Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Quality Authority

Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Galway Clinic
Undertaking Name:	Galway Clinic Doughiska Unlimited
Address of Ionising Radiation Installation:	Doughiska, Galway
Type of inspection:	Announced
Date of inspection:	23 October 2024
Medical Radiological Installation Service ID:	OSV-0007393
Fieldwork ID:	MON-0042962

About the medical radiological installation (the following information was provided by the undertaking):

The Galway Clinic is a member of The Blackrock Healthcare Group, which also includes Hermitage Clinic and Blackrock Clinic in Dublin. It is a 146 bedded hospital with 36 consultant suites and Radiology Department that provides scans, x-rays and procedures to diagnose and treat a wide range of medical conditions. Core hours for the service are Monday to Friday 8am -8pm with an emergency out-of-hours service outside of these times.

Services provided by the radiology department include: general radiography and fluoroscopy, mobile radiography, theatre screening, computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, mammography, interventional radiology, radiography support in catheterisation laboratory, positron emission tomography CT (PET CT) and nuclear medicine. The multi-disciplinary radiology team is made up of: consultant radiologists, radiographers, radiology nursing staff, medical physics, administrators and diagnostic imaging assistants. The department is involved with the University College Dublin (UCD) graduate programme for Radiography and provides training through clinical placement for radiography students.

The Radiotherapy Department provides external beam radiotherapy for the treatment of cancer patients and some benign diseases. Our department has two linear accelerators. Core hours for the radiotherapy service are Monday to Friday 7.30a.m - 8.30p.m, providing emergency cover at the weekends. The multi-disciplinary team consists of: radiation oncologists, radiation therapists, dosimetrists, medical physics, radiotherapy nurse and radiotherapy administrator. The department is involved with Trinity College Dublin (TCD) Radiotherapy undergraduate programme providing training through clinical placement for Radiotherapy students.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

1. Governance and management arrangements for medical exposures:

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Wednesday 23 October 2024	09:00hrs to 15:30hrs	Lee O'Hora	Lead
Wednesday 23 October 2024	09:00hrs to 15:30hrs	Emma O'Brien	Support

Governance and management arrangements for medical exposures

As part of this inspection, the inspectors reviewed documentation, visited the radiotherapy and radiology departments and spoke with staff and management. On this inspection, the inspectors found effective governance, leadership and management arrangements for the protection of service users undergoing medical exposures.

Inspectors were informed that Galway Clinic was part of a larger Hospital Group but operated as a separate undertaking within this group. Local responsibility for the radiation protection of service users lay with the Hospital Board. Galway Clinic used multiple platforms including a Quality Clinical Governance Committee (QCGC), a Radiation Safety Committee (RSC) and a Radiation Protection Unit (RPU) to ensure that radiation safety related issues could be considered and escalated appropriately. However, some work was required to meet regulatory requirements in relation to the clear allocation of responsibility for the clinical evaluation of the outcome and documentation updates to reflect the updated regulatory terminology and day-to-day practice at Galway Clinic.

Following a review of documents and records, and speaking with staff, the inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, the inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

After speaking with staff and reviewing radiation safety related documentation and records, the inspectors were assured that the responsibilities, advice and contributions of the medical physics expert (MPE) were commensurate with the services provided by Galway Clinic and satisfied the requirements of the regulations.

Overall, despite a few areas noted for improvement to meet regulatory compliance the inspectors were satisfied that the undertaking had implemented and maintained effective governance and management arrangements for the radiation protection of service users at Galway Clinic.

Regulation 4: Referrers

Following a review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff in both the radiotherapy and radiology departments, the inspectors were satisfied that Galway Clinic only accepted referrals from appropriately recognised referrers. In line with the regulations, both radiographers and radiation therapists were also considered

referrers in certain circumstances. The specific circumstances in which they could act as referrers was clearly outlined in documentation supplied and articulated by staff spoken with on the day. Galway Clinic also accepted referrals from advanced nurse practitioners in the radiology department and the specific circumstances in which they could act as referrers were clearly articulated to the inspectors by staff.

Judgment: Compliant

Regulation 5: Practitioners

Following the review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, the inspectors were satisfied that the undertaking had systems in place to ensure that only appropriately qualified individuals were considered practitioners at Galway Clinic.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by the inspectors outlined a clear corporate allocation of responsibility for the protection of service users by the undertaking at Galway Clinic. Galway Clinic was part of a larger Hospital Group but operated as a separate undertaking within this group. The company undertaking Galway Clinic Doughiska Unlimted was identified to inspectors as the legal entity with overall responsibility for the radiation protection of service users. The inspectors were informed that the Chief Executive Officer (CEO) communicated directly to the Hospital Board and undertaking. The many platforms used for the governance of radiation safety issues were identified and articulated to inspectors on the day of inspection. Galway Clinic used a Radiation Protection Unit (RPU) which met quarterly and fed into the Radiation Safety Committee (RSC) which met twice yearly. The RSC fed into the Quality Clinical Governance Committee (QCGC) which met weekly and could consider any relevant radiation safety issues. The inspectors were informed that the CEO was a member of the QCGC and the Chief Operating Officer (COO) and the Head of the Patient Safety Executive were members of the RSC. The RPU was comprised of clinical staff from both the radiotherapy and radiology departments, Radiation Protection Officers (RPO) and Medical Physics Experts (MPE).

While the allocation of responsibility for the protection of service users was consistently articulated to the inspectors on the day, some gaps in the documentation need to be addressed by the undertaking to ensure that radiation safety documentation reflects day-to-day practice and regulatory terminology. For example, the documents *Best practice when taking X-rays* and *Justification of The*

Use of Ionizing Radiation in Radiology state that only doctors can 'request' and 'authorise' medical radiological procedures respectively. These documents should be updated to reflect day-to-day practice and the regulations in relation to the referral and justification of medical radiological procedures. Also, documentation listing practitioners at Galway Clinic omitted radiation therapists. After speaking with staff and management and reviewing a sample of treatment records, the inspectors were satisfied that radiation therapists were considered practitioners by Galway Clinic. Therefore the relevant documentation must be updated to reflect this local practice which includes radiation therapists as practitioners at Galway Clinic.

Some work was also required by the undertaking to ensure the clear allocation of responsibility for the clinical evaluation of the outcome for a subset of fluoroscopic procedures carried out at this hospital. This area of non compliance requiring the attention of the undertaking is further discussed under Regulation 10.

Inspectors reviewed documentation in relation to the justification of new practices at Galway Clinic and were satisfied that the undertaking had developed and implemented a system for the local consideration and subsequent application to HIQA for generic justification before the use of a new practice on a routine basis, as required by the regulations.

The relevant platforms, responsibilities and lines of communication regarding the effective protection of service users was clearly articulated to the inspectors during the course of the inspection. However, some work was required by the undertaking to ensure the appropriate allocation of responsibility for clinical evaluation of the outcome for all medical exposures and some documentation needed to be updated, as outlined in this report.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Following the review of a sample of records for medical radiological procedures and by speaking with staff and management, the inspectors noted that the undertaking had ensured that all exposures to ionising radiation took place under the clinical responsibility of a practitioner in the radiotherapy department and for most radiological procedures.

However, some fluoroscopy reports, identified by staff as constituting the clinical evaluation of the outcome, were not signed off by staff entitled to act as practitioners. While it was acknowledged that this small subset of reports represented a small percentage of the radiology reports produced by Galway Clinic, it is imperative that the undertaking ensures that all medical exposures take place under the clinical responsibility of a practitioner including clinical evaluation of the outcome. This was brought to the attention of management on the day of inspection.

Despite this, the inspectors were assured that the optimisation process involved the practitioner and the MPE and the justification process for individual medical exposures involved the practitioner and the referrer in both the radiotherapy and radiology departments. Imaging protocols reviewed in the diagnostic imaging department were signed off by a multidisciplinary team including the MPE. This was considered as an effective use of the MPE in the optimisation process.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to the inspectors by staff and management. All evidence supplied satisfied the inspectors that Galway Clinic had the necessary arrangements in place to ensure continuity of MPE expertise and inspectors were also assured that recent allocation of increased MPE resources at Galway Clinic further strengthened these arrangements.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff at the hospital, the inspectors were satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners in both the radiotherapy and radiology departments.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, the inspectors established that the involvement of the MPEs was both appropriate for the service and commensurate with the risk associated with both the radiotherapy and radiology service provided at Galway Clinic.

Judgment: Compliant

Safe Delivery of Medical Exposures

The inspectors reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this hospital. Following the review of a sample of referrals for radiotherapy and radiology procedures the inspectors were satisfied that Galway Clinic had processes in place to ensure that all medical radiological procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that the practitioner's justification was recorded.

The inspectors were satisfied that DRLs were established, used and reviewed in both the radiotherapy and radiology departments. Many areas of good practice in the optimisation of service user exposure and the use of special practices where medical exposures involved high doses were noted on the day of inspection by inspectors and are detailed in this report.

However, inspectors noted that the undertaking had some work to complete to ensure that written protocols were available for every type of standard medical radiological procedure. Another area noted as not meeting the full requirements of the regulations on this occasion related to Regulation 13(2), namely that information relating to patient exposure did not form part of all patients' reports reviewed on the day of inspection.

The inspectors reviewed documentation and records of accidental and unintended exposures and significant event near misses and were assured that the undertaking had employed measures to minimise the probability and magnitude of accidental or unintended exposures of service users. Records reviewed also satisfied the inspectors that the appropriate systems were implemented for the record keeping and analysis of such events. Overall, inspectors noted a positive culture of incident reporting was developed, encouraged and maintained by the undertaking. The comprehensive approach to clinical audit at Galway Clinic was identified as driving improvement in the radiation protection of service users and was noted as an area of good practice by inspectors.

From the evidence available, the inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing. All records reviewed detailed that all testing was up-to-date and any issues identified were appropriately followed up or closed off as required.

Overall, despite some areas noted for the attention of the undertaking, many areas of good practice were noted and the inspectors were satisfied that robust systems

and processes were in place to ensure the safe delivery of medical radiological exposures to service users in Galway Clinic.

Regulation 8: Justification of medical exposures

The inspectors spoke with staff and reviewed a sample of referrals on the day of inspection from both the radiotherapy and radiology departments. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance by a practitioner and a record of this justification was maintained. In line with Regulation 8, all referrals reviewed by the inspectors were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risks of the medical exposure.

The inspectors visited the clinical areas in both the radiotherapy and radiology departments and observed multiple posters which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures.

Judgment: Compliant

Regulation 9: Optimisation

From discussions with staff and a review of documents, inspectors were satisfied that the undertaking had implemented a number of measures to ensure that all doses due to medical exposures are kept as low as reasonably achievable in both the radiotherapy and radiology departments.

Inspectors were also assured from the evidence gathered during this inspection of the radiotherapy department that radiotherapy treatments were individually planned, their delivery appropriately verified taking into account that doses to surrounding normal areas are as low as reasonably achievable and consistent with the intended outcome of the course of treatment.

Staff in the planning CT unit described how they optimised each CT exposure through the use of immobilisation equipment, and specific scanning protocols for each treatment site. Staff also informed inspectors how, for some cohorts of patients, they completed a short scan in order to assess that all preparations were optimal, before proceeding with a more comprehensive CT scan. This initiative was seen as an example of good practice in the radiation protection of service users in the department. Staff also informed inspectors that the doses from CT planning scans were recorded for each patient's CT planning scan in order to monitor these

doses and ensure that they were kept as low as possible while providing adequate information for treatment planning.

Inspectors spoke with staff in the radiotherapy planning department who explained that all treatment plans were individually planned to deliver the prescription dose to the treatment area and to keep doses to surrounding normal areas as low as possible. Staff explained to inspectors that prior to treatment commencing QA checks were completed on radiotherapy plans to provide additional assurances that doses to the treatment area would be delivered as prescribed.

Inspectors also reviewed numerous policies and procedures which outlined how optimisation was best achieved during treatment delivery. The staff and management in the radiotherapy department had also developed a number of protocols on the imaging type and frequency of imaging to be followed for each radiotherapy treatment site to ensure the accurate delivery of the dose to the treatment area.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following a review of DRLs, the inspectors were satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this hospital. In the clinical area multiple examples of local facility DRLs were displayed for staff.

Inspectors noted that the undertaking had established DRLs for CT planning scans used in the radiotherapy department. In both the radiotherapy and radiology department's inspectors noted the use of DRL reviews and subsequent multidisciplinary optimisation strategies to reduce patient dose associated with a number of medical radiological procedures. This was seen as a positive example of how the required regulatory dose reviews can be used to promote good radiation safety practice and patient dose optimisation.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, the inspectors found that written protocols were established and available for radiotherapeutic, interventional radiology and cardiology, computed tomography, nuclear medicine including PET CT and general X-ray. However, inspectors noted that written protocols for fluoroscopic procedures

carried out in theatre were not available. This must be addressed by the undertaking to ensure compliance with Regulation 13(1).

The inspectors spoke with staff and reviewed a sample of imaging reports from a number of clinical areas on the day of inspection. In the radiotherapy department, inspectors observed that a discharge letter was generated after each patient completed their radiotherapy treatment which included information on the treatment dose received by the patient. In the radiology department, the inspectors noted that medical imaging reports included information relating to patient exposure once these reports were printed or communicated electronically. Inspectors were informed that the vast majority of reports were printed or sent electronically.

However, it was noted by inspectors that information relating to patient exposure was not visible when the report was viewed using the Radiology Information System (RIS) used by Galway Clinic. The inspectors were informed that some internal referrers may use this system to view subsequent reports. Furthermore, a small subset of reports namely those generated for fluoroscopically guided procedures in theatre were not routinely printed or sent electronically to referrers. Therefore, in these instances, information relating to patient exposure did not form part of the report. This was seen a gap that must be addressed to ensure compliance with Regulation 13(2).

Inspectors acknowledged that significant work had been done by the undertaking to implement HIQA's *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* into the corporate clinical audit structures by Galway Clinic. Inspectors viewed the *Radiation Services Clinical Audit Strategy 2024* and minutes from the audit strategy group and were satisfied that the undertaking had implemented an effective framework for clinical audit in this facility.

Inspectors viewed a number of clinical audits that were ongoing and complete at Galway Clinic in the radiotherapy and radiology departments. Staff in the clinical area articulated to inspectors their ongoing involvement in the clinical audit process and the multiple formats used by the undertaking to communicate such work to them. Inspectors were also informed that the Galway Clinic was now expanding the clinical audit strategy group to include representatives from the entire facility which was seen as a positive use of such platforms to ensure the promotion of clinical audit outside the radiotherapy and radiology departments.

The comprehensive approach to clinical audit at Galway Clinic was identified as driving improvement in the radiation protection of service users and was noted as an area of good practice by inspectors.

Judgment: Substantially Compliant

Regulation 14: Equipment

The inspectors were provided with an up-to-date inventory which was verified on-site.

From the evidence available, the inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This included the implementation and maintenance of a QA programme, including appropriate acceptance and regular performance testing. Evidence was also available to show that any issues identified as part of the equipment QA had been followed up in a timely manner and the inspectors noted the quality and availability of equipment specific records reviewed on the day.

Judgment: Compliant

Regulation 15: Special practices

On the day of the inspection, inspectors observed that there was good cooperation and collaboration between the various disciplines involved in the planning and delivery of radiotherapy medical exposures at Galway Clinic. Inspectors were informed that a multidisciplinary radiotherapy team met weekly to review all treatment plans in advance of treatment commencing. This meeting was attended by radiation oncologists, radiation therapists and by medical physics experts. This multidisciplinary approach and opportunity to discuss radiation protection matters was acknowledged as an area of good practice in the department. Inspectors observed that the multidisciplinary team had also implemented a number of appropriate measures to ensure that patients receiving high dose medical exposures were appropriately protected. For example, during CT planning for treatment, specific measures were taken, for relevant patients, prior to the scan to reduce organ motion, and individualised immobilisation devices and scanning margins were carefully considered to ensure that the area scanned was limited to relevant areas only. Inspectors were also informed that the dose delivered to the patient during CT was recorded, audited and compared to internationally published data, to ensure that it was optimal.

During the course of the inspection, inspectors also spoke with staff in the radiotherapy treatment planning department, who informed inspectors that specific planning protocols were used for each treatment site to ensure that doses to normal tissue were kept as low as possible while delivering the optimal treatment dose to the treatment area. Inspectors were also informed of a contouring software system in the planning department, which automatically outlined normal tissues located close to the treatment area. This system was used to optimise contouring of these normal tissues, and improve radiation protection in treatment planning. During the course of the inspection, inspectors were satisfied that the undertaking had given special attention to appropriate radiation protection practices for patients receiving radiotherapy treatment.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation and imaging records reviewed satisfied the inspectors that Galway Clinic had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Bespoke multilingual posters, developed by Galway Clinic, were observed throughout the departments to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From speaking with staff and reviewing local incident records and associated documentation, the inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Evidence was available to show that incidents were discussed at the RSC and escalated to the QCGC as required, thus the undertaking had oversight of incidents in this Hospital.

The inspectors were also satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained. The inspectors noted that recent findings of an inspection at another one of the undertaking's sites had increased reporting of near miss incidents within the radiology department and the inspectors also noted that near miss and incident trending information was used to influence the clinical audit topics chosen by the undertaking which was seen as a positive use of incident trending to improve service quality.

Inspectors were satisfied that Galway Clinic implemented, encouraged and maintained an effective system to minimise the probability and magnitude of accidental or unintended exposures, and inspectors noted a positive culture of incident reporting had been implemented by the undertaking.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Galway Clinic OSV-0007393

Inspection ID: MON-0042962

Date of inspection: 23/10/2024

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018, as amended.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **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 person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe to* come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant
Outline how you are going to come into compliance with Regulation 6: Undertaking: All relevant policies have been updated to reflect clinical practice in relation to requesting and justification of medical radiological procedures. Relevant documents have been updated to include radiation therapists in the list of practitioners at the Galway Clinic. The workflow for some fluoroscopy examinations that previously were not signed off by a practitioner, is currently being updated and changed. This change will ensure that the name of the practitioner who is responsible for the clinical evaluation of the outcome of the procedure will be present on each report.	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: The workflow for some fluoroscopy examinations that previously were not signed off by a practitioner, is currently being updated and changed. This change will ensure that the name of the practitioner who is responsible for the clinical evaluation of the outcome of the procedure will be present on each report.	
Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures: Written protocols for all fluoroscopy procedures carried out in theatre are currently being compiled. The reports section of the Radiology Information System has been updated by the IT dept. so that information relating to patient exposure is now present on reports and is visible to all staff within the Hospital who view the reports.	

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/01/2025
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	31/01/2025

Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	31/12/2024
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	11/12/2024