



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Our Lady's Hospital Navan
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Moathill, Navan, Meath
Type of inspection:	Announced
Date of inspection:	08 September 2022
Medical Radiological Installation Service ID:	OSV-0007370
Fieldwork ID:	MON-0037515

About the medical radiological installation:

Our Lady's Hospital Navan (OLHN) is a Model 3 acute hospital, with 117 beds and provides a general acute hospital service to the catchment area of Meath and a Regional Elective Orthopaedic service. The acute services are as follows: General Medicine including Medical Assessment Unit, Elective Orthopaedics, Regional Rheumatology service, Intensive Care Unit/High Dependency Unit, Coronary Care Unit, Emergency Department, Gynaecology Day surgery and Out-patients, Medical & Surgical Day Services, Out-patient service, Pathology services, Radiology, Occupational Therapy, Physiotherapy, Pre-op Assessment, Anaesthetic Services. The Radiology Department in OLHN provides a diagnostic imaging service to inpatients; out-patients; the Emergency Department and Medical Assessment Unit; the orthopaedic theatre; and direct access for General Practitioners (plain X-rays & Ultrasound). OLHN provides 24 hr service general X-ray. Modalities and services provided are: 2 Ultrasound Rooms, 3 General X-ray rooms, 1 Fluoroscopy Interventional suite, 1 Image Intensifier in Theatre, 1 Dual-energy X-ray absorptiometry (Dexa) scanner and 1 Dental Room. The hospital is a member of the Ireland East Hospital Group and is managed by the Hospital Manager, who reports to the Chief Executive Officer of the hospital group.

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 8 September 2022	09:30hrs to 16:00hrs	Lee O'Hora	Lead
Thursday 8 September 2022	09:30hrs to 16:00hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

As part of this inspection, inspectors reviewed documentation and visited the general radiography department which included general radiography, dental and DXA rooms and spoke with staff and management. On this inspection, inspectors found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures. Our Lady's Hospital Navan operated within the Ireland East Hospital Group (IEHG) and the Health Service Executive (HSE) was the undertaking with overall responsibility for the radiation protection of service users.

Local responsibility for the radiation protection of service users lay with the hospital General Manager (GM) who communicated upwards through the IEHG to the HSE. Our Lady's Hospital Navan used a Radiation Safety Committee (RSC) which was delegated responsibility for recommendation of radiation protection measures to ensure that the hospital complied with all relevant legislation. Inspectors were satisfied that the allocation of responsibility for the protection of service users was clear as articulated by staff and management and observed throughout the inspection.

Following review of documents and records, and speaking with staff, 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. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

Inspectors reviewed documentation and spoke with senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and after speaking with staff, inspectors were assured that the level of involvement of MPEs was proportionate to the level of radiological risk at the installation and that MPEs took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

Overall, inspectors were satisfied that a clear allocation of responsibility for the protection of service users ensured the safe conduct of medical exposures at Our Lady's Hospital Navan.

Regulation 4: Referrers

Following review of documentation, a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were assured that Our Lady's

Hospital Navan only accepted referrals from appropriately recognised referrers.

Judgment: Compliant

Regulation 5: Practitioners

Following a review of radiation safety procedure documentation and a sample of referrals for medical radiological procedures and by speaking with staff and management during the inspection, inspectors were satisfied that Our Lady's Hospital Navan had systems in place to ensure that only appropriately qualified individuals, as per the Regulations, took clinical responsibility for all individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

Senior management and staff spoken with during the inspection outlined a clear allocation of responsibility, for the protection of service users by the HSE operating at Our Lady's Hospital Navan. Internal and external responsibilities and lines of communication regarding the effective protection of service users were clearly articulated to the inspectors during the course of the inspection.

The hospital operated within the IEHG and overall responsibility for the radiation protection of service users rested with the HSE. The GM was identified to inspectors as the person with responsibility for the radiation protection of service users at Our Lady's Hospital Navan. The GM of the hospital reported to the undertaking via the Chief Operations Officer (COO) and Chief Executive Officer (CEO) of the IEHG who met monthly.

Our Lady's Hospital Navan employed a RSC, with responsibility for recommending radiation protection measures to comply with the requirements of EU Directives and the appropriate Irish legislation. The GM sat on the RSC and inspectors were informed that other platforms were used within the governance structure of Our Lady's Hospital Navan where radiation safety related topics could be discussed, for example the GM also attended eight weekly Hospital Executive Committee and Quality and Patient Safety Committee meetings as well as two monthly Radiology Governance meetings. Inspectors were assured that these alternate pathways ensured that all radiation safety related issues could be considered as appropriate at Our Lady's Hospital Navan.

Judgment: Compliant

Regulation 10: Responsibilities

From speaking with staff and management and reviewing the radiation safety procedure documentation and a sample of referrals for medical radiological procedures, inspectors were satisfied that the undertaking and Our Lady's Hospital Navan had ensured that all medical exposures took place under the clinical responsibility of a practitioner. Similarly inspectors were assured that the optimisation process involved the practitioner and the MPE and the justification process for individual medical exposures involved the practitioner and the referrer.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

On the day of inspection, inspectors were informed that MPE services were supplied to Our Lady's Hospital Navan by another IEHG hospital's medical physics department with a dedicated MPE allocated to the hospital one day a week. The mechanisms in place to provide continuity of MPE expertise at the hospital were described to inspectors by staff and management spoken with on the day. Staff who spoke with inspectors reported that they had adequate access to medical physics expertise and a service level agreement (SLA), reviewed on site by inspectors, formalised this arrangement.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by inspectors and was up to date. From reviewing the documentation and speaking with staff at the hospital, inspectors were satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of quality assurance (QA) programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners. Inspectors were assured that the involvement and contribution of MPEs at Our Lady's Hospital Navan was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at Our Lady's Hospital Navan.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors found that radiation protection processes implemented by Our Lady's Hospital Navan ensured the safe and effective delivery of medical exposures.

Following a review of a sample of referrals, inspectors were assured that the hospital had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information and justified in advance by a practitioner. However, the record of justification by a practitioner was not documented for a number of referrals reviewed on the day of inspection, this was highlighted to management as an area for improvement. Information for service users on radiation risks was available throughout the radiology department on the day of inspection.

DRLs were established, used and reviewed. Where doses were identified as above national figures, inspectors were satisfied that Our Lady's Hospital Navan had systems in place to ensure such occurrences were appropriately investigated by a multidisciplinary team. One area of improvement noted by inspectors related to Regulation 13(2), namely that the information relating to the medical exposure did not form part of patients' reports as required.

Inspectors reviewed records of acceptance and performance testing for all radiological equipment at the facility and were assured that the hospital had implemented a quality assurance program and kept its radiology equipment under strict surveillance. Inspectors were also satisfied that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded, however the associated policy documentation must be reviewed and updated to align with current regulations and day-to-day practice.

A sample of records of actual and potential accidental and unintended exposures to ionising radiation were reviewed on the day of inspection. From the records reviewed, and from speaking with staff and management, inspectors were satisfied that the hospital had implemented and maintained a system of record-keeping, however the analysis of events involving or potentially involving accidental or

unintended medical exposures could be strengthened by Our Lady's Hospital Navan

Overall, inspectors were assured that Our Lady's Hospital Navan had effective systems in place to support the safe delivery of medical exposures and while there were areas noted for improvement on inspection, these did not pose current risks to the safety, health or welfare of service users.

Regulation 8: Justification of medical exposures

On the day of inspection, inspectors spoke with staff and management who explained how medical exposures are justified in advance of the medical exposure. All referrals reviewed by inspectors on the day of inspection were available 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. However the record of justification of medical radiological procedures by a practitioner in advance of the procedure, as defined by documentation and articulated by staff, was not consistently available in all the referrals reviewed by inspectors on the day of inspection. This non compliance was highlighted to staff and management on the day of inspection as an area for improvement.

Our Lady's Hospital Navan used the National Integrated Medical Imaging System (NIMIS) and inspectors were satisfied that previous diagnostic information was sought, where practicable, as articulated by staff on the day. Information relating to the benefits and risks associated with the radiation dose for general X-ray was available throughout the clinical area in both poster and pamphlet format.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

Following review of documentation and records, inspectors were satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. Inspectors visited the clinical area and observed examples of equipment specific DRLs displayed in each X-ray room.

Inspectors were informed that DRL investigations were currently underway in relation to a number of equipment DRLs that exceeded national DRLs. Records reviewed on-site and staff interaction satisfied inspectors that this process was multidisciplinary involving the MPE, radiation protection officer (RPO) and radiology services manager (RSM) and inspectors were told that this investigation team was awaiting input from the equipment manufacturer before the implementation of corrective actions.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for standard radiological procedures carried out at Our Lady's Hospital Navan were available to inspectors on the day of inspection. A sample of these were reviewed in the clinical areas visited by inspectors. Staff in the clinical areas who spoke with inspectors clearly articulated how these protocols were made available to them and were able to access these on request. Documentation and records reviewed satisfied inspectors that Our Lady's Hospital Navan routinely audited various aspects of radiation safety practice including medical procedure justification, triple identification protocol compliance, pregnancy policy compliance and patient dose optimisation.

Inspectors spoke to staff and reviewed a sample of imaging reports from a number of clinical areas on the day of inspection. Inspectors observed and were informed by staff and management that information relating to patient exposure did not form part of the report for medical imaging procedures carried out at Our Lady's Hospital Navan. Although the HSE has proposed measures for facilities using the NIMIS to come into compliance with Regulation 13(2), these were not implemented by Our Lady's Hospital Navan at the time of inspection. The HSE, as the undertaking, is responsible for ensuring compliance with this requirement of the regulations and must ensure compliance measures are implemented in Our Lady's Hospital Navan relating to Regulation 13.

Judgment: Not Compliant

Regulation 14: Equipment

An up-to-date inventory of radiological equipment was supplied to inspectors and validated on site. All information relating to equipment including policies and procedures, MPE quality assurance records, MPE acceptance testing records and radiographer quarterly QA records were reviewed by inspectors. All radiology equipment QA was up to date at the time of inspection and records reviewed satisfied inspectors that systems and processes were in place to ensure that when issues were raised during QA, that these were appropriately followed up and closed off by the undertaking. From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Processes observed and records reviewed on site satisfied inspectors that the undertaking had systems in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Staff articulated the process clearly to inspectors on the day of inspection and sample referrals reviewed by inspectors verified the consistent recording of the relevant information in line with regulatory requirements.

Multilingual posters were observed throughout the department. Inspectors were assured that measures had been taken to increase awareness of individuals to whom Regulation 16 applies.

Although, Inspectors were satisfied that only recognised practitioners inquired and recorded pregnancy status at Our Lady's Hospital Navan, the document *Policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* included the provision for a person delegated practical aspects of a medical radiological procedure to inquire and record the answer to whether an individual subject to the medical exposure is pregnant or breastfeeding. As the Regulations specify that the inquiry and recording of pregnancy and breastfeeding status can only be done by appropriately recognised referrers and practitioners the undertaking must update the relevant documentation to ensure it reflects both the regulatory requirements and day-to-day practice.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed the systems in place for the record keeping of events and potential events involving accidental or unintended medical exposures which included records and other documentation, such as the minutes of meetings and national incident report forms. Our Lady's Hospital Navan had implemented a system for the record keeping of such events. Records reviewed also demonstrated that management had good oversight of incidents including actions taken and a system was in place to provide feedback and learning including the person responsible for implementing actions arising. The presence of such feedback mechanisms were noted as areas of good practice which should be maintained at the hospital.

The document *Radiation Safety Procedures for Our Lady's Hospital Navan* stated that the *HSE's Incident Management Framework* was followed locally, and management and staff informed inspectors that consideration is given to the reasons which contributed to the occurrence of incidents, and potential incidents in the radiology department. However, the records reviewed on the day of inspection showed that the routine analysis of causes or contributing factors was not always

documented. Consistently identifying and documenting the contributory factors and following the local incident management policy should provide the undertaking with an assurance that the hospital has taken all reasonable measures to reduce the probability of significant events occurring.

Inspectors noted that a risk management function within the hospital's quality and safety department had recently been put in place and was currently implementing systems, which once in place should contribute to the analysis of events and potential events.

Notwithstanding the above area for improvement, inspectors were assured that management at the hospital demonstrated a positive approach to reporting and to supporting the safe delivery of medical exposures at Our Lady's Hospital Navan.

Judgment: Substantially 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	Substantially Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Compliance Plan for Our Lady's Hospital Navan OSV-0007370

Inspection ID: MON-0037515

Date of inspection: 08/09/2022

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	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <ul style="list-style-type: none"> • CPD session for radiographers completed on Tuesday 18/10/2022 on justification and documentation of same. • Radiation Safety guidelines and policies are discussed at monthly Radiology Staff Meetings • Audits will continue to be carried out quarterly on all staff responsible for justification of ionising radiation examinations • Results to be analysed and non-compliance addressed with individual staff members 	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <ul style="list-style-type: none"> • Letter sent from General Manager of OLHN to HSE National Radiation Protection Office asking for a computer based technical solution which will provide the actual patient radiation dose for the particular procedure using automated information transfer be expedited as soon as possible • This issue has been escalated through OLHN QPS to IEHG QPS during performance review to look at all solutions 	

Regulation 16: Special protection during pregnancy and breastfeeding	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:</p> <ul style="list-style-type: none"> • Replaced "operator" with practitioner in all policies to align with local practice 	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:</p> <ul style="list-style-type: none"> • Develop a live document between Radiology and the Quality & Risk Department which will keep a log of all radiation incidents & Near Misses and a record of actions arising from investigations • The RPO and Risk Manager will keep document updated. • Routine analysis of causes or contributing factors related to these incidents/near misses will take place on a regular basis and findings will be discussed at staff meetings, radiology governance and Radiation Safety Committee meetings 	

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.	Substantially Compliant	Yellow	30/11/2022
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.	Substantially Compliant	Yellow	30/11/2022
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report	Not Compliant	Orange	30/04/2023

	of the medical radiological procedure.			
Regulation 16(1)(a)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and	Substantially Compliant	Yellow	31/10/2022
Regulation 16(1)(b)	An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall record the answer to any inquiry under subparagraph (a) in writing, retain such record for a period of five years and provide such records to the Authority on request.	Substantially Compliant	Yellow	31/10/2022
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving	Substantially Compliant	Yellow	31/12/2022

	accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,			
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