Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Monitoring and Regulation of Healthcare Services

A guide to the inspection of dental services providing medical exposure to ionising radiation

Updated September 2023

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services —** Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Contents

Revision history

Version history	Publication date/revision date	Title	Summary of changes
Version 1.0	September 2020	A guide to the inspection of dental services providing medical exposure to ionising radiation.	Not applicable
Version 2.0	September 2023	A guide to the inspection of dental services providing medical exposure to ionising radiation.	Update in relation to the process for issuing draft and final report. Minor changes to text.

1 Introduction

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 [i] and associated amendments [*] provide a framework for regulating medical exposure[†] to ionising radiation in Ireland. The Health Information and Quality Authority (HIQA)[‡] is the competent authority in Ireland with responsibility for inspecting against and enforcing these regulations.[§]

As part of its regulatory function, HIQA is responsible for assessing if public and private dental facilities in Ireland comply with the regulations. Throughout this document, the terms 'dental facility' or 'dental practice' means an installation or service where medical radiological procedures, such as X-rays and cone beam computed tomography (CT), are performed. It does not refer to an individual piece of equipment. The terms 'dental facility' or 'dental practice' are occasionally shortened to 'facility'.

In order to carry out its functions as required by the Health Act 2007 (as amended), HIQA has adopted a common Authority Monitoring Approach (AMA).[ii] This means we use a risk-based approach to carry out our regulatory activities. HIQA has employed staff under the regulations to monitor compliance and work within the powers described in the regulations. These staff, appointed as 'authorised persons'[**] are referred to as inspectors throughout this document.

Inspectors use the following documents when assessing compliance with the regulations:

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[*] The amendments associated with the regulations (S.I. No. 256/2018) are available online from: http://www.irishstatutebook.ie/eli/2018/si/256/made/en/pdf.

[†] The term "medical exposure" is used to describe any exposure of an individual to ionising radiation, including dental exposures. For the purposes of this document the term "dental exposure" will also be used. This refers to all exposures undertaken within a dental facility, and carries the same requirements under the regulations as "medical exposure".

[‡] HIQA refers to 'the Authority' or Health Information and Quality Authority as defined in section 2 of the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 S.I. No. 256 of 2018.

[§] Throughout this document 'regulations' refers to The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and associated amendments.

[**] Authorised persons are appointed by HIQA under Regulation 24 of the regulations for the purpose of ensuring compliance with the regulations.

- *Guidance on the assessment of compliance in undertakings providing medical exposure to ionising radiation*
- *Assessment-judgment framework for undertakings providing medical exposure to ionising radiation.*

As both of these documents are applicable to dental facilities, undertakings[††] and designated managers are encouraged to use these, in conjunction with this guide. These documents are available online at www.hiqa.ie.

2 Who should use this document?

This guide provides details for dental undertakings of HIQA's monitoring approach for regulating dental services providing medical exposure to ionising radiation.

However, this inspection guide may also be used by smaller medical facilities providing medical exposure to ionising radiation, for example, stand-alone X-ray facilities.

Please note that a separate guide for medical facilities is available at www.hiqa.ie.[iii] Larger dental facilities or dental units that are part of a healthcare organisation, for example, within the Health Service Executive (HSE) or a dental hospital, may find the guidance document for medical facilities useful also.

3 What is the purpose of this document?

This guide provides undertakings and designated managers with details about HIQA's risk-based approach to regulations and gives undertakings an understanding of inspections of dental facilities against the regulations.

This guide includes information for an undertaking about:

- the format of HIQA's on-site inspections
- how we report the findings of an inspection.

Please note that this guide may be revised periodically as this inspection programme progresses and or changes. Always ensure you are using the most up-to-date version by consulting the HIQA website, www.hiqa.ie.

[††] An undertaking is defined in the regulations as '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'.

4 Who will we inspect?

HIQA uses a **risk-based approach** to regulation in accordance with Regulation 25 of S.I. No. 256 of 2018. The risk-based approach means we prioritise our activities based on an assessment of the level of risk in undertakings. HIQA uses information to inform its risk-based approach. The following list gives examples of the types of information we may have or we may receive about an undertaking or a facility. This information may trigger an inspection:

- solicited information,[‡‡] including statutory notifications and results of investigations into a significant event[§§]
- unsolicited information[***]
- results of a self-assessment questionnaire (see Appendix A for a sample)
- findings from previous HIQA inspections.

This risk-based approach informs how frequently we inspect an individual facility. It also informs the nature, intensity and type of inspection carried out. For example, we will carry out more inspections in those undertakings that expose service users[†††] to potentially higher radiological risk, such as dental facilities providing cone beam CT (CBCT) services. Undertakings providing services with potentially lower radiological risk will be routinely inspected but less frequently.

In acknowledging that more than one undertaking may be located in the same dental facility, HIQA, while working within the requirements of the legislation, aims to minimise the regulatory burden on a dental facility. HIQA will devise the inspection programme to focus on an individual undertaking while attempting to minimise disruption to other co-located undertakings within the dental facility.

[‡‡] Solicited information is information the undertaking is required to submit as part of its statutory obligations or requested by HIQA.

§§ A significant event is a radiation incident that has the potential to cause harm. For details on the types of significant events that are notifiable to HIQA under Regulation 17, please refer to our guidance document on www.hiqa.ie

[***] Unsolicited information is information not requested by HIQA but is received by HIQA from people, including staff, a member of the public or people who use the service.

[†††] Service users include patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research.

5 How will we inspect?

HIQA can use **announced** or **unannounced inspections**. Announcing an inspection means the relevant staff involved in carrying out dental exposure to ionising radiation are available to meet with the inspector and facilitate the inspection. This means our inspection findings are informed by the people working in the facility. Ten working days' notice will be given for **standard announced** inspections.

Occasionally, a **short-notice announced inspection** may be used. At least 48 hours' notice will be given of these inspections to facilitate meeting with the undertaking or the designated manager.

In some circumstances, an **unannounced inspection** may be carried out. This means that neither the undertaking nor the designated manager has been notified by us in advance either formally or informally of our inspection. The inspectors may simply turn up at the facility to carry out the inspection.

HIQA will mostly conduct announced inspections. However, unannounced inspections of facilities may happen, if needed, should HIQA become aware of a particular risk that is most appropriately evaluated through an unannounced inspection. Additionally, unannounced inspections may also be conducted, if deemed appropriate, to facilitate HIQA in carrying out its responsibility to assess compliance with the regulations.

Any significant change to this approach will be reflected in updated guidance.

6 Who will inspect?

The HIQA inspector is authorised to work within the powers described in the regulations to monitor compliance with the regulations. The inspector is obliged to comply with HIQA's Code of Conduct for staff, which is available online at www.hiqa.ie.

7 What happens before inspection?

Information from HIQA about the inspection will be communicated to the undertaking or the designated manager [‡‡‡]as appropriate. However, overall responsibility for compliance remains with the undertaking.

7.1 Scheduling

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. Every effort should be made by the undertaking to ensure relevant staff are on site on the day of inspection to meet with inspectors or to arrange for an alternative member of staff to be available should the relevant staff be unavailable. A proposed schedule outlining the inspection activities may be issued in advance of the inspection. See Figure 1 for a draft schedule of the day of inspection. The people HIQA expect to typically meet are outlined in Section 7.8 of this guide.

A **pre-inspection information request** will also be sent to the email address provided in the declaration received from the dental facility. The purpose of this request is to gather information on the management and oversight arrangements, and the safety systems and processes in place, to support exposure to ionising radiation in the facility. This information allows us to plan for the inspection and to minimise any disruption to the service on the day of inspection.

The pre-inspection information request identifies the documents that need to be submitted by email to HIQA before the inspection. A sample of this request is provided in Appendix B. The pre-inspection information request includes a request for an inventory of radiological equipment at the facility. The template attached to the notification of inspection email should be used. A sample of this template is also included in Appendix B.

As part of the pre-inspection information request, undertakings are also requested to provide a brief summary that should be limited only to the radiological service they provide. This summary is used by the inspector to populate th*e About the Service* section of the inspection report and additional information not relevant to the radiological service will be removed by the inspector before issuing the report.

Dental facilities do not need to create supplementary information or supporting evidence if the requested documents do not exist. There is no requirement to submit

[‡‡‡] Examples of appropriate designated managers for different undertaking types and the business types that may be categorised as an undertaking are available in our guidance document and are also shown in Appendix D.

other supplementary documentation or evidence in addition to the information requested.

The requested information must be returned to HIQA in soft copy, by email, **within five working days**.

7.2 Confidentiality

In line with current data protection legislation,[iv] HIQA requests that dental facilities do not send, by email or by post, information that could identify an individual service user.

7.3 Planning the inspection

We plan for all inspections in advance. To ensure the efficient running of the inspection and help to minimise any disruption to the service on the day of inspection, we review key pieces of information relating to the dental facility before going out on inspection. This information includes:

- pre-information request and related documents submitted by the undertaking to HIQA
- previous HIQA inspection reports, where applicable
- other relevant information received by HIQA in relation to the dental facility.

This review also helps to identify the specific lines of enquiry (questions to be asked) that inspectors will follow when on site at the dental facility. Lines of enquiry guide undertakings in the preparation for inspection and support inspectors in gathering evidence when assessing and making judgments on compliance.

The lines of enquiry for each regulation are detailed in the *Assessment-judgment framework for undertakings providing medical exposure to ionising radiation* document, which is applicable to all dental facilities and available on the HIQA website, www.hiqa.ie.

7.4 What happens on the day of inspection?

In most cases, inspectors will be on site for 3-4 hours, however, the inspection may take longer in certain circumstances, such as in larger facilities. During the inspection, inspectors will gather information relating to:

- the systems and processes in place for:
    - the safe delivery of ionising radiation
    - risk management and incident reporting
    - communicating with staff about radiation protection arrangements
- access to and use of policies, procedures and guidelines to support the safe use of dental exposure to ionising radiation
- monitoring arrangements in place for ionising radiation
- staff training and sharing of learning relevant to ionising radiation delivery.

The inspector will gather this evidence by talking with staff, visiting the clinical areas and reviewing documentation. They may also talk with service users.

Appendix C of this guidance document gives some practical suggestions that dental facilities may wish to consider when assessing the compliance of their service. However, undertakings should also consult the following more comprehensive documents which are available on the HIQA website:

- Assessment-judgment framework for undertakings providing medical exposure to ionising radiation and
- Guidance on the assessment of compliance in undertakings providing medical exposure to ionising radiation.

7.5 Arriving at the facility

When inspectors arrive at the dental facility, they will meet with the person that has overall accountability and responsibility for the dental facility on the day of inspection, for example, the undertaking or the designated manager. This could be the dentist as a sole trader in a smaller facility, or the undertaking representative or designated manager in a larger facility.

Inspectors will always carry personal identification and their certificate of authorisation while on inspection. At the start of the inspection, inspectors will present this documentation to the person they meet and they will explain the purpose of the inspection. Staff should always ask to see the inspector's identification documents before letting any individual enter the premises.

On arrival, inspectors will confirm the schedule for the inspection and who we will need to speak with. This will include the timing of meetings and who is required to attend in order to ensure that the relevant staff are available.

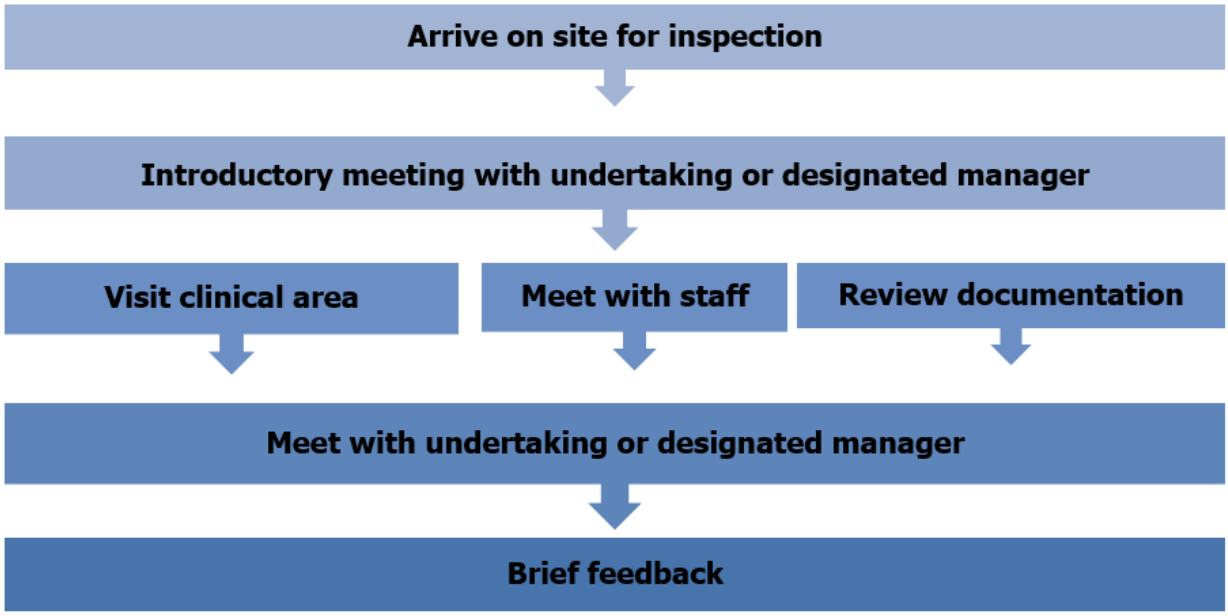
A sample outline of the on-site inspection component is shown in Figure 1. The inspection activities are subject to change depending on the information provided by the undertaking.

During the inspection, inspectors will:

- require access to X-ray referrals and accompanying records (electronic and hardcopy, as appropriate)
- wear dosimeters when on site (these will be provided and managed by HIQA)
- adhere to local rules, controls and safety measures in relation to radiation protection, including keeping to the principles of radiation protection
- wear personal protective equipment (PPE) in compliance with national guidelines and the dental facility's local policy
- follow HIQA's code of conduct for inspectors (available online at www.hiqa.ie).

While inspectors have powers of entry and inspection, these will be exercised respectfully towards staff and people using the services. We ask that relevant staff are informed that we are on site conducting an inspection and that inspectors are introduced to staff and service users, where appropriate to do so.

Figure 1. Outline of activities conducted during the on-site inspection – sample



7.6 The clinical area inspection

Inspectors will visit clinical areas where dental exposures, such as X-rays or CBCT scans, are carried out.

Information may be gathered through direct observation and review of documentation and information systems. Inspectors may also speak with service users and staff working in these areas. Service users' privacy and dignity will be respected at all times.

Inspectors will also assess if the required reference material for this clinical area is available to staff, for example, relevant policies, procedures and guidelines.

7.7 Reviewing the documentation

In addition to the documents submitted and reviewed before the inspection, inspectors will need to review further relevant documentation while on site. A sample list of this documentation is provided in Appendix B. HIQA may request some outstanding or additional documentation on the day of inspection.

During an inspection, you should ensure you respond to requests for information in a timely manner and deal with all matters as outlined in these requests. You should also ensure all the required records are available for inspection. Where hard copies of documents are requested by inspectors for removal from the dental facility, they should **not** contain data that identifies individual service users.

Additional documentation which may be requested by the inspector on the day of the inspection should be submitted electronically, in the requested format, within the timeframe specified by the inspector.

7.8 Scheduled meetings during inspection

The purpose of the meetings is to gather information about the safety systems and processes that have been implemented and evaluated to support ionising radiation safety and to protect the service user.

Generally, these meetings will take place after the clinical area inspection. The inspector will confirm these times and who they will need to meet with when they arrive on site. This will include:

- the undertaking (if available) or designated manager(s), and
- practitioner representative.

The attendance of the following list of people is desirable but not essential:

- representatives of persons that conduct dental exposures such as a dental nurse
- radiation protection officer
- chair of the radiation protection committee (if relevant, in a larger facility).

7.9 The close-out meeting

After the clinical area inspection, the document review and the meetings with staff, the inspection team will conduct a feedback meeting with the undertaking or the designated manager, as appropriate. While we will give feedback throughout the day, the purpose of the close-out meeting is to provide initial findings of the inspection. We will also identify any high risks that require immediate action throughout the inspection and at the feedback meeting.

It is the responsibility of the undertaking to devise appropriate actions to reach compliance within the facility. While inspectors may provide examples of known good practice, inspectors will **not** act as consultants or advisers on the means of achieving regulatory compliance.

8 What happens after the inspection?

After an inspection, inspectors use their professional judgment and are guided by the Authority Monitoring Approach (AMA), the assessment-judgment framework and the guidance document to assess compliance with the regulations. Inspectors will judge whether the undertaking is **compliant, substantially compliant** or **not compliant.**

These compliance descriptors are defined as follows:

- **Compliant**: a judgment of compliant means the undertaking is in full compliance with the relevant regulation.
- **Substantially compliant**: a judgment of substantially compliant means that the undertaking 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 has not complied with a regulation and that **considerable action** is required to come into compliance.

We will then generate an individual report for each inspected dental facility. The report will contain the inspection findings and judgments on the level of compliance. A compliance plan form will also be included, if relevant. (Details on the compliance plan are available in Section 8.4). We will publish the report and the compliance plan on HIQA's website, www.hiqa.ie.

8.1 The inspection report

Inspection reports are fair, balanced and reflect good practice and where improvements are required in the facility. The inspection report aims to describe:

- the quality and safety of dental exposures to ionising radiation
- how compliant the undertaking is with the regulations and the impact of this on service users
- the undertaking's management and oversight of risk, and whether this is a good service or if it needs to improve.

Inspection reports are a summary of our findings and do not need to reference all of the information reviewed by the inspector during the inspection.

Each inspection report goes through **two main stages** as it is prepared for publication:

- **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, which may or may not be different from the draft report. It is issued to the undertaking for information only and when HIQA's publication process begins.

Any non-compliance will be included in the compliance plan form that will accompany the report. The undertaking will be required to complete and return the compliance plan form with details of the actions that it has taken, or intends to take, to come into compliance. The compliance plan will be published with the report and therefore, the undertaking must **not** include individual staff names or other personal data relating to staff or people using services in the compliance plan response.

8.2 Draft report

After the inspection, the draft report is issued by email to the undertaking. We aim to issue this report to the dental facility within **20 working days** of inspection. A feedback form will also be attached with the draft inspection report.

Undertakings have the right to provide feedback on perceived factual inaccuracies and on judgments made in the report. Undertakings are asked to check the draft report for factual accuracy and submit feedback to us using the provided form. We welcome such feedback.

Additionally, if an undertaking believes our regulatory judgments in the draft inspection report are incorrect or not proportionate to the evidence reviewed by the inspector, they may choose to submit feedback to us on our judgments.

The undertaking can include proposed factual accuracy amendments along with general feedback on the form provided. However, before returning the feedback form, the undertaking is encouraged to engage, by phone and or email, with the inspector to discuss any queries or specific concerns they may have regarding the draft report.

Please note that feedback on the draft inspection report and the compliance plan (required when non-compliances were identified) are managed separately. While you **may** submit feedback on the draft report, you **must** submit a fully completed compliance plan and continue to take any necessary remedial actions required. Both the feedback form (if submitted) and the compliance plan should be submitted at the same time to HIQA.

To complete the feedback process (and having contacted the inspector, if necessary) the undertaking should formally complete the factual accuracy and feedback form and return it to HIQA within **21 calendar days** of the draft report being issued. Where no feedback is received, HIQA will progress to the finalised report.

8.3 Final report

If feedback is received on the draft report from the facility, HIQA will consider the feedback in the context of the evidence gathered on inspection and proceed to the final report stage.

If no feedback is received on the draft report on or before 21 calendar days, HIQA will proceed to the final report.

The final report is the report that will be published. This report is issued to the undertaking for information before it is published.

Once the final report is sent to the undertaking, HIQA's publication process begins. **Five working days'** notice will be given to the undertaking before the report and the compliance plan, where relevant, are published on the HIQA website.

8.4 What is a compliance plan?

When we identify a non-compliance (this is a finding of 'substantially compliant' or 'not compliant') with a regulation(s), a compliance plan will be included in our report. The compliance plan must be completed by the undertaking and detail how and when the undertaking will comply with the regulation(s) that it has failed to meet.

Each compliance plan is divided into **two sections**. Undertakings **must** submit the compliance plan in the required format. Instructions on how to complete the compliance plan are provided at the beginning of the compliance plan form and must be followed to ensure that each section is completed in the requested format.

Failure to complete the compliance plan as per instructions may result in rejection of the compliance plan and possible escalation. **Section 1** outlines the overall regulation(s) the undertaking must take action on in order to come into compliance. Each undertaking is accountable and responsible for developing, approving and implementing a compliance plan that prioritises the improvements necessary to comply with the regulations. The undertaking's compliance plan should be **SMART** in nature, that is to say:

- **S**pecific to that regulation
- **M**easurable so progress can be monitored
- **A**chievable
- **R**ealistic
- **T**ime bound.

Section 2 contains a list of all regulations where it has been assessed the undertaking is substantially compliant or not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users. Depending on the level of risk identified, a specific time frame for implementing the compliance plan may be set by HIQA. If a specific time frame is not set by HIQA, the undertaking must indicate the time frame, within a reasonable time line, by including a date in the requested format.

Undertakings should ensure that they return a satisfactory compliance plan within **21 calendar days** from the time the draft report is issued.

8.5 What happens after a completed compliance plan is received?

The inspector will check that the returned compliance plan does not contain personal data relating to staff or service users. If the compliance plan contains personal data, it is rejected and deleted and the undertaking will be informed that a new plan must be submitted without personal data.

If the returned compliance plan contains commentary that is unrelated to addressing the non-compliance but does not contain personal identifiable information as outlined above, such commentary may be removed before publishing the compliance plan in the published inspection report.

Where we have made a judgment of **not compliant**, the undertaking must take **considerable action** to comply with the relevant regulation. Where the non-compliance does not pose a high risk to service users, we will risk-rate it as a moderate risk, and the undertaking must take action within a **reasonable time frame** to come into compliance. This will be reflected in the compliance plan.

Where the non-compliance is persistent or poses a high risk to service users, undertakings will be given a **compliance deadline** in the compliance plan form that we issue.

We will determine if the undertaking's response adequately assures us that the undertaking understands the regulatory failings and can address them within the time frame provided.

It is the undertaking's responsibility to ensure that it implements the actions in the compliance plan within the set time frames. Later, as part of our continual monitoring to assess compliance, we may ask the undertaking to update us about how it is implementing its compliance plan.

During future inspections, the inspection team will check for evidence that dental facilities have taken account of the findings of its individual inspection reports and, where appropriate, that the actions detailed in the compliance plans have been put in place to address any required areas of improvement identified by HIQA.

We monitor compliance plans until undertakings have demonstrated that all identified non-compliances have been addressed, sometimes long after the on-site inspection has taken place.

Undertakings should note that if adequate assurance is not provided in the compliance plan received, the report will be published with the following inserted text after the undertaking response under the each relevant regulation.

> *This compliance plan response from the Undertaking did not adequately assure the Health Information and Quality Authority that the actions will result in compliance with the regulations.*

Whenever the inspector is not assured about the undertaking's understanding of the regulatory failing and the undertaking's ability to address the failing within the time frames outlined, we can, at that point, decide if any additional regulatory activity needs to be taken. This can include, but is not limited to, increased monitoring or escalation activity.

9 Escalation and enforcement

HIQA will take a firm but fair approach in carrying out enforcement activities. We will enforce in a way that is:

- fair and non-discriminatory
- efficient and effective
- transparent
- proportionate

- consistent.

The regulatory activities we will employ to bring about improvements may include:

- increased monitoring and focused risk-based inspections
- seeking compliance plans and assurance reports from the undertaking
- cautionary meetings with the undertaking
- warning meetings and issue of a warning letter to the undertaking.

However, should these fail to bring about compliance with the regulations or if there is a serious risk to service users, we are likely to take enforcement action. Where escalation and or enforcement are necessary, these will be in line with Part 5 and Part 6 of the regulations and may include:

- issuing a compliance notice
- issuing a prohibition order
- taking equipment out of service (prohibition order served)
- seizing of equipment (prohibition order served)
- destruction of equipment (prohibition order served)
- informing external agencies and interested parties
- prosecution.

The specific details of these processes will be provided to undertakings where escalation and enforcement is required.

10 How to contact HIQA

General queries or questions in relation to HIQA's ionising radiation programme or the information contained within this guide can be sent by email to radiationprotection@hiqa.ie. HIQA will refer any queries to a member of the Healthcare Team involved in the ionising radiation programme.

Any queries or issues with accessing or using the portal system should be directed to the portal support team at portalsupport@hiqa.ie.

11 Freedom of Information

Please note that HIQA is subject to the Freedom of Information (FOI) Act 2014.[v] HIQA may receive a request under the FOI Act for access to records that concern you. If HIQA receives an FOI request which relates to you, HIQA will consider the request in accordance with the provisions of the FOI Act and may consult with you to seek your views on the release of this information.

Please note, while your views on the release of the information will be taken into account, the FOI Act mandates that information that is commercially sensitive, information given in confidence, or personal information, should be released if the public interest is better served by granting the request than by refusing it. Accordingly, we cannot give you an assurance that confidentiality of information can be maintained in all circumstances.

12 Data protection

HIQA collects and processes personal data for the performance of its functions under the Health Act 2007. For more detailed information on how HIQA uses personal data and information about the rights of data subjects, please see our Privacy Notice: https://www.hiqa.ie/reports-and-publications/corporate-publication/hiqa-privacy-notice.

If you have any queries about the processing of your personal data, please contact HIQA's Data Protection Officer at dpo@hiqa.ie.

13 References

1 European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018. Dublin: The Stationery Office; 2019. *Available online from:* http://www.irishstatutebook.ie/eli/2018/si/256/made/en/pdf. Accessed on: 19 August 2020

2. Health Act 2007. Dublin: The Stationery Office; 2007. *Available online from:* http://www.oireachtas.ie/documents/bills28/acts/2007/a2307.pdf. *Accessed on:* 19 August 2020

3. Health Information and Quality Authority. *A guide to the inspection of services providing medical exposure to ionising radiation [online].* 2023 *Available online from*: A guide to the inspection of medical services providing medical exposure to ionising radiation | HIQA. *Accessed on*.18 September 2023

4. Data Protection Act 2018, The Stationery Office; 2018. *Available online from:* https://data.oireachtas.ie/ie/oireachtas/act/2018/7/eng/enacted/a0718.pdf *Accessed on:* 19 August 2020

5. Freedom of Information Act 2014. Dublin: The Stationery Office; 2014. *Available online from:* www.oireachtas.ie/documents/bills28/acts/2014/a3014.pdf *Accessed on:* 19 August 2020

Unless otherwise stated, all online references were accessed at the time of preparing this document. Please note that web addresses may change over time.

The amendments associated with the regulations listed in reference No.1 (S.I. No. 256/2018) are available online from: http://www.irishstatutebook.ie/eli/2018/si/256/made/en/pdf.

14 Appendix A — Example of dental self-assessment questionnaire

The self-assessment questionnaire is a regulatory tool that can be used by HIQA to assess compliance with the regulations. When issued to an undertaking, it will be accessed through the HIQA portal available on the HIQA website at www.hiqa.ie Details on using portal are also available on the website.

Your self-assessment questionnaire will be issued depending on the service types that you identified to HIQA on your *Declaration of undertaking notification form (NF200)*. Service types indicated for dental facilities may include dental **only**, or dental with cone beam CT. It is therefore important that you ensure that you indicated the correct service type to HIQA. If your service type is incorrect, or has changed, please ensure HIQA is notified by following the information available online at www.hiqa.ie or notifying HIQA through the HIQA portal.

A sample of the self-assessment questionnaire used for a dental facility with a service type of dental **only** (without CBCT) is available on the following pages.

Dental self-assessment questionnaire sample

Regulation 5: Practitioners		
Please tick yes or no	Yes	No
Is clinical responsibility for individual medical exposures only taken by a person who is a member of one or more of the following categories: ▪ dentist registered by the Dental Council in Ireland ▪ medical practitioner registered by the Medical Council in Ireland or ▪ radiographer or radiation therapist registered by the Radiographers Registration Board?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Not compliant

Regulation 6: Undertaking		
Please tick yes or no	Yes	No
Is responsibility for the protection of service users from medical exposure to ionising radiation clearly specified?		

Self-assessment of compliance — tick the box which best reflects your performance under this Regulation.

Compliant	Substantially compliant	Not compliant

Regulation 7: Justification of practices		
Please tick yes or no	Yes	No
When implementing a new practice or if new and important evidence about a practice, or a technique, or a technology emerges, have you considered that generic justification may be required?		
If you have deemed that generic justification is required, have you received approval from HIQA for this practice, or technique, or technology, or verified that approval from HIQA for this practice, or technique or technology is already in place?		

Self-assessment of compliance — tick the box which best reflects your performance under this Regulation.

Compliant	Substantially compliant	Not compliant
		

Regulation 8: Justification of medical exposures		
Please tick yes or no	Yes	No
Are all individual medical exposures justified in advance by the referrer and the practitioner? ('Justified' means the benefits outweigh the risks.)		
Are all referrals given in writing or electronic format?		
Do all referrals state the reason for requesting the particular procedure?		
Do you provide service users with information relating to the benefits and risks associated with the radiation dose from medical exposures?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant

Regulation 9: Optimisation		
Please tick yes or no	Yes	No
Do you ensure that all doses due to medical exposure are kept as low as reasonably achievable, in order to obtain the required medical information?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant

Regulation 10: Responsibilities		
Please tick yes or no	Yes	No
Are the practical aspects (physical conduct) of a medical exposure only delegated by the undertaking or a practitioner?		
Are the practical aspects (physical conduct) of a medical exposure only delegated to individuals who have completed a course in radiation safety, and are registered or recognised by the following? (i) the Dental Council (ii) the Minister for Health (under Regulation 19) (iii) the Nursing and Midwifery Board of Ireland (iv) the Radiographers Registration Board or (v) the Medical Council		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant

Regulation 11: Diagnostic reference levels		
Please tick yes or no	Yes	No
Do you establish and review your diagnostic reference levels for the exposures you conduct?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant
		

Regulation 13: Procedures		
Please tick yes or no	Yes	No
Do you have written protocols for every type of standard medical radiological procedure; for each type of equipment; for relevant categories of patients?		
Do you conduct clinical audits, in accordance with national procedures, in relation to service users?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant
		

Regulation 14: Equipment		
Please tick yes or no	Yes	No
Do you have an up-to-date inventory of radiological equipment?		
Does your X-ray equipment have the means to measure individual service users' radiation doses?		
With respect to medical radiological equipment, do you implement and maintain:		
▪ appropriate quality assurance programmes?		
▪ acceptance testing and regular performance testing?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant
		

Regulation 17: Accidental and unintended exposures and significant events		
Please tick yes or no	Yes	No
Do you have a system to identify, record and investigate potential and actual accidental and unintended exposures?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant
		

Regulation 18: Estimates of population doses		
Please tick yes or no	Yes	No
Do you record information on the number of radiological procedures per year that your installation (facility) carries out?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant

Regulation 21: Involvement of medical physics experts in medical radiological practices		
Please tick yes or no	Yes	No
Do you have access to a medical physics expert for consultation and advice, as appropriate?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant

Regulation 22: Education, information and training in field of medical exposure		
Please tick yes or no	Yes	No
Do you ensure practitioners have adequate education, information, theoretical and practical training as well as relevant competence in radiation protection?		
Are the practical aspects of radiological procedures only delegated to individuals with adequate education, information, theoretical and practical training, and competence in radiation protection?		
Do you ensure that practitioners, and individuals to whom the practical aspects of medical radiological procedures are delegated, have carried out continuing education and training after qualification?		

Self-assessment of compliance — tick the box which best reflects your performance under this regulation.

Compliant	Substantially compliant	Not compliant
		

15 Appendix B — Required inspection documentation

This document request form is a **sample** of the types of documentation that may be requested before an inspection. It is important **not** to include any personal identifiable information relating to services users in the submitted documentation.

Pre-inspection documentation request	
Please note: all personal identifiable information must be redacted in advance before forwarding to HIQA	
A.1	Radiation safety procedures or equivalent document(s) which details: ▪ the overarching management and oversight structures (accountability) in this practice or facility. ▪ the chain of responsibilities for the radiation protection of people who use your service
A.2	If applicable, the terms of reference of the Radiation Safety Committee, or local equivalent committee, and minutes of the last three meetings
A.3	Radiation safety procedures or equivalent document(s) which details: ▪ how referrals for radiological exposures are received and justified (approved) ▪ how radiological exposures are optimised ▪ how events involving or potentially involving accidental and unintended exposures and significant events are managed ▪ the policy on quality assurance and quality control of the radiological equipment
A.4	Records showing: ▪ acceptance testing of each item of radiological equipment installed after 8 January 2019 ▪ 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

A.5	An inventory of all radiological equipment (using the template attached to inspection announcement email)
A.6	i) Radiation safety procedures or equivalent document(s) which details how diagnostic reference levels (DRLs) for radiological procedures are established and reviewed
	ii) A copy of the local facility DRLs
A.7	List of other associated undertakings working within this facility or practice.
A.8	A brief summary page of all events involving or potentially involving accidental and unintended radiological exposures **for the last 12 months** to include: ▪ the records and documentation and ▪ overall trending and analysis
A.9	List of the titles and date of completion of clinical audits conducted in the last 12 months relating to radiological exposures
A.10	Written protocols or procedures for every type of radiological procedure, for each type of equipment, for relevant categories of patients (including paediatric, where relevant)

This document request form is a sample of the types of documentation that may be requested onsite during an inspection.

On site documentation review	
NOTE: Only the documents below should be provided. If contained as part of a larger documents the relevant parts should be indicated. Where available in electronic format, the soft copy will suffice.	
B.1	List of the following professionals including associated professional recognition and training documentation for: i. Practitioners, ii. Medical Physics Expert(s) and iii. other individuals delegated the practical aspects of conducting radiological exposures.
B.2	Facilitated access to referrals for radiological procedures, imaging records and reports

Information required in medical radiological inventory request
Name of equipment
Location of equipment
Manufacturer/Model
Serial number
Date of installation of equipment
Date of initial acceptance testing
Date of most recent MPE QA testing
Nominal replacement date
Record of decision to use beyond nominal replacement date (if applicable)

16 Appendix C — What to consider when assessing your level of compliance

This table gives **some** practical suggestions that you may wish to consider when assessing your dental facility's level of compliance. This is not intended to be a comprehensive summary of all the regulations that should be considered. Other regulations not included in this table, may also be included in an inspection. Therefore, it is important that dental facilities consult the following documents when preparing for an inspection as HIQA's judgments' of compliance will be based on these documents:

- Assessment-judgment framework for undertakings providing medical exposure to ionising radiation
- Guidance on the assessment of compliance in undertakings providing medical exposure to ionising radiation

These documents are applicable to all dental facilities and are available online on the HIQA website, www.hiqa.ie.

In the following table, **exposures** refers to medical exposure to ionising radiation for dental purposes, for example, dental X-rays and or cone beam CTs.

Regulation 4: Referrers	
This regulation means that:	Examples of things to consider for this regulation
▪ Only appropriately trained and recognised professionals, as defined in Regulation 4, can refer an individual for a medical exposure. ▪ Those carrying out medical exposures must ensure that people have only been referred for radiological procedures by an appropriate individual.	▪ Are all referrals for dental exposure to ionising radiation from either doctors, dentists, radiographers or nurses? ▪ Do you have documentation outlining which professions and or professionals this practice (facility) can accept referrals from?

Regulation 5: Practitioners	
This regulation means that:	Examples of things to consider for this regulation
▪ Only a person as defined in Regulation 5, takes clinical responsibility for individual medical exposures. ▪ The practitioner acts in accordance with the scope of practice of their relevant professional bodies.	▪ Do you have documentation outlining the professionals and or professions who are considered practitioners in this facility?

Regulation 6: Undertaking	
This regulation means that:	Examples of things to consider for this 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 are allocated, within this facility for the radiation protection of people using your service? ▪ Is this information documented? ▪ Is this available to, and understood by, all staff involved in exposures?

Regulation 8: Justification of medical exposures	
This regulation means that:	Examples of things to consider for this regulation
▪ The justification of a dental exposure to ionising radiation is the decision whether or not to carry out the exposure on the basis that the exposure should do more good than harm. ▪ This justification must be carried out by a suitable qualified practitioner, such as a dentist. ▪ The practitioner must take into account medical or dental information about the patient and ensure that they have been referred for the most appropriate option for them. ▪ Before the exposure takes place, information about the benefits and risks of the dental exposure should be made available to patients or their representatives.	▪ Are all referrals for dental exposures provided in writing or electronic format? ▪ Are all individual dental exposures justified in advance by a referrer and practitioner (this may be the same person) ▪ Is this recorded? ▪ Do all referrals include the relevant clinical background and the reason for the exposure? ▪ To avoid unnecessary exposures, is previous imaging considered before doing each exposure? ▪ Is information on the benefits and risks of dental exposures available and provided to patients?

Regulation 10: Responsibilities	
This regulation means that:	Examples of things to consider for this regulation

▪ The undertaking should have systems in place to ensure that the responsibilities for different aspects of exposures to ionising radiation are allocated to appropriate persons as required by Regulation 10.
▪ The practitioner taking clinical responsibility for a dental exposure to ionising radiation should be clearly identifiable and they should be aware of their responsibilities with respect of the exposure.
▪ The responsibilities allocated for justification, optimisation and the conduct of dental exposures should be clearly defined in the local radiation safety procedures.
	▪ Is each dental exposure carried out under the clinical responsibility of a practitioner and is this recognised and recorded?
	▪ Are the practical aspects of dental exposure delegated by the undertaking or the practitioner to persons other than dentists? If so;
	  ▪ Are these persons recognised in Regulation 10(4)?
	  ▪ Is this delegation documented?
	  ▪ Do you have records available of relevant radiation protection training for these individuals?
	▪ How is the practitioner, a medical physics expert (MPE) and the person doing the practical aspects involved in optimising dental exposures?
	▪ In the case of external referrals, how is the practitioner and the referrer involved in justifying all dental exposures?

Regulation 11: Diagnostic reference levels (DRLs)	
This regulation means that:	Examples of things to consider for this regulation
▪ DRLs are a benchmark of the typical dose levels for types of medical and dental exposures to ionising radiation which enables the identification of doses which consistently exceed relevant local and national DRLs. ▪ DRLs allow for comparison of doses received by patients having the same procedures in different rooms, dental facilities or organisations. ▪ The optimisation of patient protection through the implementation of DRLs ensures that patient doses delivered during dental exposures to ionising radiation are as low as reasonably achievable for the clinical purpose of the examination. ▪ Undertakings must establish and review DRLs at least every two years.	▪ Have DRLs for routine dental exposures been established in this facility? ▪ Are these DRLs reviewed at least every two years? ○ Is this review documented? ▪ Are these DRLs compared with national and or international levels?

Regulation 13: Procedures	
This regulation means that:	Examples of things to consider for this regulation

▪ An undertaking must have relevant policies, procedures and protocols for routine dental exposures that are carried out at the dental facility(s).
▪ Undertakings must ensure that information about the radiation dose for all individual patients' dental exposures is recorded with their clinical outcome (report which may be in the patient record).
▪ Undertakings should make referral guidelines or selection criteria available to referrers. Referral guidelines are a set of best practice criteria that recommend the most appropriate imaging depending on the clinical condition.
 	
An undertaking should ensure that clinical audits are carried out, in accordance with national procedures.
	▪ Are written protocols available for all types of standard dental radiological procedures, and include paediatric patients, if applicable?
	▪ How do you record information about radiation dose for a patient's dental exposures in a patient's record?
	▪ Are referral guidelines or selection criteria available? Examples of referral guidelines available for dental exposures include:
	  ▪ European Guidelines on Cone Beam CT for Dental and Maxillofacial Radiology[§§§]
	  ▪ European Guidelines on Radiation Protection in Dental Radiology[****]
	  ▪ The Faculty of General Dental facility Selection Criteria for Dental Radiography[††††]
	
	Do you conduct clinical audits in relation to the dental exposure of people who use your service?

[§§§] European Commission. Radiation Protection No. 172: Cone Beam CT for Dental and Maxillofacial Radiology, Evidence Based Guidelines. Office for Official Publications of the European Communities, Luxembourg; 2012. Available at: http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/172.pdf Accessed on: 19 August 2020

[****] European Commission. Radiation Protection 136 European Guidelines on Radiation Protection in Dental Radiology The safe use of radiographs in dental facility [online] 2004. Available at: https://ec.europa.eu/energy/sites/ener/files/documents/136_0.pdf Accessed on: 19 August 2020

[††††] Faculty of General Dental facility (UK). Selection Criteria for Dental Radiography 3rd Edition. London: Faculty of General Dental facility (UK); 2018.

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?

Regulation 17: Accidental and unintended exposures and significant events	
This regulation means that:	Examples of things to consider for this regulation
▪ Undertakings must implement and maintain arrangements to identify incidents, or potential incidents involving accidental or unintended exposures to ionising radiation. ▪ The management of local incidents should be communicated to all individuals involved in dental exposures of patients. ▪ The undertaking must ensure that any incidents that meet the criteria of a significant event are notified to HIQA in the required format and within the specified timeframe.	▪ How do you manage accidental and unintended exposures and potential accidental and unintended exposures in your facility? ▪ How do you ensure all staff are familiar with this process? ▪ Have you a system in place to record and analyse these events and potential events? ○ If so, are these records available? ▪ Is there a process to notify HIQA of significant events of accidental and unintended exposures should they occur?

Regulation 19,20,21: The Medical Physics Expert (MPE)	
This regulation means that:	Examples of things to consider for this regulation

▪ A MPE is an individual having the knowledge, training and expertise to act or give advice on matters relating to radiation physics applied to medical exposure, recognised by the Minister of Health and in transitional arrangements by the Irish College of Physicists in Medicine.
▪ It is a requirement of the regulations that an undertaking should put in place the necessary arrangements to ensure the continuity of medical physics expertise.
▪ The level of involvement of a MPE will vary relative to the radiological risk involved. For dental radiography, a named MPE provides consultation and advice on radiation protection. This advice should be provided to assist an undertaking meet the requirements of regulations that require MPE involvement. An example may be a MPE advising a dentist on the use of dosimetry to compare local DRLs to national DRLs.
	▪ Is the medical physics expert available for consultation and advice, when needed?
	▪ Is there a formal agreement in place to ensure your facility has a continuity of medical physics expertise from a recognised MPE?
	▪ How does the MPE contribute to the provision of dental exposure in this facility?
	  ▪ Is this as detailed in Regulation 20?
	  ▪ Are these roles and responsibilities documented?

Regulation 22: Education, information and training	
This regulation means that:	Examples of things to consider for this regulation

▪ Practitioners and or those that carry out the practical aspects of exposures must have education in radiation protection as required by the appropriate registering body, for example the Dental Council.
▪ Undertakings must ensure that only staff with required training, skills, experience and competencies, as required by the Dental Council, can act as practitioners and or carry out exposures.
▪ Practitioners and or those that carry out the practical aspects of exposures should complete appropriate training as part of a continual professional development programme. This should include continually updating and maintaining skills and techniques in relation to dental exposures, particularly when new technology becomes available.
	▪ Have you ensured that practitioners and or those who carry out the practical aspects of dental exposures have:
	  ▪ education, information and training in radiological practices and radiation protection as prescribed by the Dental Council and
	  ▪ completed continuing education and training after qualification, especially when new technology or techniques become available?

17 Appendix D — Examples of business types and designated managers

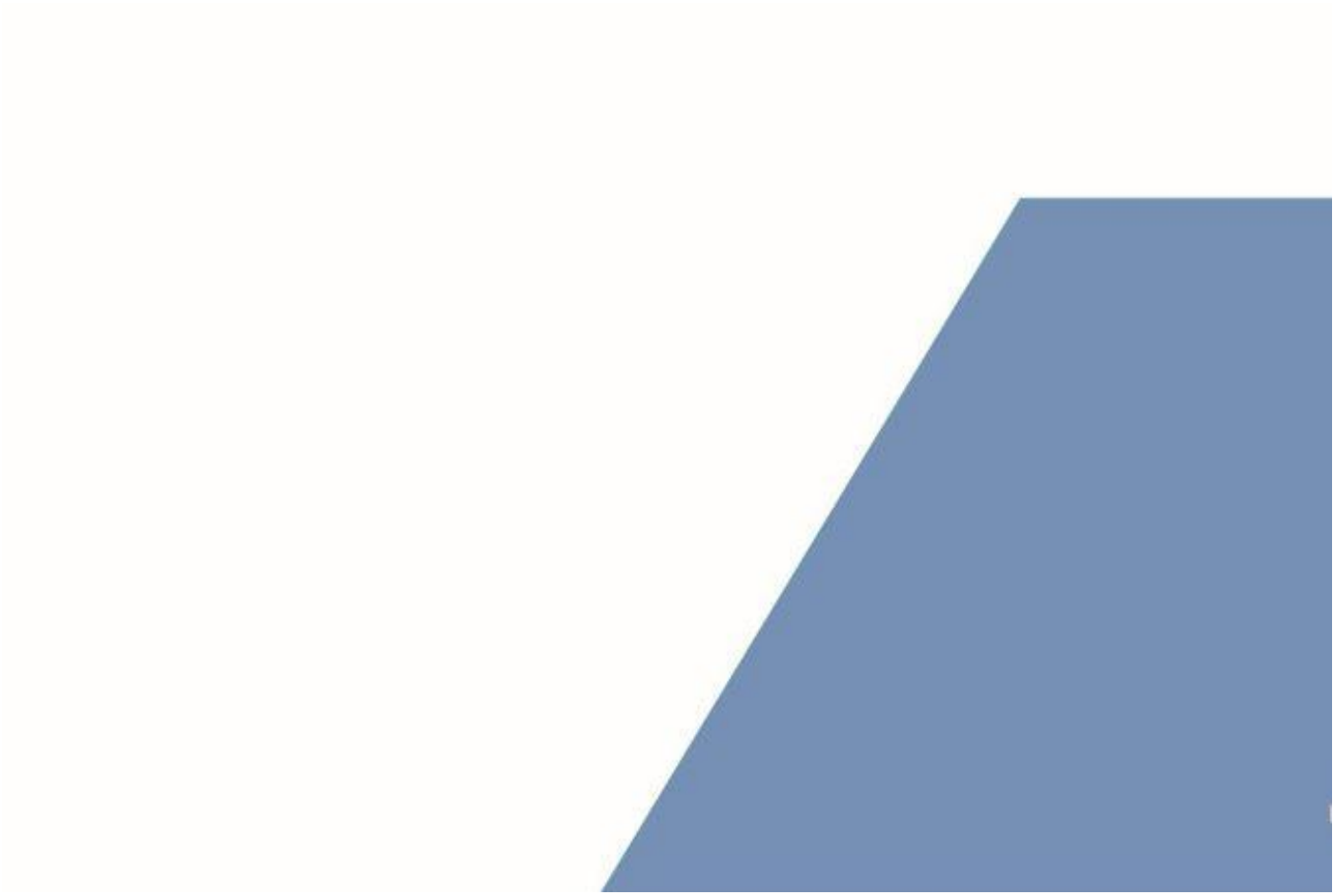
An example of the business types that may be categorised as an undertaking in line with the regulations is shown below. This table is taken from the *Undertaking information handbook*, which is available online at www.hiqa.ie.

Name	Definition
Sole trader	This is where only one single person is the legal owner/provider of the radiological service. In this case, this person (the sole trader) is an undertaking in his or her own name.
Partnership	A partnership exists where two or more persons carry on a business. A partnership is not a separate legal entity from those who run it. It is a collection of persons acting together to run a business. In the case of a partnership, the undertaking will be the persons who form the partnership, with each partner being legally responsible for the undertaking.
Company	A company is a legal form of business organisation and is established under the Companies Acts. It is a separate legal entity and is therefore distinct from those who run it. The company itself is legally responsible for the medical radiological procedures it carries out or engages others to carry out. In this case, the company is the undertaking and is legally responsible for compliance with the regulations.
Unincorporated body	An unincorporated body is formed when two or more persons come together for one or more non-business purposes such as a charitable or religious non-profit-making organisation. An unincorporated body is not a legal entity but has a distinct existence from that of its members. It is usually bound together by a set of rules or constitution.

	In this case, while the name of the body will be referenced, it is the relevant individual members or all of the members which will be the undertaking.
Body corporate	A body corporate may be a statutory body established by legislation which exercises specific functions authorised by statute. A body corporate may also be a voluntary body established, for example, by royal charter. The body corporate's board, directorate or other governance structure will exercise specific functions provided to that body by the establishing statute or charter. The body corporate is the undertaking and will be legally responsible for carrying out of the business of the undertaking.

An example of appropriate designated managers for different undertaking types is shown below. This table is taken from the *Undertaking information handbook*, which is available online at www.hiqa.ie.

Undertaking business type	Example of a designated manager
Sole Trader	The sole trader or practice manager
Partnership	A named partner or practice manager
Company	Practice manager
Unincorporated body	Operational manager
Body corporate	General manager



Published by the Health Information and Quality Authority (HIQA).

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