Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation of Health and Social Care Services

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

June 2019

Safer Better Care

About the Health Information and Quality Authority

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

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

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Office of 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 (referred to in this document as the 'regulations') provides 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. Compliance will be assessed through monitoring and inspection, while escalation and enforcement action may be taken if non-compliances are recurrent or pose a significant risk to service users.

The regulations set the minimum standards for the protection of service users when being exposed to ionising radiation which must be met by each undertaking carrying out such practices. However, an undertaking 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 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 his or her pathway of diagnosis or treatment involving ionising radiation.

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[*] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

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

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 medical radiological installations
- contribution to the improvement of the service being inspected through application of the inspection process.

1.2 Scope

This guidance relates to undertakings to which the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (Statutory Instrument No. 256 of 2018) apply.

The assessment of an undertaking's compliance with the regulations listed below has not been included in phase one of HIQA's inspection programme. These are:

- Regulation 7
- Regulation 8(4)
- Regulation 8(5)
- Regulation 8(9).

Further guidance in relation to the requirements for justification for these regulations will be published in due course. This document will be updated when the guidance has been published.

[‡] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. 256 of 2018 for the purpose of ensuring compliance with the regulations.

1.3 Purpose

This guidance should be used in conjunction with the assessment-judgment framework — one of the tools HIQA uses to assess compliance with the regulations. The assessment-judgement 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 in assessing compliance with the regulations. The framework should also be used by undertakings to self-assess their own service.

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. Assessment of compliance will be determined against the regulations. 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 how to assess compliance and what will be reviewed during inspection planning, what information and evidence will be gathered prior to an inspection and on- site, and how judgments about compliance will be made.

Furthermore, this guidance facilitates a consistent approach to monitoring compliance with the regulations by:

- supporting HIQA inspectors in developing a clear understanding of the regulations
- providing direction to undertakings on the type of findings that could demonstrate evidence of compliance, substantial compliance and non-compliance.

This guidance should also be used by undertakings in assessing their own service to ensure that they comply with the regulations.

Note: Further guidance advising undertakings on what is to be expected before, during and after a typical inspection will be published in a separate document.

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 medical radiological installation.[§]

In order to make judgments about compliance, HIQA may:

- communicate with the service users who attend for medical exposures to find out their experience of the service
- talk with staff and management to find out how they plan and deliver care and services — conversations with management and staff 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.

[§] Medical radiological installation means a facility where medical radiological procedures are performed.

2.2 When are inspections carried out?

All inspections and monitoring activity inform the undertaking's compliance with the regulations. From a regulatory perspective, there is a requirement for HIQA to establish a system or systems of inspection and to initiate surveillance and corrective action where necessary.

In line with the regulations, the inspection programme should consider the scale and nature of the potential hazard associated with practices. For example, a regulatory programme will take into account the accepted varying levels of associated risk from radiation between a dental clinic and 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, for example, 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

Once inspectors have gathered 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 will judge whether the undertaking has been found to be **compliant, substantially compliant** or **not compliant.**

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 finding 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 patients using the service — 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 patients using the service, it is risk-rated orange (moderate risk) and the undertaking must take action within a reasonable time frame to come into compliance.

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

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

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 will only be judged on the regulations or sub-regulations for which it has responsibility for.

2.4 Reporting the findings

The inspector will give feedback to the undertaking, undertaking representative and or designated manager 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
- Safe delivery of medical exposures.

Governance and management arrangements: 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 or 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 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 patient pathway may relate to a number of different regulations. Notwithstanding the association of the related regulations, judgment on the primary regulation is made independently of the other related regulations.

Part 1: What this regulation means for the service user

This section introduces the concept of the regulation and what compliance will mean for the service user. Even where regulations have been complied with, undertakings should seek out ways to continually 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) will support the planning for an inspection, gathering of information before and during inspections and making of judgments about compliance.

The types of information reviewed will be 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 service 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 there 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 have complied 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

Governance and management arrangements 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 arrangements of each installation. It considers how people who work in the installation are recruited, trained and allocated appropriate responsibility for radiation protection relevant to their role, qualifications, knowledge, skill and competencies. Table 1 sets out the relevant regulations.

Table 1. List of regulations under the dimension of governance and management arrangements

Regulation number	Description of regulation
Regulation 4	Referrers
Regulation 5	Practitioners
Regulation 6	Undertaking
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 on information to HIQA

Regulation 4. Referrers

What this regulation means for the service user

This regulation helps assure service users that only recognised healthcare professionals with appropriate knowledge and expertise have the entitlement to refer an individual for a medical exposure.

Only appropriately trained and recognised professionals, as defined in Regulation 4, can refer an individual for a medical exposure. Those carrying out medical exposures must ensure that people have only been referred for radiological procedures by an appropriate individual.

Examples of information and evidence that will be reviewed

Through review of documents pre-inspection or 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 undertaking
- a sample of professional registration records of persons referring an individual 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

Indicators of compliance 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 of non-compliance 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:

Compliant	Non-compliant	
Green	Orange	Red

Regulation 5. Practitioners

What this regulation means for the service user

Compliance with this regulation will help to assure service users that an appropriately trained and recognised healthcare professional takes responsibility for the exposure that they have been referred for.

Only a person who is a registered dentist, a registered medical practitioner, a registered radiographer or registered radiation therapist, as defined in Regulation 5, takes clinical responsibility for individual medical exposures. The health professionals acting as practitioners do so in accordance with the scope of practice of their relevant professional bodies.

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

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- local records that indicate the named practitioner with clinical responsibility for each individual medical exposure
- a sample of professional registration records for practitioners.

Through communication

Inspectors may communicate:

- with the undertaking or their representative to explain the defined structure for practitioners accepting clinical responsibility for an individual medical exposure
- with the undertaking or their representative 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 installation to assess compliance with this regulation.

Compliance indicators:

Indicators of compliance include:

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

Indicators of non-compliance include:

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

Guide to the risk rating:

Compliant	Non-compliant	
Green	Orange	Red

Regulation 6. Undertaking

What this regulation means for the service user

Compliance with this regulation by the undertaking will ensure 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. It is important that an undertaking has the appropriate governance, operational and risk management arrangements in place to meet its responsibilities. The governance and managements arrangements in place will be varied and should be appropriate to the size and complexity of the organisation.

In large organisations, effective governance arrangements ensure coordinated communication across the organisation for the benefit of patient safety. As a result, the optimum care received by service users is delivered by appropriately trained and recognised healthcare professionals who are integrated in their approach to radiation protection.

The undertaking ensures that there is a clear allocation of responsibility for radiation protection in its organisation. The undertaking may outline its internal governance structure through the use of an organogram or documented description of the lines of authority in place, relevant to the size and scale of the service provided. For example, where a dentist provides dental imaging in his or her own practice, the allocation of all radiation protection responsibilities may lie solely with the dentist himself or herself. Nonetheless, the allocation of responsibilities should be documented.

The undertaking ensures that each person working within the service is aware of his or her individual and collective responsibilities. The documentation of internal governance structures may need to be supported by evidence detailing allocations of responsibility, such as local policies and procedures. For example, where there are multiple practitioners, the allocation of responsibilities to an individual or group of practitioners must be clear. In situations where an undertaking accepts responsibility for all medical exposures carried out on patients by its employees or those engaged by it or visiting practitioners under its established governance arrangements, the undertaking shall maintain a list of practitioners and those delegated the practical aspects of the exposures.

Regardless of the size or complexity of the service provided, the undertaking is responsible for ensuring that staff understand local systems and processes and are

supported in carrying out their individual roles through the provision of documented procedures.

Effective governance and management arrangements promote an open culture among staff and service users where feedback is sought to improve practice. Continual improvement relates to a systematic, ongoing effort to raise standards, with a focus on integrated improvements with clearly defined objectives. A culture of learning and supporting staff training and development is essential to the ongoing safe delivery of medical exposures and enhancement of patient care. An example of good practice in larger services would be the implementation of a radiation safety committee, which is integrated with other organisational safe delivery of medical exposures structures, such as clinical audit and risk management committees.

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- that a Declaration of undertaking (NF200) form has been submitted by an undertaking
- local reporting structures or organograms 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 or their representative:

- 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 assurance to them that those employed or engaged by them are compliant with these regulations
- with those employed or engaged by the undertaking to determine how they raise concerns or report non-compliance with these regulations to the undertaking.

Compliance indicators:

Indicators of compliance include:

- an undertaking has submitted a declaration form to HIQA within the time frames prescribed by Regulation 6

- the undertaking has documented a clear allocation of responsibility for service users and provided evidence of same to HIQA
- an undertaking has clear lines of accountability for those engaged or employed by them to ensure compliance with these regulations.

Indicators of substantial compliance include:

- some gaps are identified in the documentation relating to the undertaking but these gaps do not result in a medium or high risk to service users.

Indicators of non-compliance include:

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

Guide to the risk rating:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 10. Responsibilities

What this regulation means for the service user

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. The undertaking should have systems in place to ensure that the responsibilities for medical exposures along the service-user pathway for medical exposure are allocated to appropriate persons as required by this regulation. Where the referrer and practitioner are the same person, as may be the case in a dental practice, this individual should have appropriate measures and processes in place to assure themselves that all the requirements of Regulation 10 are complied with.

The service-user pathway when undergoing a medical exposure involves referral, justification, optimisation, the practical conduct of the exposure and communication of the outcome. The involvement of appropriate persons along this pathway helps to ensure the safety and quality of the service provided and is central to radiation protection practices. For each medical exposure that a service user undergoes, the practitioner taking clinical responsibility for that exposure is clearly identifiable and they are aware of their clinical responsibility relative to that exposure.

Optimisation of doses arising from medical exposures ensures that doses are kept as low as reasonably achievable to maximise radiation protection for service users while accomplishing the objectives of the medical exposure. The process of optimisation for all medical exposures is mainly reliant on the involvement of recognised professionals outlined in this regulation who have the appropriate skills and competence.

An undertaking ensures that for all individual medical exposures, both the practitioner and the referrer are involved in the justification process. The involvement of both the referrer and practitioner in justifying the medical exposure is essential in protecting the service user by ensuring that only a medical exposure that is beneficial is carried out. This means that when a referrer refers an individual for a medical radiological procedure to a practitioner, both the referrer and the practitioner must consider if the procedure is justified.

The responsibilities allocated for justification, optimisation and the conduct of medical exposures should be clearly defined in local policy. The undertaking should ensure that local practices in terms of delegation of responsibilities are in line with regulations and that those involved have prescribed training in radiation safety. Only an appropriately trained person can carry out the practical aspects of a medical

exposure. The undertaking must have a documented delegation of such responsibilities.

Undertakings should monitor the involvement of persons in the justification and optimisation processes to assure themselves of appropriate and sufficient involvement.

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- records relating to medical exposures that have been carried out to identify:
  - the practitioner taking clinical responsibility for the medical exposure
  - involvement of the practitioner and referrer in justification
  - the referrer
  - 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
  - the undertaking's 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 assignment 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 or their representative:

- to establish how they are 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

Indicators of compliance include:

- a practitioner takes clinical responsibility for each medical exposure
- 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 registered or recognised by the Dental Council, the Minister for Health, the Nursing and Midwifery Board of Ireland, the Radiographers Registration Board, or the Medical Council

- the undertaking has records of each delegation of the practical aspects of medical radiological procedures.

Indicators of substantial compliance include:

- there were some gaps evident in the maintenance of documentation to support responsibilities assigned for medical exposures, but these gaps do not result in a medium or high risk to service users.

Indicators of non-compliance include:

- a practitioner does not take clinical responsibility for all medical exposures
- 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 registered or recognised by the Dental Council, the Minister for Health, the Nursing and Midwifery Board of Ireland, the Radiographers Registration Board, or the Medical Council
- 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 conduct the practical aspects of a medical radiological procedure.

Guide to the risk rating:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 18. Estimates of population dose

What this regulation means for the service user

Medical exposures are the largest man-made source of population exposure to ionising radiation. Developments in medical imaging, for example, computed tomography (CT) and interventional radiology, have led to significant increases in the number of relatively high-dose X-ray examinations performed. This has a significant impact on the individual doses of service users and for the collective dose to the population as a whole.

Population doses provide an estimate of the dose received by people living in Ireland. This regulation is concerned with observing trends in the dose received by individuals from medical exposures and how this dose is distributed.

The objectives of reporting on population doses from certain types of medical exposures can 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 the frequencies of different types of medical exposure, the typical radiation doses given 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 patients undergoing specific types of medical exposures, particularly those making a major contribution to the total collective dose.

These objectives provide information to prioritise and focus resources on the radiation protection of patients that receive the highest dose and as a result incur the highest risk from exposure to ionising radiation. HIQA is responsible for ensuring that the distribution of dose estimates resulting from medical exposure from radiodiagnostic and interventional radiology purposes is determined. This will take into consideration, where appropriate, the distribution by age and gender of service users exposed.

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.

Compliance indicators

Indicators of compliance include:

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

Indicators of non-compliance 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:

Compliant	Non-compliant
Green	Orange

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 this regulation means for the service user

A medical physics expert is an individual having the knowledge, training and expertise to act or give advice on matters relating to radiation physics applied to medical exposure, 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 both individual and collective service-user dose received as result of medical exposures. The involvement of medical physics experts in medical exposures to ionising radiation provides assurance to service users about the quality of services provided where a medical physics expert has input. Key activities of medical physics experts include advising and performing quality assurance activities on medical radiological equipment and reducing the risk to service users from medical exposures to ionising radiation.

It is a requirement of the regulations that an undertaking should put in place the necessary arrangements to ensure continuity of expertise for medical physics experts. There should be adequate succession planning for medical physics expert roles, including contingency planning for expected and unexpected leave, ongoing continual professional development and the appropriate allocation of resources.

The specific duties carried out by a medical physics expert depend on the radiological practice and should correspond with the risk involved for service users. This level of involvement will vary between services, and examples are provided below of how the involvement of a medical physics expert might vary relative to radiological risk involved. Evidence of the involvement of the medical physics expert should be available for review by HIQA.

In radiotherapy, a medical physics expert recognised in the relevant specialty is closely involved in the service. For high-dose interventional procedures, computed tomography and diagnostic and therapeutic nuclear medicine, a named medical physics expert is involved in such fashion as to meet the requirements of Regulation 20. In the instance of low dose diagnostic procedures and dental imaging, a named medical physics expert provides consultation and advice on radiation protection.

This advice should be provided to assist an undertaking meet the requirements of regulations that require medical physics expert involvement. An example in practice may be a medical physics expert advising a dentist on the use of dosimetry to compare local diagnostic reference levels to national diagnostic reference levels.

The undertaking should be assured that where tasks which are under the responsibility of the medical physics expert are delegated, roles and responsibilities for the staff accountable are clearly defined. Overall, there should be 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 that will be reviewed

Through review of documents pre-inspection or 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 evidencing 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 patients 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 installation design
    - the surveillance of medical radiological installations
    - 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 evidencing 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 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 their representative 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:

Indicators of compliance 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 patients 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 installation design
  - the surveillance of the medical radiological installations
  - 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 of substantial compliance include:

- although arrangements are in place for continuity of expertise of medical physics experts, there are gaps that do not result in a medium or high risk to service users.

- 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, but these gaps do not result in a medium or high risk to service users
- while there is evidence of involvement of the medical physics expert as defined in Regulation 21, there are gaps in documentation, but these gaps do not result in a medium or high risk to service users
- 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 of non-compliance 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 patients 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 installation design

— the surveillance of the medical radiological installations

— 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:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

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

What this regulation means for the service user

The undertaking's workforce is organised and managed in such a way to ensure that staff have the required skills, experience and competencies. 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 outlined in Regulation 22(3) are engaged to perform such functions. Relevant appropriate training is undertaken as part of a continual professional development programme. Skills and techniques in relation to medical exposures are continually updated and maintained, particularly when new technology becomes available.

For service users, this ensures that the professionals involved in medical exposure have a sufficiently high standard of education in radiation protection to provide the best care.

The undertaking ensures that the workforce is organised and managed in such a way to ensure that those involved in medical exposures have the required skills, experience and competencies to respond to the changing needs of the service. Training needs should focus on high-quality, safe and effective the radiation protection of patients.

Examples of information/evidence that will be reviewed

Through review of documents pre-inspection or 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 contacted 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:

Indicators of compliance include:

- practitioners and those carrying out the practical aspects of medical exposure have appropriate education and training, including ongoing education in line with Regulations 22(3)
- aspects of medical exposure as outlined in Regulation 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 of substantial compliance 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, but these gaps do not result in a medium or high risk to service users.

Indicators of non-compliance 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 provided by the undertaking or other parties are engaged to do so

- 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:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 28. Provision of information to HIQA

What this regulation means for the service user

It is the responsibility of each undertaking to ensure the delivery of a safe and effective service that is compliant with the regulations. Determining the level of compliance with the regulations requires HIQA inspectors to gather sufficient information and supporting evidence to make a judgment that is appropriate to the level of risk to service users. The undertaking must submit information or statistics of compliance with these regulations when requested to by HIQA and within timelines specified by HIQA.

Undertakings should ensure that all records are maintained, stored and secured in line with recommended best practice.

Compliance indicators

Indicators of compliance include:

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

Indicators of non-compliance include:

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

Guide to the risk rating:

Compliant	Non-compliant	
Green	Orange	Red

4.2 Guidance on regulations related to safe delivery of medical exposures

The focus of this section is about the experience of the people 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 the dimension of safe delivery of medical exposures

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 exposure
Regulation 13	Procedures
Regulation 14	Equipment
Regulation 15	Special practices
Regulation 16	Special protection during pregnancy and breastfeeding
Regulation 17	Accidental and unintended exposures to ionising radiation

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 should take place to determine if the net benefits outweigh the possible risks. This justification is carried out by a suitably qualified practitioner. The practitioner must take into account medical information about the patient and their individual characteristics, such as pregnancy status, when making the justification decision.

For the service user, justification ensures that the medical exposure for which they are referred is the most appropriate option for them and that there is a net benefit from the exposure. Good justification practices aim to minimise excessive or incorrect medical exposures. A service user may have, for example, undergone previous diagnostic procedures which may inform the justification process, and this information should be available and considered by the practitioner and referrer to avoid unnecessary exposure. Therefore, justification is an important safeguard for patients 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 given information about the benefits and risks of the exposure. This is to ensure that patients 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 for 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 patient or individual 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 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 need to be in place regardless of the complexity of the medical radiological procedure; however, the internal processes may vary proportionately. For example, in a dental practice

where the referrer and practitioner is the same person, the process may be relatively simple. In comparison, in radiotherapy, aspects of justification may be inherent throughout the patient pathway. Nevertheless, regardless of the complexity of the exposure, the core principles apply and evidence of justification taking place before the procedure must be evident.

Note: In line with the responsibilities of HIQA under Regulation 8, further specific guidance will be issued with respect to justification of medical exposures.

Examples of information and evidence that may be reviewed

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

Inspectors may review:

Justification

- written protocols or guidelines relating to justification may include, but are not limited to:
  - the framework for justification of individual exposures
  - delegations of responsibility for justification
  - education and training for those 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 patient 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
- 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 justification assessment
  - contain evidence that practitioners seek further medical data where necessary prior to the exposure taking place
- audits conducted on the quality of referrals and rejection rates of non justified referrals.

Research studies and asymptomatic individuals

- research study documentation evidencing relevant ethics committee approval
- policies, procedures and guidelines relevant to justification of carer and comforters

Provision of information

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

Through communication

Inspectors may communicate:

- with staff to determine their understanding of justification and if they are able to articulate 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.
  - if they can verbalise which processes are justified in general and how justification takes place for cases which fall outside this criteria

- with patients and individuals who have had an exposure to determine if information was given to them on the risks and benefits of the procedure prior to the procedure taking place.

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

Indicators of compliance include:

Justification

- policies and procedures are in place to support justification and these policies are adhered to in practice
- the policies and procedures are regularly audited and peer reviewed
- there is evidence in records that the justification process, including review of medical information and previous diagnostic procedures, has taken place and is documented for individual medical exposures.

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
- there was evidence that referrals which did not have sufficient medical data to enable the practitioner to carry out a justification assessment were rejected by the practitioner
- staff who spoke with inspectors clearly understood the requirements of this regulation and were able to articulate their role in the process
- training was provided to staff relating to the provisions of this regulation and processes in place to support compliance.

Research studies and asymptomatic individuals

- all research projects involving medical exposure have been approved by an ethics committee prior to the exposure.

Provision of information

- there is evidence that information on risks and benefits of exposure has been given to patients and or representatives and or individuals.

Indicators of substantial compliance include:

- not all staff who spoke with inspectors could clearly demonstrate their roles and responsibility in relation to justification
- local policies and procedures relevant to justification were in place but there is a lack of evidence regarding audit of practice
- there was an availability of suitable information but a lack of evidence that information on risks and benefits of exposure has been given to patients and or representatives and or individuals.

Indicators of non-compliance include:

- written referrals were not evident for all medical radiological procedures undertaken at the installation
- referrals to a practitioner for a medical radiological procedures not meeting the criteria laid out in Regulation 8(10) were accepted within the installation and medical exposures undertaken
- there was no formalised process that provided assurance on undertaking compliance with the requirements of this regulation
- there was a lack of awareness demonstrated by staff who spoke with inspectors on the requirements of this regulation
- there was no evidence that information on risks and benefits of exposure has been given to patients and or representatives and or individuals
- research projects involving medical exposure had not been approved by an ethics committee prior to the exposure.

Guide to the risk rating:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 9. Optimisation

What this regulation means for the service user

The principle of optimisation applies to all individual medical exposures. This includes diagnostic procedures such as X-ray and computed tomography (CT) but also medical procedures where ionising radiation is used to help guide a procedure or treatment. All exposures, regardless of the clinical practice, require optimisation. Therefore, the benefit for service users is the assurance that all doses they receive are as low as possible.

The optimisation of a medical exposure is the process by which the most appropriate dose for each individual exposure is delivered. For a service user, optimisation ensures that the dose they receive is as low as reasonably achievable, while ensuring that the required clinical outcome is achieved. For example, in a diagnostic imaging procedure, the dose given is as low as possible to obtain images that are of suitable quality to answer the diagnostic question for which the patient was referred for the medical exposure.

The undertaking should have systems and processes in place to ensure that all doses received by service users are as low as reasonably achievable. A local policy should clearly outline what these systems are and how the responsibilities are assigned to those involved. These systems should ensure that optimisation is a prospective process and is a consideration from the time equipment is selected for procurement to when the patient is having their medical exposure.

Optimisation should be evident right through the service user's pathway, from referral to the practical aspects of the medical exposure. In the same way, policies and procedures in place which ensure consistent practices and techniques applied in the practical aspects of medical procedures also impact on the dose the service user receives and is part of optimisation.

Examples of information and evidence that will be reviewed

Through review of documents pre-inspection or 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 patient 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 patient specific dose ,where applicable
  - local policies, procedures and guidelines for carrying out clinical audits including evaluation of patient doses received, image guided radiotherapy procedure compliance, 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 patient.

Provision of information

- guidance provided for comforters and carers and evidence that such guidance was distributed
- evidence of the information provided to patients undergoing treatment or diagnosis with radionuclides, ensuring the risks have been communicated, including restricting contact with other persons where applicable.

Research

- evidence of the information provided to patients participating in research involving medical exposures, including the risks involved, which may include review of informed consent
- documentation evidencing that this information was provided prior to the exposure
- in relation to medical or biomedical research, records of experimental procedures evidencing individual target doses set out prior to the exposure and evidence that there target doses were met.

Through communication

Inspectors may communicate:

- with undertakings 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 undertakings about the mechanisms in place to ensure clinical audits are carried out
- with individuals carrying out the practical aspects of exposure to ensure they can articulate how they optimise individual exposures using the equipment available and they 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) prior to leaving hospital
- with individuals who have had an exposure as part of a medical or biomedical research project or experimental procedure to determine if information was given 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 and
  - complex treatment procedures have adequate verification.

Compliance indicators

Indicators of compliance include:

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

Indicators of substantial compliance 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 this information is provided after the exposure

- there is insufficient information provided to patients undergoing treatment or diagnosis with radionuclides on risks and restricting contact with other persons
- in radiotherapy, insufficient dose verification systems are in place including treatment plan quality assurance and multidisciplinary review, dose verification where applicable for complex treatment delivery and appropriate imaging verification.

Indicators of non-compliance include:

- undertakings have 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 not been provided with information on risks and restricting contact with other persons
- in radiotherapy, there is a lack of dose verification systems in place, including treatment plan quality assurance and multidisciplinary review, dose verification where applicable for complex treatment delivery and appropriate imaging verification.

Guide for risk rating:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 11. Diagnostic reference levels

What this regulation means for the service user

Diagnostic reference levels are a benchmark of the typical dose levels for types of radiological and interventional practices. They provide a benchmark to compare doses received by individuals having the same procedures in different rooms, medical installations or organisations. Diagnostic reference levels are not expected to be exceeded when good and normal practice is applied.

In the case of radiopharmaceuticals, diagnostic reference levels refer to levels of administered radioactivity for groups of standard-sized patients. The optimisation of patient protection through the implementation of diagnostic reference levels ensures that patient doses are as low as reasonably achievable for the clinical purpose of the examination. Diagnostic reference levels are an important way for undertakings to manage radiation dose delivered during diagnostic and interventional medical exposures and are also a useful tool in optimising image quality. They can help to identify issues with equipment or practice by highlighting unusually high doses of radiation.

Regulation 11 outlines both the regulator's and the undertaking's responsibilities in establishing diagnostic reference levels at national and local level respectively. This regulation places responsibility on HIQA as the competent authority to establish national diagnostic reference levels for radiodiagnostic examinations and interventional radiological procedures, where appropriate.

It is important that the undertaking provides a radiation protection infrastructure to support staff in delivering safe and effective care to service users. An essential element of any arrangement is the assurance that the necessary structures in place are effective. Undertakings are obliged to establish local diagnostic reference levels and regularly review and apply these in daily practice. Therefore, it is necessary that an undertaking has a means to regularly review the doses delivered to service users. Regular review enables the identification of doses delivered which consistently exceed relevant local and national diagnostic reference levels.

Staff education and awareness in relation to the use of diagnostic reference levels is essential to good practices for radiation protection for service users. Undertakings should ensure that staff have appropriate access to the diagnostic reference levels where procedures are carried out. Diagnostic reference level guidance should be available to relevant staff with responsibility for optimisation at the point of care to ensure appropriate application. HIQA will look for assurance on how this guidance is made available.

Examples of information and evidence that will be reviewed

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

Inspectors may review documents such as:

- policies, procedures, protocols or guidance used to establish diagnostic reference levels for radiodiagnostic examinations and, where appropriate, for interventional radiology procedures
- evidence of regular reviews of diagnostic reference levels for radiodiagnostic examinations and, where appropriate, for interventional radiology procedures
- evidence of use of diagnostic reference levels for radiodiagnostic examinations and, where appropriate, for interventional procedures
- records of reviews and corrective actions carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure, typical doses or activities consistently exceed the relevant diagnostic reference level
- evidence that corrective actions are taken are without undue delay where for a given examination or procedure, typical doses or activities consistently exceed the relevant diagnostic reference level
- evidence that records of reviews and corrective actions mentioned above are available
- guidance published by HIQA to determine if it is the most recent version available.

Through communication

Inspectors may communicate:

- with the undertaking and or staff to determine how diagnostic reference levels for radiodiagnostic examinations and, where appropriate, for interventional radiology procedures, are established, regularly reviewed and used
- with the undertaking and or staff to determine if appropriate reviews have been carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure, typical doses or activities consistently exceed the relevant diagnostic reference level
- with the undertaking and or staff to determine how appropriate corrective action is taken where for a given examination or procedure, typical doses or activities consistently exceed the relevant diagnostic reference level

- with the undertaking and or staff to determine if a record of reviews and corrective actions carried out are retained for a period of five years from the date of review
- with the undertaking and or staff to determine if they are aware of the guidance published by HIQA.

Through observation

Inspectors may observe:

- to determine that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used locally.

Compliance indicators

Indicators of compliance include:

- Diagnostic reference levels for radiodiagnostic examinations and, where appropriate, for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established where available
- appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical, doses or activities consistently exceed the relevant diagnostic reference level, and the undertaking shall ensure that appropriate corrective action is taken without undue delay
- records of reviews and corrective actions carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure, typical doses or activities consistently exceed the relevant diagnostic reference level are retained for a period of five years from the date of the review
- 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 are aware of the guidance published by HIQA

Indicators of substantially compliant include:

- some gaps are identified in the documentation relating to the use of diagnostic reference levels, but these gaps do not result in a medium or high risk to service users.

Indicators of non-compliance include:

- Diagnostic reference levels for radiodiagnostic examinations and, where appropriate, for interventional radiology procedures, are not established, regularly reviewed or used
- appropriate reviews are not carried out to determine whether the optimisation of protection and safety for patients is adequate
- where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level and appropriate corrective action is not taken
- records of reviews and corrective actions carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure, 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:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 12. Dose constraints for medical exposures

What this regulation means for the service user

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

A carer and comforter is someone who incurs an exposure to ionising radiation, other than as part of their occupation, by helping in the support and comfort of a patient, or other service user having a medical exposure. For example, this may be a parent supporting a child having an X-ray at a dentist surgery.

To meet this requirement, an undertaking proactively assesses those procedures or cases that may involve a radiation dose to comforters and carers and develops a policy for the optimisation of the potential radiation dose in line with Regulation 9(5). Policies, procedures and guidelines also reflect guidance issued by HIQA and the potential dose to a carer or comforter is considered as part of the justification process of the medical exposure. Information in relation to the benefits and risk are made available to carers and comforters in line with Regulation 8(14). A dose to a comforter or carer which exceeds certain parameters is reportable 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 make sure that relevant dose constraints as specified — or approved by an ethics committee on a case-by-case basis — are met. Undertakings also have arrangements in place to ensure that ethics committees specifying or approving dose constraints are recognised in line with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004).

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 will be established and published by HIQA in due course as part of its statutory obligation.

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- the undertaking's 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
- incidences of significant event notification forms relating to 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 persons are subject to medical exposure as part of medical or biomedical research.

Through communication

Inspectors may communicate:

- with the undertaking to establish if there is an awareness 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 are used
- 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

Indicators of compliance 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 for persons subject to medical exposure as part of medical or biomedical research.

Indicators of substantial compliance include:

- some gaps are identified in the documentation relating to the use of dose constraints but these gaps do not result in a medium or high risk to service users.

Indicators of non-compliance include:

- dose constraints are not used in the optimisation of protection and safety in any radiological procedure in which an individual acts as a carer or comforter by the undertaking
- an undertaking does 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 for persons subject to medical exposure as part of medical or biomedical research

Guide for risk rating:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 13. Procedures

What this regulation means for the service user

Policies and procedures are not considered in isolation to the systems in place to ensure safe and effective care. They are essential for the safe delivery of care and to guide staff in delivering safe and appropriate medical exposures. They are about good governance from an undertaking, and they are 'living' documents that are used by staff and reviewed and updated as required.

The undertaking ensures that it has the relevant policies and procedures specific to the needs of that service for every type of standard medical radiological procedure a service user undergoes. Written procedures and evidence-based protocols for conducting medical exposure help to standardise the quality of the procedure and the radiation dose received by service users.

Procedures are in place from the point of referral to the practical aspects of the procedure. For example, when a patient is being referred for medical imaging, procedures should incorporate the use of referral guidelines to inform the referrer of the most appropriate examination for the patient. This provides assurance to patients that the examination they are having is the best option for them and that another referrer would have made the same decision.

In the same way, procedures ensure that there is consistency in the practical aspects of having a medical exposure, making sure the dose the service user receives is appropriate. For example, where a procedure is different for adults and children, local protocols indicate these differences. Therefore, written procedures provide assurance to patients that their medical exposure dose is as low as reasonably achievable.

The undertaking ensures a robust information governance system is in place, with responsibility assigned to appropriate persons. The written policies and procedures in place are adapted to the service to reflect current practice and any changes to technology or equipment. There is clear evidence that staff understand and use the policies and procedures to deliver a safe and quality service.

In the absence of published procedures by the Minister for Health on audit procedures, audits are conducted according to local procedures.

Evaluation of the effectiveness of written policies and procedures is continually reviewed and monitored through periodic audit. This evaluation provides assurance to the undertaking that all medical exposures carried out are justified and optimised in line with relevant legislation and evidence-based best practices.

Note: The Minister for Health is to publish further guidance on national procedures in relation to clinical audit. When published, an undertaking will have responsibility to ensure audit is conducted in accordance with such national procedures.

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- written protocols established for every type of standard medical exposures, for each type of equipment, and for relevant categories of patients, 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 patient 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
- results and reports of clinical audits relevant to medical exposures.

Through communication

Inspectors may communicate with the undertaking:

- to establish if written protocols are established for every type of standard medical exposure, for each type of equipment, and for relevant categories of patients
- regarding the availability of referral guidelines for medical imaging
- to assess how patient exposure forms part of the report of the medical radiological procedure
- regarding the procedures used to carry out clinical audits.

Through observation

Inspectors will observe:

- if written protocols are available at point of care
- if referral guidelines are available to referrers.

Compliance indicators

Indicators of compliance include:

- written protocols established for every type of standard medical radiological procedure, for each type of equipment, and for relevant categories of patients
- information relating to patient exposure 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
- clinical audits being carried out in accordance with established national procedures.

Indicators of substantial compliance include:

- while it is evident that there are procedures for medical exposures, gaps are identified in the documentation; however, they do not result in a medium or high risk to service users.

Indicators of non-compliance include:

- written protocols have not been established for every type of standard medical radiological procedure, for each type of equipment, and for relevant categories of patients
- information relating to patient exposure 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 accordance with established national procedures.

Guide for risk rating:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 14. Equipment

What this regulation means for the service user

Undertakings have arrangements in place to ensure that medical radiological equipment in clinical use is safe for use and fit for purpose. This ensures that service users undergoing medical exposures receive an optimal dose of radiation.

Undertakings implement and maintain an appropriate quality assurance programme to monitor and evaluate the safe delivery of medical exposures and their outcomes for service users. Quality assurance programmes are incorporated as part of the overall quality assurance systems within the undertaking. Depending on the size of the undertaking, technical committees may be formed to ensure adequate oversight is maintained by the undertaking. For a sole trader, this may mean that a sole trader, such as a dentist, would review his or her quality assurance programme with the input of a medical physics expert, at appropriate intervals, to ensure suitable oversight regarding patient radiation protection.

This means that for medical exposures, an undertaking has planned and systematic procedures in place to provide assurance that structures, systems, components and procedures involved in carrying out medical exposures will perform satisfactorily. Additionally, an appropriate programme of assessment of dose or verification of administered activity is also implemented and maintained.

Quality assurance programmes incorporate an agreed quality control plan to assess and monitor equipment. This means that an undertaking ensures that arrangements are in place for monitoring, evaluating and maintaining equipment at the required levels of acceptability. The quality assurance programme is a continual process that involves collecting data to determine if medical radiological equipment is meeting criteria of acceptability.

Undertakings are aware of, and start a review 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 patient dose. Undertakings have a responsibility to be aware of and comply with these requirements as specified in Regulation 14.

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- the inventory of medical radiological equipment for each medical radiological installation 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, practitioners, and those carrying out the practical aspects of medical radiological procedures regarding:

- the undertaking's arrangements in place to ensure that all medical radiological equipment in use is kept under strict surveillance in relation to protection from radiation
- how the undertaking implements and maintains appropriate quality assurance programmes and appropriate programmes of assessment of dose or verification of administered activity
- how an undertaking carries out acceptance testing before the first use of the equipment for clinical purposes, and performance testing on a regular basis, and after any maintenance procedure liable to affect the equipment's performance

- to find 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
- undertaking's arrangements to take necessary measures as directed by HIQA to improve inadequate or defective performance of medical radiological equipment in use
- undertaking's assurances that the acceptability of equipment criteria adopted by HIQA is complied with
- undertaking's measures to ensure compliance of medical radiological equipment with legislative requirements on the availability of information about the quantity of radiation produced and relevant parameters for assessing patient 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

Indicators of compliance include:

- there is evidence that undertakings have arrangements in place to ensure that all medical radiological equipment in use is kept under strict surveillance regarding radiation protection
- 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
- an undertaking has taken measures 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 patient 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 medical radiological installation
- an undertaking provides HIQA, on request, with an inventory of medical radiological equipment for each medical radiological installation
- an undertaking has retained records in relation to medical radiological equipment for a period of five years from their creation.

Indicators of substantial compliance include:

- while it is evident that medical exposures to ionising radiation are delivered to a high standard, gaps are identified in the documentation; however, they do not result in a medium or high risk to service users.

Indicators of non-compliance include:

- undertakings have not ensured that all medical radiological equipment in use is kept under strict surveillance regarding radiation protection
- there is evidence that a person used medical radiological equipment for clinical purposes where acceptance testing before clinical use was not carried out
- an 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:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 15. Special practices

What this regulation means for the service user

Regulation 15 recognises that certain groups of patients and service users need to have special arrangements in place to ensure they are appropriately protected when exposed to ionising radiation.

Children in particular have an increased radio-sensitivity and subsequently special attention is needed to ensure they are adequately protected when undergoing a medical exposure. Additionally, undertakings give special attention to radiation protection for asymptomatic persons exposed as part of a health screening process or patients exposed to high doses of radiation, as may be the case in interventional radiology, nuclear medicine, computed tomography (CT) or radiotherapy.

Persons carrying out the practical aspects of medical exposures to service users in these groups have appropriate education, training and competence to ensure that appropriate practical techniques are used. Similarly, an undertaking has arrangements in place to evaluate medical radiological equipment used in medical exposures in the case of special practices to ensure that it is appropriate and fit for purpose.

Additionally, undertakings implement quality assurance programmes to allow the proactive identification, evaluation and management of immediate and potential exposure risks to these groups of service users. This must include the assessment of dose or verification of administered activity and should also incorporate systems to identify when doses delivered to service users during high-dose procedures, particularly interventional radiology and cardiology, which may exceed the threshold for tissue reactions.

Undertakings ensure that policies, procedures and guidelines are in place. These are evidence-based and reflect alerts, recommendations and guidance from national regulatory bodies. Undertakings periodically review any medical exposures given to these groups of service users and assess if these are appropriate.

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- clinical audits
- specific optimisation of written protocols in case of special practices
- evidence of the allocation of responsibility for the protection of the following service users undergoing medical exposure:
  - children
  - as part of a health screening process
  - involving high doses to the patient 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:

- regarding the quality assurance programmes and the assessment of dose or verification of administered activity for special practices
- to enquire 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

Indicators of compliance include:

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

the following are in place:

  - — appropriate medical radiological equipment
  - — appropriate practical techniques in use
  - — appropriate ancillary equipment 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 of substantial compliance include:

- while it is evident that medical exposures to ionising radiation are delivered to a high standard, gaps are identified in the documentation; however, they do not result in a medium or high risk to service users.

Indicators of non-compliance include:

- an undertaking is unable to provide evidence that for the following service users undergoing medical exposure:
  - — children
  - — as part of a health screening process

— involving high doses to the patient as may be the case in interventional radiology, nuclear medicine, CT or radiotherapy

the following are in place:

— appropriate medical radiological equipment

— appropriate practical techniques in use

— appropriate ancillary equipment 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.

- 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:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 16. Special protection during pregnancy and breastfeeding

What this regulation means for the service user

Arrangements for special protection for pregnant women or breastfeeding women are established, maintained and promoted by undertakings. Children, including the unborn child, have an increased radio-sensitivity, and for that reason, the need for special considerations in such cases where this group are exposed to ionising radiation has been provided for in legislation.

Undertakings develop and implement policies, procedures and guidelines, based on national guidelines and best available evidence. Adherence to these is monitored and assessed, and undertakings should seek to promote a culture of radiation protection by proactively identifying and addressing risks during pregnancy and breastfeeding. Practitioners, referrers, and service users are encouraged and enabled to raise concerns about radiation protection during pregnancy and breastfeeding.

Special protection during pregnancy and breastfeeding is supported by clear leadership, robust accountability arrangements and good communication. Undertakings implement education and awareness programmes with a specific focus on special protection during pregnancy and breast feeding. For example, a new referrer employed by the undertaking should be made aware of their responsibility at induction regarding enquiring as to the pregnancy status of an individual they are referring and their obligation to record the answer to such an inquiry in writing.

Undertakings take measures to increase the awareness of patients and other service users who may be pregnant or breastfeeding of the need for special protection during medical exposures when pregnant and breastfeeding. Undertakings should ensure that leaflets and public notices are displayed in appropriate places, such as in a waiting room, and other methods of increasing awareness among service users should be available.

Undertakings are aware of their legislative requirement to report any inadvertent irradiation of greater than 1milliGray (mGy) of a foetus or a breastfeeding child to HIQA as a significant event.

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- policies, procedures, protocols and guidelines in relation to pregnancy determination

- 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 to a foetus
- records, reports and any other matters of relevance to the medical exposure of service users.

Through communication

Inspectors may communicate with:

practitioners and referrers

- to find out 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 relating to how pregnancy and or breastfeeding status is ruled out for obvious reasons or is deemed not relevant for the medical radiological procedure concerned.

the undertaking:

- as to how they ensure that the referrer or a practitioner establishes whether or not an individual subject to the medical exposure is pregnant or breastfeeding
- as to what policies are in place regarding the exclusion of the need to inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding for obvious reasons or if it is not relevant for the radiological procedure concerned
- 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 15
- with service users, where appropriate, to find out whether inquires where 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 individuals to who may be pregnant or breastfeeding.

Compliance indicators

Indicators of compliance include the undertakings:

- ensuring that the referrer or a practitioner enquires 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
- retains 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
- provides 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
- provides evidence that special attention is given to the justification — particularly the urgency where pregnancy or breastfeeding cannot be ruled out for an individual subject to medical exposure — and to the optimisation taking into account both the individual and the (unborn) child
- has taken measures to increase the awareness for individuals who may be pregnant or breastfeeding of the need for special protection during pregnancy and breastfeeding as outlined in Regulation 15.

Indicators of substantial compliance include:

- while it is evident that medical exposures to ionising radiation are delivered to a high standard, gaps are identified in the documentation relating to special protection during pregnancy and breastfeeding; however, they do not result in a medium or high risk to service users, breastfed children, or in the case where a service user is an expectant mother, an unborn child.

Indicators of non-compliance include:

- the undertaking:
  - — does not have arrangements in place to ensure that the referrer or a practitioner enquires 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
  - — does not have appropriate mechanisms and procedures in place to ensure that the referrer or a practitioner records in writing the answer to any inquiry 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 the medical exposure is pregnant or breastfeeding is being retained for five years
  - — is unable to provide 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
  - — cannot provide evidence that special attention is given to the justification, particularly the urgency where pregnancy or breastfeeding cannot be ruled out for an individual subject to medical exposure, and to the optimisation taking into account both the individual and an unborn child
  - — has not taken measures, or has taken insufficient measures, to increase the awareness for individuals who may be pregnant or breastfeeding of the need for special protection during pregnancy and breastfeeding as outlined in Regulation 15.

Guide for risk rating:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

Regulation 17. Accidental and unintended exposures and significant events

What this regulation means for the service user

Undertakings implement and maintain arrangements to identify incidents involving or potentially involving accidental and unintended exposures to ionising radiation through structured incident-reporting mechanisms. Such events are identified, managed, responded to and reported in a timely manner in line with national legislation, policy, guidelines and guidance. Local incident management arrangements are clearly communicated by the undertaking to all individuals involved in the medical exposure of service users.

Service users can be assured that systems are in place to minimise the possibility of accidental and unintended exposures. Where such an event occurs and is clinically significant, the patient or their representative will be informed. Learning from incidents and from potential incidents helps prevent future occurrence to other service users.

Effective information governance arrangements are in place to ensure compliance with notification requirements. The undertaking ensures that incidents are notified to HIQA in the required format within the specified timeframe and that all necessary information is submitted.

The undertaking develops and supports a culture of openness, transparency and accountability to enable effective learning from incidents and accidents. The learning from the evaluation of incident and potential incident reviews is communicated promptly and used to inform the development of best practice and ultimately improve service provision. The findings from such evaluations are reported through relevant governance structures to ensure that identified opportunities for improvement are acted upon.

Note: HIQA will share information in relation to lessons learned from significant events by publishing a written report in relation to findings at regular intervals.

Examples of information and evidence that will be reviewed

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

Inspectors may review:

- notifications of significant events to HIQA
- the results of the investigation into any significant event notified to HIQA and the corrective measures to avoid such events
- 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 been trained with respect to local incident management systems and procedures.

Through communication

Inspectors may communicate:

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

Inspectors may communicate with the undertaking:

- 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 for radiotherapeutic practices
- to ascertain the systems in place for record-keeping and analysis of events involving or potentially involving accidental and unintended medical exposures and 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 the investigation into any significant event notified to HIQA and the corrective measures to avoid such events, are reported to HIQA within 120 calendar days as specified HIQA.

Compliance indicators

Indicators of compliance 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, that 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 and the practitioner, and the patient or their 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 the investigation into any significant event and corrective measures to avoid such events notified to HIQA are reported within 120 days from the receipt of the notification by HIQA.

Indicators of substantial compliance include:

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

Indicators of non-compliance 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
  - does not have an appropriate system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures
  - does not have arrangements in place to inform the referrer and the practitioner, and the patient or their 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 the investigation into any significant event and corrective measures taken to avoid such notified events within 120 days from the receipt of the notification by HIQA.

Guide for risk rating:

Compliant	Substantial compliance	Non-compliant	
Green	Yellow	Orange	Red

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