Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation of Health and Social Care Services

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

November 2019

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

1. Introduction

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018[1] and 2019[2,3] 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 installations in Ireland comply with the regulations. Throughout this document, the term 'medical radiological installation' means an installation or facility where medical radiological procedures, such as X-rays, are performed. This term is occasionally shortened to 'installation'. It does not refer to an individual piece of equipment.

In order to carry out its functions as required by the Health Act 2007 (as amended),[4] 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 work within the powers described in the regulations. The staff appointed as 'authorised persons'[‡] are referred to as inspectors throughout this document.

Undertakings[§] and designated managers are encouraged to use the following documents in conjunction with this document:

- *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*.

[*] 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 2019.

[‡] 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'.

Both documents are available online at www.hiqa.ie. Inspectors also use these documents when assessing compliance with the regulations.

2. Who should use this document?

This guide provides details for undertakings of HIQA's monitoring approach for the regulation of medical exposure to ionising radiation. This document applies to undertakings with the following service types:

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

This inspection guide may also be used by smaller installations providing medical exposure to ionising radiation, for example, stand-alone X-Ray facilities and dental facilities with cone-beam CT services.

Please note that a separate guide about the inspection process will be provided for dental installations without cone-beam CT services.

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 an understanding of inspections of medical radiological installations 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 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. This information may trigger an inspection:

- solicited information,[**] including statutory notifications and results of investigations into any significant event
- unsolicited information [††]
- results of the 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 installation. 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 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 installation. A notice period of 10 working days will be given for **standard announced** inspections.

[**] Solicited information is information the undertaking is required to submit as part of its statutory obligations or 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.

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 installation to carry out the inspection.

Initially, HIQA will mostly conduct announced inspections. This is primarily to allow undertakings to become accustomed to the inspection and regulation processes. However, unannounced inspections of installations may happen if HIQA becomes aware of a particular risk that is most appropriately evaluated through an unannounced inspection.

As HIQA's programme of regulation of medical ionising radiation services becomes more established, HIQA will revisit this approach to using mostly announced inspections. Any significant change to this approach will be reflected in updated guidance.

6. Who are the inspection team?

The inspection team is comprised of HIQA staff that 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?

All communication from HIQA about the inspection will be communicated to the designated manager.[§§] The designated manager can remain the point of contact for the undertaking at all stages of the inspection once deemed appropriate by the undertaking. However, the undertaking will be copied on all correspondence and overall responsibility for compliance still 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. A proposed schedule outlining the inspection activities will also be included. 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 **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 installation. 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. Installations 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.

The information must be returned to HIQA in soft copy **within five working days**. All correspondence relating to the inspection should be sent to HIQA by the undertaking.

[§§] 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.

7.2 Confidentiality

In line with current data protection legislation,[5] HIQA requests that medical radiological installations do not send, by email or by post, identifiable service users' information or 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 installation 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 installation.

This review also helps to identify the specific lines of enquiry (questions to be asked) that inspectors will follow when on site. Lines of enquiry guide undertakings in their 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 available online 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 installations, for example, a stand-alone X-ray facility and a dental 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

- access to and use of policies, procedures and guidelines to support the safe use of medical exposure to ionising radiation
- monitoring arrangements in place 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 talk with service users.

8.1 Arriving at the installation

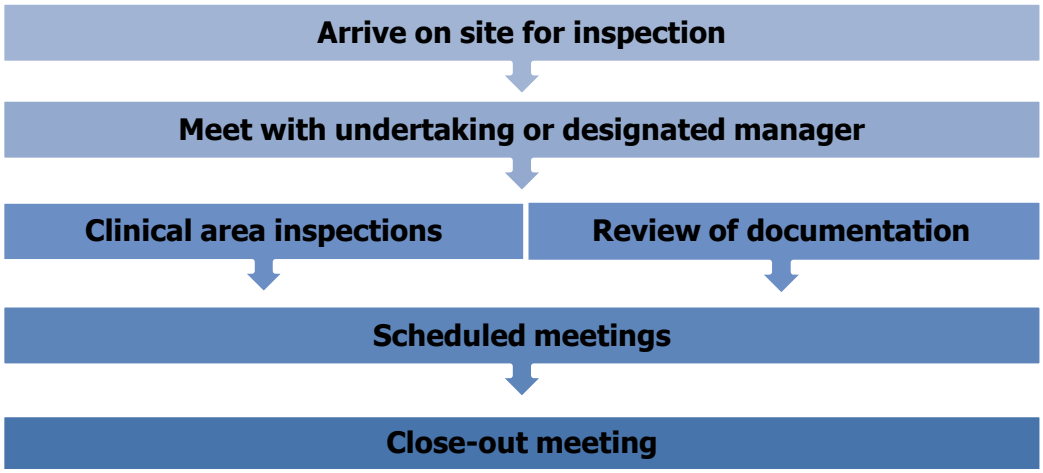
When inspectors arrive at the medical radiological installation, they will meet with the person with overall accountability and responsibility for the medical radiological installation on the day, for example, the undertaking or the designated manager. This could be the chief executive officer or the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

Inspectors will always carry personal identification and their certificate of authorisation while on inspection. At the start of the inspection, we will present this documentation to the person we meet and we 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. Sample outline of an on-site inspection schedule



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 installation 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 installation's local policy
- follow HIQA's code of conduct for inspectors (available online at www.hiqa.ie).

The means to move freely throughout the installation — 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 installations 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 can be gathered through direct observation and review of documentation and information systems. Inspectors will also speak with service users and staff working in these areas. We will be unobtrusive and discreet. Service users' privacy and dignity will be respected at all times.

Inspectors will also assess if the required reference material for that clinical area 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, 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 medical radiological installation, they should **not** contain data that identifies individual service users.

If any piece of documentation is not available on the day of the inspection, the medical radiological installation should submit this after the inspection and within the time frame specified by the inspector. This documentation should be submitted electronically, in the requested format, to radiationprotection@hiqa.ie.

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 will need to meet with. This will include:

- the undertaking (if available) or designated managers
- 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:

- representatives of persons that conduct medical exposures
- radiation protection officer
- chair of the radiation protection committee (if relevant)
- clinical directors of radiology/radiation oncology (if relevant).

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 deliver and monitor 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 their own installation.

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 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 installation. The report will contain the inspection findings and judgments on the level of compliance. A compliance plan template will also be included, if relevant. (Details on the compliance plan are available in Section 9.5). We will publish the report on HIQA's website, www.hiqa.ie.

9.1 The inspection report

Inspection reports are fair, balanced and reflect both good practice and where improvements are required in the installation. 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 **three main stages** as it is prepared for publication:

- **stage-1 inspection report:** draft report issued to undertakings — undertakings should check this version of the report for factual accuracy and can give general feedback.
- **stage-2 inspection report:** draft report issued to undertakings only if they provided feedback on a stage-1 report. Undertakings can appeal judgments in this stage-2 report.
- **stage-3 inspection report:** final report, which may or may not be different from the stage-2 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 template 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 identifiable information relating to staff or people using services in the compliance plan response.

9.2 Stage-1 report

After the inspection, the stage-1 report is issued by email to the undertaking. We aim to issue this report to the medical radiological installation within **20 working days** of inspection. A feedback form will also be attached with the stage-1 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 stage-1 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 stage-1 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 lead inspector to discuss any queries or specific concerns they may have regarding the stage-1 report.

Please note that feedback on the stage-1 inspection report and compliance plans (if required) are separate issues. Even if you submit feedback on the stage-1 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 included in the same email 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 **15 working days** of the stage-1 report being issued. Where no feedback is received, HIQA will progress to stage 3 and finalise the report.

9.3 Stage-2 report

On receipt of feedback on a stage-1 report from the installation, HIQA will consider the feedback in the context of evidence gathered on inspection. A stage-2 inspection report will be produced which will include any required amendments (if appropriate) resulting from feedback. We will then issue the stage-2 report to the undertaking for review.

Please note that the stage-2 report will only be issued to those undertakings that have completed the feedback process. If the undertaking does not engage in the stage-1 report feedback process or does not reply to the invitation to submit feedback on a stage-1 report, a stage-2 report will not be issued to them.

If the undertaking believes that a judgment(s) contained in the stage-2 report is not based on the evidence made available to inspectors at the time of the inspection or not proportionate to the evidence, they may decide to make **a formal submission appeal** to HIQA to challenge a regulatory judgment(s) in the stage-2 report.

Should an undertaking decide to make a formal submission to HIQA, this must be made within **10 working days of issue of the stage-2 report.** The process for *Making a Submissions on Regulatory Judgments on a Stage-2 Inspection report to the Director of Regulation* is available on the HIQA website, www.hiqa.ie.

If 10 working days pass without HIQA receiving a submission, the report will proceed to stage 3 and publication as outlined below.

9.4 Stage-3 report

Once the stage 1 process is completed (and the stage 2 process, if applicable), a **stage-3** inspection report is produced. The stage-3 report is the finalised report that will be published. This report is issued to the undertaking for information before it is published.

Once the stage-3 report is sent to the undertaking, HIQA's publication process begins and **five working days'** notice will be given to the undertaking before publication.

9.5 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. We will ask the undertaking to tell us in the returned compliance plan how and when they will comply with the regulation(s) that the undertaking has failed to meet. The compliance plan should be submitted to HIQA within a specified time frame.

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.

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.

Undertakings should ensure that they return a satisfactory compliance plan — by email only — within **15 working days** from the time the stage-1 report is issued. 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.

9.6 What happens after a completed compliance plan is received?

The inspector will check that the returned compliance plan does not contain personal identifiable information relating to staff or service users. If the compliance plan does contain personal identifiable information, it is immediately rejected and deleted and the undertaking will be informed that a new plan must be submitted without personal identifiable information contained in 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, such 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 installations have taken account of the findings of their 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.

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 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 its Healthcare Team involved in the ionising radiation programme. It should be noted, however, that queries about a specific inspection can only be accepted from the undertaking or the designated manager.

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.[6] 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.

13. 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.

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

2. European Union (Basic Safety Standards For Protection Against Dangers Arising From Medical Exposure To Ionising Radiation) (Amendment) Regulations 2019 (S.I. No. 332/2019)
Available online from: http://www.irishstatutebook.ie/eli/2019/si/332/made/en/pdf

3. European Union (Basic Safety Standards For Protection Against Dangers Arising From Medical Exposure To Ionising Radiation) (Amendment) (No. 2) Regulations 2019 (S.I. No. 413/2019)
Available online from: http://www.irishstatutebook.ie/eli/2019/si/413/made/en/pdf

4. Health Act 2007. Dublin: The Stationery Office; 2007. Available online from: http://www.oireachtas.ie/documents/bills28/acts/2007/a2307.pdf.

5. Data Protection Act 2018, Available online from: https://data.oireachtas.ie/ie/oireachtas/act/2018/7/eng/enacted/a0718.pdf

6. Freedom of Information Act 2014. Dublin: The Stationery Office; 2014. Available online from: www.oireachtas.ie/documents/bills28/acts/2014/a3014.pdf

[***] All online references were accessed at the time of preparing this document. Please note that web addresses may change over time.

15. Appendices

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 installations:

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

A sample of the self-assessment questionnaire used for **larger installations** is available on the following pages.

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: ▪ nurse or midwife registered by the Nursing and Midwifery Board of Ireland ▪ dentist registered by the Dental Council in Ireland ▪ medical practitioner registered by the Medical Council in Ireland ▪ radiographer or radiation therapist registered by the Radiographers Registration Board or ▪ healthcare professional registered with the General Medical Council of the United Kingdom practising 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: ▪ 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 identified?		

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: ▪ 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? (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?		
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 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 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

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 installations, for example, stand-alone X-Ray facilities and dental facilities.

When requested, the following information should be submitted in electronic format to HIQA at radiationprotection@hiqa.ie. 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 installation does not have the document.

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

Pre-inspection documentation request				
Please note: all personal identifiable information 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 or relevant committee and minutes for the last three meetings			
A.3	An inventory of all medical radiological equipment for the installation (facility)			

A.4	Radiation safety procedures or policies with regard to ○ receipt of referrals and justification/approval of medical exposures ○ optimisation of medical exposures ○ pregnancy determination for relevant medical radiological procedures ○ the system of recording and analysis of events involving or potentially involving accidental and unintended exposures and significant events			
A.5	An annual or periodical summary record demonstrating an overview of quality assurance or performance testing for all medical radiological equipment			
A.6	Medical radiological services information and layout request (see email attachment)			
A.7	Policy or protocol for the establishment and review of diagnostic reference levels for radiodiagnostic examinations and interventional radiology procedures			
A.8	List of other associated undertakings within the medical radiological installation			
A.9	Summary page of the trending and analysis of all accidental and unintended exposures for the last 9 months.			
A.10	List of the titles and date of completion of clinical audits conducted in the last 9 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		
B.1	List of practitioners and individuals delegated the practical aspects of conducting medical exposures and associated recognition and training documentation	☐
B.2	List of all referrals for medical radiological procedures from (two weeks prior to the date of the inspection) and accompanying records available for review	☐
B.3	Records indicating initial acceptance testing of each new piece of medical radiological equipment and 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	☐
B.5	Records and documentation relating to accidental and unintended exposures and significant events	☐

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. 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

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

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