



**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:	National Rehabilitation Hospital
Undertaking Name:	National Rehabilitation Hospital
Address of Ionising Radiation Installation:	Rochestown Avenue, Dún Laoghaire, Co. Dublin
Type of inspection:	Announced
Date of inspection:	11 May 2023
Medical Radiological Installation Service ID:	OSV-0007401
Fieldwork ID:	MON-0039464

About the medical radiological installation:

The National Rehabilitation Hospital (NRH) is the national tertiary referral centre in Ireland providing complex specialist rehabilitation services to adult and paediatric patients from throughout Ireland. At the NRH, services are delivered to patients who, as a result of an accident, illness or injury have acquired a physical or cognitive disability, or both, and require a specialist interdisciplinary programme of rehabilitation. Rehabilitation Programmes at the NRH are delivered by consultant-led interdisciplinary teams in the following areas of specialty:

- Brain Injury (including traumatic, and non-traumatic brain injury, and Stroke or other neurological conditions)
- Spinal Cord System of Care (including traumatic, and non-traumatic spinal cord injury)
- Prosthetic, Orthotic and Limb Absence Rehabilitation (POLAR)
- Paediatric Family-Centred Programme

Diagnostic imaging services were provided by an expanding team, comprising of a part-time consultant radiologist, a radiology services manager, two clinical specialist radiographers, one senior radiographer, one DXA clinical specialist nurse and two part-time radiology health care assistants.

The following services are provided to all inpatient and outpatient groups, including Brain Injury Programme, Spinal Cord System of Care, POLAR, Paediatric Programme and CIIRP:

- General radiography, mobile radiography, special procedures, and Dual-energy X-ray Absorptiometry (DXA) scanning.
- 24/7 on-call radiography service at the NRH.

Future Plans/Developments for 2023

- Planning for phase 2 of the new NRH development is ongoing providing a new larger multi-modality Radiology Department with cross sectional facilities. Radiology will be actively involved in planning these services and the resources required for the same.

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
Thursday 11 May 2023	09:00hrs to 13:41hrs	Kay Sugrue	Lead
Thursday 11 May 2023	09:00hrs to 13:41hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

An inspection was carried out at the National Rehabilitation Hospital (NRH) on the 11 May 2023. Inspectors reviewed the governance and management arrangements in place for the radiation protection of service users undergoing medical exposures as part of this inspection. From the documentation reviewed and discussions with staff and management at the hospital, inspectors found that the arrangements described facilitated effective oversight and communication of radiation protection matters up to the undertaking, the NRH Executive Committee and the NRH Board of Management. This upward communication was also confirmed in minutes reviewed by inspectors as part of this inspection.

The systems and processes viewed by the inspectors provided evidence to show that compliance with the regulations was regularly monitored through the monitoring of key performance indicators and clinical audit, the results of which, helped identify areas for improvement within the service. Documentation viewed showed that a document quality management system had been implemented at the hospital with evidence of multidisciplinary involvement in the development, revision and approval of hospital policy regarding radiation protection; which inspectors found to be good practice. Another area of good practice identified by inspectors was in relation to staff training on radiation protection, which was provided to all disciplines working in the radiology service. An online education programme had been developed by staff at the hospital as part of the induction of non-consultant hospital doctors to the hospital. This online module was under review by the radiologist, with input from the medical physics expert (MPE), to improve the course content and ensure alignment with the current regulations.

The allocation of responsibilities for the radiation protection of service users described by staff to inspectors was clearly understood, was consistent with responsibilities detailed in hospital policies and procedures viewed and also aligned with the regulations. This meant that only persons recognised as a referrer under Regulation 4 could refer for medical radiological procedures at this facility. Practitioner roles for each service provided, both general radiography and dual x-ray absorptiometry (DXA) imaging, were also clearly documented which was limited to either a radiographer or radiologist. The delegation of the practical aspects was articulated by staff to inspectors and met regulatory requirements as per Regulation 10.

A documented agreement was viewed by inspectors that outlined the arrangements in place for the continuity of medical physics expertise to provide specialist advice on matters relating to radiation physics to staff at this facility as required. This document also detailed the MPE role and responsibilities as per Regulation 20 and these responsibilities were confirmed as carried out by the MPE in discussions with the inspectors. Additionally, the evidence gathered during the course of the inspection demonstrated that the level of MPE involvement was appropriate and

proportionate to the radiological risk posed by this service, as per Regulation 21.

During this inspection, inspectors identified several examples of good practice regarding radiation protection at the NRH. Inspectors found that there was a strong sense of collegiality within the radiology team with a proactive and cohesive approach taken to ensure the radiation protection of service users undergoing medical exposures at this facility.

Regulation 4: Referrers

The inspectors reviewed a sample of referrals and spoke with staff and found that medical radiological procedures were only undertaken on the basis of a referral from persons defined in Regulation 4.

Inspectors viewed an approved list of nurse prescribers at the hospital who had a remit to prescribe for a limited number of X-ray procedures which were detailed in the document *Radiation Safety Procedures*. The radiographer role as a referrer was also detailed in this document which limited their scope to adapted or secondary referrals.

Judgment: Compliant

Regulation 5: Practitioners

The evidence gathered during the course of this inspection from a sample of records and documentation viewed demonstrated compliance with this regulation. Inspectors were satisfied that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures in the NRH.

Judgment: Compliant

Regulation 6: Undertaking

Governance arrangements for the radiation protection of service users were reviewed as part of this inspection. Documentation viewed outlined the reporting lines in place from staff working in the radiology service up to the CEO who also acted as the undertaking representative and designated manager.

There was a radiation safety committee (RSC) in place with responsibility and oversight for the radiation protection of service users attending for medical exposures at the NRH. The RSC reported to the NRH Quality, Safety and Risk

Committee and from there to the NRH Executive Committee. RSC minutes reviewed satisfied the inspectors that there was appropriate oversight of regulatory compliance and monitoring of compliance with radiation safety practices in place.

Radiation Safety Procedures viewed by inspectors detailed the allocation of responsibility for the conduct of medical exposures to individuals recognised under the regulations. Practitioner responsibilities were outlined and allocated to either a radiographer or radiologist for X-ray and dual x-ray absorptiometry (DXA) scans delivered in the radiology service. The allocation of responsibilities as outlined in this document were consistent with those that staff described to inspectors during discussions. A multidisciplinary hospital training plan for each professional group was also outlined in documentation viewed. The evidence provided demonstrated compliance with this regulation.

Judgment: Compliant

Regulation 10: Responsibilities

As per commentary under Regulation 5, clinical responsibility for all medical exposures was taken by recognised practitioners. Discussions with staff and records viewed demonstrated to the inspectors that a referrer and practitioner were involved in the justification process for individual medical exposures. Similarly, optimisation for medical exposures involved the MPE and a practitioner as per this regulation. The delegation of the practical aspects was detailed in the *Radiation Safety Procedures* and was found to meet the requirements of Regulation 10(4).

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors viewed documented arrangements in place and spoke with the MPE for this installation. The service level agreement viewed outlined the continuity arrangements for MPE services and advice which were also confirmed by staff and management during discussions with the inspectors. These documented arrangements also specified MPE responsibilities as per Regulation 20.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Professional registration certificates viewed by inspectors confirmed that an MPE was engaged to provide specialist advice on matters relating to medical physics and radiation protection of service users. Discussions with staff and management and documentation reviewed verified the involvement and contribution of an MPE regarding dosimetry, optimisation including the application and use of diagnostic reference levels (DRLs), the Quality Assurance (QA) programme, acceptance testing and surveillance of medical radiological equipment. An MPE also contributed to the analysis of events involving or potentially involving an accidental or unintended exposure to ionising radiation and staff training on radiation protection.

Judgment: Compliant

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

Inspectors were satisfied from the evidence gathered, through documentation viewed and discussions with staff and management, that an MPE was appropriately involved in medical radiological practices in this installation in line with the level of radiological risk.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors found following the review of documentation and discussions with staff and management, that the undertaking had ensured there were effective systems and processes in place to ensure the radiation protection of service users attending for X-ray and DXA at this installation.

The evidence gathered during this inspection demonstrated good practices in several areas which were service user centred and focused on the fundamental principles of radiation protection; such as the justification and optimisation of each medical exposure performed. Inspectors noted that there was a multidisciplinary approach taken to clinical audit, protocol development, policy and procedure revision and development, optimisation, justification, staff training on radiation protection and the strict surveillance of medical radiological equipment. This approach demonstrated to inspectors that staff working in this facility were committed to ensuring the radiation protection of the service user.

Examples of good practice described by staff to inspectors included the proactive engagement by staff within the wider radiological community. According to staff, this approach had facilitated the sharing of information regarding medical radiological equipment and had aided in the development of local protocols and

practices for the benefit of the service user.

Another area of good practice was seen in the provision of information to service users on the risks and benefits associated with medical exposure and information relating to the radiation dose received from X-ray and DXA examinations.

Information was provided in a manner that made it more easily understood which also took account of the demographics of the service user population undergoing X-ray and DXA scans at this facility. Information relating to the doses received from common X-ray examinations was provided in a table and compared to periods of natural background radiation in information available to service users. A similar approach was also taken to ensuring compliance with Regulation 13(2) with a standard line on risk from dose included in reports from medical exposures viewed by inspectors.

Overall, staff at the National Rehabilitation Hospital provided sufficient evidence to satisfy inspectors of the undertaking's full compliance with the regulations assessed during this inspection.

Regulation 8: Justification of medical exposures

Inspectors reviewed the processes implemented by staff at this facility to ensure that each medical radiological procedure was justified in advance by a practitioner. Staff described the process during discussions with inspectors which were consistent with documented procedures viewed. For example, in the DXA service, radiographers justified each procedure in advance which was evident in a sample of records viewed by inspectors on the hospital radiology information system. In general radiology, justification in advance of individual medical radiological procedures was recorded on the identification checking form by a practitioner which was then uploaded and saved onto the same system.

A sample of referrals for medical exposures were viewed during the inspection and were found to be in writing, and provided a rationale for the request with supporting clinical information to inform the justification process.

Information regarding the benefits and risks associated with the radiation dose from medical exposures were provided to service users in a number of formats.

Inspectors found that staff at the hospital had endeavoured to ensure that the information provided was comprehensive and delivered in a way that was easily understood. This was achieved by comparing the radiation exposure levels to a period of naturally occurring background radiation. For example, a DXA scan was described as equivalent to other sources of natural background radiation that the public are exposed to on a daily basis. Pregnancy posters displayed in service user waiting areas had been revised and updated ensuring that information was provided in multiple languages in consideration of the population demographics attending the hospital.

Judgment: Compliant

Regulation 9: Optimisation

On the day of inspection, inspectors were assured that the NRH had measures in place to ensure that all medical radiological procedures carried out at the hospital adhered to the 'as low as reasonable achievable' (ALARA) principle. The hospital had a *QA and Optimisation Policy* which was provided to inspectors in advance of the inspection. This policy provided information about the optimisation processes in place, including the optimisation process for new equipment and optimisation techniques in diagnostic radiology.

Inspectors also spoke with staff and management working in the radiology (X-ray) department at the hospital and reviewed records and documentation available on the day of inspection and identified examples of good practice in achieving compliance with the requirements of this regulation. In particular, inspectors found that a programme of clinical audit was in place which had a focus on identifying and implementing opportunities for optimisation in the X-ray and DXA services at the NRH. For example, inspectors reviewed the results and outcomes of a multidisciplinary clinical audit which assessed the quality of portable chest X-rays carried out in the hospital in 2022.

Similarly, inspectors noted that an audit of compliance with the hospital's QA of medical radiological equipment provided an assurance that X-ray equipment was kept under strict surveillance in line with the requirements of Regulation 14: Equipment. Inspectors were also informed about upcoming initiatives relating to DXA imaging at the NRH which would further optimise the service provided at the hospital for its patients.

Overall, inspectors were assured that staff and management at the hospital had systems in place to ensure consistent practices and techniques were applied to ensure optimisation of medical exposures. The involvement and oversight of a multidisciplinary team in the optimisation process was also seen as an example of good practice.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors viewed the hospital DRL Policy which had been reviewed in February 2023 and approved by the RSC. This policy outlined the processes for establishing facility DRLs for each modality within the Radiology Department and the circumstances in which a review should be taken to ensure the optimisation of safety and protection of service users. Inspectors were satisfied that appropriate

reviews were undertaken where facility DRLs were found to be above or significantly below national DRLs. For example, staff provided inspectors with evidence demonstrating that a review was underway regarding facility DRLs for DXA examinations which were above national DRLs.

Local facility DRLs were displayed in the clinical areas visited by the inspectors. Staff informed inspectors that there was multidisciplinary involvement in the establishment of facility DRLs which was also evident in documentation viewed during the inspection

Staff informed inspectors that low levels of paediatric X-ray examinations were carried out at this facility. This meant that there were insufficient sample sizes available to establish paediatric DRLs. To ensure that paediatric doses were monitored, a review of paediatric patient doses was undertaken by staff for medical exposures conducted in 2022 which was then discussed by the local DRL review group. This was seen as an example of good practice.

The evidence gathered demonstrated a commitment by staff at the hospital to strive to ensure the radiation protection of service users by ensuring that exposure doses are kept as low as reasonable achievable.

Judgment: Compliant

Regulation 13: Procedures

Inspectors found that the undertaking had ensured that appropriate measures were implemented to meet regulatory compliance of the aspects of this regulation which were assessed on the day of the inspection. For example, protocols for standard adult and paediatric radiological examinations had been established with evidence seen of multidisciplinary input into their development. Additionally, inspectors noted that there was a documentation management system in place with established processes for the approval and ratification of these protocols. Staff informed inspectors that as paediatric examinations were relatively low in numbers, they liaised with nearby paediatric facilities regarding protocol development to inform local practice.

The undertaking had ensured compliance with Regulation 13(2). As the majority of radiological examination performed at the hospital involved very low radiation doses, information relating to the exposure was referenced in reports. This was either auto populated in the case of DXA procedure reports or manually inputted by the radiologist for general X-ray examinations.

Referral guidelines were available on computer desktops and staff consistently gave examples of where they used criteria in discussions with inspectors.

Inspectors found that there was an established clinical audit programme in place with oversight by the RSC. A variety of clinical audits were undertaken each year.

Reports viewed by inspectors demonstrated high levels of compliance across all audits completed in 2022 and the first quarter of 2023.

Judgment: Compliant

Regulation 14: Equipment

An up-to-date inventory was provided to inspectors prior to the inspection which was verified during the inspection. Inspectors found that a QA programme to ensure the strict surveillance of medical radiological equipment was in place. Inspectors were informed that the QA programme was under review with a plan to introduce additional tests on the equipment in the future.

QA by a MPE was completed in accordance with frequencies outlined in the QA programme. Internal QA by radiographers was recorded in documentation viewed by inspectors and compliance with quality control checks was audited twice a year. Inspectors viewed one such audit carried out in April 2023 which retrospectively assessed compliance for the last quarter of 2022 and found compliance levels, overall, were very good.

A commissioning report was provided to inspectors which showed that acceptance testing had been completed by the MPE following the installation of a new detector on the general radiography unit, thereby demonstrating compliance with Regulation 14(3)(a).

Inspectors were informed that medical radiological equipment in general radiology had been procured to suit the needs of the NRH patient population where specific consideration had to be given to the management of spinal injuries during diagnostic imaging. Staff told inspectors that the radiological equipment installed was not very common to other facilities in Ireland and therefore they had proactively communicated with radiology staff in another facility with the same equipment regarding potential user issues and protocols. Inspectors found this to be an example of good practice.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Posters to raise service user awareness regarding further precautions to be taken if pregnant and undergoing X-ray were evident on the walls in service user waiting areas. These precautions were highlighted using a different colour in the information leaflets provided and available to service users in the waiting area visited.

Staff described the process for establishing the pregnancy status of relevant service

users prior to carrying out specific medical exposures to inspectors. The procedure outlined was consistent with hospital policy on pregnancy viewed. A sample of records from medical exposures were viewed by inspectors during the inspection and showed that pregnancy declarations were appropriately completed and saved up onto the radiology information system under the relevant medical radiological procedure record.

Regular pregnancy audits carried out by staff at the hospital demonstrated a high level of compliance with local procedures. There was sufficient evidence gathered during the inspection to satisfy inspectors of the undertaking's compliance with this regulation.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed hospital policy and the systems and processes in place to manage radiation incidents. Radiation incidents were recorded on the hospital reporting system and discussed at the RSC as a standing agenda item. However, on the day of the inspection, staff informed the inspectors that there was potential to improve the reporting of accidental and unintended exposures at the NRH. Notwithstanding the potential to improve the established reporting systems in place, inspectors found that the undertaking met the requirements of this regulation.

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