measures during pregnancy

Additional RP training for staff categorised as exposed workers

- General principles of radiation protection related to their working environment
- Health risks created by exposure to ionising radiation
- The importance of the risk assessment and of staff inputting to its development/maintenance

Operators of a handheld unit

- The operator of a handheld unit must be fully trained.

Additional training for RPOs

In addition to the topics covered in RP training for all staff, the RPOs should be provided with training on:

- Legal responsibilities and duties of the RPO as outlined in Section 3.3 of the code of practice;
- An understanding of relevant legislation and the code of practice;
- An understanding of the conditions attached to the undertaking/dentist's authorisation.

Other persons

- The undertaking must also provide sufficient information to other persons who are working in the environment of ionising radiation to ensure their safety

- Training records must be maintained
- Refresher training every 3-5 years or if anything changes

Training

- As prescribed by the Dental Council
- Delegated duties – additional information for Auxiliary Dental Workers

The Dental Council confirms that the Certificate in Dental Radiography delivered by the Dublin Dental University Hospital (DDUH) and the Certificate in Dental Radiography delivered by the Cork University Dental School and Hospital (CUDSH) each meet the expectations of the Dental Council as expressed in this document

https://www.dentalcouncil.ie/code-of-practice/ionising-radiation

Training

- As prescribed by the Dental Council
- CBCT

In order to undertake duties involving Cone Beam CT, specific additional training is necessary as per the requirements of the European Guidance ***Cone Beam CT for dental and maxillofacial radiology*** *(evidence-based guidelines) (Radiation Protection No. 172).*

dental professionals, according to their roles and responsibilities, should seek confirmation from training providers that the training recommendations contained in the 2014 position paper ***Basic training requirements for the use of dental CBCT by dentists: a position paper*** *prepared by the European Academy of DentoMaxilloFacial Radiology will be met.*

https://www.dentalcouncil.ie/code-of-practice/ionising-radiation

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Equipment

Equipment requirements

Acquisition of new equipment

- All equipment must be CE marked
- Should be purchased by a reputable supplier

Installation

- X-ray equipment must be installed by suitably competent and qualified installers
- The installer shall provide a written installation report, which should include details of the safety checks carried out

Commissioning

- Equipment shall not be used on patients until it has been successfully 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
- These provisions also apply to X-ray equipment which is being relocated or has undergone major modifications affecting radiation output, such as the fitting of a new X-ray tube

Installation and servicing to be done by person who holds EPA authorisation for installation/servicing of radiological equipment.

Clear written arrangements for radiation safety responsibility are required before handover.

Equipment requirements

Maintenance and servicing of equipment

- All X-ray equipment 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.
- 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 equipment must be subject to a biennial quality assurance assessment undertaken by an RPA.
- 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.

When not in regular use, irradiating apparatus shall be safely and securely stored and clearly identified as being capable of producing ionising radiation. Appropriate measures shall be put in place to ensure that irradiating apparatus cannot be switched on.

Equipment Quality Assurance (QA) process

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- Describe the process to ensure that radiological equipment is kept “under strict surveillance”

- Has the undertaking implemented and maintained an appropriate QA programme (Is this programme defined)

- Records of MPE, Service engineer and other QA (acceptance testing and regular performance testing)

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Inspection

Inspection Format

- Planned or reactive
- Announced or unannounced
- Accredited to ISO 17020:2012

- Inspector may have requested and reviewed documentation in advance
- Entrance meeting – RPO, other relevant personnel
- General review of administrative aspects of licence & issues arising from documentation review, previous site visit

- Inspect some or all location(s) where licensed items are located
- Review of records (relevant to inspection scope)
- Exit Meeting - all findings are communicated verbally to the licensee at the end of the inspection

Common Inspection Findings

- Incorrect authorisation/ licence inaccuracies
- No radiation protection advisor/ no current agreed arrangements in place.
- Inadequate risk assessments
- Incorrect categorisation of workers
- Staff not adequately trained
- Radiation Safety Procedures not reviewed/updated/provided to staff
- No evidence that staff directly involved in work with ionising radiation had the code of practice made available to them.
- QA programme not documented or implemented
- No evidence of equipment service/ maintenance
- No evidence of quality assurance.
- Signage issues i.e. missing or inappropriate / Isolation switches not labelled.
- Records not maintained

Site Visit Report

- Reports published to leap online.

- A verbally summary will be given at the closing meeting. The undertaking representatives will have an opportunity to discuss further if they do not agree with any of the findings raised.
- After the inspection is finished the findings that will be listed in the inspection report will not be subject to change.

- Within 28 working days of the inspection the undertaking shall receive the site visit report via EDEN.
- Site visit reports - published **30** days after being issued to the undertaking
- Undertaking responses to findings will be published simultaneously if received within 21 days
- Subsequent updates to findings that you send will be published the day after they have been reviewed by an inspector

https://www.epa.ie/publications/licensing--permitting/radiation/LEAP-Online-Guidance-for-Undertakings.pdf

Inspections

The aim of the on-site inspection is to gather evidence to assess compliance with the regulations

On-site inspections may be:
announced inspections
a short notice announced inspection
unannounced inspection

Duration:
Smaller practices such as small radiology facility or dentist - 3-4 hours
Larger facility - 8 hours

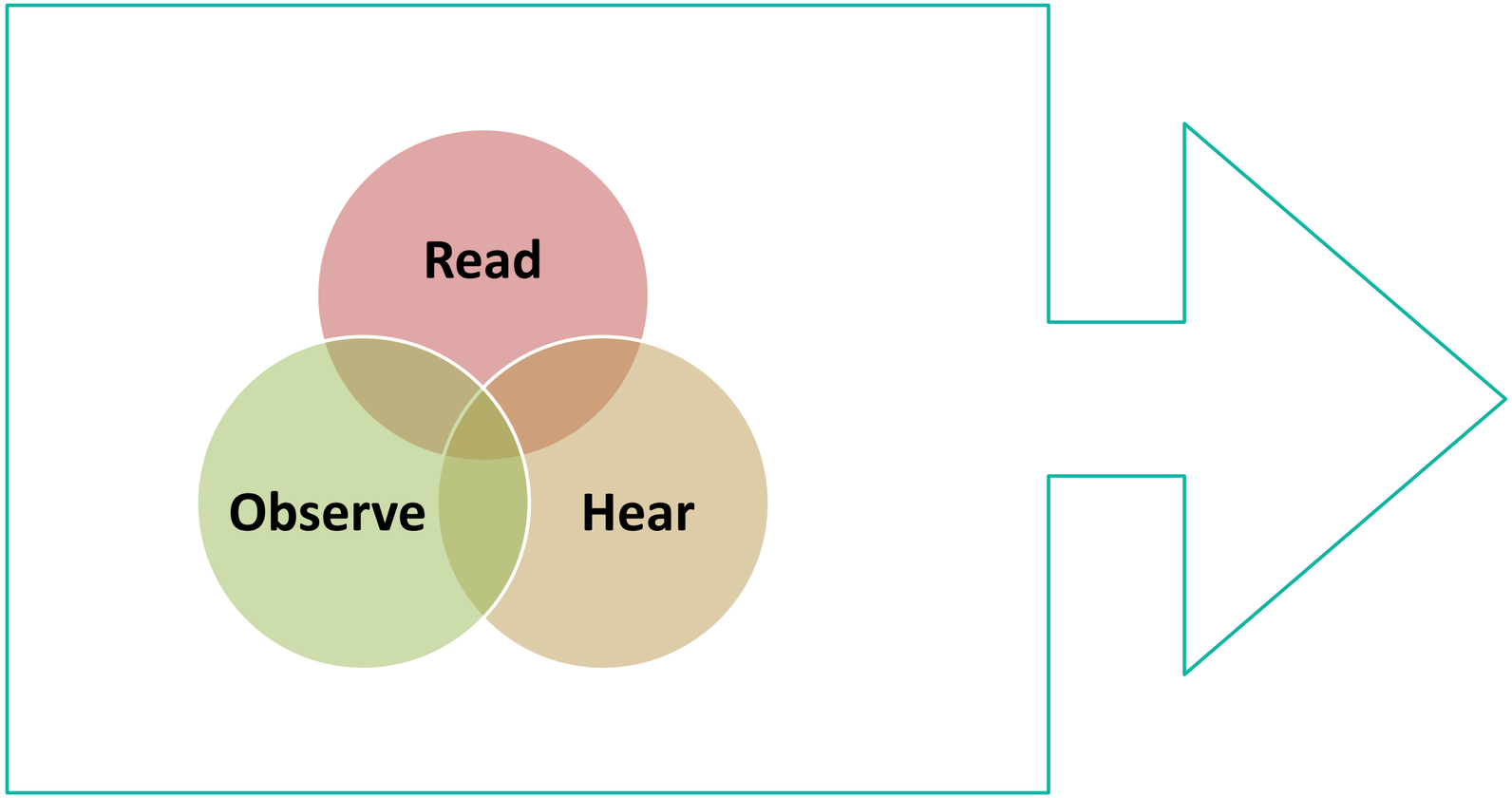
Announced Inspections

When a standard announced inspection occurs, HIQA will issue the undertaking with a notification of inspection confirming the date of the announced inspection **10 working days** before the inspection.

All communication from HIQA about the inspection will be communicated to the **designated manager** email address and copied to the **undertaking** email address.

Pre inspection documentation will be requested **5 working days** before the inspection.

Triangulation of evidence



Compliant: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation.

Substantially compliant: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant.

Not compliant: a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance.

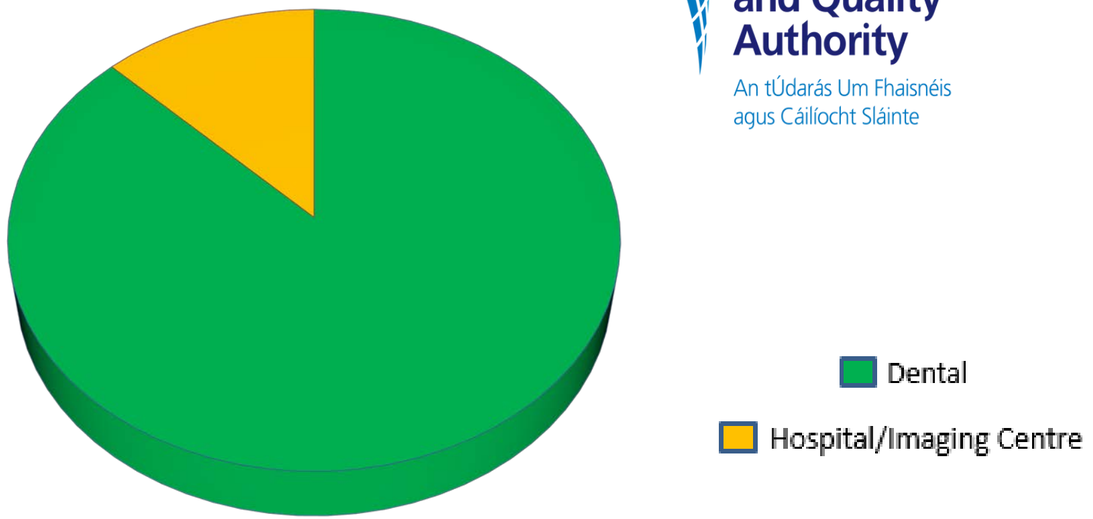
Inspections to date

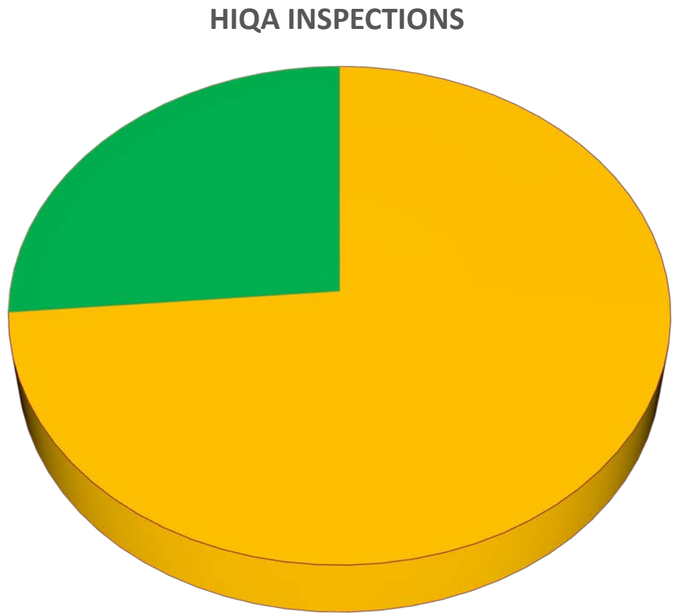
HIQA started inspection schedule in late 2019.

We currently have 1240 dental undertakings declared to us and 178 non-dental undertakings.

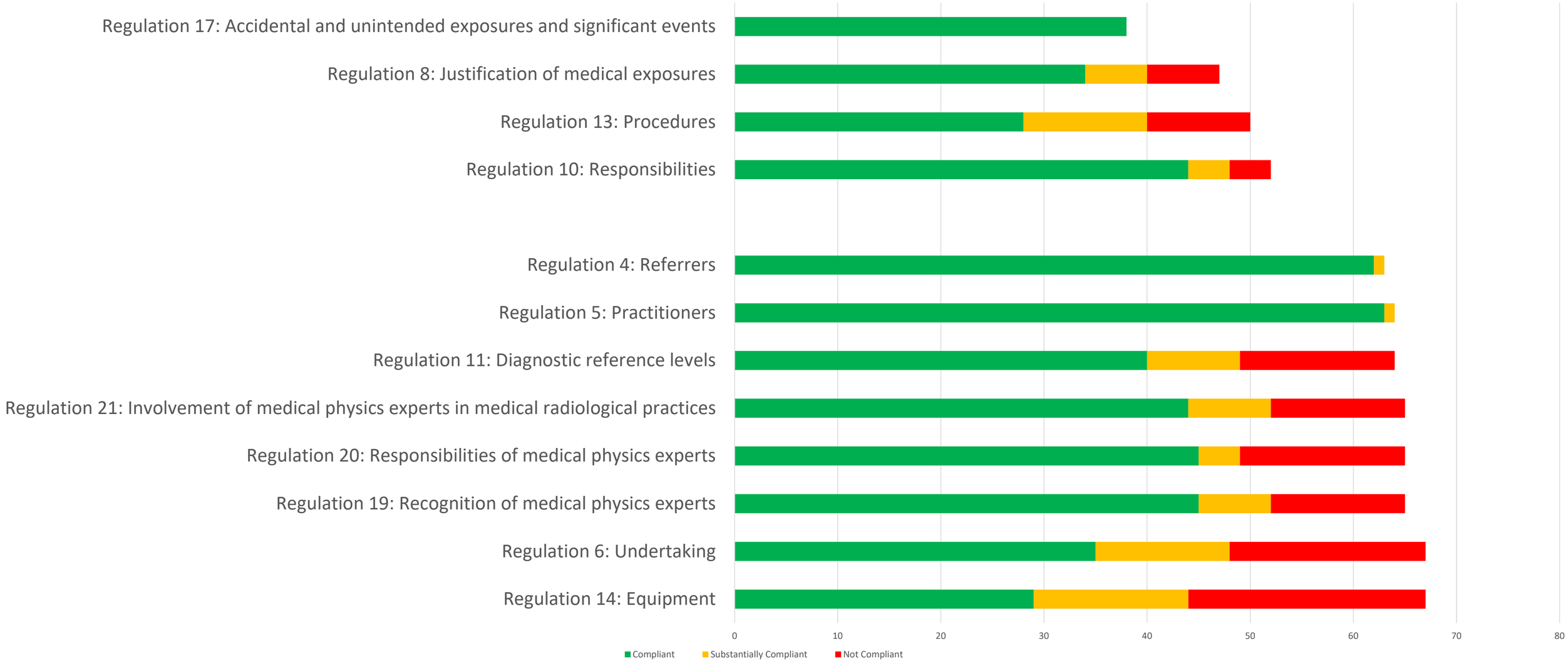
To date HIQA have inspected 296 ionising radiation services, 78 of which were dental facilities.

In 2023 of a total of 55 ionising radiation inspections 20 were dental. In 2024 thus far, of 37 inspections 7 have been dental

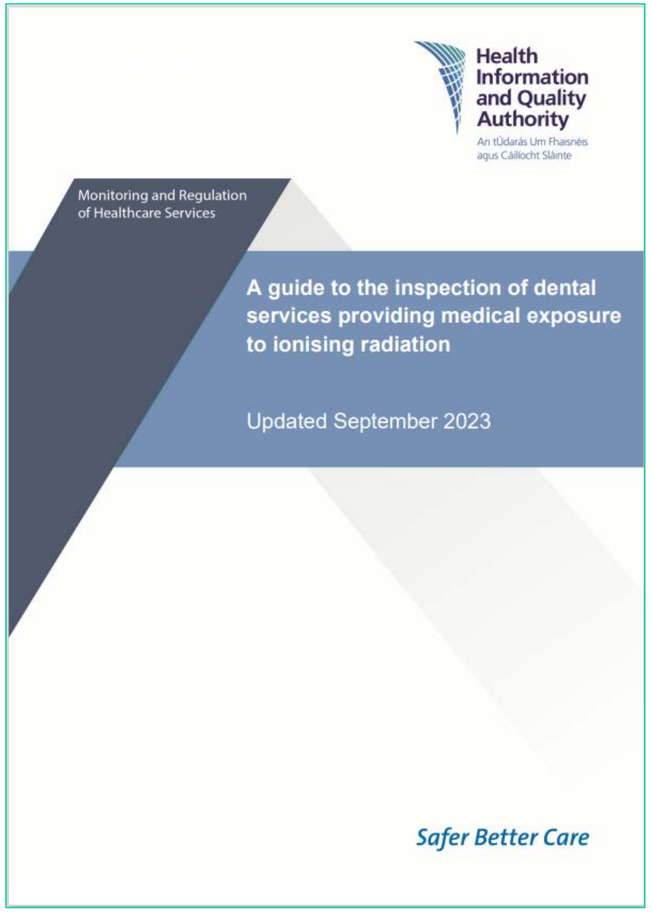


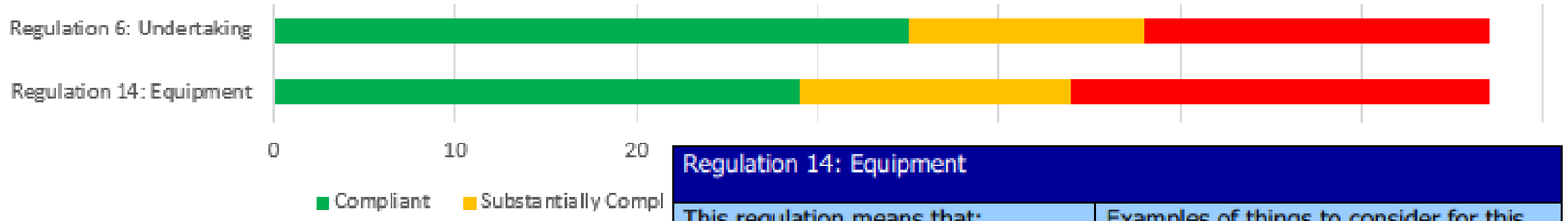


Inspections to date -Regulations inspected and compliance



HIQA Guidance - Appendix C



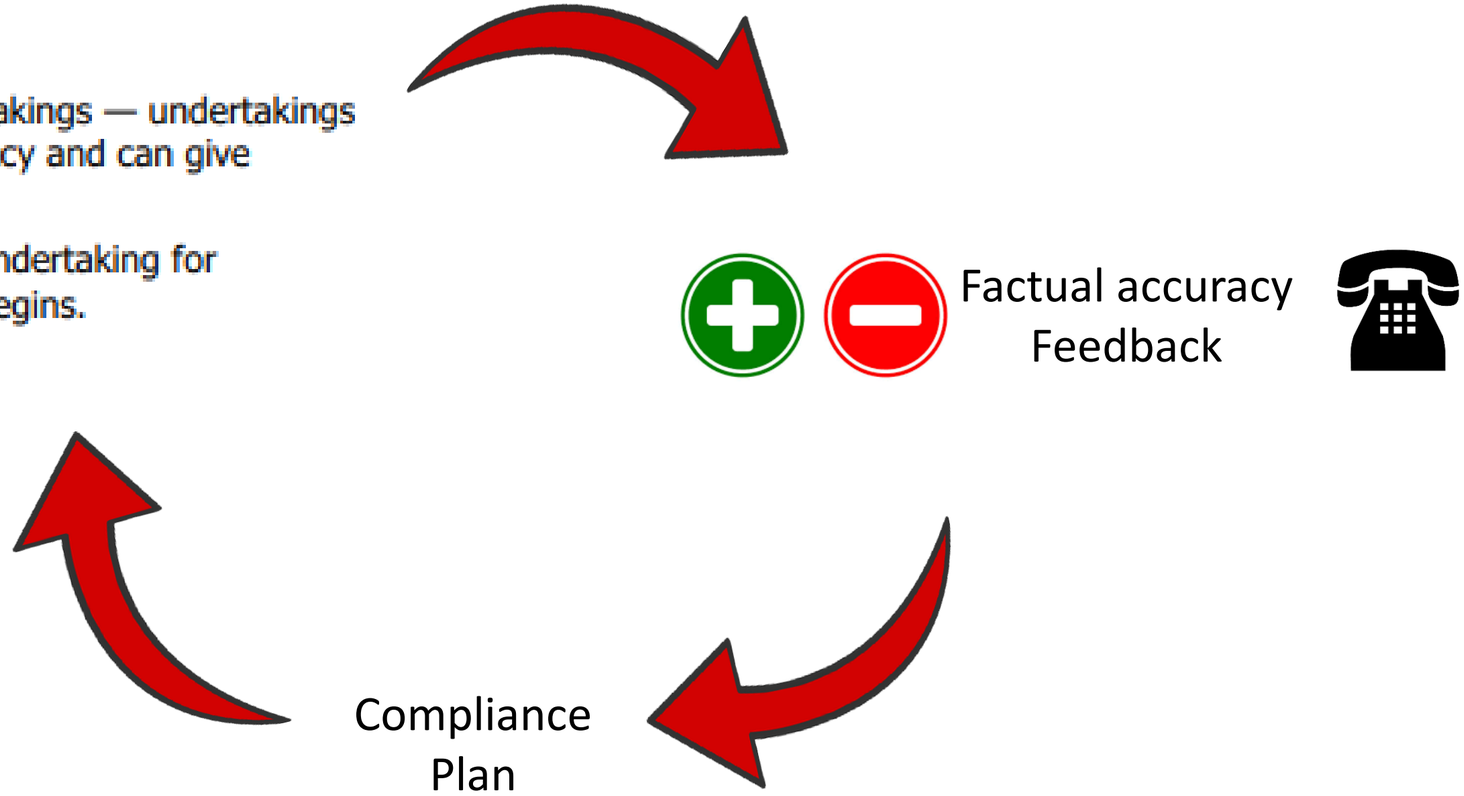


Regulation 6: Undertaking	
This regulation means that:	Examples of things to consider fo regulation
▪ An undertaking is responsible for providing safe, effective and person-centred care to service users undergoing dental exposure to ionising radiation in compliance with the regulations. ▪ The undertaking must ensure that there is a clear allocation of responsibility for the radiation protection of service users within its facility.	▪ Have you clearly outlined responsibilities, and how these allocated, within this facility fo radiation protection of people your service? ▪ Is this information documente ▪ Is this available to, and under by, all staff involved in exposu

Regulation 14: Equipment	
This regulation means that:	Examples of things to consider for this regulation
▪ Undertakings have arrangements in place to ensure that the radiological equipment is safe for use and fit for purpose. ▪ Undertakings must implement and maintain an appropriate quality assurance programme to monitor and evaluate the safe delivery of dental exposures and their outcomes for patients. ▪ The undertaking's quality assurance programme should incorporate an agreed quality control plan to assess and monitor equipment. ○ This should include an appropriate programme to assess radiation dose.	▪ How is your radiological equipment kept under strict surveillance to ensure the radiation protection of those using your service? ▪ Do you have relevant records of the acceptance testing of your radiological equipment available for review? ▪ Are the relevant records of performance testing or equipment service also available?

Report (2 Stage Process)

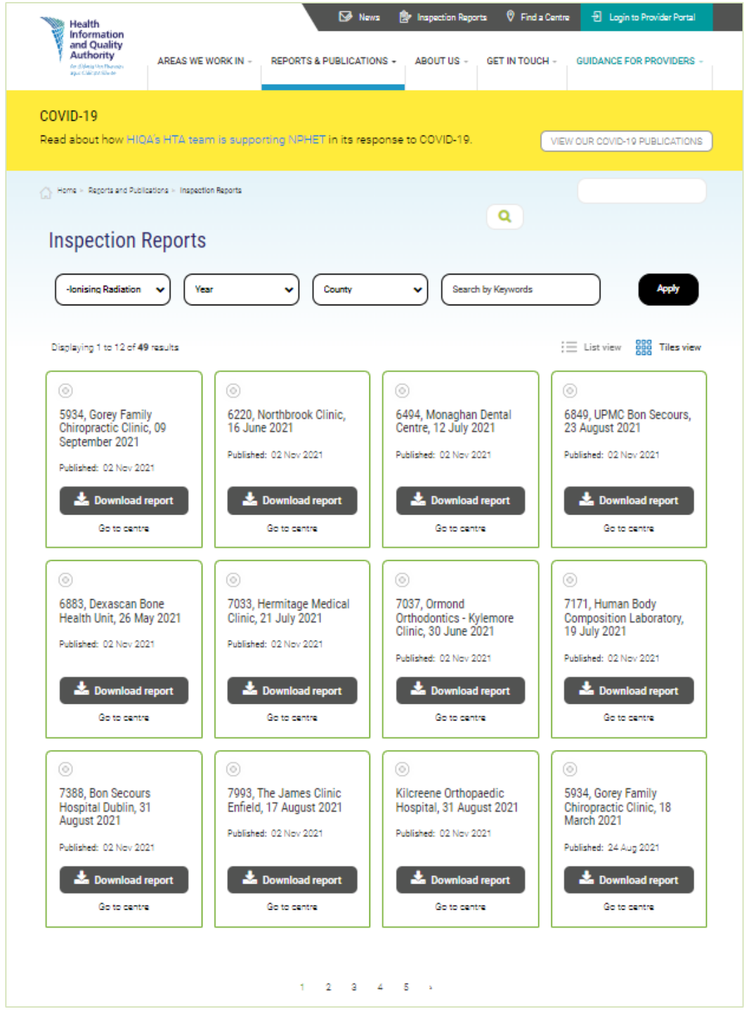
- **Draft inspection report:** draft report issued to undertakings — undertakings should check this version of the report for factual accuracy and can give general feedback.
- **Final inspection report:** final report is issued to the undertaking for information only and when HIQA's publication process begins.



Report (2 Stage Process)

All communication from HIQA about the inspection will be communicated to the **designated manager** email address and copied to the **undertaking** email address.

Report issued within 20 working days after inspection factual accuracy, feedback and compliance plan due within 21 calendar days of issue



Summary

Any dentist using ionising radiation is subject to regulation and subsequent inspection from BOTH the EPA and HIQA

HIQA and the EPA are separate entities and inspect independently of each other

However, there are similarities in many aspects of our regulatory work, information required and the inspection process

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

&

epa
Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Thank You