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:	Hermitage Medical Clinic
Undertaking Name:	Hermitage Medical Clinic
Address of Ionising Radiation Installation:	Old Lucan Road, Lucan, Dublin 20
Type of inspection:	Announced
Date of inspection:	21 July 2021
Medical Radiological Installation Service ID:	OSV-0007033
Fieldwork ID:	MON-0033537

About the medical radiological installation:

The Hermitage Medical Clinic is part of the Blackrock Healthcare Group which also includes Blackrock Clinic and Galway Clinic. The hospital has 112 inpatient beds, oncology, day-care, operating theatres, emergency, radiotherapy, cardiology and diagnostic imaging facilities. Consulting and dental suites are also located on the campus. Radiology perform approximately 60,000 imaging examinations per year with 25% performed on inpatients and 75% performed on outpatients. Radiology operates a seven day service with an on-call facility for general X-ray and computed tomography. Services provided by the radiology department include:

- General radiography, dental X-rays (orthopantography) and fluoroscopy
- Mobile radiography, theatre, wards and day surgery
- Computed Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Ultrasound
- Mammography
- Interventional Radiology
- Nuclear Medicine and Positron Emission Tomography (PET/CT)
- Radiography support for the interventional cardiology department.

The radiotherapy service provides CT simulation, treatment planning and treatment delivery, for patients undergoing external beam radiotherapy. CyberKnife services are also provided by the radiotherapy department.

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 21 July 2021	10:00hrs to 16:30hrs	Agnella Craig	Lead
Wednesday 21 July 2021	10:00hrs to 16:30hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

At the time of inspection, inspectors found leadership, governance and management arrangements were in place in the Hermitage Medical Clinic (HMC) which provided effective oversight of this facility.

The chief executive officer is the undertaking representative and the chairperson of the Radiation Safety Committee (RSC) who reports to the undertaking. Based on the RSC terms of reference, the membership of the RSC, and the minutes of the meetings, inspectors were satisfied that effective systems were in place to ensure oversight of the radiation protection of those using the medical radiological services in this facility. The designated managers are members of the RSC and are also members of two other committees where issues relating to radiation protection are discussed and managed. From reviewing the documents associated with these committees, speaking with staff and visiting two clinical areas, inspectors were satisfied that effective mechanisms were in place to ensure the safe conduct of medical exposures in this facility. However, it was noted that there was a lack of representation from one area involved in high radiological dose procedures. The undertaking should strive to ensure that representatives consistently attend the RSC meetings.

On the day of inspection, inspectors visited the radiotherapy department and the interventional cardiology department. Only those entitled to act as referrers and practitioners, as detailed in the regulations, were referrers and practitioners in this facility. However, although the allocation of responsibilities for the radiation protection of services users was known by staff who spoke with inspectors, documentation should be updated to explicitly detail the specific circumstances when personnel can act as referrers. Evidence that this facility had appropriate involvement from medical physics experts (MPEs) was available to inspectors and the level of involvement was relative to the level of risk posed by the services provided in this facility.

Notwithstanding the areas for improvement identified above which were discussed with and accepted by management staff on the day on inspection, inspectors were assured of the radiation protection of service users in this facility.

Regulation 4: Referrers

From the documentation reviewed and from speaking with staff, inspectors were assured that only those entitled to refer service users for medical exposures acted as referrers in this hospital. Samples of recent referrals for both radiotherapy and interventional cardiology procedures were reviewed on the day of inspection and inspectors noted that only radiation oncologists referred patients for radiotherapy

and referrals for cardiology procedures were from cardiologists. In line with the regulations, radiographers and radiation therapists are also considered referrers in this facility. Although satisfying the requirements of Regulation 4, the specific circumstances where radiographers and radiation therapists can act as referrers should be clearly outlined in local policies.

Judgment: Compliant

Regulation 5: Practitioners

From reviewing policies and guidance documentation and speaking with staff inspectors found that only those who are entitled to act as practitioners took clinical responsibility for medical exposures in this facility. A review of a sample of records in both the radiotherapy department and the interventional cardiology department was further evidence of compliance with this regulation.

Judgment: Compliant

Regulation 6: Undertaking

From reviewing documents in advance of this inspection, inspectors were informed of the governance structures in place for the radiation protection of service users within this facility. This included the use of a Radiation Safety Committee which met on a quarterly basis and was chaired by the chief executive officer who is also the undertaking representative. This committee had oversight of two committees relating to the radiation protection of service users which aimed to meet monthly; the Radiation Protection Governance Group (RPGG) and the Radiation Services Governance Group (RSGG).

The terms of reference for all three committees were provided to inspectors and details of the membership of these committees was noted to include representatives from all areas conducting procedures involving high dose medical exposures. Attendance records for the last four meetings were examined and inspectors noted the absence at the RSC meetings of a representative from one of the high dose areas in this facility. This lack of representation had also been recorded in the meeting minutes. Evidence that the undertaking, through the RSC, had already acted on this to ensure a consistent attendance of representatives from all areas involving high dose radiation procedures was subsequently provided.

The minutes from recent meetings listed the agenda items discussed at these meetings and these included equipment, quality assurance, optimisation, incidents, education and training, risk management, and audits.

Clear lines of responsibility were known by staff who spoke with inspectors on the day of inspection and the HMC had measures in place to ensure that only individuals, as defined in the regulations, were allocated the responsibilities of practitioners. Staff explained the specific circumstances where they can refer patients or adapt a referral. However, information about these specific situations and circumstances where staff, for example, radiographers and radiation therapists, can act as referrers should be clearly outlined in the documentation. Similarly, it is essential that the undertaking ensures the information held by HIQA is up-to date by providing details to HIQA in a timely manner. For example, changes to one of the designated managers in this facility was only formally identified to HIQA following the inspection. Furthermore, ensuring attendance at the RSC of representatives from areas with high risk such as interventional cardiology would provide further assurance to HIQA of the undertaking's oversight of all areas using radiological equipment. However notwithstanding these areas for improvement, inspectors were assured of the governance arrangements in place for radiation protection.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors found that all medical exposures took place under the clinical responsibility of a practitioner as defined in the regulations, with practitioner status assigned to some non-radiology consultants in the cardiology department. Inspectors were informed that clinical responsibility during interventional cardiology procedures is shared between cardiologists and radiographers, with both disciplines involved in all procedures involving medical exposures in the interventional cardiology department. This arrangement was both documented and described by staff to inspectors on the day of inspection. In the absence of nationally defined training requirements on aspects of radiation protection for non-radiology consultants, this arrangement provided assurance of the radiation protection of service users.

Evidence that practitioners and MPEs were involved in the optimisation process for medical exposures was available for review and further information in relation to this is detailed under Regulation 9.

Judgment: 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. In addition, evidence that this regulation had

been discussed at the RSC meeting and had been acted on to ensure the appropriate mechanisms were in place was also available to inspectors.

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 HMC had arrangements in place to ensure the involvement and contribution of MPEs was in line with the requirements of Regulation 20.

Judgment: Compliant

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

Mechanisms were in place to ensure that MPEs were appropriately involved in medical radiological procedures in this facility and this was in line with the level of radiological risk. MPEs were found to be appropriately involved in all aspects of medical exposure to ionising radiation conducted in both the radiotherapy and interventional cardiology departments.

Judgment: Compliant

Safe Delivery of Medical Exposures

This undertaking was found to have appropriate systems and processes in place to ensure the safe and effective delivery of medical exposures to ionising radiation. From visiting the interventional cardiology department and the radiotherapy department, inspectors were assured that the appropriate personnel assessed the benefits and risks of medical radiological procedures in advance of procedures and this justification was documented. A summary of the dose given to patients was also included in the patients' records and inspectors noted that information relating to patient exposure was included in the discharge letter produced for each patient.

Relevant documentation was provided to inspectors to demonstrate that a quality assurance (QA) programme was implemented and maintained and all quality assurance testing was up-to-date at the time of inspection. Evidence that the undertaking had also addressed a previous issue with respect to a backlog in QA testing was also available and demonstrated that the undertaking had strict

surveillance of the medical radiological equipment in this facility.

A good example of how undertakings can use DRL studies to ensure the safe delivery of medical exposures was seen in the optimisation studies carried out in this facility. These studies conducted for a number of procedure types had resulted in a reduction in dose while retaining image quality. Examples of the special attention that was given in the areas conducting high radiation dose procedures, such as radiotherapy and interventional cardiology, was also provided and is detailed under Regulation 15.

Although inspectors were satisfied with the processes in place for locally reporting accidental and unintended exposures, some gaps in the documentation of categories of incidents which are notifiable to HIQA were identified and discussed with staff. A review of the radiation incident policies is therefore required to ensure clarity in relation to notifiable incidents. Similarly, although compliant with Regulation 16, a review of the pregnancy policy is also required to ensure full alignment between the policy and the day-to-day practices in this facility.

Notwithstanding the required document updates, inspectors were assured by the processes and procedures in place that this service was providing safe medical exposures to ionising radiation in this facility.

Regulation 8: Justification of medical exposures

On the day of inspection, inspectors spoke with radiographers, radiation therapists and other practitioners who explained how medical exposures are justified in advance of a medical exposure. This included a review of the referral form by cardiologists in the interventional cardiology department and a review of the booking request form by the senior radiation therapist in the radiotherapy department. The justification process was also detailed in the document *'Justification Procedure for all Radiology Referrals'*. Information about the process of recording justification was also provided in both clinical areas visited on the day of inspection.

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. Information given to patients about the benefits and risks associated with radiation was described to inspectors and the consent form signed by patients was reviewed in a number of patients' records. Inspectors also observed that the provision of information leaflets is one of the tasks identified in the checklist for completion by radiation therapists for each patient.

Judgment: Compliant

Regulation 9: Optimisation

The document titled *'Optimisation and Management of Local Diagnostic Reference Levels'* was reviewed by inspectors in advance of the inspection. The primary focus of this policy was on the use of diagnostic reference levels (DRLs) to help keep the radiation dose received by patients as low as reasonably possible without impacting on the quality of diagnostic images. Roles and responsibilities of staff in relation to optimisation and DRLs was also included in this policy.

Details of proactive measures taken to optimise dose was documented in the minutes of the RSC meetings. This included the establishment of a number of working groups to examine optimisation, including a radiotherapy optimisation group, a general X-ray optimisation group for adult examinations, and a group to examine the optimisation of protocols for paediatric patients undergoing pelvic imaging. These working groups had succeeded in reducing the dose received by these patient cohorts, for example, the addition of filtration had resulted in a significant reduction in dose for paediatric patients.

In addition, the optimisation of medical exposures for patients undergoing radiotherapy was discussed with staff on the day of inspection. A further example of good practice included the involvement of a multidisciplinary team if any deviations from the standard protocols are required in order to optimise the radiotherapy dose. Inspectors were also satisfied that treatments were optimised by individually planning all exposures to the target area, while reducing the dose to nearby organs as much as possible. The method of imaging used to ensure the dose is delivered consistently was also explained and a report produced following a comprehensive optimisation project in radiotherapy was provided to inspectors.

From the evidence available, inspectors were assured that doses due to medical exposures were kept as low as reasonable without affecting the intended required outcome, and that the undertaking had taken comprehensive measures to reduce radiation dose where possible.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

From reviewing documents and speaking with staff, 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 facility. This included reviewing the DRLs for the pre-imaging scans used to plan the radiotherapy treatments.

Inspectors were provided with evidence that an extensive and in-depth analysis and optimisation study was conducted when the local DRLs were found to be greater

than the national DRLs for a number of procedure types in general radiography. One such example included details of a comprehensive optimisation study which had examined a number of specific procedures including abdomen, pelvic and lumbar spine radiographs. Metrics such as contrast to noise and signal to noise ratios were calculated and compared with previous imaging to assess image quality. This facilitated the undertaking to implement new optimised protocols with the assurance that the dose reduction had not affected the quality of the image and is a good example of how facilities should review local DRLs to optimise dose without negatively impacting on image quality.

Judgment: Compliant

Regulation 13: Procedures

Inspectors were informed that all protocols are available and are pre-programmed into the equipment in the cardiology department and this was verified by inspectors when they visited the clinical area. In radiotherapy, inspectors observed that the *'radiotherapy request form'* is linked to the relevant protocol and a *'quality checklist'* is then generated with the appropriate associated tasks.

From the patient reports viewed in both the cardiology and the radiotherapy departments, inspectors were satisfied that information relating to patient exposure was documented on the summary report in the patients electronic charts. This information was also included in the discharge letter produced for patients in both the radiotherapy and cardiology department.

The specific referral guidelines used in this facility were documented in the *'Radiation Safety Procedures for the use and application of Ionising Radiation at the HMC'* policy. In addition, the personnel with overall responsibility for selecting referral guidelines was also documented in this policy.

A number of clinical audits were available to inspectors to review and the process that is completed when clinical audits are conducted was explained to inspectors. Examples of recent clinical audits relevant to radiation protection conducted in the radiotherapy department included; a patient identification audit, radiotherapy planning scan diagnostic reference level audit, and an audit of the scan lengths used. Audits in relation to pregnancy status had been conducted in both the radiotherapy and the general diagnostic department. The general diagnostic department had also completed audits on referrals and had completed a plain film reject analysis. The patient dose in the interventional cardiology department was also audited.

Judgment: Compliant

Regulation 14: Equipment

From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation of a comprehensive quality assurance and performance testing programme. Equipment and QA were discussed at the RSC meetings and inspectors noted that a backlog in QA had been discussed and subsequently addressed by allocating specific responsibility and dedicated time to complete testing. From the inventory of equipment provided to inspectors and further documentation reviewed on-site, inspectors were assured that all QA was up-to-date at the time of inspection. Evidence was also available to show that any issues identified as part of the equipment services had been followed up in a timely manner.

Further evidence of equipment surveillance by the undertaking included the use of an assessment form which is completed for equipment in use beyond the suggested replacement date. Following an assessment of the equipment, a team comprising of an MPE, the clinical director, the service engineer and the manager of the relevant department declare if equipment is suitable for continued use and this completed form is then discussed by the RSC.

Inspectors enquired if any contingency plans were in place for older equipment and were informed of an informal agreement with another radiotherapy department should issues arise. A business plan for replacing equipment in the radiotherapy department had also been developed and was sent to the board of the overarching hospital to review. Inspectors were satisfied the equipment had passed the quality assurance testing and based on the evidence detailed above, the undertaking had appropriate processes in place to ensure ongoing oversight.

Judgment: Compliant

Regulation 15: Special practices

The Hermitage Medical Clinic had mechanisms in place to ensure special attention was given to optimising medical exposures involving high doses to the patient. For example, the interventional cardiology department used a high dose alert system to prompt practitioners if a procedure was reaching a pre-defined radiation dose threshold. Inspectors were informed that a record was made in the patient's chart if a threshold was reached during a procedure and information provided to patients on discharge. Patients were also routinely followed up by the cardiologist at their next appointment. Processes such as this allow undertakings to identify and record any tissue reactions following interventional radiology or interventional cardiology procedures thus facilitating undertakings to report significant events should they occur.

Other examples of the special attention given to high dose procedures such as

during radiotherapy included the use of the local RSGG to discuss any deviations from protocol for individual patients. In addition, from reviewing the DRLs in the CT scanning rooms, the CT scanner with lower DRLs was used for all patients' pre-treatment scans before undergoing CyberKnife procedures.

Special attention was also given to paediatric patients as inspectors were provided with a report of the optimisation study completed for paediatric patients undergoing pelvic imaging which resulted in a decrease in the dose required for imaging this patient group.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were available in public places such as waiting areas and entry into the cardiology procedure room.

In the radiotherapy department, in line with the regulations, both the radiation oncologists and the radiation therapists took responsibility for inquiring about and recording pregnancy status. From samples of records reviewed on the day of inspection, inspectors saw evidence that pregnancy status is checked at the initial referral stage, before the pre-treatment planning scan and again before the first radiation treatment. However, even though the hospital policy stated that chemotherapy cannot be used as a reason to rule out pregnancy, staff had accepted chemotherapy as a reason to rule out the possibility of pregnancy in some of the records reviewed. Therefore, the practice was not in line with the pregnancy policy in this facility.

Although compliant with the requirements of this regulation, a review of the accepted rationale to rule out pregnancy is recommended along with a review of the current practice to ensure alignment.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents in advance of this inspection, 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 appropriate committee level within the facility and subsequently reported to the RSC, thus the undertaking had

oversight of incidents in this facility. Staff informed inspectors of the electronic system used to record accidental or unintended exposures and near-miss events, which are then reviewed by senior staff who determine if the incident is deemed reportable to relevant agencies, including HIQA.

Inspectors also reviewed two policies relevant to incident reporting. These policies titled *'Reporting of radiation incidents'* and *'Management of incidents, near-miss events and non –conformances in radiotherapy'* had detailed the processes in place should an incident or near-miss relating to medical exposures occur. Inspectors noted some gaps in the documentation for example, a number of significant event categories relevant to potential incidents that can occur in radiotherapy were not included in the radiotherapy policy document. This was discussed with staff on the day of inspection and although there were no examples of notifiable incidents which had not been reported, staff acknowledged that this omission could potentially result in some incidents not being reported to HIQA as required by the regulations.

Although a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained, this needs to be reviewed to ensure it appropriately represents all categories of incidents that are notifiable and that staff are aware of all categories relevant to the area they work in.

Judgment: Substantially 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	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	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	Substantially Compliant

Compliance Plan for Hermitage Medical Clinic OSV-0007033

Inspection ID: MON-0033537

Date of inspection: 21/07/2021

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: Lack of representation from one of the high dose areas in this facility (Interventional Cardiology). Action: Cathlab staff member to attend the RSC in 24th September 2021. Cath Lab manager has confirmed that a member will attend RSC meetings in the future. Information about these specific situations and circumstances where staff, for example, radiographers and radiation therapists, can act as referrers should be clearly outlined in the documentation. Action: Appendix 1, section "Referrer" page 34 in the main Radiation Protection policy (HMC-MP-RSPP-01) – V16 is amended to add the specific situations and circumstances where Radiographers and Radiation therapists can act as referrers. The amended draft (Version 17) will be circulated to relevant staff for approval in the next RSC on 24th September 2021. The approved HMC-MP-RSPP-01-V17 will be circulated to the relevant clinical staff within Radiology and Radiotherapy. HMC will ensure HIQA are informed in a timely manner when there is a change in designated manager so HIQA have the most up-to-date information available. A standing agenda item will be added to the monthly RSGG regarding HIQA portal updates.	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events: Gaps in the documentation.	

Action: The two policies: (Reporting of radiation incidents – HMC-MP-RSPP-26) and (Management of incidents, near-miss events and non –conformances in radiotherapy – HMC-RTD-QM-1) are amended based on HIQA stage 1 report recommendations. The draft will be circulated and approved in next RSGG and RSC 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	24/09/2021
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of	Substantially Compliant	Yellow	24/09/2021

	events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,			