Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Monitoring and Regulation of Healthcare Services

# A guide to the inspection of medical 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 | November 2019 | A guide to the inspection of services providing medical exposure to ionising radiation | Not applicable |
| Version 2.0 | September 2020 | A guide to the inspection of medical services providing medical exposure to ionising radiation | Title and content changed to align specifically with medical services as a separate guide for dental services published in September 2020. Minor changes to the sample lists provided in Appendix B. |
| Version 3.0 | September 2023 | A guide to the inspection of medical 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[1] 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 medical radiological facilities in Ireland comply with the regulations Throughout this document, the term 'medical radiological facility' means an installation or service where medical radiological procedures, such as X-rays, are performed. It does not refer to an individual piece of equipment. The term 'medical radiological facility' is occasionally shortened to 'facility'.

In order to carry out its functions as required by the Health Act 2007 (as amended),[2] HIQA has adopted a common Authority Monitoring Approach (AMA). 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 to 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:

- *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.*

Undertakings[**] and designated managers are encouraged to use these documents in conjunction with this guide. Both documents are available online at www.hiqa.ie.

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

[†] HIQA refers to 'the Authority' or Health Information 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 European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018) for the purpose of ensuring compliance with the regulations.

[**] 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'.

## 2 Who should use this document?

This guide provides details for undertakings of HIQA's monitoring approach for regulating medical exposures to ionising radiation. It is primarily relevant to undertakings providing:

- general radiography
- radiotherapy
- nuclear medicine
- interventional radiology
- interventional cardiology
- computed tomography (CT).

To help gain an insight into the regulatory process, this guide may also be used by smaller installations providing medical exposure to ionising radiation; for example, larger dental practices or dental units that are part of a larger healthcare organisation, for example, a dental hospital. Please note that a separate guide about the inspection process in dental facilities is available at www.hiqa.ie.[3]

## 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 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.

## 4 Who will we inspect?

HIQA uses a **risk-based approach** to regulation in line 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 any 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 or facilities that expose service users[§§] to potentially higher radiological risk, such as interventional radiology and radiotherapy. Undertakings providing services with potentially lower radiological risk will be inspected less frequently.

## 5 How will we inspect?

HIQA can use **announced** or **unannounced inspections**. Announcing an inspection means the relevant staff involved in carrying out medical 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 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 our approach to announcing inspections will be reflected in updated guidance.

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

[‡‡] Unsolicited information is information not requested by HIQA but is received by HIQA from any member of the public.

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

# 6 Who are the inspection team?

The inspection team are authorised to work within the powers described in the regulations to monitor compliance with the regulations. Inspectors are 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 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.

A **pre-inspection information request** will also be sent. The purpose of this request is to provide information on the governance arrangements and the safety systems and processes in place to support medical exposure to ionising radiation safety 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 (see Appendix B for a sample) identifies the documents that need to be submitted to HIQA before the inspection. 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.

Facilities do not need to create supplementary information or supporting evidence if the requested documents do not exist. There is no requirement to submit other supplementary documentation or evidence in addition to the information requested.

*** 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 C.

The requested information must be returned to HIQA in soft copy **within five working days** of being requested. All correspondence relating to the inspection should be sent to HIQA by the designated manager on behalf of the undertaking.

### 7.2 Confidentiality

In line with current data protection legislation,[4] HIQA requests that medical radiological facilities do not send 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 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 medical radiological facility.

This review also helps to identify the specific lines of enquiry (questions to be asked) that inspectors will follow when on site. 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 available on the HIQA website, www.hiqa.ie.

## 8 What happens on the day of inspection?

In most cases, inspectors will be on site for one day; however, the inspection may take longer in certain circumstances. A shorter inspection may be sufficient in smaller facilities, for example, a stand-alone X-ray facility.

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 clinical staff about radiation protection arrangements
- access to and use of policies, procedures and guidelines to support the safe use of medical exposure to ionising radiation

- monitoring arrangements in place to ensure oversight for ionising radiation
- staff training and sharing of learning relevant to ionising radiation delivery.

Inspectors gather this evidence by talking with staff, visiting the clinical areas and reviewing documentation. They may also speak with service users.

## 8.1 Arriving at the facility

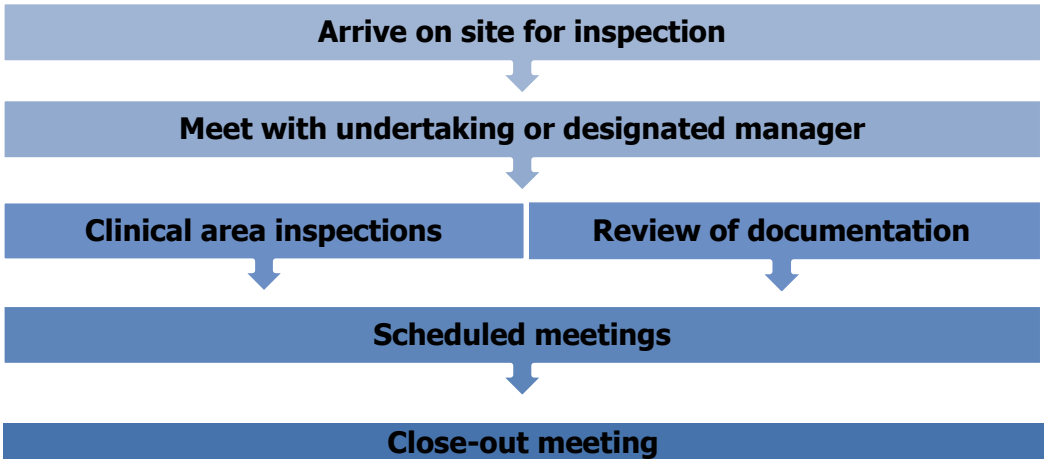
When inspectors arrive at the medical radiological facility, they will meet with the person with overall accountability and responsibility for the medical radiological facility on the day of inspection; for example, the undertaking or the designated manager. This could be the chief executive officer or the general manager in a hospital or a sole trader in a smaller 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 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.

Inspectors will confirm the schedule outlining the activities for the inspection. This will include the schedule of meetings and meeting times 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 schedule is subject to change depending on the information provided by the undertaking.

**Figure 1. Outline of an on-site inspection schedule- sample**




During the inspection, inspectors will:

- request access to a secure room for holding scheduled meetings and reviewing documentation
- require access to referrals and accompanying records (electronic and hardcopy,

as appropriate)

- request visitor name badges and be provided with the means to move freely throughout the facility during the inspection
- 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 and dose limitation, including keeping to the principles of radiation protection
- wear personal protective equipment (PPE) in compliance with the facility's local policy
- follow HIQA's code of conduct for inspectors (available online at www.hiqa.ie).

The means to move freely throughout the facility — such as keys, key fobs or key cards — should be made available to the inspection team as soon as possible following their arrival on site. These means of access will be returned to the designated manager or their representative at the end of the inspection.

While inspectors have powers of entry and inspection, these will be exercised respectfully towards staff and people using 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.

Large medical radiological facilities will be asked to nominate a liaison person who will be responsible for engaging with HIQA during the course of the on-site inspection.

## 8.2 The clinical area inspection

Members of the inspection team will visit a number of clinical areas to gather information. These clinical areas can include any areas that procedures relating to medical exposure to ionising radiation are carried out, for example, the radiology department and theatre.

Information and evidence 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 the clinical areas is available to staff, for example, relevant policies, procedures and guidelines.

## 8.3 Reviewing the documentation

In addition to the documents submitted and reviewed before the inspection (a sample list of this documentation is provided in Appendix B), inspectors will need to review further relevant documentation while on site. 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 medical radiological 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. Please ensure they do not contain information that identifies individual service users.

## 8.4 Scheduled meetings during inspection

The purpose of the scheduled 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, but the inspectors will confirm these times when they arrive on site. The inspection schedule will also list the members of staff that inspectors may need to meet with. This will include:

- the undertaking (if available) or designated manager
- practitioner representative (this individual should **not** be the chair of radiation protection committee or a clinical director)
- medical physics experts.

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

- representative(s) of persons that conduct medical exposures, for example, a radiography services manager
- radiation protection officer
- chair of the radiation protection committee (if relevant)
- clinical directors of radiology or radiation oncology (if relevant).

The meetings will focus on:

- the structures in place to provide governance and assurance of a safe service in relation to medical exposure to ionising radiation
- the safety systems and processes that have been implemented to monitor and deliver the services that are provided to service users
- clarification of any issues raised from the information submitted pre-inspection
- clarification of any issues identified on site.

### 8.5 The close-out meeting

After the clinical area inspection, the document review and the meetings with staff, the inspection team will conduct a close-out 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 **preliminary findings** of the inspection. We will also identify any high risks that require immediate action throughout the inspection and at the close-out meeting.

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

## 9 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 associated guidance documents to assess compliance with the regulations. Inspectors will judge whether the undertaking is **compliant, substantially compliant** or **not compliant.**

The assessment-judgment framework supports HIQA inspectors in gathering evidence when monitoring or assessing an undertaking and making judgments on compliance. It also sets out the lines of enquiry (questions) to be explored by inspectors in order to assess compliance, and it outlines the compliance descriptors which are:

- **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.

After we have determined compliance with the regulations, we will write a report for each inspected facility. The report will contain the inspection findings and our judgments on compliance. We will publish the final report on HIQA's website, www.hiqa.ie. A compliance plan may also be included with the report, if relevant. Details on the compliance plan are available in Section 9.4 .

### 9.1 The inspection report

Inspection reports are a fair, balanced and accurate summary of our findings. They reflect both good practice and where improvements are required in the

facility. The inspection report aims to describe:

- the quality and safety of medical exposures to ionising radiation
- how compliant the undertaking is with the regulations and the impact of this on service users
- the undertaking's leadership, governance and management 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 is issued to the undertaking for information only and when HIQA's publication process begins.

Any non-compliances 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 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.

## 9.2 Draft report

When ready, the draft report and compliance plan template (if required) are issued to the undertaking. We aim to issue this report to the medical radiological facility within **20 working days** of inspection. A feedback form will also be attached with the draft 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 on the feedback form provided.

However, before returning the feedback form, the undertaking is encouraged to engage, by phone and or email, with the lead 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 (if required) are managed separately. Even if you 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 lead inspector, if deemed 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.

### 9.3 Final report

Once the draft report process is completed a **final** inspection report is produced. This finalised report is the report that will be published. This final report is issued to the undertaking for information before it is published. Once sent to the undertaking, HIQA's publication process begins and **five working days'** notice will be given to the undertaking before publication.

### 9.4 What is a compliance plan?

When we identify a finding of 'substantially compliant' or 'not compliant' with the regulation(s), a compliance plan template will be included in our report. Undertakings should complete the template, telling us in the completed template how and when they will comply with those regulations that they have failed to meet.

Each undertaking is accountable and responsible for the development and approval of the compliance plan that prioritises the improvements necessary to comply with the regulations. Depending on the level of risk identified, a specific time frame for implementing the compliance plan may be set by HIQA.

Each compliance plan is divided into **two sections.** Instructions on how to complete the compliance plan are provided at the beginning of the compliance plan template 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.

## 9.5 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 it does contain such information, it is immediately rejected and deleted by HIQA and the undertaking will be informed that it must submit a new plan without such information contained within it.

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 — this commentary may be removed prior to publishing the compliance plan in the published inspection report.

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

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 template 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. We will also assess this as part of subsequent inspections.

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 in the compliance plan, we can, at that point, decide if additional regulatory activity needs to be taken. This can include, but is not limited to, increased monitoring or escalation activity.

## 10 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.

## 11 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.

## 12 Freedom of Information

Please note that HIQA is subject to the Freedom of Information (FOI) Act 2014.[5] 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.

Therefore, we cannot give you an assurance that confidentiality of information can be maintained in all circumstances.

## 13 Data protection

HIQA collects and processes personal data for the performance of its functions under the Health Act 2007, (as amended)[2]. 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.

# 14 References


1. European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256/2018) *Available online from:* http://www.irishstatutebook.ie/eli/2018/si/256/made/en/pdf. *Accessed on:* 21 September 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:* 21 September 2020
3. Health Information and Quality Authority. *A guide to the inspection of dental services providing medical exposure to ionising radiation [online].* September 2020. *Available online from*: https://www.hiqa.ie/reports-and-publications/guide/guide- inspection-dental-services-providing-medical-exposure-ionising. *Accessed on:* 21 September 2020
4. Data Protection Act 2018, Available online from: https://data.oireachtas.ie/ie/oireachtas/act/2018/7/eng/enacted/a0718.pdf. *Accessed on:* 21 September 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:* 21 September 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 No.1 above (S.I. No. 256 of 2018) are available online from: http://www.irishstatutebook.ie/eli/2018/si/256/made/en/pdf.

# 15 Appendix A — 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 can 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.

Self-assessment questionnaires can be issued for one of four different types of facilities:

- multiple service types
- general radiography
- dental imaging **with** cone-beam computed tomography
- dental imaging **without** cone-beam computed tomography.

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)*. 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 **larger facilities** with **multiple service types** is available on the following pages. A sample of the self-assessment questionnaire used for a dental facility is provided in the separate guide for dental services providing medical exposure to ionising radiation.

# Self-assessment questionnaire – sample

| Regulation 4: Referrers | | |
|---|---|---|
| *Please tick yes or no* | Yes | No |
| Do you only accept referrals made by one or more of the following healthcare professionals:<br>▪ nurse or midwife registered by the Nursing and Midwifery Board of Ireland<br>▪ dentist registered by the Dental Council in Ireland<br>▪ medical practitioner registered by the Medical Council in Ireland<br>▪ radiographer or radiation therapist registered by the Radiographers Registration Board or<br>▪ healthcare professional registered with the General Medical Council of the United Kingdom practicing medicine in Northern Ireland? | | |

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

| Compliant | Not compliant |
|---|---|
| | |

| 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:<br>▪ dentist registered by the Dental Council in Ireland<br>▪ medical practitioner registered by the Medical Council in Ireland or<br>▪ 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 identified? | | |

**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/ technique/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 practice/ technique/technology, or verified that approval from HIQA for practice/ technique/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? | | |
| Do all referrals state the reason for requesting the particular procedure? | | |
| Are all referrals always accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment? | | |
| Are all previous medical records or diagnostic information relevant to a planned exposure considered in advance of the planned exposure? | | |
| Do you always 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? | | | |
| *Please tick yes, no or not applicable* | Yes | No | N/A |
| For all medical exposure of patients for radiotherapeutic purposes, for all treatment plans:<br>▪ Are exposures of target volumes individually planned? | | | |
| ▪ Is the delivery of exposures appropriately verified? | | | |
| ▪ Does the planning and verification process ensure doses to non-target tissues are as low as reasonably practicable? | | | |
| For patients undergoing diagnosis or treatment with radionuclides, have you provided written instructions (with a view to restricting doses to persons in contact with the patient)? | | | |

**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 all medical exposures performed under the clinical responsibility of a practitioner? | | |
| 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?<br>(i) the Dental Council<br>(ii) the Minister for Health (under Regulation 19)<br>(iii) the Nursing and Midwifery Board of Ireland<br>(iv) the Radiographers Registration Board or<br>(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? | | |
| Do you compare these to a national diagnostic reference level, where available? | | |

**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 provide referrers with referral guidelines for medical imaging? | | |
| 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 |
| Does your equipment have the means to measure individual service users' radiation doses? | | |
| Can your equipment transfer this to the individual service users' examination record? *(only applicable for equipment installed after 6 Feb 2018)* | | |
| Do you implement and maintain: | | |
| ▪ appropriate quality assurance programmes? | | |
| ▪ acceptance testing and regular performance testing? | | |
| Do you have an up-to-date equipment inventory? | | |

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

| Compliant | Substantially compliant | Not compliant |
|---|---|---|
| | | |

| Regulation 16: Special protection during pregnancy and breastfeeding | | |
|---|---|---|
| *Please tick yes or no* | Yes | No |
| Do you have a method, where appropriate, to establish if an individual who is receiving a medical exposure is pregnant or breastfeeding? | | |

**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 procedures per year that your facility (installation) 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 |
|---|---|---|
| | | |

A guide to the inspection of medical services providing medical exposure to ionising radiation
Health Information and Quality Authority

| 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 |
|---|---|---|
|  |  |  |

# 16 Appendix B — Required documentation

This document request form is a **sample** of the types of documentation that may be requested **before** inspection, from **a hospital**. The document request will be customised for smaller facilities, for example, stand-alone X-Ray facilities.

When requested, the following information should be submitted electronically to HIQA in the requested format. The **related number** in the **title of each file submitted** should also be included. For example: A.1 Organogram, A.2 Terms of reference of Radiation Safety Committee.

Please tick 'Yes' if the document is available and supplied, or 'No, Not available' if the medical radiological facility does not have the document.

If the document requested does not apply to your medical radiological facility please tick 'No, Not relevant'.

| **Pre-inspection documentation request** | | | | |
|---|---|---|---|---|
| | **Please note:** all personal data must be redacted in advance before forwarding to HIQA | Yes | No (Not available) | No (Not relevant) |
| A.1 | Documentation or organogram which details both the overarching governance structures for medical exposures to ionising radiation and the chain of responsibilities for the protection of service users | | | |
| A.2 | Terms of reference of Radiation Safety Committee and relevant oversight committee and minutes for the last three meetings | | | |
| A.3 | Radiation safety procedures or policies with regard to: | | | |
| | i. receipt of referrals and justification/approval of medical exposures | | | |
| | ii. optimisation of medical exposures | | | |

| | | | | |
|---|---|---|---|---|
| | iii. pregnancy determination for relevant medical radiological procedures | | | |
| | iv. the system of recording and analysis of events involving or potentially involving accidental and unintended exposures and significant events | | | |
| A.4 | Evidence of quality assurance and regular performance testing to include: | | | |
| | i. policy on quality assurance and quality control of medical radiological equipment | | | |
| | ii. annual or periodical summary record demonstrating an overview of quality assurance or performance testing for all medical radiological equipment | | | |
| A.5 | Medical radiological services information, layout and medical radiological inventory request (see email attachment) | | | |
| A.6 | i. Policy or protocol for the establishment and review of diagnostic reference levels (DRLs) for radiodiagnostic examinations and interventional radiology procedures | | | |
| | ii. A copy of the local facility DRLs | | | |
| A.7 | List of other associated undertakings within the medical radiological facility | | | |
| A.8 | Summary page of the trending and analysis of all events involving or potentially involving accidental and unintended exposures for the last 12 months. | | | |

| | | | | |
|---|---|---|---|---|
| A.9 | i. List of the titles and date of completion of clinical audits conducted in the last 12 months relating to medical exposure of ionising radiation | | | |

This document request form is a **sample** of the types of documentation that may be requested while **on site**.

| **Documents for review on site** | | |
|---|---|---|
| **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 soft copy will suffice. | | |
| B.1 | List of the following professionals including associated professional recognition and training documentation for:<br>i. Practitioners,<br>ii. Medical Physics Expert(s) and<br>iii. other individuals delegated the practical aspects of conducting medical exposures. | ☐ |
| B.2 | Facilitated access to medical radiological procedure referrals, imaging records and reports | ☐ |
| B.3 | Records of the following:<br>i. acceptance testing of each item of medical radiological equipment installed after 8 January 2019 and<br>ii. regular performance testing thereafter for all medical radiological equipment | ☐ |
| B.4 | Written protocols or procedures for every type of medical radiological procedure for each type of equipment for relevant categories of patients (including paediatric, where relevant) | ☐ |
| B.5 | All records and documentation relating to accidental and unintended exposures and significant events and potential accidental and unintended exposures and significant events for the last 12 months | ☐ |

| 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)** |

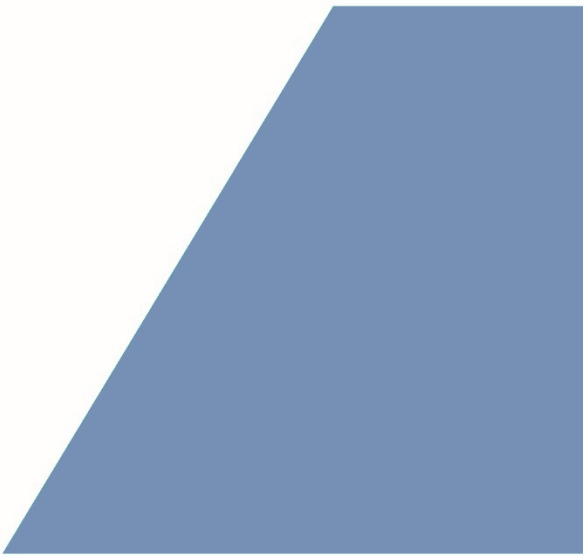
# 17 Appendix C — Examples of business types and designated managers

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.<br>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.<br>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.<br>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.<br>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.<br>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 |



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