

Regulation of
Health and Social
Care Services

Undertaking information handbook

Guidance on the responsibilities under Regulation 6 of undertakings providing medical exposures under the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019

Updated September 2019

About the Health Information and Quality Authority (HIQA)

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.

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1. Introduction

New regulations have designated the Health Information and Quality Authority (HIQA) as the regulator of medical exposure to ionising radiation (such as from X-rays and radiotherapy) in Ireland.

The Council of the European Union Directive 2013/59/Euratom¹ — commonly known as the Basic Safety Standards (BSS) Directive — was transposed into Irish law in 2019 as the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 (referred to in this document as the “regulations”).^{2,3,4} The regulations define new minimum safety requirements to protect people from the hazards associated with medical exposure to ionising radiation.

In the regulations, HIQA is defined as the competent authority for regulating medical exposure to ionising radiation in Ireland. The regulations extend HIQA's role and regulatory powers to include public and private radiological, radiotherapy, nuclear medicine and dental installations. HIQA's remit also extends to medical exposures to ionising radiation incurred by carers and comforters; and by volunteers in medical or biomedical research.

In related but separate legislation, the Environmental Protection Agency (EPA) Office of Radiation Protection and Environmental Monitoring is designated as the competent authority with responsibility for occupational and public exposures to ionising radiation.

HIQA and the EPA will work together in the regulation of ionising radiation in Ireland under their respective regulations. Indeed, under Regulation 3(4), HIQA is required to co-operate with the EPA when the EPA is carrying out its functions under the Basic Safety Standards (BSS) Directive, and HIQA may share data with the EPA for that purpose. In that regard, HIQA and the EPA have signed a data sharing agreement that is available at www.hiqa.ie.

The new regulations are now the main legal instrument for protecting service users* undergoing medical exposure to ionising radiation, and previous regulations from 2002 have been revoked.⁵ As of 8 January 2019, the responsible person or body, (other than an employee), who carries out or who engages others to carry out a medical radiological procedure[†] is now termed an ‘undertaking’. An undertaking must

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

† A medical radiological procedure means any procedure giving rise to a medical exposure. This includes radiodiagnostic, radiotherapeutic, interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes.^{2,3}

comply with its specific statutory responsibilities under these regulations for protecting service users having medical exposures to ionising radiation.

2. Purpose of this guide

This document provides information to undertakings carrying out or engaging others to carry out medical radiological procedures about their statutory responsibilities under Regulation 6 of the regulations. This document does not define all the roles and responsibilities of an undertaking in the regulations. Further guidance in relation to the assessment of compliance with the regulations is available at www.hiqa.ie. There is an obligation on each undertaking to familiarise itself with the regulations in order to ensure that statutory requirements are being met, and that appropriately registered or recognised personnel are in place.

This guidance sets out:

- the definition of an undertaking under Regulation 2(1)
- legal requirements of undertakings under Regulation 6
- regulatory requirement for an undertaking to notify HIQA of its existence (Declaration of undertaking [NF200 notification forms])
- potential undertaking business types
- an explanation of the type of named representatives required from each undertaking
- practical examples of different undertaking types and appropriate representatives.

This guidance document may be revised periodically in line with national and international requirements and has been developed in line with national legislation and nationally-approved standards.^{6,7}

3. Definition of an undertaking

An undertaking is defined in Regulation 2(1) 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

This means that each sole trader, company, partnership, unincorporated body or body corporate that carries out, or engages others to carry out, medical exposures of ionising radiation in Ireland is considered an undertaking. All undertakings have a statutory responsibility to ensure that they comply with the regulations.

A Regulatory Notice[†] on the “Clarification of the Definition of an Undertaking in the medical exposure to ionising radiation regulations” (referred to in this document as the “regulatory notice”), published on www.hiqa.ie, should be used as an aid to determine what constitutes an undertaking for the purposes of the regulations. While the regulatory notice is intended to be of assistance, responsibility in law rests with the individual or entity to determine what constitutes an undertaking under the regulations.

The regulatory notice outlines two scenarios which healthcare providers[§] should consider carefully before making a Declaration of undertaking to HIQA.

HIQA considers each of the following scenarios to constitute an undertaking under the Regulations:

- A healthcare provider who carries out, or employs others to carry out, a medical radiological procedure is an undertaking and is responsible for compliance with the Regulations.
- A healthcare provider who engages others to carry out a medical radiological procedure is the undertaking and is responsible for compliance with the Regulations.

The undertaking must notify HIQA of its existence, as described in Regulation 6, ensuring that regulatory communications between HIQA and each undertaking happen at the appropriate level within the service. This is to ensure that HIQA will always be able to readily communicate with the legal entity responsible for providing medical radiological procedures. In making the declaration, the healthcare provider must satisfy itself that, irrespective of the manner of engagement or employment with those that carry out medical radiological procedures, the undertaking must have robust oversight arrangements in place to ensure that those carrying out medical radiological procedures comply with the Regulations and in so doing the healthcare provider itself accepts responsibility for compliance with the Regulations.

Furthermore, any undertaking registered outside the jurisdiction of Ireland but carrying out medical radiological procedures within Ireland must also comply with the requirements of the regulations.

[†] Laws, rules and regulations may change from time to time. HIQA reserves the right to revise, amend, alter or delete the information provided in the regulatory notice.

[§] For the purpose of the regulatory notice, a healthcare provider means any sole trader, company, partnership, unincorporated body, body corporate or statutory body that carries out or engages others to carry out medical radiological procedures as defined in Section 2 of the regulations. This may include but is not limited to; hospitals, healthcare clinics, dental practices or sole trader practitioners.

4. Clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research

An undertaking plays a critical role in leading, building and maintaining a culture that places the service user and the quality and safety of services at the centre of the delivery of care. The importance of clearly-defined and formalised governance arrangements that identify clear lines of delegation at individual, team and service level cannot be underestimated when delivering a safe and sustainable service. Where responsibilities are delegated, the undertaking must be confident that everyone working in the service is acutely aware of their individual responsibilities.

Regulation 6(3) states that an undertaking shall provide for a clear allocation of responsibilities for the protection from medical exposure to ionising radiation of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research.² Therefore, overall accountability for the delivery of medical exposures rests with the undertaking which must ensure clear lines of authority, responsibility and communication are in place at all levels of the organisation.

An undertaking may describe and record its internal governance structure by means of an organogram or documented description of the governance arrangements in place, relevant to the size and scale of the service provided. For example, a dentist providing dental imaging in his or her own practice may have sole responsibility within the service for radiation protection of individuals undergoing medical exposure. This must be appropriately reflected in local standard operating procedures.

Alternatively, a larger medical radiological installation** providing a diverse range of medical radiological procedures to a large volume of service users will require clearly defined radiation protection governance arrangements. These arrangements should be aligned and integrated within the overall organisational quality and safety structures of the undertaking for the protection of patients and other service users.

An undertaking shall provide evidence of such allocation of responsibility and associated governance arrangements to HIQA on request in any such form as may be prescribed by HIQA from time to time. Failure to ensure a clear allocation of responsibilities and an inability to provide evidence of such allocation to HIQA on request is an offence under Regulation 29(1)(c).

** A medical radiological installation is a facility where medical radiological procedures are carried out.^{1,2}

5. Undertaking Responsibilities

Regulation 6(4) states that an undertaking is responsible for the failure of any person employed or engaged by an undertaking to comply with these regulations.² Therefore, the undertaking must ensure that its employees, and those it engages to carry out medical radiological exposures, comply with the regulations.

The undertaking retains overall responsibility for the safe provision of medical exposures, and therefore, it is responsible for ensuring that the service is carried out in the same manner as if the undertaking was providing the service itself.

6. Regulatory requirement of an undertaking to notify HIQA that it is carrying out or intends to carry out medical radiological procedures

Under Regulation 6(2), an existing undertaking that has already been carrying out, or engaging others to carry out, medical radiological procedures on or before 8 January 2019 was required to submit a declaration of undertaking notification form to HIQA. The declaration should have been submitted by the **8 April 2019**.

Under Regulation 6(1) after 8 January 2019 any **new** undertaking intending to commence practices shall notify HIQA, no later than **one month before** the proposed commencement, by submitting a Declaration of undertaking notification form to HIQA.

The information in the completed Declaration of undertaking notification form will help HIQA to identify:

- the appropriate legal entity responsible for medical exposures, referred to as the undertaking
- the appropriate person authorised to communicate with HIQA on behalf of the undertaking, termed the “undertaking representative”
- the appropriate person responsible for operational management of the service, referred to as the “designated manager”.

Further information on the roles and responsibilities of an undertaking representative and a designated manager is outlined in Sections 8 and 9 of this document.

Undertakings should keep to the guidance provided in order to prevent delays in processing declaration forms. Failure to comply with the statutory requirement to notify HIQA of the existence of an undertaking is an offence under Regulation 29(1)(c).

The regulatory notice should be considered before submitting a Declaration of undertaking notification form to HIQA. A person or body who is unclear about whether they should make declarations to HIQA, can contact HIQA at radiationprotection@hiqa.ie with their queries.

For healthcare providers who are undertakings as per *Scenario 1* and *Scenario 2* (outlined in section 3 of this document), a Declaration of undertaking (NF200) notification form should be submitted.

The Declaration of undertaking (NF200) notification form is in writable PDF format and is available on www.hiqa.ie. The completed form should be emailed to radiationprotection@hiqa.ie. Please note the following information before completing this form:

- **Only softcopy versions** of the completed Declaration of undertaking (NF200) notification form will be accepted.
- Adobe Acrobat Reader or similar software is required to view and complete the form.
- It is advisable that each undertaking locally save a softcopy version of their completed Declaration of undertaking (NF200) notification form.
- Details on who can sign the Declaration of undertaking (NF200) notification form are available in Section 12 of this guidance document.
- Practical examples of different undertaking business types are illustrated in Appendix A.
- Instructions on how to complete this form are available in Appendix B.

7. Undertaking business types

The different business types that may be categorised as an undertaking, in line with the regulations, are outlined in Table 1 below.

Table 1. Business types that may be categorised as an undertaking in line with the regulations

Name	Definition
Sole trader	<p>This is where only one single person is the legal owner/provider of the radiological service.</p> <p>In this case, this person (the sole trader) is an undertaking in his or her own name.</p>
Partnership	<p>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.</p> <p>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.</p>
Company	<p>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.</p> <p>In this case, the company is the undertaking and is legally responsible for compliance with the regulations.</p>
Unincorporated body	<p>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.</p> <p>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.</p>

^{††} The word person can mean a legal person such as a limited liability company or an unincorporated body of persons, as well as an individual.

Body corporate	<p>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.</p> <p>The body corporate is the undertaking and will be legally responsible for carrying out of the business of the undertaking.</p>
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8. Nomination of the undertaking representative

Many radiological service providers are organisations made up of multiple persons such as companies, voluntary bodies or statutory bodies. To ensure that HIQA can effectively communicate with the person legally responsible for the delivery of care, HIQA requires that all undertakings (with the exception of sole traders) put forward the name of their representative. This person is known as **the undertaking representative**. In the case of a sole trader, HIQA will communicate directly with the individual who is the sole trader. When completing the Declaration of undertaking notification form the sole trader should provide their own name and contact details when asked to nominate an undertaking representative.

The undertaking representative will have the knowledge, ability, autonomy and authority to answer for and act on behalf of the undertaking. The undertaking representative must hold a senior position within the undertaking and have appropriate involvement in the executive governance and management of the service. They should be able to provide clarity in relation to the governance of the service in line with the regulations and nationally-approved standards. The undertaking representative will also have a role in engaging with HIQA in response to escalated or significant concerns or risks. However, the undertaking representative does not replace or negate the legal responsibility of the undertaking. Enforcement actions to be taken by HIQA will always be communicated directly with the undertaking. Table 2 gives examples of who will be accepted by HIQA as an appropriate undertaking representative.

Table 2. Examples of who will be accepted by HIQA as an appropriate undertaking representative.

Undertaking business type	Appropriate undertaking representative
Sole trader	The sole trader
Partnership	A partner of the partnership
Company	A director of the company
Unincorporated body	A member of the committee of management or other controlling authority of the unincorporated body
Body corporate	A person with delegated authority as per a scheme of delegation provided for or by the relevant Act for the statutory body, or a member of the board, directorate or other governance structure of the body.

9. Nomination of a designated manager

For day-to-day management issues, HIQA requires all undertakings to nominate a **designated manager** of each medical radiological installation. This is to facilitate communications between HIQA and the undertaking for operational matters, such as the scheduling of an inspection.

The designated manager must be engaged in and responsible for the day-to-day management of the medical radiological installation and must have the full support of the undertaking to ensure a safe and quality service is being delivered in the medical radiological installation. A named designated manager can be responsible for more than one medical radiological installation or service.

The undertaking should identify the designated manager by providing the name and contact details when completing the designated manager section of their Declaration of undertaking notification form. In the case of a sole trader, the undertaking and the designated manager may be the same person. Table 3 provides examples of an appropriate designated manager.

Table 3. Examples of a designated manager.

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

10. Notification of change of details (NF201) of an undertaking to HIQA

Regulation 6 allows HIQA to request an undertaking to submit relevant information about the commencing of practices and the allocation of responsibilities for the protection of persons from medical exposure to ionising radiation. HIQA must have accurate and up-to-date contact details for the undertaking, undertaking representative and designated manager. Once a Declaration of undertaking has been made, along with the nomination of an undertaking representative and designated manager, the undertaking must also notify HIQA if any of those details change.

An undertaking must submit a change of details (NF201) form to HIQA following a change in any of the submitted prescribed information as soon as possible. HIQA will **not** process a change of details (NF201) form without having first received a Declaration of undertaking notification form.

A change in circumstances may include the following examples:

- when there is:
 - a change of undertaking details
 - a change of undertaking representative details or when an undertaking representative is expected to be absent from their post for a prolonged period of time
 - a change of medical radiological installation details or service type
 - an addition of a new medical radiological installation
 - a change of designated manager or contact details of the current designated manager changes
 - a change of partnership details
 - a change of details of an unincorporated body.

HIQA's online portal system (<https://portal.hiqa.ie>) facilitates undertakings to submit notification forms to HIQA.

The portal system provides access to each undertaking and offers benefits such as:

- the ability to navigate to up to date forms
- immediate acknowledgment of receipt, including the reference notification number
- a record of previous significant events submitted to HIQA.

The notification forms are also available on the website in PDF format. If you require assistance completing the notification form, please email radiationprotection@hiqa.ie.

10.1 Change to legal entity

If a change of an undertaking's details results in a change to its legal entity, the undertaking is considered a new legal entity providing medical exposures and a change of details (NF201) form will **not** be accepted. Instead, in such circumstances the undertaking must:

- notify HIQA it has **ceased** to practise using a cessation of practice (NF202) form one month before intending to cease, and
- submit a new **Declaration of undertaking** notification form one month before beginning practices as a new undertaking.

11. Notification of cessation of practice of an undertaking to HIQA

When an undertaking intends to stop providing medical exposures to ionising radiation, a cessation of practice (NF202A) form must be submitted to HIQA at least **one month** before the cessation of practice. A cessation of medical radiological installation (NF202B) form should be used if an undertaking intends to stop providing medical exposures to ionising radiation at one or more installations listed in the NF200 declaration. For example, this form should be used if an undertaking has declared for two installations, but now intends to cease practice at one of these installations.

The notification forms are available on the website in PDF format, however undertakings are encouraged to use HIQA's online portal system (<https://portal.hiqa.ie>) to submit notifications. If you require assistance completing the notification form, please email radiationprotection@hiqa.ie.

12. Who can submit the following forms on behalf of the undertaking: Declaration of undertaking (NF200); a change of details (NF201); a cessation of practice (NF202)

A Declaration of undertaking (NF200) form, a change of details (NF201) form or a cessation of practice (NF202) form should be submitted by the undertaking or an individual^{††} who is an inherent part of the undertaking, such as:

- the sole trader
- a director of the company
- a partner of the partnership
- a member of the committee of management or other controlling authority of an unincorporated body
- a member of the board, directorate or other governance structure of the body corporate
- the person with delegated responsibility on behalf of a statutory body.

13. Appointment of authorised signatory

Occasionally, after initial submission of a Declaration of undertaking (NF200) form, an undertaking that is a **company**, a **partnership**, or **unincorporated body** may wish to appoint an individual to act as an authorised signatory with the ability to sign relevant documentation on its behalf.

The appointment of an authorised signatory does not negate the responsibilities of an undertaking. Instructions on the process of appointing an authorised signatory by an undertaking, and how to notify HIQA of an authorised signatory, are available in Appendix C.

^{††} It is the responsibility of such an individual to ensure that he or she has been authorised by the undertaking to make the declaration on its behalf.

Glossary

Brachytherapy: a radiotherapy procedure that involves placing radioactive material inside a patient's body for the purpose of killing or shrinking cancerous cells.

Computed tomography (CT): a technique for imaging the body in sections or slices using specialised computers and imaging equipment. An alternative name for CT is computer-aided tomography or CAT scan.

Designated manager: a person engaged in and responsible for the day to day management of the medical radiological installation. The designated manager must have the full support of the undertaking to ensure a safe and quality service is being delivered in the medical radiological installation.

Diagnostic medical exposure: a medical exposure to ionising radiation undertaken to identify a disease or injury.

Dual-energy X-ray absorptiometry (DXA or DEXA): is a type of medical exposure used to assess bone density in patients where low bone density or osteoporosis is suspected.

Environmental Protection Agency: an independent public body established under the Environmental Protection Agency Act 1992. It has a broad range of functions relating to environmental protection in Ireland, including environmental licensing; enforcement of environmental law; environmental planning, education and guidance; monitoring, analysing and reporting on the environment; regulating Ireland's greenhouse gas emissions; environmental research development; strategic environmental assessment; waste management; and radiological protection.

External beam radiotherapy: a technique that uses specialised radiotherapy machines to aim beams of radiation to kill or shrink cancerous cells. Radiotherapy treatments are most commonly carried out on linear accelerator machines.

Fluoroscopy: a type of medical exposure that uses a continuous beam of ionising radiation to create an image on a monitor. During a fluoroscopy procedure, the image that is transmitted to the monitor displays the movement of a body part, instrument or contrast agent through the body in real-time.

Individuals participating in research: any persons who participate in medical or biomedical research involving a medical exposure of ionising radiation.

Interventional cardiology/radiology: procedures involving the use of fluoroscopy equipment to obtain real-time medical exposure to ionising radiation to help introduce and guide devices and equipment used for diagnostic or treatment purposes.

Ionising radiation: radiation with enough energy so that during an interaction with an atom, it can remove tightly bound electrons from the orbit of an atom, causing the atom to become charged or ionised. It has a higher energy than light and therefore can pass through the body. Ionising radiation is not without risks, as the body can absorb some of the energy however, ionising radiation is a valuable medical tool for the diagnosis and treatment of diseases and injuries. Types of ionising radiation commonly used in medical exposures are alpha, beta, gamma radiation and X-rays.

Mammography: the specialised area of radiology involved in the imaging of breast tissue.

Medical exposure (ionising radiation): an exposure of ionising radiation delivered to patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment. Medical exposures are intended to benefit an individual's own health. Additionally, comforters or carers and volunteers in medical or biomedical research can also receive medical exposures.

Medical ionising radiation incident: accidental, unintended or other incidents occurring or potentially occurring within an undertaking which could impact on the safety and welfare of patients, asymptomatic individuals, comforters and carers or research volunteers.

Medical physics expert (MPE): an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure and whose competence is recognised by the Minister for Health.

Medical radiological installation: means a facility where medical exposures are carried out.

MERU: the HSE Medical Exposure Radiation Unit, which acted on behalf of the Department of Health (as the former competent authority) to audit patient radiation practice in medical radiological installations in Ireland.

National Radiation Safety Committee: a statutory committee established under Statutory Instrument No. 478 in 2002 to advise the Directory General of the HSE on matters relating to patient radiation protection in both public and private medical radiological.

Nuclear medicine: a type of medical exposure where a radiopharmaceutical or radioactive dye designed to go to a target organ and administered to a patient by injection, inhalation or ingestion. Areas of disease and injury can then be diagnosed by imaging the patient under a detector called a gamma camera.

Patient: a person who is receiving healthcare or treatment (sometimes referred to as the service user).

Positron emission tomography (PET): a specialist, functional type of nuclear medicine which uses a radiopharmaceutical to assess the metabolic processes within the body. PET scanners are often combined with CT scanners which allow highly detailed images to be obtained. This procedure is often referred to as PET/CT imaging.

Practitioner: a person who is entitled to take clinical responsibility for a medical exposure under the regulations.

Radiographs: often referred to as X-rays, these are two-dimensional images obtained to identify disease or injury.

Radiopharmaceutical: pharmaceuticals (drugs) that are labelled (attached) with a radioactive tracer designed to go to a target organ such as the thyroid or bones. Radiopharmaceuticals can have diagnostic or therapeutic uses.

Referrer: a person who is entitled to refer individuals for medical radiological procedures to a practitioner in line with the regulations.

Service user: a person or persons who attends an undertaking for the purpose of undergoing a medical exposure. This includes a patient, comforters and carers and volunteers participating in research.

Stochastic effect: the random or probable occurrence of a hereditary change or the possibility of an induced cancer due to a medical exposure to ionising radiation.

Therapeutic medical exposures: medical exposures to ionising radiation that are used to treat a disease.

Undertaking: a person or body who has a legal responsibility for carrying out, or engaging others to carry out, a medical radiological practice, or the practical aspects of a medical radiological procedure, as defined by the regulations. For the purpose of this guidance, this means the person or body legally responsible for medical exposures of ionising radiation. Please refer to the *Regulatory Notice* for more information.

Undertaking representative: a person who has the knowledge and ability to answer for, and on behalf of the undertaking in relation to medical exposures to ionising radiation and any associated matters. The undertaking representative must hold a senior position within the undertaking, and should demonstrate an appropriate level of knowledge in relation to the executive governance arrangements in place to assure compliance with the regulations.

References^{ss}

- 1 Council of the European Union. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. Official Journal of the European Union. 2014 January 17;57:ppL13/1-L13/73. Available online from: <https://ec.europa.eu/energy/sites/ener/files/documents/CELEX-32013L0059-EN-TXT.pdf> Accessed on: 19 September 2018.
2. European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 S.I. No. 256 of 2018. Dublin: The Stationary Office; 2019.
3. European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2019 S.I. No. 332 of 2019. Dublin: The Stationary Office; 2019.
4. European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2019 S.I. No. 413 of 2019. Dublin: The Stationary Office; 2019.
5. S.I. No. 478/2002 - European Communities (Medical Ionising Radiation Protection) Regulations 2002. Dublin. 2002 Available online from: http://www.irishstatutebook.ie/eli/2002/si/478/made/en/print._ Accessed on: 13 December 2017.
6. Health Information and Quality Authority. National Standards for Safer Better Healthcare. Dublin: Health Information and Quality Authority; 2012. Available online from: <https://www.hiqa.ie/sites/default/files/2017-01/Safer-Better-Healthcare-Standards.pdf>. Accessed on: 13 December 2017.
7. Health Information and Quality Authority. National Standards for the Conduct of reviews of Patient Safety Incidents. Dublin: Health Information and Quality Authority; 2017. Available online from: <https://www.hiqa.ie/sites/default/files/2017-10/National-Standards-Patient-Safety-Incidents.pdf>. Accessed on: 13 December 2017.

^{ss} If not already cited, all online references were accessed at the time of preparing this handbook. Please note that online addresses may change over time.

Appendix A — Practical examples of different undertaking business types

These scenarios illustrate possible arrangements that an undertaking may have in place. It is important to note that some undertaking's circumstances may be more complex. For instance, one or more undertakings could be located on one geographical site. In such cases, it is the responsibility of each undertaking to ensure it declares for the medical radiological services for which it has responsibility.

Sole trader

An example of a sole trader is a dentist who runs his or her own practice. The dentist could be assisted by a dental nurse or other staff.

In line with the regulations, the dentist is an undertaking. As HIQA will communicate directly with the sole trader, the sole trader should provide their own name and contact details when asked to nominate an undertaking representative. The dentist has also nominated himself as the designated manager. Correspondence issued from HIQA will be sent to the undertaking.

Partnership

A family run dental practice has been in business for 30 years. The dental practice is run as a partnership by a father and daughter. The partnership is the undertaking in this scenario, with each partner being legally responsible for the undertaking.

One of the partners has been nominated as the undertaking representative for the partnership. A practice manager with responsibility for the operational running of the service has been nominated by the undertaking as the designated manager. Correspondence issued from HIQA will be sent to the undertaking.

Company

X-Ray Ltd. provides a nationwide diagnostic imaging service to the general public and specialises in computed tomography (CT) imaging. It has eight sites throughout Ireland, and each site has its own manager.

The company is run by a board of directors, one of which has been nominated by X-Ray Ltd. as the undertaking representative. The site managers are nominated as the designated managers for each different geographical location where X-Ray Ltd. provides imaging. When completing the declaration of undertaking (NF200) form, X-Ray Ltd is the undertaking and a company director is named as the undertaking representative. Each individual site manager's details are provided to HIQA as the designated manager of their respective medical radiological installation. Correspondence issued from HIQA will be sent to X-Ray Ltd.

Unincorporated body

Everytown Care is a registered, not-for-profit charity providing free DXA scanning for the elderly. The charity is run by a religious order and has five medical radiological installations in the same city. Everytown Care is the undertaking responsible under the regulations. However, whilst Everytown Care will be referenced as the undertaking, the charity is not a separate legal entity and the relevant individual members or all of the members will have responsibility for medical exposures to ionising radiation provided by the charity.

The charity has nominated a member of its management committee as the undertaking representative on behalf of the charity. There is an operational manager covering two medical radiological installations on the north side of Cork and another manager covering the remaining three medical radiological installations on the south side of Cork. When completing the Declaration of undertaking (NF200) form, Everytown Care is the undertaking, a member of the body's management committee is the undertaking representative and Everytown Care has two named designated managers with responsibility for managing their respective individual sites on a day-to-day basis. Communications issued from HIQA will be sent to Everytown Care.

Body corporate (statutory hospital)

Ireland Hospital Network is a statutory body established by the Ireland Hospitals Act 1990. It operates 30 public acute hospitals throughout Ireland. Ireland Hospital Network is the undertaking in this instance. An undertaking representative must be nominated at a sufficiently senior level, with the appropriate knowledge and authority to represent and make decisions on behalf of the undertaking.

The Ireland Hospitals Act 1990 also allows for a scheme of delegation. Ireland Hospital Network has delegated the undertaking representative function to a named national lead with responsibility for patient radiation safety. Delegation of day-to-day operations is the responsibility of the general manager of each hospital.

When Ireland Hospital Network completes the Declaration of undertaking (NF200) form, Ireland Hospital Network is the undertaking, the National Lead with responsibility for radiation safety is the undertaking representative and 30 named general managers have been nominated as designated managers identified for the purposes of this legislation (one designated manager for each hospital). Communications issued from HIQA will be sent to Ireland Hospital Network.

Body corporate (voluntary hospital)

Anytown Hospital is a voluntary hospital provided with funding under Section 38 of the Health Act, 2004. Anytown Hospital was established by royal charter and is run by a board of governors.

When Anytown Hospital completes the declaration of undertaking (NF200) form, Anytown Hospital is named as the undertaking; a member of the board is named as the undertaking representative; and the Chief Executive Officer of Anytown Voluntary Hospital is named as the designated manager. Communications issued from HIQA will be sent to Anytown Hospital.

Appendix B — Instructions on how to complete and submit a Declaration of undertaking (NF200) form to HIQA

The Declaration of undertaking (NF200) form is available at www.hiqa.ie in writable PDF format. Adobe Acrobat Reader or similar software is required to view and complete the form. The required details should be entered onto the downloaded form and the completed form should be saved as a PDF file and submitted to radiationprotection@hiqa.ie.

An undertaking with responsibility for carrying out medical radiological procedures is required to submit a Declaration of undertaking (NF200) form to HIQA. Instructions on how to complete the **Declaration of undertaking (NF200)** form are demonstrated below.

Section A: Undertaking Information

Undertaking address — please enter the address and relevant Eircode of the principal place of business of the undertaking. If the undertaking has registered itself as a business (where applicable), please use the address associated with that registration (www.cro.ie).

The address submitted by the undertaking must be regularly monitored and should enable HIQA to readily communicate with the undertaking.

Section A. Undertaking information			
A1. Undertaking details			For official use
Undertaking name	X-ray Ltd.		
Undertaking address	Address line 1	123 ABC Road	
	Address line 2	ABC Town	
	County	Town	
	Eircode	123 ABC	
Undertaking email address	X-ray@975.ie		
Undertaking contact number	123 456789		
Number of medical radiological installations for the undertaking's remit	3		

The **undertaking email address and contact number** must relate to the undertaking business type and be regularly monitored. It should not be an individual's personal email address.

This is referring to the **number of individual addresses, sites or geographical locations** where the undertaking carries out medical exposures to ionising radiation, and not the individual pieces of equipment.

Complete all fields in Section A2 **undertaking representative details**.

A2. Undertaking representative details						For official use
No.	Undertaking representative name	Undertaking representative type	Undertaking representative job title	Undertaking representative email address	Undertaking representative contact number	
1.	John Doe	Director	General Manager	j.doe@975.ie	123 456321	

Section A3 must be completed for **all** facilities under the undertakings remit. Please list **each** medical radiological installation (for example, the name of the dental practice, or the hospital's name) and complete all fields for each installation listed.

The medical radiological installation address is the address where **each** of the undertaking's facilities are located.

A3. Information on medical radiological installation – Undertaking service type										For official use
No.	Medical radiological installation name	Medical radiological installation address (include Eircode)	Medical radiological installation service type							
			Dental	General Radiography	Radiotherapy	Nuclear Medicine	Interventional Radiology/Immunology	Computed Tomography		
1.	X-ray Ltd (Cork)	1 Street, Cork	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
2.	X-ray Ltd (Dublin)	1 Street, Dublin	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
3.	X-ray Ltd (Limerick)	1 Street, Limerick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
4.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
5.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
6.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
7.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
8.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
9.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
10.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
11.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
12.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
13.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
14.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
15.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
16.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
17.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
18.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
19.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
20.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		

Tick all medical **radiological procedure types** that apply. Please refer to guidance below when completing this section.

In relation to the **medical radiological service** or services provided at a medical radiological installation, please note the following:

- **Only** tick dental if the medical radiological installation **only** carries out dental radiological procedures.
- If dental imaging is provided using Cone Beam Computed Tomography, please **also** tick computed tomography in addition to dental.

- Please tick general radiography if the following services are carried out: general radiography, DXA or mammography.
- Where nuclear medicine, interventional cardiology and or interventional radiology (**including** fluoroscopy) and or computed tomography services are provided, please select as relevant.
- Please tick radiotherapy if the medical radiological installation provides radiotherapeutic procedures to patients (**excluding** therapeutic nuclear medicine).
- Where a medical radiological installation provides more than one service type, please select all relevant service types (**excluding** dental).

The designated manager's job title is the role that they perform on a day-to-day basis.

A4. Information per medical radiological installation – Designated manager(s)							For official use
No.	Medical radiological installation name	Medical radiological installation address (include Eircode)	Designated manager name	Designated manager job title	Designated manager email address	Designated manager contact number	
1.	X-ray Ltd (Cork)	1 Street, Cork	Mary Doe	Operations Manager	m.doe@975.ie	123 456987	
2.	X-ray Ltd (Dublin)	1 Street, Dublin	Jane Doe	Practice Coordinator	j.doe@975.ie	123 987656	
3.	X-ray Ltd (Limerick)	1 Street, Limerick	Micheal Doe	Team Lead	michael.doe@975.ie	123 963547	
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							

This section must be completed if the undertaking has **one** or **multiple radiological installations** under its remit. Please list each medical radiological installation and complete all fields for each installation listed.

A regularly monitored **email address** and direct **contact number** should be provided for the site manager of each installation.

Section B: Undertaking business type information

Tick the **business type** that applies to the undertaking.
Any change to the undertaking business type requires that a new declaration of undertaking (NF200) form be submitted to HIQA.

Section B. Undertaking business type information				For official use
B1. Undertaking business type				
Undertaking business type	Partnership	<input type="checkbox"/>	Proceed to Section B2	
	Unincorporated body	<input type="checkbox"/>	Proceed to Section B3	
	Sole trader	<input type="checkbox"/>	Proceed to Section C	
	Company	<input checked="" type="checkbox"/>	Proceed to Section C	
	Body corporate	<input type="checkbox"/>	Proceed to Section C	
Company Registration Office number (if applicable)				

This is the number issued to businesses and companies by the **Companies Registration Office** (the statutory authority for registering new companies in the Republic of Ireland). See www.cro.ie for further information.

B2. Partnership details				For official use
If you have selected partnership as the undertaking business type, please state the names of all partners in the partnership.				
No.	Name	No.	Name	
1.	Paul Doe	11.		
2.	Pauline Doe	12.		
3.		13.		
4.		14.		
5.		15.		
6.		16.		
7.		17.		
8.		18.		
9.		19.		
10.		20.		

Ensure that the names of **all partners** entered in Section B2 are **listed and up to date**. Should any of the details relating to the partnership change, the undertaking must notify HIQA. See Section 10 in the Undertaking Information Handbook for more information.

B3. Unincorporated body details				For official use
If you have selected unincorporated body as the undertaking business type, please state the name of each member of the unincorporated body .				
No.	Name	No.	Name	
1.	James Doe	11.		
2.	Janice Doe	12.		
3.	Rose Doe	13.		
4.	Ross Doe	14.		
5.	Owen Doe	15.		
6.	Olivia Doe	16.		
7.		17.		
8.		18.		
9.		19.		
10.		20.		

Ensure that the names of **all members** of an unincorporated body entered in Section B3 are **listed** and **up to date**. Should any of the members of the unincorporated body change, the undertaking must notify HIQA using change of details (NF201) form. See Section 10 in the Undertaking Information Handbook for more information.

Section C: Declaration

Only an **individual** who is an inherent part of the undertaking entity as outlined in Section 12 of this document is eligible to sign this declaration. It is the responsibility of the undertaking to ensure the person who signs the form is duly authorised to do so.

Section C. Declaration of undertaking			For official use
C1. Declaration			
I, the undersigned, declare as the undertaking/on behalf of the undertaking that the information I have provided in this notification form is true to the best of my knowledge and belief.			
Signed by (tick as appropriate)	Sole trader	<input type="checkbox"/>	
	Partner of the partnership	<input type="checkbox"/>	
	Director of the company	<input checked="" type="checkbox"/>	
	Member of the committee of management or other controlling authority of an unincorporated body	<input type="checkbox"/>	
	Member of the board, directorate or other governance structure of the body corporate	<input type="checkbox"/>	
Name	John Doe		
Job title	General Manager		
Signature	J.Doe		
	If completing the PDF version of the notification form, type your name in the signature field		
Date	10-Jan-2019		

Appendix C — Instructions on how to appoint an authorised signatory and notify HIQA of authorisation

An undertaking that is a company, a partnership, an unincorporated body, or body corporate may appoint an individual to act as an authorised signatory on behalf of an undertaking with the ability to sign relevant documentation, under the regulations on its behalf.

Where an authorised signatory has been appointed, an original hard copy letter signed by the undertaking — stating that the authorised signatory or signatories has or have been validly authorised to sign documentation on behalf of the undertaking — must be sent to HIQA in advance of the authorised signatory exercising signing authority.

The authorisation must take the form of a resolution duly passed by:

- the board of directors of the company named as being the undertaking or
- the partners of the partnership named as being the undertaking or
- the members of the unincorporated body named as being the undertaking.

The letter notifying HIQA of the appointment of an authorised signatory **must** be signed by an individual who is an inherent part of the undertaking entity, such as:

- a director of the company
- a partner of the partnership
- a member of the committee of management or other controlling authority of an unincorporated body
- a member of the board, directorate or other governance structure of the body corporate.

The letter notifying HIQA of the appointment of an authorised signatory should be submitted as an **original hard copy** letter signed by the undertaking and forwarded to:

Radiation Protection,
Regulatory Support Services,
Health Information and Quality Authority,
Unit 1301, City Gate,
Mahon,
Cork,
T12 Y2XT.

Once validly appointed, an authorised signatory or authorised signatories will be authorised to sign relevant forms on behalf of the undertaking, until such time as the authorisation is revoked by the undertaking and notified to HIQA in writing. The letter, notifying HIQA of the appointment of an authorised signatory, must include the following information:

- confirmation that a resolution has been passed by those persons or directors named as the undertaking
- confirmation that the appointment of the named authorised signatory or signatories has been validly authorised by the undertaking in line with all applicable laws and in line with the terms of the rules of establishment or constitutional documents or deed or other documentation or governing principles of the undertaking
- confirmation that the appointment of an authorised signatory or signatories has taken place with the knowledge and consent of all relevant parties, including those nominated by the undertaking to be an authorised signatory
- confirmation that there are no limits or restrictions of any kind on the undertaking that would prevent the appointment of an authorised signatory or signatories
- an acknowledgement by the undertaking to notify HIQA immediately and in writing of any change to the authorised signatory or signatories.

Revision history

Revision History	Publication date/revision date	Title/version	Summary of changes
Version 1.1	January 2019	Guidance on the responsibilities under Regulation 6 of undertakings providing medical exposures under the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018	
Version 1.1	June 2019	Guidance on the responsibilities under Regulation 6 of undertakings providing medical exposures under the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019	This guidance was revised to reflect the amendments to the primary regulations.
Version 1.2	September 2019	Guidance on the responsibilities under Regulation 6 of undertakings providing medical exposures under the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019	This guidance was revised to reflect an update to the regulatory notice and to provide details of HIQA's online portal system.



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