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:	Cavan General Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Cavan, Cavan
Type of inspection:	Announced
Date of inspection:	16 October 2024
Medical Radiological Installation Service ID:	OSV-0007350
Fieldwork ID:	MON-0036809

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

Cavan Monaghan Hospital has a catchment population of over 120,000 people covering Counties Cavan and Monaghan, and parts of Counties Longford, Leitrim, and Meath. Cavan Monaghan Hospital provides a range of acute medical, surgical, obstetric, and gynaecological, paediatric services, day care, outpatient, diagnostic and support services. Emergency services are provided on a 365-day, 24 hour basis. Cavan General Hospital has a total in-patient bed complement of 255 and 102 day beds.

In Cavan Hospital, some 48,000 examinations are performed annually that use ionising radiation for a medical diagnostic purpose. The radiology department delivers diagnostic tests via the following modalities, MR, CT, X-ray, Dental, ultrasound and Interventional radiology. A governance structure for radiation protection is facilitated by both the local implementation group and the Radiation Safety Committee, that report up to the Diagnostic Imaging Clinical Governance Committee, the Hospital General Manager and ultimately the HSE as the undertaking.

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 16 October 2024	09:15hrs to 14:55hrs	Margaret Keaveney	Lead
Wednesday 16 October 2024	09:15hrs to 14:55hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the radiological services at Cavan General Hospital on 16th October 2024, to monitor the services' compliance with the regulations. While it was evident that the undertaking, who is the Health Service Executive (HSE), had many good radiation protection measures in place, some improvements were required to ensure full compliance with Regulations 6, 10 and 13. This is further discussed throughout this report.

The radiology department in Cavan General Hospital consists of two computerised tomography (CT) units, two general X-ray units, three mobile X-ray units, an interventional radiology and fluoroscopy unit and a dental orthopantomogram (OPG) unit, that provide medical exposures of ionising radiation to both in-patients and out-patients referred by in-house and external medical practitioners, appropriately trained advanced nurse practitioners (ANPs) and dentists.

Inspectors were assured that the undertaking had effective governance and management arrangements in place, to oversee the safe delivery of medical exposures in the radiology service in Cavan General Hospital. The undertaking had established a Radiation Task Force (RTF) which met every three months to discuss radiation protection matters such as the equipment quality assurance (QA) programme, the review of diagnostic reference levels (DRLs) and any incidents that had occurred in the radiology service. The RTF membership comprised of radiology service managers (RSMs), radiation safety officers (RSOs) and was chaired by a medical physics expert (MPE). The RTF fed into the undertaking's Radiation Safety Committee (RSC), which met twice annually to further discuss items raised at the RTF meetings, and other matters such as clinical audit and regulatory compliance requirements. The RSC meetings were chaired by a nominated consultant radiologist lead, and were attended by, amongst others, the General Manager of Cavan General Hospital, MPEs, RSMs, RSOs and a representative from the Quality and Patient Safety Department.

Inspectors noted that matters discussed at the RSC were subsequently discussed at meetings of the Diagnostic Imaging Clinical Governance Committee, and that newly developed and revised documents, relating to the radiology service, were also discussed and approved by this group. The General Manager (GM) of Cavan General Hospital was also the Designated Manager of the radiology service, and from a review of meeting minutes it was noted that they attended both the RSC and Diagnostic Imaging Clinical Governance Committee meetings, and thereby were informed of all radiation protection matters in the service. On the day of the inspection, inspectors were informed that although changes to HSE structures were in progress, Cavan General Hospital remained part of the HSE RCSI North East Hospitals Group, and the GM of the service met monthly with the senior management team of this group to inform the undertaking of any radiation protection matters in the service.

A sample of radiological procedures records were reviewed by inspectors during the inspection and showed that appropriate persons as per the regulations were involved in referring and justifying medical exposures completed at the service. Inspectors were also satisfied that, in instances where clinical responsibility for medical exposures was clearly allocated, only those entitled to act as practitioners, as defined in Regulation 5, were taking such clinical responsibility in the service. Although many of the roles and responsibilities relating to radiation protection had been allocated within the service, the inspectors identified that action was required to clearly allocate roles and responsibilities of staff working in the service, when completing a sub-set of medical exposures. This is further discussed under Regulations 6 and 10 within this report.

MPE involvement in the service was determined to be proportionate to the radiological risk posed by the service, and the undertaking had robust arrangements in place to assure the continuity of this service. Inspectors were also informed that the MPE team had provided practitioner staff with regular radiation protection training, which could be frequently completed by staff members as required. These arrangements were identified as areas of good practice within the service.

Notwithstanding the gaps in compliance under Regulations 6, 10 and 13, inspectors were assured that service users were receiving a safe radiological service at Cavan General Hospital.

Regulation 4: Referrers

From discussions with staff and a review of a sample of medical exposure records, inspectors were satisfied that referrals for medical radiological procedures were only accepted from persons, as defined in Regulation 4.

In the radiology department of Cavan General Hospital, medical practitioners and dentists were allocated the role of referrer, while radiographers, as referrers, could make adapted and secondary referrals in the service. Inspectors also noted that hospital approved advanced nurse practitioners could act as referrers for specific general X-ray procedures.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that the undertaking had systems in place to ensure that only appropriately qualified individuals were considered practitioners at Cavan General Hospital, namely radiologists and radiographers.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors were satisfied that the undertaking had established governance and management arrangements, which provided oversight of the radiology service at Cavan General Hospital.

As discussed under Regulations 4, 5 and 20 in this report, individuals allocated with roles and responsibilities met the regulatory requirements. However, despite these arrangements, inspectors noted that action was required to ensure that all aspects regarding the allocation of responsibility aligned with the regulations, and were documented in the relevant documentation. For example, from a review of service user's records on medical exposures, inspectors noted that for a sub-set of fluoroscopy exposures completed in the service, the undertaking had not allocated responsibility for the evaluation of the clinical outcome of the exposure to a practitioner. This is further discussed under Regulation 10: Responsibilities below.

From a review of documentation, inspectors also noted that the document quality management system in the radiology department required action. For example, a significant number of written protocols for standard medical radiological procedures had not been reviewed and approved within the timeframe specified by the management team. Inspectors also noted that although some of these protocols had been revised, both the unapproved versions and the older approved versions were available to staff in the clinical area. This resulted in some staff who spoke with inspectors being unclear on which protocol version to adhere to. An effective document management system is a key element in the radiation protection of service users.

While improvements were required in the allocation of roles and responsibilities in some areas of the service, and in the documentation to support staff in these roles, inspectors were satisfied that many good processes were in place to ensure that service users, in the radiology department of Cavan General Hospital, received safe exposures of ionising radiation.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Practitioners and the MPE team were found to be involved in the optimisation of medical exposure to ionising radiation. In addition, inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures as required by Regulation 10.

Inspectors noted that the majority of medical exposures, including general X-ray, CT and some fluoroscopy exposures took place under the clinical responsibility of a practitioner as defined in the regulations. However, from discussions with the management team, a review of the documented roles and responsibilities and a review of radiology reports, inspectors noted that a sub-set of fluoroscopy medical exposures did not take place under the clinical responsibility of a practitioner, specifically the clinical evaluation of the outcome of these exposures. Inspectors found that the undertaking must take action to ensure that all aspects of clinical responsibility are allocated to a practitioner as per Regulation 10(1).

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that there were arrangements in place to ensure the continuity of medical physics expertise at the hospital. This arrangement was outlined in a service level agreement, which was provided to inspectors.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that the involvement and contribution of the MPE, in the radiology department of Cavan General Hospital, met the requirements of this regulation.

A review of documentation and discussions with staff demonstrated that the MPE team were involved in the quality assurance and acceptance testing of medical radiological equipment, patient dosimetry and in the dose calculation and review of radiation incidents. They were also involved in dose optimisation, for example by the review and sign off of facility diagnostic reference levels (DRLs). Inspectors also noted that a member of the MPE team attended the meetings of committees established in the service to provide oversight of the radiation protection of service users for example, the RSC and the Diagnostic Imaging Clinical Governance Committee.

An MPE had been assigned the role of Radiation Protection Advisor in the service, which met the requirements of Regulation 20(3).

Judgment: Compliant

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

From documentation viewed and discussions with the MPE and staff, inspectors were satisfied that the level of MPE involvement in the radiology department was commensurate with the radiological risk posed by the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

From discussions with staff and a review of documentation, inspectors saw that the undertaking was committed to the radiation protection of service users. This was achieved, amongst other ways, by the use and regular review of diagnostic reference levels (DRLs), the analysis and trending of all actual and potential incidents involving medical exposures that occurred in the service, and the introduction of a clinical audit programme. However, inspectors noted that action was required by the undertaking to achieve full compliance with Regulation 13(2), as dose information was not available on the patient reports for one sub-set of fluoroscopy exposures completed in the service. This is further discussed under Regulation 13 below.

During the inspection all referrals reviewed by inspectors were in writing, stated the reason for the request and were accompanied by sufficient medical data to allow the practitioner to consider the benefits and the risk of the medical exposure. The justification of medical exposures in advance, by a practitioner, was evident for the sample of medical radiological procedures reviewed by inspectors over the course of the inspection.

Inspectors were satisfied, from a review of documentation, that local DRLs had been established, regularly reviewed and were used for all medical radiological procedures conducted in the service. It was also noted that where additional reviews of DRLs were required, such reviews were promptly completed by the multidisciplinary team in the radiology department.

From a review of an up-to-date inventory of equipment and QA reports, inspectors were satisfied that there was an appropriate QA programme in place in the service. Inspectors saw from a review of RSC meeting minutes that quality assurance and equipment replacement programmes were routinely discussed at these meetings. During discussions with the management team, inspectors were also assured that there was appropriate oversight arrangements in place to ensure that regular performance testing was completed within the planned timeframes.

Inspectors were assured that there was a process in place to determine the pregnancy status of service users, where relevant. From a review of service user

records and clinical audits of this process**,** inspectors were assured that the process was safe and effective.

The management team had made good efforts to create a culture of incident awareness and reporting in the service. Inspectors reviewed records that evidenced that there were good arrangements in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation, and radiology staff received regular feedback on all actual and potential incidents through frequently issued newsletters and staff meetings.

Overall, inspectors were satisfied that the undertaking had good systems and processes in place to ensure the safe delivery of medical radiological exposures to service users in Cavan General Hospital.

Regulation 8: Justification of medical exposures

Inspectors reviewed a sample of written referrals on the day of the inspection and noted that each was in writing, stated the reason for requesting the particular procedure and was accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment.

Inspectors also noted that there was a process in place to ensure that medical exposure procedures were justified in advance by practitioners, and this process was outlined in *Vetting and Justification of Radiology Examinations Policy for Referrers & Practitioners* to guide and support staff. A sample of records were viewed by inspectors, and evidenced that this justification process had been completed.

Information in relation to the benefits and risks associated with radiation was available to service users undergoing medical exposures on posters in service user waiting areas. There were information posters specific to each of the imaging modalities in use in the service, for example CT and general X-ray, and inspectors noted that the management team had made good efforts to ensure that this information was presented in a way that it could be easily understood by service users.

In order to monitor compliance with the justification process, the management team in Cavan General Hospital had included the process of justification in the local audit programme, and this was noted as an example of good practice in the service.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

For each imaging modality within the radiology department, inspectors observed that DRLs for common procedures were displayed in the console areas. These DRLs were reviewed in February 2024 and, where available, compared to national DRLs. Inspectors also noted that DRLs had been established for some examination types, and compared to international levels where national DRLs were not available. This was identified as good practice in the radiation protection of service users within the service.

Within the radiology service, there was a multi-disciplinary approach to the review of DRLs, with reviews and actions discussed at the local RSC. Inspectors also noted that, where necessary, further prompt reviews of DRLs were completed and corrective actions implemented to ensure that all DRLs were below national recommended levels.

The management team had developed a policy titled *Establishment and Review of Diagnostic Reference Levels*, which outlined the roles and responsibilities for establishing and reviewing the DRLs for each imaging modality in use in the service.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at Cavan General Hospital for standard radiological examinations as required by Regulation 13(1). A version of these protocols was readily available to practitioners in the clinical areas, however as discussed under Regulation 6, action was required to ensure that the most up-to-date version was approved in a timely manner and subsequently made available to staff.

Inspectors noted that referral guidelines were available to referrers and practitioners as required by Regulation 13(3). In addition, inspectors noted the hospital's management team had recently implemented a clinical audit programme in the radiology service that was in line with the *National Procedures for Clinical Audit of Medical Radiological Procedures* issued by HIQA. This programme included the development of a clinical audit strategy which considered the nine principles and essential criteria that undertakings must consider when developing their clinical audit strategy. The programme had also identified appropriate governance and management structures for clinical audit and had allocated specific resources to ensure that the programme was implemented and maintained. Inspectors were informed of audit topics that had been identified, and saw that they were in line with the level of radiological risk within the service.

Inspectors reviewed a sample of reports for general X-ray, CT and video fluoroscopy and found that information relating to the patient exposure formed part of the report for each modality, with the exception of a particular cohort of the fluoroscopy records reviewed. The undertaking, the Health Service Executive, should ensure that

information relating to the patient exposure forms part of the report of all medical radiological procedures to ensure full compliance with Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment in the service and saw that a quality assurance programme for the equipment had been established and implemented. This included annual testing by the MPE and manufacturer's engineers. It also included regular performance testing by the radiography team. Inspectors were also informed that regular QA testing for the CT units had been reviewed and that a monitoring system was in place to ensure that it was completed as planned. This monitoring of the QA programme was identified as an area of good practice within the service.

There were records available which evidenced that acceptance testing for all radiological equipment had been completed, by the MPE team, before the first use for clinical purposes. Inspectors were also informed of the monitoring system in place to ensure that as radiological equipment reached a defined age, its clinical performance was more closely considered by the multidisciplinary team at the RSC, and a decision made on the time frame within which to replace the equipment. Inspectors noted that the equipment age, as outlined in the *Radiation Safety Procedures*, at which this discussion was triggered required review to ensure that it aligned with the practice in the service.

Notwithstanding this review, inspectors were satisfied that the undertaking had arrangements in place to ensure that all medical radiological equipment in use in the service was kept under strict surveillance regarding radiation protection.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors were satisfied that there was an effective process in place in the service to determine the pregnancy status of service users, and that this process was documented in the *Pregnancy Status Declaration Policy*. Inspectors noted that the policy contained clear and concise flowcharts on the process to be followed for both low and high dose radiological procedures, and that these flowcharts were on display in the relevant console areas to guide and support staff. The development and use of these flowcharts was identified as an area of good practice within the service.

Within the service, practitioners were appropriately assigned responsibility for inquiring on and recording patients' pregnancy status, where relevant. The responses to these inquiries were recorded on declaration forms, which also contained information on risks of radiation to an unborn child. Inspectors noted that special efforts had been made to enhance the radiation protection of all services users by developing these forms in a large number of languages. This was also identified as an area of good practice within the service.

Inspectors observed that a number of notices, some in a variety of languages, were displayed in service user waiting areas and service user changing rooms, to raise awareness of the special protection required during pregnancy in advance of a medical exposure to ionising radiation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed a *Reporting of Radiation Incidents and Near Misses* policy which outlined the process for reporting and managing actual or potential unintended medical exposures to ionising radiation. Throughout the clinical area, staff who spoke with the inspectors were able to describe this process, which included details on the requirement to notify HIQA of certain significant events.

There was a system in place to record, analyse and categorise incidents involving medical exposures, with evidence that these incidents and corrective actions were subsequently discussed at the RSC and Diagnostic Imaging Clinical Governance meetings. Inspectors also noted that there was a positive culture of reporting near misses in the service, and that trending and analysis of these events was completed by management staff in conjunction with the hospital's Quality and Patient Safety Department. Inspectors were informed that staff received updates on the details and corrective actions for incidents and near misses through a *Radiation Safety Newsletter* and staff meetings.

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 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Cavan General Hospital OSV-0007350

Inspection ID: MON-0036809

Date of inspection: 16/10/2024

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: • Report template for a sub-set of fluoroscopy medical exposures to be built on PACS system (estimated to be complete within 4 weeks). • Dose report will be added to diagnostic report for a sub-set of fluoroscopy medical exposures with immediate effect once the report template has been built by the PACS manager (estimated to be complete within 4 weeks). • The responsibility for the clinical outcome of the exposure for a sub-set of fluoroscopy medical exposures will be allocated to appropriate practitioners with immediate effect once the report template has been built by the PACS manager (estimated to be complete within 4 weeks). • PPPG for a sub-set of fluoroscopy medical exposures to be developed within a 4 week period that identifies the responsibility for clinical outcome of the exposure for a sub-set of fluoroscopy medical exposures as one that is allocated to appropriate practitioners. This PPPG will be presented to Diagnostic Imaging Governance Committee for approval within a 3 month period (5th March 2024). DOCUMENT QUALITY MANAGEMENT SYSTEM (DQMS) • By way of response a DQMS is to be established within the Department of Radiology for Cavan Monaghan Hospital. Work on this will begin with immediate effect and will be completed within three calendar months. The DQMS will include • A database of all PPPG and other relevant time bound documentation held by the Department of radiology for Cavan Monaghan Hospital • A traffic light function that identified when a document or PPPG is due for updating 3 months in advance of its renewal date. This will allow sufficient time for the document to be updated and submitted to the next Diagnostic Imaging Governance Committee meeting. CT AND IR PROTOCOLS • CT and IR protocols have been amended, updated, circulated for comment as of now • Their content of all these documents has separated adult and paediatric scanning practices.	

• The protocols are being presented to the Diagnostic Imaging Governance Committee for discussion and approval on the 4th December 2024.

Regulation 10: Responsibilities	Substantially Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
• Report template for a sub-set of fluoroscopy medical exposures to be built on PACS system (estimated to be complete within 4 weeks).
• Dose report will be added to diagnostic report for a sub-set of fluoroscopy medical exposures with immediate effect once the report template has been built by the PACS manager (estimated to be complete within 4 weeks).
• The responsibility for the clinical outcome of the exposure for a sub-set of fluoroscopy medical exposures will be allocated to appropriate practitioners with immediate effect once the report template has been built by the PACS manager (estimated to be complete within 4 weeks).
• PPPG for a sub-set of fluoroscopy medical exposures to be developed within a 4-week period that identifies the responsibility for clinical outcome of the exposure for a sub-set of fluoroscopy medical exposures as one that is allocated to appropriate practitioners. This PPPG will be presented to Diagnostic Imaging Governance Committee for approval within a 3 month period (5th March 2024)

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
• Report template for a sub-set of fluoroscopy medical exposures to be built on PACS system (estimated to be complete within 4 weeks).
• Dose report will be added to diagnostic report for a sub-set of fluoroscopy medical exposures with immediate effect once the report template has been built by the PACS manager (estimated to be complete within 4 weeks).
• The responsibility for the clinical outcome of the exposure for a sub-set of fluoroscopy medical exposures will be allocated to appropriate practitioners with immediate effect once the report template has been built by the PACS manager (estimated to be complete within 4 weeks).
• PPPG for a sub-set of fluoroscopy medical exposures to be developed within a 4 week period that identifies the responsibility for clinical outcome of the exposure for a sub-set of fluoroscopy medical exposures as one that is allocated to appropriate practitioners. This PPPG will be presented to Diagnostic Imaging Governance Committee for approval within a 3 month period (5th March 2024).

DOCUMENT QUALITY MANAGEMENT SYSTEM (DQMS)

• By way of response a DQMS is to be established within the Department of Radiology for Cavan Monaghan Hospital. Work on this will begin with immediate effect and will be completed within three calendar months. The DQMS will include

• A database of all PPPG and other relevant time bound documentation held by the Department of radiology for Cavan Monaghan Hospital

• A traffic light function that identified when a document or PPPG is due for updating 3 months in advance of its renewal date. This will allow sufficient time for the document to be updated and submitted to the next Diagnostic Imaging Governance Committee meeting.

CT AND IR PROTOCOLS

• CT and IR protocols have been amended, updated, circulated for comment as of now

• Their content of all these documents has separated adult and paediatric scanning practices.

• The protocols are being presented to the Diagnostic Imaging Governance Committee for discussion and approval on the 4th December 2024.

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	05/03/2025
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Substantially Compliant	Yellow	05/03/2025

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	05/03/2025