Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Monitoring and Regulation of Healthcare Services

Guidance on the assessment of compliance in undertakings providing medical exposure to ionising radiation

Updated November 2023

Safer Better Care

About the Health Information and Quality Authority

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

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, 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. About the guidance

1.1 Introduction

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and associated amendments (referred to in this document as "the regulations") provide a framework for the regulation of medical exposure to ionising radiation in Ireland. The Health Information and Quality Authority (HIQA)[*] is the competent authority in Ireland with responsibility for inspecting and enforcing these regulations. As part of its regulatory function, HIQA is responsible for ensuring that radiation protection practices for service users[†] in public and private radiological facilities in Ireland are compliant with the regulations. HIQA will assess compliance through monitoring and inspection, and may take escalatory[‡] action if non-compliances happen more than once or pose a significant risk to service users.

The regulations set the minimum standards for the protection of service users when exposed to ionising radiation during a medical exposure which must be met by the undertaking carrying out such practices. However, undertakings striving to deliver a safe and effective service should constantly seek ways to go beyond the minimum requirements set out in these regulations in order to promote best practice in radiation protection.

Regulation of medical exposures reflects a system of radiation protection based on the two principles of justification and optimisation. The application of the justification principle helps to ensure that each planned exposure of a service user to radiation provides a net benefit from having the imaging or treatment. Once a referral for imaging or treatment has been justified by an appropriate person, each undertaking[»]

[*] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and associated amendments.

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

[‡] HIQA defines escalatory action as increased regulatory activity up to and including the decision to take enforcement action due to concerns about the quality and safety of care being delivered to service users and poor compliance by undertakings with their obligations under the regulations.

[»] 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.

must have systems, processes and personnel in place to ensure that each exposure is optimised so as to keep the radiation dose to the service user as low as reasonably achievable.

The regulations provide the framework on which the principles of justification and optimisation are applied, helping safeguard each service user along their pathway of diagnosis or treatment involving ionising radiation.

In order to carry out its functions as required by the Health Act 2007 (as amended), HIQA has adopted a common 'Authority Monitoring Approach' (AMA). All HIQA staff involved in the regulation of services are required to use this approach and any associated policies, procedures and protocols. However, HIQA's monitoring approach does not replace inspectors'[‡] professional judgment. Instead, it gives a framework for staff to use professional judgment and supports them to do this. The aim of AMA is to ensure:

- a consistent and timely assessment and monitoring of compliance with regulations
- a responsive and consistent approach to regulation and assessment of risk within facilities
- an improvement in inspected services by applying the inspection process.

1.2 Scope

This guidance relates to undertakings regulated by the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and associated amendments. This document was developed to help support undertakings but does not replace or take away from undertakings' responsibilities to ensure that they comply with the regulations.

This document has been updated to provide further details on the requirements for Regulation 13(4) and to include information on the following regulations:

- Regulation 7
- Regulation 8(4)

[‡] Inspector refers to an authorised person 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 and associated amendments for the purpose of ensuring compliance with the regulations.

- Regulation 8(5)
- Regulation 8(9).

Further guidance in relation to the requirements for generic justification has been published and is available on the HIQA website at Justification of Practices.

Further guidelines in relation to the specific justification of medical radiological procedures on an asymptomatic individual, performed for the early detection of disease but not as part of a health screening programme will be published in due course by HIQA.

1.3 Purpose

This guidance should be used in conjunction with the related assessment-judgment framework — one of the tools HIQA uses to assess compliance with the regulations. The framework supports inspectors in gathering evidence when monitoring or assessing an undertaking and making judgments on compliance with the regulations. It sets out the lines of enquiry which will be explored by inspectors when they are assessing compliance against the regulations. The framework should also be used by undertakings to self-assess their services.

The purpose of this guidance is to provide further information to undertakings about how the regulations will be assessed and how compliance will be measured. Inspectors from HIQA will use this guidance alongside the assessment-judgment framework to provide additional supporting information when assessing compliance against the regulations.

Therefore, the guidance is intended to provide greater detail on what information and evidence will be gathered prior to an inspection and on-site during an inspection. It will also inform how judgments about compliance will be made.

Furthermore, this guidance facilitates a consistent approach to monitoring compliance with the regulations. It also provides direction to undertakings on the type of findings that could demonstrate evidence of compliance and non-compliance. This guidance should also be used by undertakings in assessing their services to ensure compliance with the regulations.

Note: Further guidance advising undertakings on what is to be expected before, during and after a typical inspection has been published in separate documentation. Please see the HIQA website for both updated guidance documents on the inspection of medical and dental services providing medical exposure to ionising radiation.

2. Assessing compliance

2.1 Inspection

HIQA carries out inspections in order to assess compliance with the regulations. Before an inspection, HIQA comprehensively reviews available information on the undertaking to inform what needs to be reviewed on inspection of the facility.[§]

In order to make judgments about compliance, HIQA may:

- communicate with the service users who attend for medical exposures about their experience of the service
- talk with staff and management to find out how they plan and deliver care and services — conversations with staff and managers concentrate on their understanding of areas relevant to their work and care they deliver, their experience and training
- observe day-to-day practice to see if it reflects what people have stated
- review documents to see if appropriate records are kept and that they reflect practice and what people have stated.

At the beginning of the inspection, inspectors introduce themselves and outline the purpose and duration of the inspection to the designated manager, or undertaking, if applicable. The designated manager is asked to inform staff that HIQA is conducting an inspection and to introduce the inspectors to service users where it is appropriate and necessary to do so.

While inspectors have powers of entry and inspection, these will be exercised in a respectful manner and will take into consideration each service user's privacy, dignity and human rights. Observation on inspection will be unobtrusive, discreet and will not negatively impact on service provision.

2.2 When are inspections carried out?

All inspections and monitoring activities inform the undertaking's compliance with the regulations. From a regulatory perspective, HIQA is required to establish a

[§] The term facility is used in this document to mean a medical radiological installation where medical radiological procedures are performed.

system or systems of inspection to monitor compliance with the regulations, and direct undertakings to take corrective action where necessary.

In line with the regulations, the inspection programme considers the scale and nature of the potential risk associated with medical exposure to ionising radiation practices. For example, a regulatory programme will take into account the accepted varying levels of associated risk from medical exposures delivered in a dental clinic compared with those provided in a radiotherapy treatment facility.

Furthermore, regulatory activities are prioritised and resources relating to monitoring,** inspection and enforcement are organised based on the assessment of the risk that the regulated services pose. Available information on each installation, such as history of compliance, receipt of notifications and unsolicited information, will be considered in this assessment of risk. This approach informs how frequently HIQA inspects an undertaking. It also informs the nature, intensity and type of any inspection carried out.

HIQA carries out the following types of inspection:

- *Monitoring inspections:* these are routine inspections that monitor the quality of the service provided by an undertaking and the level of compliance.
- *Inspections in response to risk:* these are in addition to routine inspections and are carried out when information has been received and assessed which indicates that there may be a risk posed to service users.

2.3 Judgments on compliance with regulations

When inspectors have gathered and assessed all relevant information, they make a judgment about the level of compliance against each regulation reviewed. While some regulations attribute individual responsibility to a defined person or persons along the service user's pathway, overall responsibility for compliance is with the undertaking.

Inspectors judge whether the undertaking has been found to be **compliant, substantially compliant** or **not compliant**.

** Monitoring: HIQA define monitoring as the routine oversight and regulation of services to assess compliance with regulations. This includes reviewing, analysing and risk-rating information in order to assess compliance with regulations.

Once a judgment on non-compliance is made, inspectors review the risk to service users as a result of the non-compliance. Inspectors report on this risk as being:

- **Green:** very low risk.
- **Yellow:** low risk associated with the non-compliance.
- **Orange:** moderate risk associated with the non-compliance.
- **Red:** high risk associated with the non-compliance.

The compliance descriptors are defined as follows:

- **Compliant:** a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation.
- **Substantially compliant:** a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This judgement will have a risk rating of yellow, which is low risk.
- **Not compliant:** a judgment of not compliant means the undertaking or other persons has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action within a reasonable time frame to come into compliance.

Compliant	Substantially compliant	Not compliant	
			

Note: Although the undertaking is responsible for compliance with these regulations, some sub-regulations place additional responsibilities on HIQA and other bodies. When judging compliance against the regulation, an undertaking is only judged on the regulations or sub-regulations for which it has responsibility for.

2.4 Reporting the findings

The inspector provides feedback to the undertaking, undertaking's representative, designated manager and or relevant staff in the facility on the preliminary findings

from the inspection. The inspector then writes an inspection report to summarise the findings.

In order to summarise the inspection findings, the regulations are organised into two sections called dimensions:

- Governance and management arrangements for medical exposures.
- Safe delivery of medical exposures.

Governance and management arrangements for medical exposures: this section describes the governance, leadership and management arrangements required by the undertaking to assure itself that the radiation protection practices in place are effective and that a quality and safe radiological service is provided to service users. The integration and interdependency between good governance arrangements and clinical practice is essential in ensuring the delivery of high-quality, safe and effective care. Governance and management arrangements are key components in ensuring the safe delivery of medical exposures.

Safe delivery of medical exposures: this section describes the technical arrangements that are required by an undertaking to assure itself of the radiation protection measures required and implemented to ensure the safe delivery of medical exposures. Central to good radiation practice and safe delivery of medical exposures is providing a safe environment to ensure that the potential risks associated with medical radiological exposures are minimised and that doses are kept as low as possible to achieve the desired result.

3. Structure of the guidance on each regulation

Service users undergoing medical exposures follow a defined pathway which starts with the referrer requesting a medical exposure, the practitioner justifying the referral, the exposure being carried out by a trained professional leading to the outcome of the exposure, which provides a net benefit to the service user. Each step along the service user pathway can relate to a number of different regulations. Notwithstanding the association of the related regulations, the HIQA inspector makes a judgment on the primary regulation independently of the other related regulations.

In the guidance that follows, each regulation number and title is presented along with a discussion on:

- what this regulation means for the service user
- examples of the information and evidence reviewed to assess compliance
- indicators for compliance judgments with the regulations
- risk-rating of compliance.

Part 1: What this regulation means for the service user

This section introduces the concept of the regulation and what compliance means for the service user. Regardless of the regulations being complied with, undertakings should continually seek out ways to improve the quality of their services and potential outcomes for service users.

Part 2: Examples of the information and evidence reviewed to assess compliance

This provides examples of information and evidence that are reviewed to assist with assessing compliance. The examples are listed under the headings of documentation, communication and observation. These examples (while not an exhaustive list) support the planning for an inspection, gathering of information before and during inspections, and making judgments about compliance.

The information reviewed is determined by the history of compliance, specific areas of risk and outcome of the inspection planning.

Part 3: Indicators which demonstrate the undertaking's level of compliance with the regulations

The inspections give the undertaking an opportunity to demonstrate how they have complied with the regulations. The expectation is that undertakings continually review and assess their services and put measures in place to comply with the requirements set out in the regulations.

The examples detailed are not an exhaustive list but are to assist undertakings and inspectors when determining an undertaking's level of compliance with the regulations.

Part 4: Risk-rating of compliance

The level to which undertakings are compliant with the regulations has an impact on potential outcomes for service users. Each regulation can be assigned a maximum risk-rating based on the severity of impact on service users from non-compliance and the likelihood of occurrence and or reoccurrence. Continued non-compliance resulting from a failure by the undertaking to put appropriate measures in place to address the areas of risk may result in escalated regulatory action.

4. Guidance

4.1 Guidance on regulations related to governance and management arrangements for medical exposures

Governance and management are a measure of the undertaking's capacity and capability to be able to provide a quality and safe service. This section describes regulations related to the governance and management of each facility. It considers how people who work in the facility are recruited, trained and allocated appropriate responsibility for radiation protection, relevant to their role, qualifications, knowledge, skills and competencies. Table 1 sets out the relevant regulations.

Table 1. List of regulations under this dimension

Regulation number	Description of regulation
Regulation 4	Referrers
Regulation 5	Practitioners
Regulation 6	Undertaking
Regulation 7	Justification of practices
Regulation 10	Responsibilities
Regulation 18	Estimates of population doses
Regulation 19	Recognition of medical physics experts
Regulation 20	Responsibilities of medical physics experts
Regulation 21	Involvement of medical physics experts in medical radiological practices
Regulation 22	Education, information and training in field of medical exposure
Regulation 28	Provision of information to HIQA

Regulation 4. Referrers

What this regulation means for the service user

This regulation assures service users that only appropriately trained and recognised healthcare professionals, as defined in Regulation 4, can refer a service user for a medical exposure of ionising radiation. Those carrying out the medical exposures must ensure that only referrals made by these healthcare professionals are accepted for medical exposures.

Examples of information and evidence for Regulation 4

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- referrals for medical exposures to assess if the referral is from a healthcare professional entitled to act as a referrer as defined in Regulation 4
- written policies, procedures and guidelines defining who is entitled to refer to a practitioner for a medical exposure, or type of medical exposure, within the facility
- a sample of professional registration records of persons making referrals for a medical exposure
- the processes and procedures in place for accepting referrals.

Through communication

Inspectors may communicate:

- with practitioners to demonstrate how they assure themselves that they only accept referrals from a person entitled to act as referrer.

Through observation

Inspectors may observe:

- if persons are carrying out medical exposures on the basis of a referral from a person other that a referrer
- process for accepting referrals.

Compliance indicators for Regulation 4

Indicators for a judgment of compliant include:

- each referral is from a referrer as defined in Regulation 4
- a person only carries out a medical exposure on the basis of a referral from a person that is a referrer.

Indicators for a judgment of substantially compliant include:

- some gaps are identified in the documentation relating to the referral procedure, in that, those entitled to make a referral for medical exposures are not clearly identifiable
- some gaps are identified in practice such as non-adherence by staff to the referral policy and procedure.

Indicators for a judgment of not compliant include:

- a person referred an individual for a medical exposure to a practitioner where the referring person was not entitled to act as a referrer
- a person carried out a medical radiological procedure on the basis of a referral from a person who was not entitled to act as a referrer.

Guide to the risk rating for Regulation 4

Compliant	Substantially compliant	Not compliant	
			

Regulation 5. Practitioners

What this regulation means for the service user

This regulation serves to assure service users that an appropriately trained and recognised healthcare professional takes responsibility for the medical exposure of ionising radiation that they have made a referral for.

Only appropriately trained and recognised healthcare professionals, as defined in Regulation 5, can be allocated clinical responsibility for individual medical exposures. The health professionals acting as practitioners do so in line with the scope of practice of their relevant professional bodies.

For each individual medical exposure carried out, the practitioner is identified and the undertaking has a system in place to monitor compliance with local procedures.

Examples of information and evidence for Regulation 5

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- local records that indicate a named practitioner for each individual medical exposure carried out
- a sample of professional registration records for practitioners.

Through communication

Inspectors may communicate:

- with the undertaking and or staff in the facility to discuss the defined structure for practitioners accepting clinical responsibility for an individual medical exposure
- with the undertaking and or staff in the facility as to how they are assured persons taking clinical responsibility for individual medical exposures are practitioners
- with practitioners to determine their understanding of the practical application of local policies and procedures.

Through observation

Inspectors may observe:

- practices within the facility to assess compliance with this regulation.

Compliance indicators for Regulation 5

Indicators for a judgment of compliant include:

- only persons who are practitioners take clinical responsibility for individual medical exposures.

Indicators for a judgment of substantially compliant include:

- some gaps are identified, for example, in the documentation relating to those entitled to act as a practitioner with clinical responsibility for individual medical exposures.

Indicators for a judgment of not compliant include:

- persons who are not practitioners take clinical responsibility for individual medical exposures.

Guide to the risk rating for Regulation 5

Compliant	Substantially compliant	Not compliant	
			

Regulation 6. Undertaking

What this regulation means for the service user

Compliance with this regulation by the undertaking ensures that the service user is placed at the centre of the delivery of safe and effective care in relation to medical exposures to ionising radiation.

An undertaking is responsible for providing safe, effective and person-centred care to service users undergoing medical exposures to ionising radiation. The undertaking must assure itself as to quality and safety of any medical exposures carried out within its service.

Undertakings must appropriately govern and manage risks in services in order to ensure that those carrying out medical radiological procedures comply with the regulations. This requires that the undertaking ensures that any persons employed or engaged are complying with the regulations, irrespective of how they are employed or engaged.

How a service is governed and managed may vary and should be appropriate to the size and complexity of the organisation. In large organisations, good governance ensures a coordinated approach to radiation protection across the organisation. As a result, beneficial care is delivered to service users by appropriately trained and recognised healthcare professionals, who apply a multidisciplinary approach to radiation protection.

The undertaking ensures that there is a clearly documented allocation of responsibility for radiation protection in its organisation. It may outline its corporate and internal governance structures through the use of an organisational chart or documented description of the lines of authority in place, relevant to the size and scale of the service provided. For example, in a dental facility, all radiation protection responsibilities may lie solely with the dentist.

The undertaking must ensure that each person working in the facility is aware of and understands their individual and collective responsibilities when carrying out medical exposures to ionising radiation. For example, in a facility that employs practitioners from different disciplines or engages visiting practitioners to carry out medical exposures, the allocation of their responsibilities needs to be specified. Similarly, the allocation of responsibilities of the medical physics expert and those delegated the practical aspects for all medical exposures needs to be clearly documented in local policies and procedures.

Effective governance and management structures promote staff and service users to provide feedback on the service in order to refine and develop practices. To improve

the quality and safety of medical exposures provided to service users, undertakings are encouraged to see beyond the regulations in an effort to raise standards. A culture of continual improvement and learning, and of supporting staff training and development, is essential to the ongoing safe delivery of medical exposures for the benefit of service users. An example of good practice in larger services is collaboration between committees, such as the radiation safety committee, and clinical audit and risk management committees, to ensure that medical exposures provided are safe.

Overall, there are clear lines of accountability at individual, team and organisational level so that all staff working in the service are aware of their responsibilities and who they are accountable to.

Examples of information and evidence for Regulation 6

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- that a Declaration of undertaking (NF200) form has been submitted by the undertaking
- local reporting structures or organisation charts that outline the organisational structure of each undertaking
- local policies that describe the allocation of responsibility for radiation protection within the service.

Through communication

Inspectors may communicate with the undertaking and or staff in the facility:

- to describe the management structures in place to provide for radiation protection of service users
- to determine if there are systems in place to provide relevant staff in the facility with assurance that those employed or engaged by them are complying with the regulations
- to determine how they raise concerns or report non-compliance with the regulations to the undertaking.

Compliance indicators for Regulation 6

Indicators for a judgment of compliant include:

- the undertaking has submitted a declaration form to HIQA within the time frames specified by Regulation 6
- the undertaking has documented a clear allocation of responsibility for radiation protection of service users and provide evidence of this to HIQA
- the undertaking has clear lines of accountability for those engaged or employed by them to ensure compliance with these regulations.

Indicators for a judgment of substantially compliant include:

- some gaps are identified in the documentation relating to the clear allocation of responsibilities for radiation protection of service users.

Indicators for a judgment of not compliant include:

- the undertaking has not submitted an accurate declaration form to HIQA within the time frames specified by Regulation 6
- the undertaking has not demonstrated evidence of a clear allocation of responsibilities for radiation protection of service users
- the undertaking fails to take responsibility for non-compliance with these regulations by those employed or engaged by them.

Guide to the risk rating for Regulation 6

Compliant	Substantially compliant	Not compliant	
			

Regulation 7. Justification of practices

What this regulation means for the service user

A new practice is defined as a class or type of radiological procedure that had not been used before the regulations were introduced, that is to say, before 8 January 2019. For service users, the justification of a new practice ensures that the health benefits from the practice outweigh the health detriments it may cause them. This is known as 'generic justification'. Further information on generic justification, and the specific instances when this should be considered, can be found on the HIQA website on the ionising radiation webpage called 'Justification of Practices'.

When considering the implementation of new practices the undertaking must demonstrate an awareness of Regulation 7 and there is evidence of a system to determine if a new practice requires justification before being generally adopted. The undertaking must also demonstrate how it was determined if generic justification for the practice is already in place, or that an application to HIQA for generic justification of the new practice was made. If uncertain on aspects of this, the undertaking can demonstrate that they engaged with HIQA before adopting a new practice.

If it is concluded that justification of a new practice is required, an application to HIQA for justification of the practice is made. The undertaking has a clearly documented implementation process in place, which includes the responsibilities of those involved for each step of the process. A multidisciplinary approach to the justification of a new practice has been taken where appropriate, which can include the local radiation protection governance structures. For example, in larger services, the implementation of a new practice could involve the radiation safety committee, and clinical audit and risk management committees. The responsibilities of these groups or individuals should be clearly detailed by the undertaking and understood by those involved.

The undertaking can also show that there is appropriate staff awareness that justification of new practices may be required. When implementing a new practice, staff requirements for education, training and competence in radiation protection associated with the new practice have been considered, and an appropriate risk assessment completed where appropriate.

There is a process in place to monitor the need for generic justification for new practices commenced since 8 January 2019. This monitoring process should ensure that generic justification is considered for any type of practice that has to date been

justified on a case-by-case basis, but not generally adopted and the need for wider implementation within the service has now been identified. There is also a process in place to monitor and inform HIQA if new and important information becomes available which is relevant to the justification of existing practices. This would include, for example, new and important evidence about the efficacy and potential consequences of the practices carried out by the service, or about other techniques and technologies.

Note: Generic justification does not apply to new practices that are being offered solely in the context of a clinical trial, clinical investigation or research study. In Ireland, such research comes under the governance of the relevant clinical trial and clinical investigation legislation implemented by the Health Products Regulatory Authority and research ethics committees.[††] However, if on completion of the trial, investigation or research study, the undertaking favours implementing the practice, it needs to consider, and where necessary, apply for justification of this practice to HIQA.

Examples of information and evidence for Regulation 7

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review documents such as:

- written protocols or guidelines relating to justification of practice which may include, but are not limited to:
- local framework for the implementation of new practices, to include consideration of justification by HIQA and identifies the local formal approval processes in place
- education and training for those involved in the implementation of the practice
- evidence in records that justification of practice has been considered for all new practices in advance of them being generally adopted into clinical practice
- evidence of the rationale for not applying to HIQA for justification of a new practice

[††] Ethics committee means an ethics committee recognised in accordance with Part 8 of the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and associated amendments.

- evidence of an application to HIQA for justification of a new practice
- evidence of a decision by HIQA on an application for justification of a practice
- reviews conducted on existing practices to identify the practices implemented since 2019 that may require generic justification
- reviews conducted on an existing practice if new and important evidence about the practice emerges, or if new and important evidence about other techniques and technologies (including non-ionising practices) emerges.

Through communication

Inspectors may communicate:

- with the undertaking and or staff to determine their understanding of justification of new practices, if they are able to describe the process in line with local policy and that they have a clear awareness of their role within the process for justification of new practices in line with local policy
- with the undertaking and or staff to determine their understanding of justification of an existing practice if new and important evidence about the practice emerges, or if new and important evidence about other techniques and technologies (including non-ionising practices) emerges.

Through observation

Inspectors may observe:

- the systems in place — electronic or otherwise — to ensure that all new and existing practices have been considered for generic justification
- the systems in place — electronic or otherwise — to identify the practices that were implemented before 8 January 2019 and therefore do not require generic justification, unless new and important evidence about the practice emerges, or if new and important evidence about other techniques and technologies (including non-ionising practices) emerges.

Compliance indicators for Regulation 7

Indicators for a judgment of compliant include:

- there is evidence that the justification of new practices has been considered and approved locally, and that an application has been made to HIQA where required
- where a decision has been made not to apply to HIQA for generic justification, there is evidence to demonstrate that:
  - — the practice is not a new practice and was generally adopted in Ireland before 8 January 2019

    or
  - — the undertaking has established that generic justification for the practice has been applied for by an another undertaking and approved by HIQA

    or
  - — engagement with HIQA outlining that the practice doesn't meet the requirement for generic justification
- evidence that an appropriate assessment has been carried out before the new practice is implemented in the facility
- policies and procedures are in place to support justification of new practices, are available to staff, regularly reviewed and compliance with these policies is monitored.

Indicators for a judgment of substantially compliant include:

- while local policies and procedures relevant to justification of new practice are in place and implemented, some minor gaps in documentation are evident
- the undertaking and or staff are not all familiar with their roles and responsibilities in relation to justification of new practices.

Indicators for a judgment of not compliant include:

- there is no formalised process to provide assurance that an undertaking complies with the requirements of this regulation
- a policy for the generic justification of new practices has been developed but it has not been implemented

- there is a lack of monitoring of practices in the facility to determine if generic justification of new practices is required
- a new type of practice has been generally adopted in the facility without generic justification
- a type of practice, new or existing, is being carried out in the facility that was judged by HIQA to be not generically justified.

Guide to the risk rating for Regulation 7

Compliant	Substantially compliant	Not compliant	
			

Regulation 10. Responsibilities

What this regulation means for the service user

The respective responsibilities of the undertaking, the practitioner, the medical physics expert, the referrer, and persons entitled to carry out practical aspects for all medical exposures are set out in Regulation 10.

For a medical exposure, the service-user pathway involves referral, justification, optimisation, the practical carrying out of the exposure and evaluation of the exposure outcome. Appropriate persons are involved along this pathway to ensure that a safe and quality service is being delivered. This is central to radiation protection practices.

The responsibilities allocated for justification, optimisation and the conduct of medical exposures are clearly delegated in local policy. The undertaking ensures that the allocation of responsibilities for carrying out medical exposures are in line with the regulations and that those involved receive training in radiation safety.

Both the practitioner and the referrer are involved in the justification process for each medical exposure, in order to consider that the exposure is justified in advance of it being completed. This is essential to protect the service user by ensuring that the benefits of the medical exposure outweigh the associated risks.

For each medical exposure, that the practitioner taking clinical responsibility for that exposure is clearly identifiable, and aware of their clinical responsibilities for the exposure. Only an appropriately trained person carries out the practical aspects of a medical exposure. Where the referrer and practitioner are the same person, as may be the case in a dental practice, this person has appropriate processes in place to ensure that all requirements of Regulation 10 are being met.

Optimisation of medical exposure doses ensure that the doses are kept as low as reasonably achievable, to maximise radiation protection for service users, while also achieving the benefits of the exposure. A key element of optimisation is the involvement of healthcare professionals, as outlined in this regulation, who have the appropriate skills and competence in carrying out medical exposures.

The undertaking has systems in place to ensure that the responsibilities for medical exposures, along the service-user pathway, are allocated to appropriate persons as required by this regulation. There are also systems in place to monitor and ensure the appropriate and adequate involvement of persons in the justification and optimisation processes for medical exposures.

Examples of information and evidence for Regulation 10

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- records relating to medical exposures that have been carried out to identify:
  - the referrer
  - involvement of the practitioner and referrer in justification
  - the practitioner taking clinical responsibility for medical exposures
  - the individual carrying out the practical aspects of the exposure
  - medical physics expert involvement in optimisation
- training records for individuals who are delegated the practical aspects of a medical radiological procedure
- records of each delegation of the practical aspects of a medical radiological procedure as made by the undertaking or the practitioner
- records of registration or recognition by the appropriate body for individuals who are delegated the practical aspects of a medical radiological procedure
- rotas and rosters for practitioners, referrers, those delegated the practical aspects of a medical radiological procedure and medical physics experts
- clinical audits, for example:
  - monitoring allocation of clinical responsibilities to exposures
  - monitoring compliance with local optimisation procedures
  - monitoring compliance with local justification procedures
  - policies, procedures, protocols and guidelines for optimisation and justification.

Through communication

Inspectors may communicate with the undertaking and or staff in the facility:

- to establish how the undertaking is assured that all medical exposures take place under the clinical responsibility of a practitioner
- to ensure that the justification and optimisation processes involve all the required individuals

- to establish who carries out the practical aspects of medical radiological procedures
- regarding the delegation of practical aspects of medical radiological procedures.

Through observation

Inspectors may observe:

— the justification and optimisation process for medical exposures to see if the required individuals are appropriately involved

— if persons carrying out the practical aspects of a medical radiological procedure are practitioners or a person delegated by the undertaking or the practitioner

— if those delegated to carry out the practical aspects of medical radiological procedures are registered or recognised by an appropriate body.

Compliance indicators for Regulation 10

Indicators for a judgment of compliant include:

- a practitioner took clinical responsibility for each medical exposure reviewed by inspectors
- the practitioner, the medical physics expert and those entitled to carry out the practical aspects of medical radiological procedures are involved in the optimisation process for all medical exposures
- the practitioner and the referrer are involved in the justification process of individual medical exposures
- the practical aspects of medical radiological procedures are only delegated by the undertaking or the practitioner
- the practical aspects of medical radiological procedures are only delegated to individuals who are listed in Regulation 10(4)
- the undertaking has records of each delegation of the practical aspects of medical radiological procedures.

Indicators for a judgment of substantially compliant include:

- there were some gaps evident in how documents to support the allocation of responsibilities were being maintained.

Indicators for a judgment of not compliant include:

- a practitioner did not take clinical responsibility for all medical exposures reviewed by inspectors
- the practitioner, the medical physics expert, or those entitled to carry out the practical aspects of medical radiological procedures are not involved in the optimisation process of all medical exposures
- the practitioner and the referrer are not involved in the justification process for individual medical exposures
- the practical aspects of medical radiological procedures are delegated to individuals other that those who are listed in Regulation 10(4)
- records of each delegation of the practical aspects of medical radiological procedures are not maintained and are not available on request to HIQA
- persons other than a practitioner or an individual delegated the practical aspects of the medical radiological procedure conducted the practical aspects of a medical radiological procedure.

Guide to the risk rating for Regulation 10

Compliant	Substantially compliant	Not compliant	

Regulation 18. Estimates of population dose

What this regulation means for the service user

Medical exposures are the largest artificial source of population exposure to ionising radiation. Developments in technology, such as computed tomography (CT) and interventional radiology, have resulted in improved diagnostic and therapeutic benefits from medical imaging. Therefore, a greater number of service users are undergoing these relatively high-dose X-ray examinations. This has significantly contributed to the individual doses of service users and to the collective dose of the population as a whole.

By gathering information, records and data, population doses are determined and provide an estimate of the dose received by people living in Ireland. It is the responsibility of the undertaking to provide information, records and data on medical exposures to HIQA to facilitate the estimation of population doses.

The objectives of reporting on population doses from certain types of medical exposures include the following:

- to determine the contributions of different imaging modalities and types of procedures to the total collective dose from all medical exposures
- to determine the relationship between how many times different types of medical exposures are carried out, the typical radiation doses delivered to service users and their contribution to the total collective population dose
- to determine whether there are any regional variations within the country regarding the frequency or collective doses from particular types of medical exposures
- to determine the age and sex distribution of the service users undergoing specific types of medical exposures, particularly those making a major contribution to the total collective dose.

These objectives provide information that allow the prioritisation and focus of resources on the radiation protection of service users that receive the highest doses, and as a result incur the greatest risks from exposure to ionising radiation. HIQA is responsible for ensuring that dose estimates resulting from medical exposure from radiodiagnostic and interventional radiology purposes are determined, and that where appropriate these population doses are distributed by the age and gender of service users.

Compliance indicators for Regulation 18

Indicators for a judgment of compliant include:

- information, records and data on medical exposures are provided to HIQA to facilitate the estimation of population doses.

Indicators for a judgment of substantially compliance include:

- there are some gaps evident in the information, records and data on medical exposures that are provided to HIQA to facilitate the estimation of population doses.

Indicators for a judgment of not compliant include:

- information, records and data on medical exposures are not provided to HIQA to facilitate the estimation of population doses.

Guide to the risk rating for Regulation 18

Compliant	Substantially compliant	Not compliant	
			

Regulation 19. Recognition of medical physics experts

Regulation 20. Responsibilities of medical physics experts

Regulation 21. Involvement of medical physics experts in medical radiological practices

What these regulations mean for the service user

A medical physics expert is a person with the knowledge, training and expertise to act or give advice on matters relating to radiation physics applied to medical exposures, and whose competence in this respect is recognised by the Minister for Health and in transitional arrangements by the Irish College of Physicists in Medicine.

Medical physics experts play a vital role in the optimisation of service-user doses received as result of medical exposures. The involvement of medical physics experts in a facility assures service users that a safe and quality service is being provided. Key activities of medical physics experts include advising and performing quality assurance activities on medical radiological equipment.

The undertaking has arrangements to ensure continuity of expertise for the medical physics expert. There is adequate succession planning for the role, including planning for expected and unexpected leave, ongoing continual professional development and the appropriate allocation of resources. Evidence of the involvement of the medical physics expert in a facility is available for review by HIQA.

The specific duties of a medical physics expert correspond with the radiological risk to service users in the facility. Therefore, the level of involvement varies between services. For example, in radiotherapy and high-dose interventional procedures, such as CT and diagnostic and therapeutic nuclear medicine, a medical physics expert with appropriate training and competencies is closely involved in the service.

In low-dose diagnostic procedures and in dental imaging, a named medical physics expert can provide consultation and advice on radiation protection. This advice ensures that the undertaking is meeting the requirements of regulations that necessitate medical physics expert involvement. For example, a medical physics expert may advise a dentist on the use of dosimetry to compare local diagnostic reference levels with national diagnostic reference levels.

The undertaking is assured that tasks which are the responsibility of the medical physics expert are appropriately delegated, and the roles and responsibilities for the staff accountable are clearly defined.

Examples of information and evidence for Regulations 19, 20 and 21

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review documents such as:

- evidence of the continuity of expertise provided by medical physics experts, ensuring no gaps in the availability of such expertise; for example, staff rotas
- records showing succession planning; for example, contractual arrangements outlining responsibilities of medical physics experts
- the register of medical physics experts
- evidence that the medical physics expert takes responsibility for dosimetry depending on the medical radiological practice
- evidence that the medical physics expert advises on equipment
- evidence of the contribution of a medical physics expert in:
  - records demonstrating the optimisation of the radiation protection of service users and other individuals subject to medical exposure, including the application of diagnostic reference levels
  - the definition and performance of quality assurance of medical radiological equipment
  - acceptance testing of medical radiological equipment
  - technical specifications for medical radiological equipment and facility design
  - the surveillance of facilities
  - analysis of events involving, or potentially involving, accident or the unintended medical exposures
  - the selection of equipment required to perform radiation protection measurements
  - the training of practitioners and other staff in relation to radiation protection, including training records
  - local policies, procedures, protocols and guidance in relation to the responsibilities of the medical physics expert
  - employment records; for example, job descriptions outlining responsibilities of medical physics experts

- training records in relation to radiation protection
- policies, procedures, protocols and guidance demonstrating involvement of medical physics experts in medical radiological practices
- employment records, such as contracts and job descriptions, for medical physics experts to determine their involvement in medical radiological practices.

Through communication

Inspectors may communicate:

- with the undertaking and or staff in the facility to determine if the necessary arrangements are in place to ensure continuity of expertise for medical physics experts
- with medical physics experts to correlate their understanding of the local arrangements in practice
- with the undertaking or staff at the facility to outline the responsibilities of medical physics experts in medical radiological practices under their remit
- with the medical physics experts to determine their level of responsibility in relation to the service
- with staff in relation to radiation protection training received.

Inspectors may observe through observation:

- practices to determine the level of involvement of the medical physics expert and assignment of responsibilities.

Compliance indicators for Regulations 19, 20 and 21

Indicators for a judgment of compliant include:

- the necessary arrangements to ensure continuity of expertise for medical physics experts are in place
- an undertaking provides evidence that a medical physics experts acts or gives specialist advice relating to radiation physics
- dosimetry and physical dose measurements are under the responsibility of the medical physics expert dependent on the type of medical radiological practice
- a medical physics expert is closely involved in radiotherapeutic practices
- a medical physics expert is involved in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in Regulation 15(c)
- a medical physics expert is involved, as appropriate, for other medical radiological practices, including those referred to in Regulation 15, for consultation and advice on matters relating to radiation protection concerning medical exposure
- the medical physics experts gives advice on medical radiological equipment
- the medical physics expert contributes to:
  - — the optimisation of the radiation protection of service users and other individuals subject to medical exposure, including the application and use of diagnostic reference levels
  - — the definition and performance of quality assurance of the medical radiological equipment
  - — acceptance testing of medical radiological equipment
  - — the preparation of technical specifications for medical radiological equipment and facility design
  - — the surveillance of the facility
  - — the analysis of events involving, or potentially involving, accidental or unintended medical exposures

— the selection of equipment required to perform radiation protection measurements

— the training of practitioners and other staff in relevant aspects of radiation protection.

Indicators for a judgment of substantially compliant include:

- although arrangements are in place for continuity of expertise of medical physics experts, there are gaps in these arrangements
- there is evidence of medical physics expert involvement in radiation physics, but there are minor gaps evident in responsibilities, advice given or contribution to the service
- while there is evidence of involvement of the medical physics expert as defined in Regulation 21, there are gaps in documentation
- there is evidence of medical physics expert involvement, but there are minor gaps evident in involvement, including advice given or contribution to the service.

Indicators for a judgment of not compliant include:

- the undertaking has not assured HIQA that a medical physics expert is closely involved in radiotherapeutic practices
- the undertaking has not assured HIQA that a medical physics expert is involved in standardised therapeutical nuclear medicine practices as well as other procedures involving high doses as referred to in Regulation 15(c)
- the undertaking has not assured HIQA that a medical physics expert is involved, as appropriate, for other medical radiological practices, excluding those referred in Regulation 15(c), for consultation and advice on matters relating to radiation protection concerning medical exposure
- the necessary arrangements to ensure continuity of expertise for medical physics experts are not in place
- an undertaking does not assure HIQA that a medical physics expert acts or gives specialist advice relating to radiation physics
- there is no responsibility for dosimetry within an undertaking
- the medical physics expert does not give advice on medical radiological equipment
- the medical physics expert does not contribute to:

- the optimisation of the radiation protection of service users and other individuals subject to medical exposure, including the application and use of diagnostic reference levels
- the definition and performance of quality assurance of the medical radiological equipment
- acceptance testing of medical radiological equipment
- the preparation of technical specifications for medical radiological equipment and facility design
- the surveillance of the facility
- the analysis of events involving, or potentially involving, accidental or unintended medical exposures
- the selection of equipment required to perform radiation protection measurements
- the training of practitioners and other staff in relevant aspects of radiation protection.

Guide to the risk rating for Regulations 19, 20 and 21

Compliant	Substantially compliant	Not compliant	
			

Regulation 22. Education, information and training in field of medical exposure

What this regulation means for the service user

The undertaking is organised and managed in such a way that ensures the required skills, experience and competencies are available along the service user's medical exposure pathway. The practitioners and those carrying out the practical aspects of medical exposures are competent in radiation protection.

The undertaking is assured that only those with training, as outlined in Regulation 22(3), are allocated to perform functions appropriate to that training. There are systems in place to support ongoing continual professional development in relation to medical exposures, particularly in response to the changing needs of the service, such as when new technology and practices are available.

For service users, this ensures that the professionals involved in their medical exposure have a sufficiently high standard of radiation protection training to provide high-quality, safe and effective care.

Examples of information and evidence for Regulation 22

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- training records for practitioners and those carrying out the practical aspects of medical exposure
- training records for practitioners and those carrying out the practical aspects of medical exposure where services are contracted to other parties
- evidence of ongoing training and education
- policies, procedures, protocols and guidelines, including corporate policies to meet the requirements of Regulation 22.

Through communication

Inspectors may communicate:

- with practitioners and those carrying out the practical aspects of medical exposure to determine if they undertake ongoing education and training
- with trainees or students participating in the practical aspects of medical exposure to ensure that their activities are always supervised.

Through observation

Inspectors may observe:

- the supervision and participation of trainees or students carrying out the practical aspects of medical exposure
- individuals acting as practitioners and those carrying out the practical aspects of medical exposure to ensure they have adequate levels of education and training.

Compliance indicators for Regulation 22:

Indicators for a judgment of compliant include:

- practitioners and those carrying out the practical aspects of medical exposure have appropriate education and training, including ongoing education in line with Regulation 22(3)
- aspects of medical exposure as outlined in Regulations 22(3) and 22(4) are met
- there is evidence that practitioners and those delegated the practical aspects undertake continual education and training after qualification
- trainees or students carrying out the practical aspects of medical exposure are supervised in their activities
- evidence of training records are received and kept by an undertaking in relation to third-party contracted work.

Indicators for a judgment of substantially compliant include:

- some gaps are identified in the documentation relating to education and training of practitioners and those carrying out the practical aspects of medical exposure.

Indicators for a judgment of not compliant include:

- practitioners and those carrying out the practical aspects of medical exposure do not have the appropriate education and training in line with Regulation 22(3), whether services are carried out by the undertaking or other parties are engaged to carry out these services
- practitioners and those carrying out the practical aspects of medical exposure have inadequate continuing education and training in relation to new technology and techniques

- trainees or students carrying out the practical aspects of medical exposure are not always supervised in their activities.

Guide to the risk rating for Regulation 22

Compliant	Substantially compliant	Not compliant	
			

Regulation 28. Provision of information to HIQA

What this regulation means for the service user

It is the responsibility of the undertaking to ensure that a safe and effective service is delivered to service users, and that the service is compliant with the regulations. In assessing compliance with the regulations, HIQA inspectors gather information and evidence to support a judgment of compliance or otherwise. The undertaking provides and submits information or statistics of compliance with these regulations when requested by HIQA and within timelines specified by HIQA.

The undertaking ensures that all records are maintained, stored and secured in line with best practice.

Compliance indicators for Regulation 28

Indicators for a judgment of compliant include:

- information and statistics requested by HIQA to determine the level of compliance are submitted within timelines defined by HIQA.

Indicators for a judgment of substantially compliant include:

- some gaps are identified in the information and statistics provided to HIQA to determine the level of compliance within timelines defined by HIQA.

Indicators for a judgment of not compliant include:

- information and statistics requested by HIQA are not provided by the undertaking to HIQA.
- information and statistics requested by HIQA are not made available by the undertaking within timelines defined by HIQA.

Guide to the risk rating for Regulation 28

Compliant	Substantially compliant	Not compliant	
			

4.2 Guidance on regulations related to safe delivery of medical exposures

The focus of this section is on the experience of the service users undergoing a medical exposure to ionising radiation. This includes how service users undergoing medical exposures:

- only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks
- are only exposed to medical radiological procedures where radiation doses are kept as low as reasonably achievable to maximise the radiation protection for service users and to attain the objectives of the medical exposure
- do so in a safe environment
- are empowered to exercise their right to receive information and make choices about the medical radiological procedure they receive.

Table 2. List of regulations under this dimension

Regulation number	Description of regulation
Regulation 8	Justification of medical exposures
Regulation 9	Optimisation
Regulation 11	Diagnostic reference levels
Regulation 12	Dose constraints for medical exposures
Regulation 13	Procedures
Regulation 14	Equipment
Regulation 15	Special practices
Regulation 16	Special protection during pregnancy and breastfeeding
Regulation 17	Accidental and unintended exposures and significant events

Regulation 8. Justification of medical exposures

What this regulation means for the service user

The justification of a medical exposure is the decision whether or not to carry out the medical exposure on the basis that the exposure should do more good than harm. Before a service user is exposed to ionising radiation, the practice of justification of that particular medical exposure determines if the net benefits outweigh the possible risks and if the examination is indicated and useful.

The justification is carried out by a suitably qualified practitioner. When making the justification decision, the practitioner takes into account medical information about the service user and their individual characteristics, such as their pregnancy status if relevant. For example, a service user may have had a previous diagnostic procedure which is considered and informs the justification process. This information is available to and considered by the practitioner and referrer in order to avoid unnecessary exposure.

For the service user, justification ensures that the medical exposure, for which they have been referred, is the most appropriate option for them. The justification process aims to minimise excessive or incorrect medical exposures. Therefore, justification is an important safeguard for service users against potential adverse health effects from ionising radiation.

The justification process weighs up the risks and benefits of the medical exposure. Before the exposure takes place, patients or their representatives are provided with information about the benefits and risks of the exposure. This is to ensure that service users are fully informed of potential side effects or outcomes from the exposure.

At local level, the justification process is clearly documented and includes the responsibilities of those involved in each step of the process. The responsibilities for professional groups or individual practitioners are clearly delineated and understood by those involved. Practices are supported by education and training.

When a service user is referred for a medical radiological procedure, the core principles and requirements of justification outlined in Regulation 8 must be satisfied before the exposure takes place. The practitioner is satisfied that the referral meets the criteria for suitability and that sufficient information is provided to justify the exposure. There is a system in place to conduct this evaluation and foster challenge of referrals, with evidence that referrals are rejected or changed, if appropriate. In a dental practice, this evidence may be provided in the form of a written record of the justification by the dentist.

The core requirements for individual justification, outlined in Regulation 8, apply to all medical radiological procedures, and evidence of justification taking place before the procedure must be evident. However, the process may vary in line with the type of facility and complexity of the medical radiological procedure. For example, in a dental practice where the referrer and practitioner are the same person, the process may be relatively simple. In contrast, in a radiotherapy facility, aspects of the justification process may be inherent throughout the service-user pathway.

Occasionally, a non-standard specific exposure to ionising radiation may be medically required for an individual service user. Such exposures can be required for either diagnostic or treatment purposes, are not generally adopted and each requires specific justification on a case-by-case basis. In this regard, the undertaking has a process in place for such individual justifications. The process clearly highlights the role and responsibilities of those involved in these justifications; for example, the practitioner who can make a decision for individual justification on a case-by-case basis. A record of individual justification by the practitioner is also maintained. There is also evidence of monitoring of these non-standard procedures by the undertaking and assurances that they are completed in line with the agreed local policies and procedures, and that they comply with regulations.

When conducting a health screening programme, the undertaking ensure that only medical radiological procedures performed as part of this health screening programme are carried out in the service. There are policies, procedures and guidelines in place that support the programme, that all appropriate persons involved in the programme and that they are conducted in accordance with HIQA guidance relating to generic justification and health screening programmes.

The undertaking ensures that medical radiological procedures carried out on asymptomatic individuals, performed for the early detection of disease but not as part of a health screening programme, are justified and conducted in line with the relevant guidance published by HIQA.

Note: HIQA is to publish further guidance in relation the specific justification of medical radiological procedures on asymptomatic individuals, performed for the early detection of disease but not as part of a health screening programme. When published, an undertaking will have responsibility to ensure medical exposures of ionising radiation are conducted in accordance with these guidelines.

Examples of information and evidence for Regulation 8

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

Justification

- written protocols or guidelines relating to justification include, but are not limited to:
  - the framework for justification of individual exposures
  - education and training for those with delegated responsibility
  - the recommended use of referral guidelines, where applicable
- evidence in records that justification has taken place and is documented for individual medical exposures
- evidence that all parts of the justification process have taken place, including but not limited to:
  - review and appraisal of the referral
  - review of medical information and evidence that further medical information is sought where relevant
- evidence that individual service-user characteristics have been considered
- evidence that justification is carried out by a practitioner and that this designation is in line with the regulations and local policy
- where a specific individual procedure has not been generally adopted but is carried out on a case-by-case basis, there is evidence that a practitioner has evaluated and justified the procedure before it is carried out and a record of this specific individual justification process is documented
- reviews that identify that specific individual procedures that are not generally adopted practice are evaluated and justified in advance by a practitioner
- evidence that in health screening programmes, only medical radiological procedures that form part of the programme are carried out
- reviews that ensure that the undertaking has adequate oversight that medical radiological procedures carried out on asymptomatic individuals, performed for the early detection of disease but not as part of a health screening

programme, are justified and conducted in line with guidelines when published by HIQA

- in radiotherapy, evidence that information such as diagnosis, histology, clinical staging and findings were available at the time of justification of a course of treatment.

Referrals

- referral records:
  - — are in writing
  - — include the reason for the request
  - — contain adequate medical information for a justification assessment
  - — contain evidence that practitioners seek further medical data where necessary before the exposure takes place
- clinical audits conducted on the quality of referrals and rejection rates of non-justified referrals.

Research studies, health screening programmes and asymptomatic individuals

- research study documentation shows evidence of relevant ethics committee approval
- policies, procedures and guidelines relevant to justification of medical exposures for carers and comforters
- records of medical radiological procedures that are carried out as part of a health screening programme
- policies, procedures and guidelines relevant to a health screening programme.

Provision of information

- evidence of information provided to patients, such as information leaflets, radiation protection information and documentation in medical records of information provided
- evidence that information on risks and benefits of exposure has been provided to patients or their representatives
- availability of hardcopy information where this is provided
- clinical audits conducted on the provision of information to patients or their representatives.

Through communication

Inspectors may communicate:

- with the undertaking and or staff in the facility to determine their understanding of justification and if they are able to describe the process in line with local policy
- with referrers, practitioners and those carrying out the practical aspects of exposures to ensure there is clear awareness as to their role within the justification process in line with local policy
- with practitioners to determine their understanding of how referrals are appraised and the process of rejection of non-justified referrals
- with practitioners to determine if they can describe which procedures are justified in general and how justification takes place for procedures not generally adopted but which are carried out on a case-by-case basis
- with patients or their representative to determine if information has been provided to them on the risks and benefits of the exposure

Through observation

Inspectors may observe:

- the systems in place — electronic or otherwise — to ensure that all medical exposures are justified in advance
- the practices in place for referral and justification of medical exposures
- the availability of information to inform the justification process, including but not limited to:
  - — access to the referral
  - — access to referral guidelines
  - — access to national and local imaging systems, where relevant, and any other access to previous diagnostic information
  - — access to medical records containing the characteristics of the individual involved.

Compliance indicators for Regulation 8

Indicators for a judgment of compliant include:

Justification

- policies and procedures are in place to support justification and these policies are adhered to in practice and in line with regulations
- the policies and procedures are regularly audited and peer reviewed
- records that the justification process, including review of medical information and previous diagnostic procedures, has taken place and is documented for individual medical exposures
- records of specific individual evaluation and justification in advance by a practitioner for medical exposures not generally adopted but which are carried out on a case-by-case basis.

Referrals

- all referrals to a practitioner for a medical radiological procedure viewed by inspectors:
  - are in writing
  - state the reason for requesting the particular procedure
  - are accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment
- evidence that referrals which do not have sufficient medical data to enable the practitioner to carry out a justification assessment are rejected by the practitioner
- referrers, practitioners and other relevant staff clearly understand the requirements of this regulation and are able to describe their role in the process
- training is provided to staff relating to the provisions of this regulation and processes in place to support compliance.

Research studies, health screening programmes and asymptomatic individuals

- all research projects involving medical exposure are approved by an ethics committee before the exposure is carried out
- all medical radiological procedures carried out as part of a health screening programme are specifically justified by HIQA before the programme starts.

Provision of information

- there is evidence that information on risks and benefits of exposure is provided to patients and or representatives.

Indicators for a judgment of substantially compliant include:

- not all staff who spoke with inspectors can clearly demonstrate their roles and responsibility in relation to justification
- local policies and procedures relevant to justification are in place but there is a lack of evidence regarding audit of practice
- information on risks and benefits of exposure is available but there is a lack of evidence that it is being provided to patients or their representatives
- gaps in documentation available to support staff completing medical exposures of ionising radiation as part of a health screening programme
- gaps in documentation available to support staff completing medical exposures of ionising radiation on asymptomatic individuals, performed for the early detection of disease but are not as part of a health screening programme.

Indicators for a judgment of not compliant include:

- written referrals are not evident for all medical radiological procedures conducted at the facility
- referrals are made to practitioners for a medical radiological procedures which do not meet the criteria laid out in Regulation 8(10), but these referrals are accepted and medical exposures completed
- where a type of practice is not generally adopted but is carried out on a case-by case basis for individual service users at the facility, there is no record that a practitioner completed an evaluation for that specific individual medical exposure in the facility
- no formalised process in place to provide assurance on compliance with the requirements of this regulation
- a lack of awareness is demonstrated by staff on the requirements of this regulation
- no evidence that information on risks and benefits of exposure is provided to patients or their representatives

- research projects involving medical exposure are not approved by an ethics committee prior to the exposure
- medical radiological procedures are being carried out as part of a health screening programme, but the health screening programme is not specifically justified by HIQA before it begins
- medical radiological procedures are being carried on asymptomatic individuals for the early detection of disease but are not part of a health screening programme and are not in line with guidelines (when published by HIQA).

Guide to the risk rating for Regulation 8

Compliant	Substantially compliant	Not compliant	
			

Regulation 9. Optimisation

What this regulation means for the service user

The principle of optimisation must be applied to each medical exposure of ionising radiation carried out, such as a general X-ray, CT and medical exposures where ionising radiation is used to guide a treatment or procedure. Optimisation assures service users that the risks associated with an exposure to ionising radiation are minimised while also delivering the required clinical outcome, and that the most appropriate dose for each individual exposure is delivered.

For example, in a general X-ray procedure, the dose delivered to the service user should be as low as possible and also result in an image of suitable quality to provide the diagnostic information for which the service user was referred.

The undertaking has a system and processes in place to ensure that each medical exposure is optimised, and these processes are constantly reviewed to ensure that optimisation is an ongoing process within the facility. A local policy clearly outlines these processes and the allocation of responsibilities to those involved in the processes.

Optimisation comprises multiple considerations, such as the selection of appropriate radiological equipment and ancillary features, a comprehensive quality assurance programme and the use of dosimetry audits. It is evident that optimisation is considered throughout the service user's pathway.

Examples of information and evidence for Regulation 9

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review documents such as:

Optimisation

- policies, procedures, protocols and guidelines relevant to optimisation, including but not limited to:
  - optimisation policy outlining the roles and responsibilities of those involved
  - quality assurance
  - dose management systems in place
  - consistency in the practical aspects of medical exposures

— local policies, procedures and guidelines for carrying out clinical audits, including evaluation of service user doses received, image quality, technique, rejection of images and repeat of imaging analysis.

Optimisation in radiotherapy

- policies, procedures, protocols and guidelines for treatment sites relevant to that facility, including but not limited to:
- dose prescriptions, planning aims and dose constraints
- delineation of target volumes and organs at risk
- planning and simulation imaging
- verification imaging (image guided radiotherapy protocols)
- quality assurance including quality assurance of treatment plans, verification of treatment delivery and service-user specific dose where applicable
- local policies, procedures and guidelines for carrying out clinical audits, including evaluation of service-user doses received, image guided radiotherapy procedure compliance and repeat imaging
- treatment plans ensuring:
- they are planned individually to a target volume
- dose to organs at risk are considered with respect to the therapeutic goal for that service user.

Provision of information

- appropriate guidance on medical exposures and information on the associated risks is developed for comforters and carers, and there is evidence that this guidance and information is available to them
- risk and benefits information on medical exposures for service users undergoing treatment or diagnosis with radionuclides, and includes restricting contact with other persons where applicable.

Research

- evidence of the information provided to service users participating in research involving medical exposures, including the risks involved, which may include review of informed consent
- documentation showing that this information was provided before the exposure

- in relation to medical or biomedical research, records of experimental procedures show that individual target doses had been set out prior to the exposure and evidence that there target doses had been met.

Through communication

Inspectors may communicate:

- with the undertaking and or staff in the facility to establish how they are assured that all doses are kept as low as reasonably achievable
- with practitioners and persons carrying out the practical aspects of medical radiological procedures to assess their awareness of and adherence to the written protocols with respect to optimisation
- with the undertaking and or staff in the facility about the strategy in place to ensure clinical audits are completed
- with individuals carrying out the practical aspects of exposure to ensure they can articulate how they optimise individual exposures using the equipment available and are aware of the local policies and procedures that apply
- with patients undergoing treatment or diagnosis with radionuclides to validate that they have been provided with information relating to contact with other persons (as appropriate) before leaving the facility
- with individuals who have had an exposure as part of a medical or biomedical research project or experimental procedure to determine if information was provided to them on the risks and benefits of the procedure prior to the procedure taking place.

Through observation

Inspectors may observe:

- systems to assist with optimisation, including the use of diagnostic reference levels and referral guidelines
- that local policies and procedures for optimisation of dose are practically implemented
- dose verification practices in radiotherapy to ensure:
  - doses to non-target volumes are as low as possible
  - verification practices are consistent with the intended purpose of the exposure

— complex treatment procedures have adequate verification.

Compliance indicators for Regulation 9

Indicators for a judgment of compliant include:

- the undertaking considers dose optimisation when selecting equipment
- the quality assurance programme ensures consistency of diagnostic information or therapeutic outcomes
- evidence of consistent practices in the practical aspects of medical exposures
- adequate quality assurance to ensure consistency of activities and dose
- guidance for carers and comforters and there is evidence that it is provided to such individuals prior to exposure
- patients undergoing treatment or diagnosis with radionuclides are provided with information on risks and restricting contact with other persons
- in radiotherapy:
  - — suitable dose verification systems are in place, including quality assurance and multidisciplinary review
  - — dose verification is in place, where applicable, for complex treatment delivery
  - — appropriate imaging verification is in place.

Indicators for a judgment of substantially compliant include:

- there is insufficient quality assurance to ensure consistency of diagnostic information or therapeutic outcomes
- there are some inconsistent practices in the practical aspects of medical exposures
- there is insufficient quality assurance to ensure consistency of activities and dose
- there is guidance for carers and comforters and but there is no evidence that this is provided to such individuals prior to exposure or that this information is provided after the exposure
- there is insufficient information provided to service users undergoing treatment or diagnosis with radionuclides on risks and restricting contact with other persons

- in radiotherapy, the following are not fully in place, and or not consistently in place:
  - — suitable dose verification systems, including quality assurance and multidisciplinary review
  - — dose verification, where applicable, for complex treatment delivery
  - — appropriate imaging verification.

Indicators for a judgment of not compliant include:

- the undertaking has not considered dose optimisation when selecting equipment
- there is inadequate quality assurance to ensure consistency of diagnostic information or therapeutic outcomes
- there is a lack of consistent practices in the practical aspects of medical exposures
- there is inadequate quality assurance to ensure consistency of activities and dose
- there is no evidence of guidance for carers and comforters on risks of exposure
- there is no evidence that patients undergoing treatment or diagnosis with radionuclides have been provided with information on risks and the need to restrict contact with other persons
- in radiotherapy, the following are not in place:
  - — suitable dose verification systems, including quality assurance and multidisciplinary review
  - — dose verification, where applicable, for complex treatment delivery
  - — appropriate imaging verification.

Guide for risk rating for Regulation 9

Compliant	Substantially compliant	Not compliant	
			

Regulation 11. Diagnostic reference levels

What this regulation means for the service user

Diagnostic reference levels are a benchmark for typical dose levels of medical exposures to ionising radiation. They allow the comparison of service user doses, for a particular procedure, between similar equipment within a facility, and across medical facilities and organisations. Diagnostic reference levels are not expected to be exceeded when good and normal practice is applied.

The use of diagnostic reference levels are a key part of the optimisation system in a facility. They are a useful tool in optimising images and support the delivery of doses to service users which are as low as reasonably achievable. The use of diagnostic reference levels can help to identify issues with equipment or practice by highlighting exceptional doses of radiation.

In the use of radiopharmaceuticals in nuclear medicine procedures, diagnostic reference levels refer to levels of administered radioactivity.

Regulation 11 outlines both HIQA's responsibilities and the responsibilities of the undertaking in establishing diagnostic reference levels at national and local facility level respectively. This regulation states that HIQA, as the competent authority, is responsible for establishing national diagnostic reference levels for radiodiagnostic examinations and interventional radiological procedures, where appropriate.

The regulation places responsibility on the undertaking to establish local facility diagnostic reference levels, and to regularly review and apply them in daily practice. Therefore, the undertaking has a clear process for determining and reviewing the doses delivered to service users. Through the system of regular review, doses which consistently exceed relevant local and national diagnostic reference levels are identified and addressed.

Staff education and awareness on the use of diagnostic reference levels is essential for good radiation protection of service users. Staff in a facility have good access to local and national diagnostic reference levels where procedures are carried out, and diagnostic reference level guidance is available to relevant staff at the point of care.

Examples of information and evidence for Regulation 11

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review documents such as:

- policies, procedures, protocols or guidance on establishing and reviewing diagnostic reference levels for medical exposures
- evidence that diagnostic reference levels for medical exposures are used in practice
- evidence that regular reviews of diagnostic reference levels for medical exposures are completed
- records of reviews and corrective actions carried out where typical doses or activities consistently exceed the relevant diagnostic reference level
- evidence that corrective actions are completed without delay when typical doses are found to exceed a local or national diagnostic reference level
- evidence that records of reviews and corrective actions mentioned above are available
- guidance published by HIQA and in use in the facility to determine if it is the most recent version available.

Through communication

Inspectors may communicate with the undertaking and or staff in the facility to determine:

- how diagnostic reference levels for medical exposures are established, regularly reviewed and used
- that regular reviews of medical exposure doses are completed to ensure that they are in line with local and national diagnostic reference levels
- if appropriate reviews and corrective actions are carried out where typical doses or activities consistently exceed the relevant diagnostic reference level
- how appropriate corrective actions are taken where typical medical exposures completed in the facility exceed local and national diagnostic reference levels
- if a record of reviews and corrective actions carried out are retained for a period of five years from the date of review
- if they are aware of the guidance published by HIQA.

Through observation

Inspectors may observe:

- that diagnostic reference levels for medical exposures are established, regularly reviewed and used locally.

Compliance indicators for Regulation 11

Indicators for a judgment of compliant include:

- diagnostic reference levels for medical exposures are established, regularly reviewed and used, having regard to the national diagnostic reference levels established where available
- appropriate reviews are carried out where typical doses or activities consistently exceed the relevant diagnostic reference level, and the undertaking ensures that appropriate corrective actions are completed without delay
- records of appropriate reviews and corrective actions, carried out where typical doses or activities consistently exceed the relevant diagnostic reference level, are retained for a period of five years from the date of the reviews
- the guidance published by HIQA is available to the practitioner, the medical physics expert, and those entitled to carry out practical aspects of medical radiological procedures as specified by the undertaking or practitioner under Regulation 10(4)
- staff in the facility are aware of the guidance published by HIQA.

Indicators for a judgment of substantially compliant include:

- some gaps are identified in the documentation relating to the use of diagnostic reference levels.

Indicators for a judgment of not compliant include:

- diagnostic reference levels for medical exposures are neither established, regularly reviewed nor used
- appropriate reviews are not carried out to determine whether the optimisation of medical exposures for service users is adequate

- where for a given medical exposure typical doses or activities consistently exceed the relevant diagnostic reference level and appropriate corrective action is not taken
- records of appropriate reviews and corrective actions, carried out where typical doses or activities consistently exceed the relevant diagnostic reference level, are not retained for a period of five years from the date of the review
- the guidance published by HIQA is not available to the practitioner, the medical physics expert, and those entitled to carry out practical aspects of medical radiological procedures as specified by the undertaking or practitioner under Regulation 10(4)
- staff are not aware of the guidance published by HIQA.

Guide for risk rating for Regulation 11

Compliant	Substantially compliant	Not compliant	
			

Regulation 12. Dose constraints for medical exposures

What this regulation means for the service user

A dose constraint is not viewed as a dose limit, but rather as an upper threshold above which a dose should not exceed when best practice is applied. Dose constraints are a tool for prospective optimisation of the dose to carers and comforters, and to individuals participating in medical or biomedical research.

A carer and comforter is a person who receives an exposure of ionising radiation, other than through their work, when supporting and comforting a service user having a medical exposure. For example, they may be a parent supporting a child having an X-ray at a dentist practice.

In order to provide adequate radiation protection to this cohort of people, the undertaking identifies the procedures or scenarios which may result in a dose to carers and comforters, and have developed a policy for the optimisation of any potential radiation dose in line with Regulation 9(5). Policies, procedures and guidelines also reflect guidance issued by HIQA. The potential dose to a carer or comforter is also considered during the justification process of the medical exposure. Information in relation to the benefits and risk is available to carers and comforters in line with Regulation 8 (14).

The undertaking and or staff in the facility are aware of their responsibilities to report a dose to a comforter or carer that exceeds certain parameters and to HIQA as a significant event under Regulation 17.

In the case of individuals exposed to ionising radiation as part of medical or biomedical research, the undertaking has arrangements in place to ensure that the dose constraints as specified, or as approved by an ethics committee on a case-by-case basis, are met. The undertaking is able to provide assurances that the ethics committees specifying or approving dose constraints are recognised in line with the requirements of the regulations.

Note: Under previous legislation, dose constraints in relation to comforters and carers were established by the Irish Medical Council and the Irish Dental Council. Updated dose constraints have been established and published by HIQA and are available on www.hiqa.ie.

Examples of information and evidence for Regulation 12

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- policies, procedures and guidelines on the use of dose constraints in the optimisation of protection and safety of carers and comforters, and individuals participating in medical or biomedical research
- record of the approval by an ethics committee of dose constraints as part of a proposal for medical or biomedical research
- significant event notification forms relating to incidence of dose constraints to carers and comforters being exceeded
- results of clinical audits assessing the application of dose constraints
- records of persons acting as carers or comforters, or people who are subject to medical exposure as part of medical or biomedical research.

Through communication

Inspectors may communicate:

- with the undertaking and or staff in the facility to establish if there is an awareness of the use of dose constraints, as established by HIQA, for the medical exposure of carers and comforters, and individuals participating in medical or biomedical research involving medical exposure
- with practitioners and persons conducting the medical exposure to determine their awareness regarding the use of dose constraints in the optimisation of protection and safety of carers and comforters, and individuals participating in medical or biomedical research involving medical exposure.

Compliance indicators for Regulation 12

Indicators for a judgment of compliant include:

- the undertaking ensures the use of relevant dose constraints in the optimisation of protection and safety in any radiological procedure in which an individual acts as a carer or comforter
- the undertaking ensures that relevant dose constraints, as specified or approved by an ethics committee on a case-by-case basis as part of a proposal for medical or biomedical research, are used in the optimisation of protection and safety of people subject to medical exposure as part of such medical or biomedical research.

Indicators for a judgment of substantially compliant include:

- some gaps are identified in the documentation relating to the use of dose constraints.

Indicators for a judgment of not compliant include:

- dose constraints are not used by the undertaking in the optimisation of any radiological procedure in which an individual acts as a carer or comforter
- the undertaking did not ensure that relevant dose constraints, as specified or approved by an ethics committee on a case-by-case basis as part of a proposal for medical or biomedical research, are used in the optimisation of protection and safety of people subject to medical exposure as part of such medical or biomedical research.

Guide for risk rating for Regulation 12

Compliant	Substantially compliant	Not compliant	
			

Regulation 13. Procedures

What this regulation means for the service user

The development and oversight of relevant policies and procedures on matters relating to medical exposures to ionising radiation is a key part of effective governance arrangements and quality control within a facility. Policies and procedures promote the delivery of consistent care, and provide staff with support and guidance to deliver safe and appropriate medical exposures.

The undertaking ensures that there are relevant policies and procedures in place for each type of standard medical radiological procedure that may carried out in the facility. These evidence-based documents help to standardise the quality of medical exposures and the radiation dose received by service users.

Written procedures cover the entire service-user pathway, from the point of referral to the practical aspects of the medical exposure. For example, there is a procedure in place that clearly outlines the referral process and includes the referral guidelines in use in the facility that guide the referrer on the most appropriate examination for the service user. There are also procedures in place for each type of medical exposure carried out by each piece of equipment in the service. Where relevant, these procedures also account for different service-user groups, such as children.

Procedures are considered dynamic documents, and there is a good information governance system in place in the facility, with responsibility assigned to appropriate people to ensure that the procedures are periodically reviewed and updated as required. Procedures are adapted to the service and reflect any changes in the service, such as new technology or equipment and other service developments.

Staff in the facility have easy access to all policies and procedures, in particular at the point of care. There is clear evidence that staff understand and use the policies and procedures to deliver a safe and quality service.

In line with the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* (hereafter referred to as 'national procedures') published by HIQA, the undertaking ensures that there is a clinical audit strategy for medical radiological procedures performed in the facility. The undertaking and relevant staff in the facility are familiar with the national procedures, and understand the purpose of the clinical audit strategy and their roles and responsibilities associated with the strategy. A key part of the facility's clinical audit strategy is that audit results and learning are used to improve the delivery and

quality of medical exposures of ionising radiation in the service. The effectiveness of the implementation of written policies and procedures is continually evaluated and monitored through periodic audit. This evaluation provides assurance to the undertaking that all medical exposures carried out are in line with relevant legislation and evidence-based best practices.

Examples of information and evidence for Regulation 13

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- written protocols established for each type of standard medical exposure, for each piece of equipment and for relevant categories of service users, such as:
  - the reason a particular medical exposure may be carried out
  - instructions for correct operation of the particular type of equipment
  - optimal technical and physical parameters for the particular procedure
  - consideration of the characteristics of the category of service user and any adaption of technique that may be required to optimise the exposure (for example, age, gender, body composition)
  - any relevant supporting aspects and ancillary equipment needed
  - recording of the radiation dose, including consideration of national and local diagnostic reference levels where relevant
- a sample of reports for medical procedures to review dose information
- referral guidelines for medical radiological procedures to ensure they:
  - are evidence-based
  - are reviewed periodically
  - consider radiation doses
  - provided in an easily retrievable format which must be available at the point of referral
- in dental practice referral criteria or selection criteria, may include best practice evidence-based guidelines approved by an appropriate body recommending the most appropriate imaging for a given clinical condition
- local policies, procedures and guidelines for carrying out clinical audits which are in line with national procedures
- results and reports of clinical audits relevant to medical exposures.

Through communication

Inspectors may communicate with the undertaking and or staff in the facility:

- to establish if written protocols are established for every type of standard medical exposure, for each type of equipment, and for relevant categories of service users
- regarding the availability of referral guidelines for medical imaging
- to assess how service user exposure to ionising radiation forms part of the report of the medical radiological procedure
- to establish the systems in place to complete clinical audits
- regarding the procedures used to carry out clinical audits.

Through observation

Inspectors will observe:

- if written protocols are available at point of care
- if information relating to medical exposures is contained in the report
- if referral guidelines are available to referrers
- if clinical audit results and learning are available to staff.

Compliance indicators for Regulation 13

Indicators for a judgment of compliant include:

- written protocols established for every type of standard medical radiological procedure, for each type of equipment, and for relevant categories of service users
- information relating to service user exposure to ionising radiation forming part of the report of the medical radiological procedure
- referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers
- there is documented evidence that clinical audit is prioritised, promoted and resourced within the service

- clinical audits are carried out in accordance with national procedures established by HIQA
- national procedures on clinical audit are available to all staff involved in medical radiological procedures.

Indicators for a judgment of substantially compliant include:

- gaps in relation to the written protocols on standard procedures in the facility are identified
- gaps in documentation relating to the clinical audit strategy are identified
- gaps in the implementation of clinical audit are identified.

Indicators for a judgment of not compliant include:

- written protocols have not been established for every type of standard medical radiological procedure, for each type of equipment, or for relevant categories of service users
- information relating to service user exposure to ionising radiation does not form part of the report of the medical radiological procedure
- referral guidelines for medical imaging, taking into account the radiation doses, are not available to referrers
- clinical audits are not carried out in line with established national procedures.

Guide for risk rating for Regulation 13

Compliant	Substantially compliant	Not compliant	
			

Regulation 14. Equipment

What this regulation means for the service user

The undertaking has arrangements in place to ensure that medical radiological equipment, in clinical use, is operationally safe and fit for purpose. An appropriate quality assurance programme is implemented and maintained to ensure that equipment is meeting the necessary requirements and standards to deliver a controlled and optimal dose of ionising radiation. Such a programme ensures that delivery of medical exposures and their outcomes is monitored and evaluated as safe for service users.

Quality assurance programmes are part of the overall quality assurance system within a facility. The size of the facility often determines the structure of this system. For example, in larger facilities, technical committees may be formed to ensure adequate oversight of the programme, while in a sole trader situation, such as a dentist, they may work closely with a medical physics expert, at appropriate intervals, on a quality assurance programme. All arrangements must ensure good oversight of the programme and radiation protection for service users.

The undertaking has developed and implemented guidance documents on the quality assurance programme. These documents outline the quality assurance process, test tolerances and action levels, and provide guidance on how to manage unexpected test results. They also define the resources allocated to carrying out the programme. These documents provide assurance to the undertaking that the structures, systems and procedures involved in carrying out medical exposures will perform satisfactorily for the benefit of service users. Additionally, an appropriate quality programme for the assessment of dose or verification of administered activity is implemented and maintained.

Quality assurance programmes incorporate an agreed quality control plan to assess and monitor equipment. The quality assurance programme is a continual process that involves collecting data to determine if medical radiological equipment is meeting criteria of acceptability.

The undertaking is aware of the legislative requirements for medical radiological equipment installed after 6 February 2018. This includes ensuring that all equipment used for interventional radiology, including interventional cardiology and CT (including cone-beam CT), has a device for assessing the service-user dose.

Examples of information and evidence for Regulation 14

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- the inventory of medical radiological equipment for each facility which should include:
  - location of equipment
  - manufacturer
  - model
  - serial number
  - installation date
  - nominal replacement date
  - record of decision to use beyond nominal replacement date (if applicable)
- all records relating to all medical radiological equipment, including equipment maintenance, quality control testing, faults and errors logs, records of any corrective actions
- records relating to the maintenance of an appropriate quality assurance programme, and an appropriate programme of assessment of dose or verification of administered activity
- policies, procedures and guidelines relating to medical radiological equipment.

Through communication

Inspectors may communicate with the undertaking and or staff in the facility regarding:

- the arrangements in place to ensure that all medical radiological equipment in use is kept under strict surveillance (including at a minimum, regular quality assurance and maintenance) in relation to radiation protection of service users
- how appropriate quality assurance programmes and appropriate programmes of assessment of dose or verification of administered activity are implemented and maintained

- how acceptance testing before the first use of the equipment for clinical purposes, regular performance testing and testing after any maintenance procedure liable to affect the equipment's performance is carried out
- the systems in place to ensure that a person does not use:
  - medical radiological equipment for clinical purposes before acceptance testing is carried out
  - fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device
- the arrangements in place to take the necessary measures, as directed by HIQA, to improve inadequate or defective performance of any medical radiological equipment in use
- assurances that the acceptability of equipment criteria, as adopted and published by HIQA, is complied with
- measures in place to ensure compliance of medical radiological equipment with the regulations on the availability of information on the quantity of radiation produced, and on the relevant parameters for assessing service-user dose at the end of a procedure.

Through observation

Inspectors may observe:

- fluoroscopy equipment in use to ensure that such equipment has a device to automatically control the dose rate and an image intensifier or equivalent device.

Compliance indicators for Regulation 14

Indicators for a judgment of compliant include:

- there is evidence of the arrangements in place to ensure that all medical radiological equipment in use is kept under strict surveillance (including at a minimum, regular quality assurance and maintenance) in relation to radiation protection of service users
- appropriate quality assurance programmes have been implemented and maintained by the undertaking

- there is evidence that appropriate programmes of assessment of dose or verification of administered activity have been implemented and maintained by the undertaking
- acceptance testing is carried out before the first use of medical radiological equipment for clinical purposes
- the undertaking has implemented processes to ensure performance testing is carried out on medical radiological equipment on a regular basis
- performance testing is carried out when any maintenance takes place which is liable to affect the performance of medical radiological equipment
- the undertaking has taken action to improve inadequate or defective performance of medical radiological equipment in use, if directed by HIQA, and, can provide evidence of compliance
- an undertaking complies with the specific criteria for acceptability of equipment adopted by HIQA
- medical radiological equipment used for interventional radiology and CT has a device or feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the service-user dose
- medical radiological equipment installed after 6 February 2018 meets the requirements of Regulation 14(8)
- the undertaking has an up-to-date inventory of medical radiological equipment for each facility
- the undertaking provides HIQA, on request, with an inventory of medical radiological equipment for each facility
- the undertaking has retained records in relation to medical radiological equipment for a period of five years from their creation.

Indicators for a judgment of substantially compliant include:

- while it is evident that medical exposures to ionising radiation are delivered to a high standard, gaps are identified in the documentation
- the undertaking has not ensured that all medical radiological equipment in use is consistently kept under strict surveillance, as appropriate (including at a minimum, regular quality assurance and maintenance) in relation to radiation protection of service users

Indicators for a judgment of not compliant include:

- the undertaking has not ensured that all medical radiological equipment in use is kept under strict surveillance, as appropriate (including at a minimum, regular quality assurance and maintenance) in relation to radiation protection of service users
- there is evidence that a person used medical radiological equipment for clinical purposes where acceptance testing before clinical use had not been carried out
- the undertaking does not comply with the specific criteria for acceptability of equipment adopted by HIQA
- a person uses fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device
- medical radiological equipment does not meet the requirements as required under Regulation 14(8).

Guide for risk rating for Regulation 14

Compliant	Substantially compliant	Not compliant	
			

Regulation 15. Special practices

What this regulation means for the service user

This regulation recognises that certain groups of service users require special radiation protection to ensure they are appropriately protected when exposed to ionising radiation.

In particular, children have a greater radio-sensitivity than adults, and subsequently particular consideration to radiation protection is given to them when undergoing a medical exposure. Additionally, the undertaking gives special attention to radiation protection for asymptomatic persons, exposed during a health screening process and to service users exposed to high doses of radiation; for example, during interventional radiology, nuclear medicine, CT or radiotherapy.

When carrying out the practical aspects of medical exposures to service users in these groups, staff have appropriate education, training and competence to ensure that appropriate practical techniques are used.

Similarly, the undertaking has an appropriate quality assurance in place to evaluate the medical radiological equipment used for these special practices in order to ensure that it is appropriate and fit for purpose. These programmes also facilitate the identification, evaluation and management of actual and potential exposure risks to these groups of service users. This includes the assessment of dose or verification of administered activity, and also incorporates systems to alert staff if doses delivered to service users exceed the threshold for tissue reactions.

The undertaking has developed and implemented policies, procedures and guidelines that reflect local practice, and are evidence-based to reflect recommendations and guidance from national regulatory bodies. The undertaking should periodically review any medical exposures delivered to these groups of service users and assess if these are appropriate.

Examples of information and evidence for Regulation 15

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- clinical audits
- specific optimisation in written protocols for special practices

- evidence of the allocation of responsibility for the radiation protection of the following service users undergoing medical exposure:
  - children
  - those partaking in a health screening process
  - those receiving high doses, as may be the case in interventional radiology, nuclear medicine, CT or radiotherapy
- medical exposure records, documentation and reports
- documentation, results and associated data relevant to quality assurance programmes and assessment of dose or verification of administered activity for special practices
- records relating to medical radiological equipment
- training and education records for individuals carrying out the practical aspects of the medical exposure.

Through communication

Inspectors may communicate with the undertaking and or staff in the facility:

- regarding the quality assurance programmes and the assessment of dose or verification of administered activity for special practices
- to inquire as to how they ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment are used.

Inspectors may communicate with practitioners and those involved in the practical aspects of medical exposures to:

- determine if appropriate medical radiological equipment, practical techniques and ancillary equipment are used.

Through observation

Inspectors may observe:

- practitioners and those involved in the practical aspects of medical radiological procedures to determine if appropriate medical radiological equipment, practical techniques and ancillary equipment are used for medical exposure in the case of special practices.

Compliance indicators for Regulation 15

Indicators for a judgment of compliant include:

- the undertaking can provide evidence that for the following service users undergoing medical exposure:
  - — children
  - — those partaking in a health screening process
  - — those receiving high doses, as may be the case in interventional radiology, nuclear medicine, CT or radiotherapy

  the following measures are in place:
  - — appropriate medical radiological equipment
  - — appropriate practical techniques are in use
  - — appropriate ancillary equipment is in use
  - — evidence that special attention is given to quality assurance programmes and the assessment of dose or verification of administered activity for special practices.

Indicators for a judgment of substantially compliant include:

- while it is evident that medical exposures to ionising radiation are delivered safely, gaps are identified in the documentation.

Indicators for a judgment of not compliant include:

- the undertaking is unable to provide evidence that the following measures are in place:
  - — appropriate medical radiological equipment
  - — appropriate practical techniques are in use
  - — appropriate ancillary equipment is in use
  - — evidence that special attention is given to quality assurance programmes and the assessment of dose or verification of administered activity for special practices.

  for the following service users undergoing medical exposure:
  - — children

— those partaking in a health screening process

— those receiving high doses, as may be the case in interventional radiology, nuclear medicine, CT or radiotherapy

- special attention is not given to quality assurance programmes and the assessment of dose or verification of administered activity for special practices.

Guide for risk rating for Regulation 15

Compliant	Substantially compliant	Not compliant	
			

Regulation 16. Special protection during pregnancy and breastfeeding

What this regulation means for the service user

There are arrangements established, maintained and promoted by the undertaking for the special protection of pregnant women or breastfeeding women. Children, including the unborn child, have an increased radio-sensitivity, and, therefore, special consideration should be given to minimising the exposure of this group to ionising radiation.

The undertaking develops and implements policies, procedures and guidelines that guide referrers and practitioners on how to best achieve radiation protection for this group of service users. These documents are based on national and best practice guidelines. Adherence to these policies and procedures is monitored and assessed.

The undertaking promotes a culture of radiation protection by proactively identifying and addressing risks associated with medical exposures, pregnancy and breastfeeding. Practitioners and referrers are trained and facilitated to identify and raise concerns for the radiation protection of service users during pregnancy or when breastfeeding.

Awareness of the risks of medical exposures and the special protection required during pregnancy and breastfeeding are supported by clear leadership, good accountability arrangements and good communication. The undertaking implements education and awareness programmes on additional radiation protection required during pregnancy and breastfeeding. For example, at induction, relevant staff are made aware of their responsibility to inquire about the pregnancy status of service users, where relevant, and the requirement to record in writing the answers to such enquiries.

The undertaking takes appropriate measures to increase the awareness of service users, who may be pregnant or breastfeeding, of the need for special protection during medical exposures when pregnant and breastfeeding. They provide information leaflets and display public notices in appropriate places, such as in a waiting room, and implement other appropriate measures to increase awareness among service users.

The undertaking is aware of the legislative requirement to report a significant event to HIQA any inadvertent irradiation greater than 1milliGray (mGy) of a foetus or 1 millisievert (mSv) to a child who is being breast-fed.

Examples of information and evidence for Regulation 16

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- policies, procedures, protocols and guidelines in relation to determining pregnancy status
- records of answers to inquiries as to pregnancy or breastfeeding status of individuals subject to a medical exposure
- evidence of special attention to justification and urgency in cases where pregnancy or breastfeeding cannot be ruled out
- clinical audits
- service-user questionnaires, comments, complaints or other communications
- records of incidents involving inadvertent exposure of a foetus to ionising radiation
- records, reports and any other matters of relevance to the medical exposure of service users.

Through communication

Inspectors may communicate with the undertaking, service users and or staff in the facility, in particular referrers and practitioners:

- to learn about practices and procedures in place to establish whether or not an individual subject to a medical exposure is pregnant or breastfeeding and to record the answer in writing
- on the arrangements in place for identifying the pregnancy and or breastfeeding status of service users as relevant
- as to how they ensure that the referrer or a practitioner establishes whether or not a service user undergoing a medical exposure is pregnant or breastfeeding
- on the policies and processes in place that guide referrers or a practitioner on the need for them to establish if a service user undergoing a medical exposure is pregnant or breastfeeding
- to find out if the measures taken by the undertaking are sufficient to increase the awareness of individuals who may be pregnant and or breastfeeding of

the need for special protection during pregnancy and or breastfeeding as outlined in Regulation 16

- to find out whether enquiries were made, where relevant, as to whether an individual subject to a medical exposure was pregnant or breastfeeding.

Through observation

Inspectors may observe:

- adherence by practitioners and referrers to policies, procedures and guidelines as they relate to pregnancy or breastfeeding status of individuals subject to medical exposure
- signs and notices publicly displayed to increase the awareness of the need for special protection for individuals who may be pregnant or breastfeeding and who are subject to a medical exposure.

Compliance indicators for Regulation 16

Indicators for a judgment of compliance include:

The undertaking:

- ensuring that the referrer or a practitioner inquires as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned
- ensuring that the referrer or a practitioner records in writing the answer to any enquiry as to whether an individual subject to the medical exposure is pregnant or breastfeeding
- retaining for five years the written records of the answer to any enquiry as to whether an individual subject to the medical exposure is pregnant or breastfeeding
- providing the written records of the answer to any enquiry as to whether an individual subject to the medical exposure is pregnant or breastfeeding to HIQA as required
- providing evidence that special attention is given to the justification, particularly the urgency, and to the optimisation taking into account both the expectant individual and the (unborn) child, where pregnancy or

breastfeeding cannot be ruled out for an individual subject to medical exposure

- taking measures to increase the awareness of individuals who may be pregnant or breastfeeding of the need for special protection during pregnancy and breastfeeding as outlined in Regulation 16.

Indicators for a judgment of substantially compliant include:

- while it is evident that medical exposures to ionising radiation are delivered safely, gaps are identified in the documentation relating to special protection during pregnancy and breastfeeding, breastfed children, or in the case where a service user is an expectant mother, an unborn child.

Indicators for a judgment of not compliant include:

- The undertaking
  - — did not have arrangements in place to ensure that the referrer or a practitioner inquires as to whether an individual subject to a medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned
  - — did not have appropriate mechanisms and procedures in place to ensure that the referrer or a practitioner records in writing the answer to any enquiry as to whether an individual subject to the medical exposure is pregnant or breastfeeding
  - — cannot provide evidence that written records of the answer to any enquiry as to whether an individual subject to a medical exposure is pregnant or breastfeeding are being retained for five years
  - — is unable to provide the written records to HIQA as required of the answer to any enquiry as to whether an individual subject to the medical exposure is pregnant or breastfeeding
  - — cannot provide evidence that special attention is given to the justification, in particular the urgency, and to the optimisation taking into account both the expectant individual and an unborn child, where pregnancy or breastfeeding cannot be ruled out for an individual subject to medical exposure
  - — has not taken measures, or has taken insufficient measures, to increase the awareness of individuals who may be pregnant or breastfeeding of the

need for special protection during pregnancy and breastfeeding as outlined in Regulation 16.

Guide for risk rating for Regulation 16

Compliant	Substantially compliant	Not compliant	
			

Regulation 17. Accidental and unintended exposures and significant events

What this regulation means for the service user

The undertaking implements and maintains arrangements that identify, record and manage incidents involving or potentially involving accidental and unintended exposures to ionising radiation. There is a structured incident reporting mechanism in place to facilitate this. Such events are identified, reported, managed and responded to in a timely manner and in line with national legislation, policy, guidelines and guidance. Local incident management arrangements are clearly communicated by the undertaking, the undertaking's representative, or delegated staff, to all individuals involved in the medical exposure of service users.

Service users are assured that systems are in place to minimise the possibility of accidental and unintended exposures. However, when such an exposure occurs and is deemed clinically significant, the patient or their representative are informed. Learning from accidental and potential incidents is used to improve the quality and safety of the service, and prevent future such incidents occurring.

Effective information governance ensures compliance with notification requirements to HIQA, in that notifiable incidents are submitted to HIQA in the required format, within the specified time frame and that all information is submitted.

The undertaking develops and supports a culture of openness, transparency and accountability to encourage effective learning from incidents. The learning from the evaluation of an incident, and or potential incident, is communicated promptly to all relevant staff. There are appropriate governance structures in place to ensure that identified improvements are implemented and used to develop best practice.

Note: At regular intervals, HIQA publishes a written report on the findings, learning and actions implemented from notifiable incidents. This facilitates shared learning among staff in facilities providing medical radiological services.

Examples of information and evidence for Regulation 17

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- notifications of significant events submitted to HIQA
- the results of the investigation into any significant event notified to HIQA and the corrective measures implemented to prevent such incidents reoccurring
- records of actual and potential incidents, including:
  - — the analysis of such data
  - — confirmation of submission to HIQA where the event exceeds significance thresholds defined by HIQA
- quality assurance programmes for radiotherapeutic practices studying the risk of accidental or unintended exposures
- policies, procedures, protocols and guidelines
- clinical audits
- evidence that staff have received training and education in local incident management systems and procedures.

Through communication

Inspectors may communicate:

- with the undertaking and or staff in the facility involved in medical exposures to ensure that systems to minimise the probability and magnitude of accidental and unintended exposures of individuals are implemented and maintained.

Inspectors may communicate with the undertaking and or staff in the facility:

- to establish the governance, reporting and accountability structures within the undertaking to ensure that a quality assurance programme includes a study of the risk of accidental or unintended exposure from radiotherapeutic practices
- to discuss the systems in place for record-keeping and analysis of events involving or potentially involving accidental and unintended medical exposures and to minimise the probability and magnitude of accidental and unintended exposures

- regarding arrangements to inform the referrer, practitioner and the patient or their representative about clinically significant accidental and unintended exposures and the results of the analysis
- to establish what measures are in place to ensure that HIQA is notified within three working days of the discovery of any significant event
- regarding the procedures and processes in place to ensure that the results of an investigation into any significant event notified to HIQA, and the corrective measures taken to avoid such events, are reported to HIQA within 120 calendar days as specified HIQA.

Compliance indicators for Regulation 17

Indicators for a judgment of compliant include:

- The undertaking has ensured that:
  - all reasonable measures are taken to minimise the probability and magnitude of accidental and unintended exposures
  - for radiotherapeutic practices, quality assurance programmes include a study of the risk of accidental and unintended exposures
  - an appropriate system of record-keeping and analysis of events involving or potentially involving accidental of unintended medical exposures has been implemented and maintained
  - arrangements are in place to inform the referrer, practitioner, patient or the patient's representative about clinically significant unintended or accidental exposures and the results of the analysis
  - HIQA has been notified within three working days from the discovery of the significant event using the appropriate form
  - the results of an investigation into any significant event and corrective measures taken to avoid such events recurring are reported within 120 calendar days from the receipt of the notification by HIQA.

Indicators for a judgment of substantially compliant include:

- while it is evident that radiation protection is of a high standard, gaps were identified in the documentation; however, they did not result in a medium or high risk to service users.

Indicators for a judgment of not compliant include:

- The undertaking:
  - — has not taken all reasonable measures to minimise the probability and magnitude of accidental and unintended exposures
  - — has not ensured that for radiotherapeutic practices, quality assurance programmes include a study of the risk of accidental and unintended exposures
  - — did not have an appropriate system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures
  - — did not have arrangements in place to inform the referrer, practitioner, patient or the patient's representative about clinically significant unintended or accidental exposures and the results of the analysis
  - — has not notified HIQA promptly and as soon as possible of the significant event
  - — has not reported to HIQA the results of an investigation, into any significant event and the corrective measures taken to avoid such events recurring, within 120 calendar days from the receipt of the notification by HIQA.

Guide for risk rating for Regulation 17

Compliant	Substantially compliant	Not compliant	
			

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Revision history

Version	Publication date/revision date	Summary of changes
Version 1	June 2019	First published
Version 1.1	September 2019	This guidance was revised to reflect the amendments to S.I 256 of 2018.
Version 1.2	November 2023	This guidance was updated to revise wording and judgment descriptors and to include additional information about Regulations 7, 8(4), 8(5), 8(9) and 13(4), in line with amendments to S.I 256 of 2018. The front and back cover pages were also updated.

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