



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	St Columcille's Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Loughlinstown, Dublin 18
Type of inspection:	Announced
Date of inspection:	04 July 2023
Medical Radiological Installation Service ID:	OSV-0007375
Fieldwork ID:	MON-0039934

About the medical radiological installation:

St Columcille's Hospital provides services to a diverse population covering South County Dublin and County Wicklow. In 2013, the hospital was designated a Model 2 Hospital and it currently has 118 hospital beds. Inpatient services include general medicine, care of the elderly, stroke rehabilitation, and orthopaedic rehabilitation. An endoscopy unit and a memory resource room are available, in addition to the following services; cardiac rehabilitation, weight management, out-patient, antenatal and gynaecology. St Columcille's Hospital has a national specialty in obesity management and is a referral centre for bariatric surgery. It is also the site for the National Gender Service.

The St Columcille's Hospital Radiology Department provides diagnostic imaging services for in-patients, local Injuries Unit (>14yrs) patients / Medical Assessment Unit (>16yrs) patients, OPD of the Hospital and for GP patients in the South Dublin and Wicklow region. The radiology department is equipped with the following imaging modalities: - general and mobile X-ray - fluoroscopy - computerised tomography (CT) - DXA Scanning.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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
Tuesday 4 July 2023	09:00hrs to 14:30hrs	Margaret Keaveney	Lead
Tuesday 4 July 2023	09:00hrs to 14:30hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Inspectors completed an inspection of the radiological services at St. Columcille's Hospital on 4th July 2023, to follow up on the compliance plan of the previous inspection carried out during February 2020, and to monitor the service's ongoing compliance with the regulations. It was evident that, since the previous inspection, the undertaking, who is the Health Service Executive (HSE), had taken action to address and progress compliance with the regulations.

The radiology department in St. Columcille's Hospital consists of a computerised tomography (CT) unit, a general X-ray unit, three mobile X-ray units, a fluoroscopy unit and a DXA unit, that provide medical exposures of ionising radiation to both in-patients referred by in-house medical practitioners and to out-patients attending the hospital's injury unit and the medical assessment unit, and others referred by external medical practitioners.

Inspectors were assured that the undertaking had effective governance and management arrangements in place to facilitate the safe delivery of medical exposures at the hospital. The undertaking had established a Radiation Safety Committee (RSC), which met twice annually to discuss items such as diagnostic reference levels (DRLs), the quality assurance programme for equipment, incidents, clinical audit and training. The meetings were chaired by a nominated consultant radiologist, and were attended by, amongst others, the General Manager of St. Columcille's Hospital, Medical Physics Experts (MPEs), the Radiation Protection Officer (RPO), the Acting Radiology Services Manager and the Quality and Risk Manager.

Inspectors observed that staff had completed a range of clinical audits to identify areas of good practice, and areas requiring action to ensure the safe delivery of medical radiological exposures to service users. There was also a good document control system in place for policies, procedures, protocols and guidelines (PPPGs) used in the radiology department, and all PPPGs reviewed by inspectors had been reviewed and approved by a multi-disciplinary team, and were within their specified review dates. Inspectors were also informed that the MPE team had provided all staff with online access to a radiation protection course, which could be frequently completed by staff members as required. These arrangements were identified as areas of good practice within 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 only those entitled to act as practitioners, as defined in Regulation 5, were taking clinical responsibility for medical exposures in the service.

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.

Overall, inspectors were assured that service users were receiving a safe radiological service at St. Columcille's Hospital.

Regulation 4: Referrers

From discussions with staff and the sample of records of medical exposures reviewed on the day of inspection, inspectors was satisfied that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at this service.

In St. Columcille's Hospital, medical practitioners and dentists had been allocated the role of referrers, while radiographers as referrers could make adapted and secondary referrals. Hospital approved nurse prescribers could also act as referrers for a limited number of general X-ray procedures.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at St. Columcille's Hospital.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed governance structure and documentation and an organogram (organisation chart) which clearly outlined the allocated roles and responsibilities for the radiation protection of service users within St. Columcille's Hospital.

St. Columcille's Hospital has established a number of forums at local level to ensure that there was adequate oversight of the radiological services in the hospital. A Radiation Safety Committee (RSC) had been established and met at least twice yearly. The committee was chaired by a consultant radiologist, and meetings were attended by the acting RSM, the RPO, MPE staff and the Quality and Risk Manager and the General Manager of the hospital. Inspectors reviewed a sample of meeting minutes and noted that standing agenda items included, amongst others, DRLs, the

equipment QA and replacement programme, clinical audit, radiation safety incidents, dose optimisation and staff training.

Inspectors were also informed that the chair of the RSC reported any radiation safety matters to the chair of the local Clinical Governance Committee, for discussion and information sharing purposes at their meetings. Inspectors were also informed that the Quality, Safety and Risk Department in St. Columcille's Hospital supported the document management and incident management systems in the hospital's radiology department.

The general manager of St Columcille's Hospital had been allocated the role of designated manager (DM) for the service, and inspectors saw that they attended the local RSC meetings, and also chaired the hospital Quality, Safety and Risk committee meetings. This gave the DM oversight of radiation safety issues in St Columcille's Hospital, and enabled them to adequately inform the HSE, the undertaking, of any such issues. The DM reported to the undertaking via the Chief Operations Officer of the Ireland East Hospital Group, which is the hospital group that oversees St. Columcille's Hospital. This reporting structure had been established as a compliance action following the previous inspection in February 2020.

Judgment: Compliant

Regulation 10: Responsibilities

On the day of the inspection, inspectors were satisfied that all individual medical exposures took place under the clinical responsibility of a practitioner, as defined in the regulations. From a review of documents and discussions with staff, inspectors observed that radiologists and radiographers were allocated the role of practitioner in the service.

There was also evidence that practitioners and MPEs were involved in the optimisation of medical exposures. Inspectors were provided with examples of optimisation by members of the multidisciplinary team, which included the ongoing refinement of equipment parameters to ensure that the dose delivered to service users was as low as reasonably achievable.

Inspectors also observed that only those recognised as practitioners conducted medical exposures at St. Columcille's Hospital.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and reviewing documentation that there were arrangements in place to ensure the continuity of medical physics expertise at the hospital.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that the involvement and contribution of MPE in the service met the requirements of this regulation.

Inspectors noted that the MPE was responsible for dosimetry and gave advice on medical radiological equipment. 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 advising on radiation incidents. They were also involved in dose optimisation, for example by the review and sign off of facility diagnostic reference levels (DRLs). An MPE had been assigned the role of Radiation Protection Advisor in the service, and attended the RSC meetings.

Judgment: Compliant

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

From documentation viewed and discussions with the MPE and management staff, inspectors were satisfied that the level of MPE involvement in medical radiological practices 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 improving the radiation protection of service users by ensuring that medical radiological procedure doses were kept as low as reasonably achievable. This was achieved, amongst other ways, by the use and regular review of diagnostic reference levels (DRLs), strict surveillance on the performance of equipment and the analysis and trending of all actual and potential incidents

involving medical exposures that occurred in the service.

All referrals reviewed by inspectors during the inspection were 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. The justification of medical exposures in advance, by a practitioner, was evident for 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.

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, which included the QA of calibration equipment used by the MPEs. Inspectors saw from a review of RSC meeting minutes that quality assurance and equipment replacement programmes were routinely discussed at these meetings.

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, inspectors were assured that this process was safe and effective.

The undertaking had developed a positive culture of incident awareness and reporting in the service. Inspectors found that the management team had a positive approach to incident management 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.

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

Regulation 8: Justification of medical exposures

Inspectors reviewed a sample of written referrals on the day of the inspection and also spoke with radiographers conducting medical exposures. There was evidence that procedures were justified in advance by practitioners and there was a system in place to ensure that records of justification were available for each medical exposure from the date of the procedure as per regulatory requirement. The management team in St. Columcille's Hospital monitored compliance with the process of justification by means of an audit programme. For example, an audit of CT brain examinations had recently been completed to ensure that referrals for the medical exposure type adhered to international best practice referral guidelines.

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 and in clinical 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.

Inspectors were informed that service users undergoing a DXA scan were requested to complete an osteoporosis questionnaire prior to completing the scan. This questionnaire aimed to gather further information to assist in the justification decision making process, and was identified as an area of good practice in the service.

Judgment: Compliant

Regulation 9: Optimisation

Inspectors reviewed documentation and spoke with staff about the measures in place to ensure that the medical radiological procedures were optimised. The management team had developed a *Radiation Optimisation Policy Document* to outline the optimisation systems and to clarify the responsibilities of those involved in the optimisation of service users' doses. Optimisation of medical exposure examinations is key to ensuring that the required diagnostic information is received, while delivering as low a dose as possible to the service user.

The RPO had completed a range of optimisation audits on medical exposure information with the aim of reducing the doses delivered. For example, an audit on one cohort of X-ray examinations identified that they required additional vetting by the radiologists to ensure that the examinations would provide the information required, and this proposal was being discussed by the multi-disciplinary team at the RSC. This was identified as an area of good practice in the service.

Optimisation systems in St. Columcille's Hospital included the use of DRLs for each imaging modality in the service, and the regular review of these DRLs to ensure that they remained as low as possible. From a review of documentation and discussions with staff, inspectors were also informed that CT scanning protocols were continually refined to reduce the dose delivered to service users during CT examinations. Inspectors observed that the current DRL values for commonly completed CT examinations in the service, were significantly below national DRLs. An audit of CT scan image quality had been completed and images reviewed and approved by the Clinical Director Radiologist, which provided assurances that adequate diagnostic information was provided by the examinations, whilst delivering as low a dose as possible. Inspectors were also informed that extensive image information had been gathered and analysed for another piece of imaging equipment, and inspectors observed that as result the doses delivered during routine examinations were significantly reduced. These optimisation measures were

seen as areas of good practice within the service.

A quality assurance programme for the medical radiological equipment in use in the service was established and implemented, which also contributed to optimisation. It included regular performance testing by radiography staff and by MPEs. The MPEs were also noted to review and sign off all quality control results, which was seen as an additional assurance that any issues with equipment performance could be identified and actioned promptly.

Other optimisation systems included the use of written protocols and the conduct of clinical audits in the service. The management team had developed written documents on all medical procedures performed in the service, to ensure that they were completed safely and consistently. They were accessible to staff in clinical areas and guided them on the optimised patient preparation and positioning, and exposure parameters for different medical exposures. The clinical audits performed included audits on the assessment of dose, and adherence to checking pregnancy status and that the clinical justification of medical exposures was completed by staff. Inspectors also noted that there were mechanisms in place to ensure that audit results were reviewed and appropriate corrective or improvement actions implemented where necessary.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Throughout the radiology department, inspectors observed that DRLs for common procedures were displayed in the console areas. These DRLs were last reviewed in January 2023 and, where available, compared to national DRLs. As mentioned previously in this report, there was a proactive multi-disciplinary approach to the frequent review of DRLs and refinement of examination doses to ensure that DRLs were below national recommended levels.

The management team had developed *Radiology Policy on Diagnostic Reference Levels*, which outlined the method and frequency by which DRLs were established and reviewed for each imaging modality in use in the service.

Judgment: Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment in the service and found that a quality assurance programme for the equipment had been established and implemented. This included annual testing by

the MPE and regular performance testing by radiographers. Inspectors were also informed by MPE staff that the regular QA testing for the CT and X-ray units was being reviewed and refined. This monitoring of the QA programme was identified as an area of good practice within the service.

Inspectors also reviewed records that acceptance testing for all radiological equipment had been completed before the first use for clinical purposes, and were informed that QA measuring equipment was calibrated annually.

Inspectors also saw evidence that effective systems were in place to ensure that the medical radiological equipment was delivering optimised doses to service users, and that any actual or possible performance issues were promptly actioned. For example, the management and MPE teams had developed a quality control action plan for one piece of equipment that required additional enhanced monitoring to ensure that it continued to meet the criteria of acceptability for use. Inspectors were also informed that radiology equipment that required routine replacement had been risk assessed and entered on a radiology risk register with appropriate measures in place and a risk owner assigned. Overall, 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. This process was documented in both the local radiation safety procedure and the pregnancy policy, both of which could undergo a minor review to enhance clarity on the process for staff.

From a review of a sample of referrals, inspectors saw practitioners had inquired on and recorded in writing the pregnancy status of patients, where relevant. This was in line with the local pregnancy procedure, which stated that practitioners were assigned the responsibility for inquiring on patients' pregnancy status, where relevant.

Inspectors observed a number of notices, in a variety of languages, were displayed in service user waiting areas and clinical areas, to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation. Inspectors were informed that special efforts had been made to ensure that these posters encouraged all patient cohorts, using the service, to discuss pregnancy status with staff, where relevant.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed a local policy which outlined the process for the management of accidental and unintended exposures and significant events, and staff who spoke with the inspectors were able to describe this process. This process included information on the requirement to notify HIQA of certain reportable incidents.

Incidents and potential incidents were recorded, analysed and categorised, with evidence of discussion of radiation incident summary reports as a standard agenda item at the RSC meetings. Inspectors noted that there was a positive culture of reporting near misses in the service, and that the trending and analysis of this incident data was used to drive change and improve the safety of the service. For example, inspectors noted that a number of near misses had been reported on referral information. A review of this information identified that, although referrals were correctly made, further training was required to ensure that they were scheduled as per the referral information. Inspectors were informed that a multi-disciplinary team had been formed to provide this training, and improve the scheduling process.

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	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 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant