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:	Croom Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Corrabul, Croom, Limerick
Type of inspection:	Announced
Date of inspection:	02 August 2022
Medical Radiological Installation Service ID:	OSV-0007354
Fieldwork ID:	MON-0030680

About the medical radiological installation:

Croom Hospital is an Orthopaedic Hospital and a member of the University of Limerick Hospital Group (ULHG). There are 44 in-patient beds and 4 theatres in Croom Hospital. The radiology service in Croom Hospital consists of: 1 General x-ray room, 1 DR mobile unit, 2 mobile C-arms in service. The service is provided to in-patients and outpatients attending the hospital. The outpatient clinics are consultant led, and include orthopaedic, rheumatology services and the pain management service is provided by anaesthetic consultants. There are also clinics which are run by advanced nurse practitioners. There is a mobile X-ray service for post-operative imaging and when patients require urgent imaging on wards; there is also an "in-op" mobile c-arm imaging service. There has been an expansion of wards and theatres recently in Croom Hospital which has led to an increase in activity. There has also been an increase in orthopaedic consultants to meet the demand of the service. There are some radiographers who are based full time in Croom Hospital and radiographers from University Hospital Limerick (UHL) also work on rotation in Croom Hospital. There is a very limited out of hours service for urgent plain X-ray only.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 2 August 2022	09:30hrs to 14:27hrs	Kay Sugrue	Lead
Tuesday 2 August 2022	09:30hrs to 14:27hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Croom Hospital is an orthopaedic hospital and a member of the University of Limerick Hospital Group (ULHG). The Health Service Executive (HSE) is the undertaking with overarching responsibility for the radiation protection of service users at Croom Hospital. This responsibility has been delegated, through a formal delegation process, down to the Chief Executive Officer (CEO) of ULHG who was also the designated manager for this facility. Radiology governance arrangements in charts and documentation viewed by inspectors detailed the formal sub-delegation from the CEO to the Diagnostic Directorate General Manager. The CEO was a member of the hospital group radiation safety committee (RSC) which provided assurance that there was an effective means of communication for matters relating to radiation protection of service users to the CEO and upwards to the HSE. The RSC was supported in its role by a Radiation Audit Committee and Radiation Protection Task Force with responsibility for the day-to-day operations and radiation protection within the radiology service at Croom Hospital.

On the day of the inspection, inspectors reviewed documentation and records relating to medical radiological procedures and also spoke with staff working in the radiology service. The evidence gathered satisfied inspectors that the undertaking had ensured that there was a clear allocation of responsibility at the hospital in line with Regulation 6(3). This meant that only persons entitled to refer acted as referrers and that medical exposures took place under the clinical responsibility of a recognised practitioner. Additionally, a practitioner and referrer were involved in the justification process and similarly, a practitioner and a medical physics expert (MPE) were involved in the optimisation of medical radiological procedures as per regulations.

Inspectors found that MPE involvement was evident within the radiology service at the hospital with the level of involvement proportional to the radiological risk posed by the service. The hospital had ensured that there was also contingency arrangements in place for the continuity of MPE expertise provided by contracted MPE services should the need arise.

Inspectors found inconsistencies in hospital compliance with respect of Regulation 13(2) where a small number of medical radiological reports included information relating to the patient exposure while others did not. Contrary to these findings, inspectors found from review of the ULHG's Radiation safety Procedures applied at Croom Hospital and discussions with hospital management that it was the hospital's decision not to implement the HSE's measures available to ensure compliance with Regulation 13(2). Inspectors were informed that a software solution was the preferred option which would take time to implement. The undertaking in conjunction with ULHG and the hospital must therefore address this deficiency to ensure compliance with Regulation 13(2).

Regulation 4: Referrers

Inspectors reviewed a sample of referral records each of which contained medical council registration numbers of referrers and therefore demonstrated that these referrals were from referrers as defined in the regulations. Staff clearly outlined to inspectors during discussions the referral role of radiographers for adapted and secondary referrals. A list of hospital referrers was available for inspectors to view and daily work flows listed those consultants who were the primary referrers for each day. Overall, inspectors were satisfied that that only referrals from appropriately recognised referrers as per Regulation 4 were accepted by the Radiology Department at Croom Hospital.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors reviewed a sample of records in relation to medical exposures on the day of inspection in general radiology and fluoroscopy and found that only persons entitled to act as a practitioner had taken clinical responsibility for individual medical radiological procedures.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors reviewed several documents relating to the governance structures in place for radiation protection of service users at Croom Hospital and the overarching governance of the ULHG. These documents also included governance arrangements and reporting lines up to the HSE, as the undertaking, with overall responsibility for the radiation protection of service users. The CEO of ULHG was the designated manager and a member of the hospital's RSC. This committee was incorporated into local governance structures, reporting to the Quality, Safety and Risk Committee which reported upwards to the Executive Management Committee and from this committee to the Hospital Board. In addition, the hospital group had a Radiation Audit Committee and Radiation Protection Task Force which reported into the RSC. The RSC terms of reference were in the process of being updated to reflect this reporting relationship.

Inspectors viewed minutes from radiation protection governance committees demonstrating multi-disciplinary membership and attendances at meetings and were satisfied that there were good reporting lines to the designated manager via the

formal sub-delegation processes within each directorate of the ULHG.

Inspectors were assured that referrals were only accepted from those entitled to refer service users for medical exposures as per regulations. From review of documentation and speaking with staff, inspectors were also satisfied that medical exposures took place under the clinical responsibility of a practitioner and the practitioner and medical physics expert (MPE) were involved in the optimisation process as per regulations.

Inspectors found from review of the ULHG's Radiation safety Procedures applied at Croom Hospital and discussions with hospital management that it was the hospital's decision not to implement the HSE's measures to ensure compliance with Regulation 13(2). The undertaking in conjunction with ULHG and the hospital must therefore address this deficiency to ensure compliance with Regulation 13(2).

Judgment: Compliant

Regulation 10: Responsibilities

Following review of documentation, medical exposure records and discussion with staff, inspectors were satisfied that the hospital met the requirement of Regulation 10. Inspectors found that all medical exposures took place under the clinical responsibility of persons entitled to act as practitioners. Medical exposure records reviewed by inspectors demonstrated that the undertaking had ensured that a practitioner and referrer was involved in the justification process in line with this regulation. Similarly, a practitioner and MPE were involved in the optimisation as per regulations. Inspectors were informed that it was hospital policy that all medical exposures took place with a radiographer practitioner present. This practice was evident in the operating theatres where a radiographer was rostered for planned procedures involving medical exposures each day if required.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The Medical Physics Department of ULHG provided MPE services at Croom Hospital and also to the hospitals within the wider hospital group. On the day of the inspection, inspectors found that the undertaking had ensured the continuity of the MPE service at the hospital. Deficiencies in MPE resources experienced by the ULHG over a number of years were being addressed with the recruitment of additional medical physics staff in progress. Interim contingency arrangements were in place provided by a contracted external service if required.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied from documentation viewed and discussions with staff that an MPE was available to give advice on medical radiological equipment and contributed to the annual quality assurance (QA) programme. Inspectors viewed records and found that equipment QA was up-to-date and acceptance testing had been completed as per regulations. An MPE contributed to the establishment and review of diagnostic reference levels (DRLs) at the hospital. Minutes from the RSC viewed by inspectors showed that an MPE attended each scheduled RSC meeting. MPEs advised on equipment if required and also provided advice in relation to the analysis of events involving or potentially involving accidental or unintended medical exposures. There was evidence from documents reviewed to show that an MPE contributed to radiation protection training delivered to staff by a member of medical physics staff and the radiation protection officer.

Judgment: Compliant

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

From discussion with staff and documentation reviewed, inspectors were assured that the level of involvement of the MPE was commensurate to the radiological risk posed by medical exposures provided by the service. While regulatory requirements were met, medical physics staff identified to inspectors that there was potential to increase the level of MPE involvement once allocated resources had improved. Particular areas of involvement identified included protocol development, training and optimisation of medical exposures.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure that safe and effective medical exposures were provided to service users undergoing medical radiological procedures delivered by the hospital. While the hospital was found to be compliant with Regulations 14, and 17, inspectors identified that improvements were required with respect to Regulations 8, 13 and 11.

An up-to-date inventory and quality assurance reports were provided to inspectors

which showed that an appropriate quality assurance programme was in place. Inspectors were assured that the equipment was kept under strict surveillance and any issues or faults that were reported were addressed without delay. Equipment in general X-ray that was beyond the nominal date for replacement was due to be replaced by the end of this year. Minutes from the RSC meetings showed that there was appropriate oversight of issues relating to this ageing equipment and replacement requirements.

Staff demonstrated a good understanding on the process for the management of accidental and unintended exposures and significant events which aligned with the hospital policy. Inspectors were satisfied, following the review of actions taken to reduce the risk of recurrence of an incident reported to HIQA, that the measures implemented were appropriate with higher level risk mitigation strategies employed. Inspectors also found that there was a system in place to track and trend those incidents and potential incidents that do not meet the criteria for reporting to HIQA.

From a review of patient records, inspectors noted that information relating to the patient exposure did not consistently form part of the report of medical radiological procedures. Inspectors found that the hospital should review practices relating to this issue to ensure a consistency in approach and compliance with Regulation 13(2).

Inspectors found that staff who spoke with inspectors consistently described how justification in advance was carried out for each medical exposure and recorded on the triple identification form. However, this record was not retained and therefore not evident in medical radiological records reviewed on the day of the inspection. As a consequence, inspectors found that the hospital did not comply with Regulations 8(8) and 8(15) and therefore these non-compliances must be addressed following on from this inspection.

A review of processes for the establishment and regular review of facility DRLs did not provide assurance to inspectors that DRLs referenced by staff on a daily basis and applied in the clinical area on the day of the inspection were based on contemporary data. Inspectors found that collation of data leading to the establishment of facility DRLs was a protracted process with time taken to conduct image quality reviews impacting on the establishment of more current DRLs. To ensure compliance with Regulation 11, the hospital should ensure that DRLs are established, finalised and approved for use as an aid to the optimisation of patient radiation doses.

While noting that there are improvements required to come into full compliance with regulations, the findings of this inspection outlined in this report primarily relate to gaps in documentation and do no represent a radiological risk to service users attending the hospital.

Regulation 8: Justification of medical exposures

Inspectors found that improvements were required in relation to the record of justification in advance which was not retained for each medical radiological procedure conducted at the hospital. Staff consistently described the process of justifying medical exposures in advance where they routinely recorded that justification had taken place on the triple identification form, however this form was not scanned onto the radiology information system or stored as evidence of justification from the date of the medical exposure. Inspectors were informed by management that an upgrade to the radiology information system was due to be implemented in early 2023 which would facilitate the recording of justification in advance for each examination. In the meantime, to ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that records evidencing compliance with the justification of medical exposures in advance should be kept for a period of five years from the date of the medical exposure.

Information on the benefits and risks associated with radiation was available in a variety of formats in service user waiting areas and included posters on walls and information leaflets which were also visibly displayed and accessible to the service user.

Judgment: Not Compliant

Regulation 11: Diagnostic reference levels

Facility DRLs referenced by staff for clinical use on the day of the inspection were approved in 2020. Although data from 2021 had been collated and reviewed by an MPE, a number of DRL values were found to be notably lower than national DRL values which required further review. Inspectors noted that the DRLs for 2020 and the higher doses seen in data collated in 2021 remained below national DRLs. Inspectors were informed that the disparities found required further image quality reviews to be undertaken. As a consequence, the establishment of facility DRLs for 2021 had not progressed and the image quality review had also not been completed at the time of the inspection. Inspectors were not satisfied that DRLs based on contemporary data had been established in line with local policy or as per regulations.

Judgment: Not Compliant

Regulation 13: Procedures

Written protocols were available for standard medical radiological procedures and accessible to staff in the clinical area. These protocols were specific to the requirements of individual consultants. However, inspectors viewed supplementary information in a folder which was devised by and referred to by staff in the X-ray

room and found that some of the information included was obsolete with written amendments also evident. Inspectors were informed that this supplementary information, some of which was relevant to daily practice, had not been approved for use in the clinical areas. Therefore, protocols should be reviewed to ensure all relevant information is included and formally approved for use.

Documentation viewed demonstrated that referral guidelines for medical imaging were available and accessible on desktops in each clinical area.

Clinical audits were conducted within the radiology department but were not conducted as part of an audit schedule. Hospital management had identified to inspectors that this was an area that required improvement.

Measures put in place by the HSE to come into compliance with Regulation 13(2) were not consistently evident in reports of medical radiological procedures viewed by inspectors. For example, inspectors reviewed a sample of reports and found that a small number of reports contained information relating to the patient exposure. These included reference to a relevant dose band (as per the HSE guidance), while another indicated where the dose could be found if required. Others reviewed did not include any reference to the patient dose. The inclusion of information relating to the patient exposure in the reports differed to the hospital's position on this issue as described by staff to inspectors and also clearly documented in ULHG Radiation Safety Procedures applied in this facility. Inspectors determined that inclusions of information relating to the patient exposures observed were more anomalies than consistent practice. Disparities in practice should be reviewed and documentation should be updated to ensure that day-to-day practice is consistent and complies with the requirements of Regulation 13(2).

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment before inspection. Records reviewed demonstrated that there were appropriate QA and quality control programmes in place which were maintained appropriately and kept up-to-date. Staff described the processes in place to inspectors for logging equipment faults with the Radiology Service Manager and service engineers. Inspectors were informed that funding had recently been received to replace the X-ray equipment in general radiology and it was planned that replacement would take place by the end of 2022.

From the documentation reviewed and discussions with staff, inspectors were satisfied that equipment was kept under strict surveillance and there was an appropriate process in place for the replacement of ageing equipment.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from these documents and from speaking with staff, that there was a process in place to record radiation incidents and near misses. This process was underpinned by hospital policy. Follow up measures implemented to mitigate the potential for recurrence of issues which led to a reportable incident to HIQA provided assurance that higher level risk mitigation strategies were applied and corrective actions taken.

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	Not Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Croom Hospital OSV-0007354

Inspection ID: MON-0030680

Date of inspection: 02/08/2022

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 8: Justification of medical exposures	Not Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: The Radiographer practitioners are now recording within the electronic NIMIS RIS referral that the ionising exposure is justified in advance of being undertaken. This change in practice was implemented as a corrective action on the day of the inspection subsequent to verbal feedback from the inspectors. This modification in practice addresses the non-compliance with Regulation 8 as outlined in the report. The direction to retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure is noted and will be complied with.	
Regulation 11: Diagnostic reference levels	Not Compliant
Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels: A discussion regarding the DRLs took place with the Lead Radiologist for Croom Hospital on the 27th Sept. A review of image quality where appropriate is almost complete. DRL values will be approved for Croom Hospital by the end of October to complete the annual DRL approval process for 2022.	

Regulation 13: Procedures	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: The Senior Radiographer in Croom Orthopaedic Hospital has redeveloped and amended the written protocols. Key clinical stakeholders in the facility have reviewed and contributed to same. It is envisaged that the issue of the dose on the report will be addressed by the upgrade to the NIMIS system early next year.	

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 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Not Compliant	Orange	16/09/2022
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Not Compliant	Orange	16/09/2022
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and	Not Compliant	Orange	29/10/2022

	where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.			
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Not Compliant	Orange	16/09/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	31/07/2023