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 Ltd
Address of Ionising Radiation Installation:	Doughiska, Galway
Type of inspection:	Announced
Date of inspection:	06 October 2021
Medical Radiological Installation Service ID:	OSV-0007393
Fieldwork ID:	MON-0033540

About the medical radiological installation:

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 7.30am -8.30pm, 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 and 2019. 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. Governance and management arrangements for medical exposures:

[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.

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 6 October 2021	10:00hrs to 15:30hrs	Lee O'Hora	Lead
Wednesday 6 October 2021	10:00hrs to 15:30hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

As part of this inspection, inspectors reviewed documentation and visited the interventional cardiology suite, computed tomography (CT) and general radiography department and spoke with staff and management. Inspectors found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures at the Galway Clinic.

Overall responsibility for the radiation protection of service users lay with the undertaking, Galway Clinic Doughiska Ltd. The hospital chief executive officer (CEO) was the undertaking representative. Reporting structures were well defined and clearly articulated to inspectors on the day of inspection. The Galway Clinic used a radiation safety committee (RSC), which reported to the CEO and undertaking via the patient safety executive and the allied health executive. Both the patient safety executive and the allied health executive reported to the CEO via the clinical governance committee. The Galway Clinic also used a quality and patient safety group which communicated radiation safety events directly to the CEO and undertaking board.

Inspectors reviewed terms of reference and minutes of the RSC and noted an absence of representation on the committee from one of the high dose areas in this facility. While some alternate pathways of communication did exist, ensuring attendance at the RSC of representatives from areas with high risk would enhance the undertaking's oversight of all areas using radiological equipment. Inspectors also noted that the undertaking may benefit from establishing the designated manager post at a level consistent with operational management of the entire service to include diagnostic imaging and radiation therapy.

Following review of documents and records, and speaking with staff, inspectors were assured that systems and processes were in place to ensure that only those entitled to act as referrers and practitioners, as defined in the regulations, did so in this facility. Inspectors found that all medical exposures took place under the clinical responsibility of a practitioner and the optimisation and justification process for all medical exposures involved the appropriate staff as required by the regulations. After speaking with staff, inspectors were satisfied that the practical aspects of medical imaging for cardiology and theatre fluoroscopy procedures were always shared between non-radiological specialists and radiographers, this arrangement provided assurances of the radiation protection of service users in the absence of nationally defined training requirements for non-radiological specialists. However, documentation should be updated to reflect the day-to-day practice with regard to the presence of a radiographer for medical radiological fluoroscopic procedures.

Inspectors reviewed documentation and spoke with staff regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. Evidence of professional registration and arrangements to ensure continuity of MPE expertise

was also supplied to inspectors. From the documentation reviewed, inspectors were assured that the level of MPE involvement was proportionate to the level of radiological risk at the installation and that the MPE took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

Notwithstanding the minor areas for improvement identified above, inspectors were satisfied that governance and management arrangements ensured the radiation protection of service users at the Galway Clinic.

Regulation 4: Referrers

Following review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were satisfied that the Galway Clinic only accepted referrals from appropriately recognised referrers. In line with the regulations, radiographers were also considered referrers in this facility and the specific circumstances in which radiographers could act as referrers were clearly outlined in local policies and articulated to inspectors by staff.

Judgment: Compliant

Regulation 5: Practitioners

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that the Galway Clinic had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Documentation reviewed by the inspectors outlined a clear allocation of responsibility for the protection of service users by the Galway Clinic. The Galway Clinic had a radiation safety committee (RSC), which met twice yearly and reported to the undertaking representative and undertaking via the patient safety executive and the allied health executive. Both the patient safety executive and the allied health executive reported to the undertaking representative by means of a weekly clinical governance committee where relevant radiation safety issues were discussed.

Inspectors were also informed that a separate communication pathway for radiation specific safety events via the quality and patient safety group and quarterly patient safety executive paper also ensured oversight of radiation safety incidents and near misses at the Galway Clinic.

Terms of reference and minutes from the last three meetings of the RSC, minutes of the clinical governance committee and a recent patient safety executive board paper were provided to inspectors. Inspectors reviewed attendance records for the last three RSC meetings and the absence of a representative from the interventional cardiology suite was noted. Although it was highlighted that the allied health executive sat on the cardiology users group and this served as an alternate communication pathway, attendance at the RSC of representatives from areas with potential high risk, such as interventional cardiology would enhance the undertaking's oversight of all areas using radiological equipment.

Inspectors noted that at the time of inspection the designated manager for the Galway Clinic was responsible for the operational management of the diagnostic imaging department only but was not engaged or responsible for the management of the entire medical radiological installation to include the radiotherapy department. As noted in HIQA's 'Undertaking information handbook', the designated manager should be engaged in and responsible for the day-to-day management of the medical radiological installation and the allocation of this responsibility at a level with oversight of the entire service would give further assurances of clear and appropriate allocation of responsibility for the protection of service users.

Notwithstanding these two areas for improvement, inspectors were satisfied that strong governance and oversight arrangements were employed by the undertaking to ensure the safe delivery of medical radiological exposures at the Galway Clinic.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From reviewing the documentation and speaking with staff at the hospital, inspectors found that all medical exposures took place under the clinical responsibility of a practitioner as defined in the regulations.

Following a review of documentation and a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were assured that the optimisation process involved the practitioner and the medical physics expert (MPE). Similarly, the justification process for individual medical exposures involved the practitioner and the referrer.

Inspectors were informed that for cardiology and theatre fluoroscopy procedures, the practical aspects of medical imaging were always shared between non-radiological specialists and radiographers. This arrangement was well described by staff to inspectors on the day of inspection, but the document *'Best practice when*

taking X-rays' suggested that radiographers' presence was not routinely required. In the absence of nationally defined training requirements on radiation protection for non-radiological specialists, the presence of a radiographer for all cardiology and theatre fluoroscopy procedures would provide better assurances of the radiation protection of service users. Documentation should be updated to reflect current practice in the Galway Clinic.

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 inspectors and the details were available in documents reviewed as part of this inspection. Inspectors noted that documents assigned responsibility for diagnostic imaging, including responsibility for radiation incident review and external reporting as required, to a single MPE. Inspectors were informed that continuity of this specific role was ensured by input, as required, from the RPA, who was also a registered MPE, an assigned MPE for nuclear medicine and a staff medical physicist who was completing MPE training. This arrangement provided assurances that the associated time bound responsibilities could be consistently addressed within specified time frames. Multiple appropriately qualified individuals were involved in the provision of radiation therapy MPE services ensuring continuity of expertise.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff at the hospital, inspectors were satisfied that the Galway Clinic had arrangements in place to ensure the involvement and contribution of MPEs was in line with the requirements of Regulation 20. MPE professional registration was reviewed by inspectors and was up to date.

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, inspectors established that the involvement of the MPE was both

appropriate for the service and commensurate with the risk associated with the service provided. Additionally, recent radiotherapy workload increases had been escalated to management and resulted in increased staffing resources. This ability to assess and address increased workloads, and associated risks, assured inspectors that the MPE service at the Galway Clinic was both commensurate and adaptive.

Judgment: Compliant

Safe Delivery of Medical Exposures

On the day of inspection, inspectors were satisfied that radiation protection processes implemented by the Galway Clinic ensured the safe and effective delivery of medical exposures.

Following review of a sample of referrals across a number of clinical areas, inspectors were assured that the Galway Clinic had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information and justified in advance by a practitioner. Information relating to the benefits and risks associated with the radiation dose from a range of medical exposures was readily available in both poster and pamphlet format throughout the radiology department on the day of inspection.

Information available to inspectors demonstrated that diagnostic reference levels (DRLs) were established, used and reviewed by the Galway Clinic. Records reviewed established that the Galway Clinic had systems and processes in place to ensure that the appropriate investigations and corrective actions were taken when local facility DRLs exceeded national levels. Inspectors noted that annual local facility DRL reviews investigated all deviations in patient dose routinely and accounted for year-on-year variations. In some cases, significant patient dose reductions were recorded and this was considered a positive use of patient dose reviews to optimise service user outcomes.

While inspectors were assured that written protocol and referral guideline regulatory requirements were in place, information relating to patient exposure did not consistently form part of the medical radiological procedure report.

Inspectors were satisfied that radiation safety specific audits were routinely undertaken, reviewed and findings communicated appropriately. Inspectors noted that the Galway Clinic also used the hospital's quality and patient safety group to ensure relevant radiation safety audits could be considered, acted upon and communicated on a hospital level. This was considered a positive use of existing structures to investigate and communicate radiation safety audits as necessary.

Inspectors reviewed records of acceptance and performance testing for all radiological equipment at the facility and were assured that the undertaking had implemented and maintained an extensive quality assurance (QA) program.

Inspectors were also assured that the undertaking had implemented a system that highlighted and addressed outstanding MPE QA. However, some equipment performance issues noted by MPE QA records had not been acted on at the time of inspection. In order to assure themselves that equipment is kept under strict surveillance, the undertaking should have systems and processes in place to address and record any equipment performance issues highlighted during the QA process.

Inspectors reviewed comprehensive records of incident capture, trending and analysis. The Galway Clinic had effective incident management systems in place satisfying requirements of Regulation 17, but also supporting regulatory compliance in relation to aspects of Regulations 6, 13 and 15. The Galway Clinic demonstrated a strong culture of quality improvement through safety event analysis.

Notwithstanding the areas for improvement noted, inspectors were assured by the processes and procedures in place to provide medical exposures to ionising radiation in this facility.

Regulation 8: Justification of medical exposures

Inspectors spoke to staff and reviewed a sample of referrals covering a number of clinical areas on the day of inspection including nuclear medicine, CT, interventional cardiology, mammography and general X-ray. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded. Staff spoken to on the day clearly and consistency articulated the mechanisms and processes used to record individual justification by a practitioner and that this always took place in advance of the exposure.

In line with Regulation 8, all referrals reviewed by inspectors on the day of inspection 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 risk of the medical exposure. Staff spoken to on the day consistently informed inspectors that previous diagnostic information was routinely sought to avoid unnecessary exposure and inspectors observed that the radiology information system used provided a platform to evidence this.

Inspectors visited the clinical area and observed multiple posters, both general and procedure specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. Pamphlet versions of similar information were also available to service users in the radiology department.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following review of documentation pertaining to DRLs, inspectors were satisfied that DRLs had been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. Inspectors visited the clinical area and observed multiple examples of local facility DRLs displayed in the clinical areas.

When a local facility DRL exceeded the national DRL, inspectors were provided with records of the investigation and corrective actions. Inspectors were satisfied that all regulatory requirements in relation to Regulation 11 were satisfied.

Records supplied to inspectors detailed local facility DRL year-on-year comparison. Where values deviated, the deviations were investigated and accounted for. Examples of patient dose reductions for embolisation procedures in the hybrid theatre and barium swallow procedures were noted. This was achieved by reducing fluoroscopy frame rate in both areas and was seen as a positive use of local facility dose information to review standard imaging protocols and subsequently reduce patient dose.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard radiological procedure carried out at the Galway Clinic were made available to inspectors. Staff spoken to in the clinical areas clearly articulated how these protocols were made available to them.

Inspectors spoke to staff and reviewed a sample of imaging reports in the CT and general X-ray departments. A sample of referrals and reports from the nuclear medicine and mammography departments were also reviewed. Information relating to patient exposure did not routinely form part of the report.

Inspectors were satisfied that the Galway Clinic ensured that referral guidelines were made available to all referrers. Staff spoken to on the day articulated a clear knowledge of these guidelines.

A number of clinical audits from both the radiotherapy and diagnostic imaging departments were available to inspectors to review. Clinical audit was a standing agenda point on the RSC minutes reviewed by inspectors. Diagnostic imaging audits and relevant results were displayed in the clinical area on the day of inspection. Inspectors were also informed that diagnostic imaging audits were discussed at a monthly diagnostic imaging staff meeting and evidence of the associated minutes of these meetings was reviewed by inspectors.

Inspectors were informed that radiation safety audits were also considered by the hospital's quality and patient safety group when appropriate. The relevant audits were communicated using the RSC and the patient safety executive. Inspectors were informed that the hospitals quality and patient safety group allowed relevant radiation safety audits to be considered, discussed and acted upon at a hospital level if required.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors reviewed records of acceptance and performance testing for all radiological equipment at the facility and were assured that the undertaking had implemented and maintained an extensive quality assurance program. Inspectors noted some annual MPE QA was outstanding at the time of inspection. Minutes of monthly MPE meetings had outstanding QA as a standing agenda point and inspectors were satisfied that the undertaking had a process in place to identify and address outstanding equipment QA.

However, inspectors noted that certain aspects of equipment performance noted in annual MPE reports had not been addressed at the time of inspection. For example, MPE testing carried out in January 2021 on a piece of radiological equipment suggested that certain parameters identified as being at remedial levels should be addressed by the manufacturer engineer. Inspectors reviewed the associated engineer's report, dated September 2021, which did not address the issues highlighted by the MPE QA and noted the same parameter tests as 'not applicable'. No other documentation or communication relating to this issue was available to inspectors. In order to assure themselves that equipment is kept under strict surveillance the undertaking should have systems and processes in place to address and record any issues highlighted during the QA process.

Judgment: Substantially Compliant

Regulation 15: Special practices

The Galway Clinic had mechanisms in place to ensure special attention was given to optimising medical exposures involving high doses to the patient. For example, inspectors reviewed policies and procedures utilised in the interventional cardiology department to identify potential high skin doses in patients undergoing cardiac interventional procedures. Inspectors were assured that systems were in place to monitor, identify and follow up patients who may be exposed to relatively high skin doses. Inspectors reviewed evidence of all stages of this process recorded using the hospitals digital incident management system and were satisfied that these

incidences were identified and followed up in line with the hospitals policy. This was seen as a positive use of the existing incident management software to record all stages of the process involved in the identification, follow up and subsequent outcomes associated with potential high patient skin doses.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied inspectors that the Galway Clinic had processes in place to ensure that all service users were asked about pregnancy status, where appropriate, by a practitioner and the answer was recorded. Staff articulated the process clearly to inspectors on the day of inspection and sample referrals reviewed by inspectors verified the consistent recording of the relevant information in line with local policies and procedures. Multilingual posters observed throughout the radiology department satisfied inspectors that the undertaking had taken measures to increase the awareness of individuals to whom this regulation applies.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The Galway Clinic used an electronic incident management system to record all radiation safety incidents, documents reviewed clearly outlined the process for reporting of incidents and this was consistently articulated by staff to inspectors. Organograms of the incident reporting and review process were displayed throughout the clinical areas visited on the day.

Inspectors were informed that all incidents and near misses are discussed at a weekly quality and patient safety (QPS) meeting, chaired by the patient safety executive. For incidents which require further investigation, the patient safety executive organised a subsequent review meeting with staff involved in the incident and relevant members of the local radiation incident panel. All incidents and near misses subsequently fed into the RSC and the quality and patient safety group via the patient safety executive. Documents reviewed clearly outlined that the quality and patient safety group had oversight and co-ordinated the investigations and analysis of near misses, adverse events and the implementation of corrective actions following such events.

Incident capture, trending and analysis records supplied to inspectors demonstrated a culture of quality improvement through safety event analysis at the Galway Clinic. Inspectors were satisfied that a comprehensive approach to the analysis and communication of all safety events at the Galway Clinic ensured that all accidental

and unintended exposures, significant events and near misses were subsequently used to minimise the probability and magnitude re occurrence.

Inspectors also reviewed an audit in relation to staff training and education around incident reporting in the radiotherapy department. A staff education drive undertaken between 2019 and 2020 resulted in a 312.5% increase in the number of radiation incidents and near miss events reported in the radiotherapy department alone. This demonstrated a positive culture of reporting and learning within the Galway Clinic.

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 and 2019. 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 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially 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-0033540

Date of inspection: 06/10/2021

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 and 2019.

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: Action 1 : Allied Health Executive with oversight of all Radiation services in both Limerick and Galway shall now be the designee manager on the HIQA portal Action 2: Full time RPO appointed and commencing January 2022. RSO for IR and Cardiology will be given protected time for meetings with RPO and RSC.	
Regulation 10: Responsibilities	Substantially Compliant
Outline how you are going to come into compliance with Regulation 10: Responsibilities: Action: Policy updated Procedure A- optimisation of general radiological procedures has been edited to reflect current practice "The practical aspects of a medical radiological procedure cannot be delegated to any person other than an individual deemed a practitioner (radiographer) and without prior approval by the RSC. A person therefore shall not carry out practical aspects of a medical radiological procedure unless he or she is a radiographer. Therefore a radiographer must be present for and take clinical responsibility for all cardiology, theatre and fluoroscopy procedures involving ionizing radiation".	

Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: Action: A project meeting was held on 8th October. Vendor notified and awaiting implementation date.	
Regulation 14: Equipment	Substantially Compliant
Outline how you are going to come into compliance with Regulation 14: Equipment: Action: MPE contacted Service Engineer to discuss QA findings. Follow up testing by engineer to be carried out to confirm results at earliest possible date. QA results to be confirmed before remedial action is undertaken. MPE roles and responsibilities in relation to substantial findings of routine QA and QC as set out in the Equipment Maintenance and Quality Assurance policy have been updated. These are to include discussion of substantial QA and QC findings and any follow up actions at Radiation Safety committee meetings.	

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	01/11/2021
Regulation 10(6)	An undertaking or practitioner shall not delegate practical aspects of a medical radiological procedure to a person other than	Substantially Compliant	Yellow	01/11/2021

	an individual referred to in paragraph (4).			
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	04/02/2022
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	14/12/2021