



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:	19 February 2020
Medical Radiological Installation Service ID:	OSV-0007375
Fieldwork ID:	MON-0028239

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 radiology department is equipped with the following imaging modalities:

- general and mobile X-ray
- fluoroscopy
- computerised tomography (CT)
- DXA Scanning.

Diagnostic imaging services are provided for the local injury unit, the medical assessment unit, acute medical inpatients, day surgery patients, and outpatients. In addition, the radiology department provides diagnostic imaging services for general practitioner (GP) patients in the South Dublin and Wicklow region, and inpatient X-ray and CT scanning services for St. Vincent's University Hospital which is within the same hospital group. Approximately 31,300 medical exposures are carried out on an annual basis.

The hospital is part of the Health Service Executive (HSE) National Integrated Medical Imaging System (NIMIS) Radiology Information System/Picture Archiving and Communication System (RIS/PACS) programme. The department is linked to the University College Dublin, School of Diagnostic Imaging and provides training for radiography students. In addition to consultant radiologists, nursing staff, administration and attendant staff, there are approximately 13 whole time equivalent radiography staff including clinical specialist, clinical tutor, senior and staff grades and a radiology services manager.

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 18 February 2020	09:00hrs to 16:00hrs	Agnella Craig	Lead
Tuesday 18 February 2020	09:00hrs to 16:00hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

Inspectors found that there were clear systems and processes in place detailing a clear allocation of responsibility for the radiation protection of service users within St Columcille's Hospital. In addition, evidence of effective leadership, governance and management arrangements was demonstrated within this installation. The general manager (GM) was the designated person responsible for radiation protection for the hospital and was a member of the Radiation Safety Committee (RSC) which reports to the Clinical Governance Committee. Based on the terms of reference of the RSC reviewed by inspectors, this committee provides oversight and is an effective mechanism for ensuring the quality and safe conduct of medical exposures in this facility. The general manager also reports to the Ireland East Hospital Group on a monthly basis.

Although the reporting structures within the installation were well known, as were the reporting structures to the hospital group, the process to report to the Health Service Executive (HSE) as the undertaking with overall responsibility for this undertaking was not as well understood. The specific mechanisms to communicate with the HSE through the National Radiation Protection Office was also not known by staff or evidenced in the documentation reviewed by inspectors. To ensure the undertaking has full oversight of the local facility, it is important that responsibilities and lines of accountability are clearly delineated and understood at local level as well as hospital group and national HSE level.

From the documents and records reviewed, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. All procedures involving medical exposure to ionising radiation were conducted under the clinical responsibility of those recognised in the regulations as practitioners. Furthermore, inspectors were assured that both the practitioner and the medical physics expert were involved in the optimisation process.

From the documentation reviewed, inspectors were assured that the level of involvement of the medical physics expert was proportionate to the level of risk in the service. Inspectors were informed that a contract is in place with a local teaching hospital within the same hospital group. This ensures involvement and continuity of medical physics expertise. A medical physicist, under the supervision of the registered medical physics expert, was also in training and inspectors were informed that this was for succession planning purposes.

Overall, inspectors were assured of the management of this installation and its effectiveness in ensuring the quality and safe conduct of medical exposures.

Regulation 4: Referrers

St Columcille's Hospital receives referrals in electronic format from referrers within the hospital. Only staff entitled to refer have access to the Radiology Information System (RIS). Although ordering rights were not customised in the system to reflect the scope of practice for advanced nurse practitioners (ANP), nursing staff were able to explain their scope of practice and the procedures they were authorised to order, and radiography staff were aware of the procedures that ANPs could order. The majority of referrals from sources external to the hospital come from general practitioners (GPs) through an electronic system (Healthlink).

Referrals for medical radiological procedures reviewed on the day of inspection were only accepted from those entitled to refer as per the regulations. Staff that spoke with inspectors demonstrated a comprehensive understanding of the referral process and this was consistent with local policy.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied that only those entitled to act as practitioners as per the regulations are practitioners in this facility. Although the document - "Radiation safety procedures - local rules" - reviewed in advance of the inspection did not specify that radiographers are considered practitioners in this facility, inspectors were informed that radiographers are considered practitioners in line with the regulations. The version of the "Radiation safety procedures - local rules" document shown to inspectors on the day of inspection did list radiographers as practitioner. It is important that the documentation is reviewed to ensure the information contained within versions aligns across all documentation.

Judgment: Compliant

Regulation 6: Undertaking

From the documentation reviewed and the meetings with staff, it was clear that systems and processes were in place to ensure the protection of service users within this facility. There was a clear allocation of responsibility from the designated manager to staff in the clinical area; however, the line of reporting and accountability up from the hospital to the HSE, as the undertaking with overall responsibility for this installation, was not well understood and could be improved. Staff acknowledged they were unsure of the specific mechanism available to communicate directly with the HSE, or the systems in place to communication with

the National Radiation Protection Office in the HSE.

At a local level the general manager (GM) is a member of the Local Radiation Safety Committee (RSC) which presents an annual report to the Clinical Governance Committee. The GM also reports to the Ireland East Hospital Group on a monthly basis. The system to report to this hospital group was outlined in the documentation provided and staff were aware of this process.

It is important that lines of communication, responsibility and accountability are clearly communicated and understood by all staff, to assure the undertaking of the radiation protection of service users within the HSE.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

From the documentation reviewed and discussions with staff, inspectors were assured that all medical exposures took place under the clinical responsibility of a practitioner. Inspectors were also assured that the optimisation process included the practitioner and the medical physics expert and that the justification process included both the referrer and the practitioner.

In this facility, medical exposures were only performed by radiographers and or radiologists. Although a list of practitioners, viewed by inspectors, contained non-radiology consultants, inspectors were informed that radiographers are always present for the practical aspects of an exposure. In the absence of nationally defined training requirements for non-radiology doctors, having a radiologist or radiographer present for the practical aspects of all ionising radiation procedures is an assurance for the undertaking of the radiation protection of service users.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were informed that a medical physics expert (MPE) was available as required and onsite at least once a week. A contract between this hospital and a large teaching hospital in the same hospital group was in place for the provision of medical physics expertise and provided assurance of the continuity of services available for this facility. This contract is a good example of how facilities can share resources and learning across hospitals. In addition to this MPE, inspectors were informed that a medical physicist is in training for succession planning purposes, and the work of this physicist is supervised by the registered MPE.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Specific documentation outlining the roles and responsibilities of an MPE as distinct from a radiation protection advisor was provided to inspectors in the form of a contract with a local teaching hospital. Additionally, from the policies, procedures and guidelines reviewed and from speaking with staff, it was evident that the MPE gave advice on medical radiological equipment. Additionally, the MPE took responsibility for measuring doses delivered to service users, reviewing diagnostic reference levels (DRLs), and conducting quality assurance and acceptance testing. The MPE was also involved in the training and education of staff.

Judgment: Compliant

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

Although inspectors were informed that the MPE was keen to expand on their input in this installation, no regulatory deficits were noted. From the documentation reviewed and from speaking with staff, inspectors were assured that the level of involvement of the medical physics expert was in line with the level of risk posed by the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

Overall, inspectors found that St Columcille's Hospital had implemented measures to ensure the safe delivery of medical exposures to ionising radiation. This included policies and procedures in place to protect service users during pregnancy, with posters highlighting the risks associated with radiation exposure available throughout the department. Diagnostic reference levels were established and appropriate quality assurance and maintenance testing programmes were in place for all equipment. In addition, the hospital had two methods available to record justification and the justification policy document outlined the allocation of responsibilities for justification by procedure type.

Inspectors found evidence that reasonable measures were taken within this facility to minimise the probability of accidental or unintended exposures and oversight

from senior management within this hospital was in place as radiation incidents is a standing item at the RSC meetings. Although the flow chart included in the radiation incident policy clearly outlines the local reporting structures, updating this to include the process to report incidents to the HSE's National Radiation Protection Office would improve the undertaking's oversight of any incidents in this installation.

Inspectors also found that areas identified as non-compliance in the self-assessment questionnaire had either been addressed or were in the process of being addressed at the time of inspection. For example, all referrers are now provided with access to referral guidelines. This proactive approach to addressing gaps identified in the self-assessment is an example of positive steps that can be taken by installations to come into compliance.

Regulation 8: Justification of medical exposures

Inspectors reviewed the radiation justification policy document in advance of inspection. This document outlined the hospital's position in relation to the justification of radiological examinations, and the specific personnel with responsibility for justifying procedures; for example, radiographers can justify X-ray and DXA examinations, and CT and fluoroscopic procedures are justified by radiologists. As detailed in the policy, the process to record the justification of general X-ray procedures is by ticking and signing the order form, whereas justification of CT examinations and plain film abdominal X-rays is recorded in the vetting module of the electronic radiology information system. These two methods of recording justification were known by all staff who spoke with inspectors on the day of inspection. Samples of records of justification reviewed by inspectors were in line with this policy, with 12 of the 15 referrals reviewed on the day of inspection having a record of justification. This process of recording justification would benefit from audit, due to the three reviewed referrals which were not consistent with the policy.

All referrals reviewed by inspectors on the day of the inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff informed inspectors of the process they follow to obtain previous medical information and inspectors noted that information in relation to the benefits and risks associated with radiation was available to individuals undergoing medical exposure.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Diagnostic reference levels (DRLs) have been established for radiological procedures

in this hospital and were compared to national levels. DRLs were displayed in the radiology department and staff demonstrated an awareness of the availability and use of DRLs. Inspectors noted that DRLs were included in the minutes of a previous RSC meeting, however additional record keeping on the discussion and actions taken following the review of DRLs would provide further evidence of compliance with this regulation.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, staff were able to access the written protocols for routine procedures conducted at this facility. Referral guidelines were available to staff in both hard and soft copy and a memo reminding staff to use these guidelines was noted by inspectors. Inspectors were also informed that regular meetings are held with external referrers, such as local GP's, and this is a useful forum to highlight the importance of using referral guidelines, and discuss any issues in relation to referral criteria.

A positive culture towards conducting clinical audit was noted by inspectors, however the specific processes for following up on these and implementing quality improvement plans was not as evident. A new initiative in this hospital to take a hospital wide view of clinical audit may help facilitate quality improvement planning.

In order for the undertaking to be compliant with Regulation 13(2), a system to record information relating to patient exposure needs to be included in the patients' reports. Inspectors observed that information relating to patient exposure is currently only recorded on some patient reports in this hospital, such as those undergoing CT scans and fluoroscopic procedures. A system or process to record information relating to patient dose for all procedures needs to be implemented in order to come into compliance with this regulation.

Judgment: Substantially Compliant

Regulation 14: Equipment

From the documentation reviewed and from speaking with staff, inspectors were satisfied that appropriate quality assurance and quality control programmes were in place in this facility. The role of the MPE in relation to equipment was also evident from the records reviewed. In addition, inspectors were provided with a draft document which detailed the process to be followed after servicing of radiological equipment. This document outlined the specific roles and responsibilities of staff in following up on any actions identified during the service. When implemented, this

may provide the undertaking with further oversight of the equipment; however no regulatory deficits were identified.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

From the documentation reviewed and speaking with staff, inspectors were assured of the systems in place to inquire about pregnancy status with service users. Posters alerting patients to inform staff of their pregnancy status were on display in the waiting areas of the department. The roles and responsibilities of staff were outlined in the hospital's pregnancy policy and staff demonstrated a knowledge and understanding of this. Results of an audit conducted in 2019 on pregnancy status, viewed by inspectors, showed good compliance with this policy.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were assured of the radiation safety of service users by the systems, processes and procedures in place within this facility. Inspectors reviewed the radiation incident reporting policy which detailed the types of incidents, the roles and responsibilities of personnel, and the processes in place if an incident should occur within this facility. The flow chart included within this policy detailed the specific pathways to be followed in the event of an incident or near miss occurring. Staff who spoke with inspectors on the day of the inspection demonstrated a knowledge and understanding of the incident reporting processes within the hospital. However, the process to report incidents to the HSE's National Radiation Protection Office was not as well understood.

Inspectors found evidence that reasonable measures were taken within this facility to minimise the probability of accidental or unintended exposures and oversight from senior management within this hospital was in place as radiation incidents is a standing item at the RSC meetings. Additionally, inspectors were informed that a recent initiative of running regular safety huddles (short informal meetings) has begun in this hospital with the aim to increase awareness of patient safety.

Judgment: Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	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 St Columcille's Hospital OSV-0007375

Inspection ID: MON-0028239

Date of inspection: 19/02/2020

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: The General Manager of St Columcille's Hospital, is on the mailing list of the NPRO.</p> <p>The General Manager has received confirmation from the HSE that they report to the undertaking representative of the HSE, through the Ireland East Hospital Group (IEHG).</p> <p>Authority in relation to "Undertaking" has been delegated down from the HSE to IEHG to the General Manager of St Columcille's Hospital.</p> <p>SCH organogram has been amended to demonstrate the above.</p>	
Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: There is an active Radiology Clinical Audit committee in place. Terms of reference to be finalized and agreed by 30th June 2020. The Radiology Audit committees will directly report into the hospital audit committee which meet on a quarterly basis and reports to the Clinical Governance Committee.</p> <p>We are now recording patient exposures by dictating the DLP (in mGycm) into the report for CTs and DAP in Fluoroscopy cases but are awaiting a technical solution from NIMIS for the plain films and Dexa.</p> <p>A requests have been made from St Columcille's Hospital to NIMIS management to have an automatic patient exposure transfer feature included in the next version of the NIMIS software. This is a step that has also been taken by many other HSE hospitals and hopefully this is something that will become available in due course.</p>	

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	03/04/2020
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Substantially Compliant	Yellow	30/06/2020

	procedure.			
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