



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Louth County Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Dublin Road, Priorland, Dundalk, Louth
Type of inspection:	Announced
Date of inspection:	25 October 2022
Medical Radiological Installation Service ID:	OSV-0007360
Fieldwork ID:	MON-0037516

## About the medical radiological installation:

Louth County Hospital, Dundalk is a statutory hospital owned and managed by the Health Service Executive (HSE). Louth County Hospital, together with Our Lady of Lourdes Hospital, Drogheda forms Louth Hospitals which is part of the Royal College of Surgeons in Ireland (RCSI) Hospital Group governance structure. The hospital is a step-down general hospital delivering medical, surgical, geriatric & palliative services.

The radiology department at Louth County Hospital provides a diagnostic imaging service to patients from all across the North East, both as in-patients and out-patients and also provides an imaging service for Dundalk Local Injuries Unit which operates 09:00 to 20:00 Monday to Sunday including Bank Holidays. The department accepts general practitioner referrals and oncology referrals.

The imaging services provided at the hospital include orthopaedic imaging, portable X-rays, computed tomography (CT), ultrasound, vascular ultrasound and dual-energy X-ray absorptiometry (DXA). Louth County Hospital performs all out-patient computed tomography (CT) procedures from Our Lady of Lourdes Hospital. However, as the CT equipment is currently being replaced at Louth County Hospital the CT service has been temporarily moved to Our Lady of Lourdes Hospital. Louth County Hospital is part of the HSE National Integrated Medical Imaging System (NIMIS) Radiology Information System (RIS) Picture Archiving Communication System (PACS) programme.

## 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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:**

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>4</sup> 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 25 October 2022	09:00hrs to 15:30hrs	Kirsten O'Brien	Lead

## Governance and management arrangements for medical exposures

An inspection of Louth County Hospital (LCH), Dundalk was carried out on the 25 October 2022 to assess compliance against the regulations. As part of this inspection, the inspector visited the radiology department at LCH, including the dual-energy x-ray absorptiometry (DXA) and general radiography (X-ray) areas. The computed tomography (CT) area was not visited on the day of inspection as it was undergoing refurbishment as part of the replacement of the CT scanner at LCH.

On the day of inspection, the inspector was satisfied that all medical radiological procedures took place under the clinical responsibility of a practitioner, as defined in the regulations. There was also evidence that referrers and practitioners were involved in the justification of individual medical radiological procedures. Furthermore, radiographers, radiologists and a medical physics expert (MPE) were found to be involved in optimising medical exposures. The practical aspects of medical radiological procedures were only carried out at the hospital by individuals entitled to act as practitioners in the regulations.

The inspector also reviewed local governance and management arrangements in place to facilitate the safe delivery of medical exposure to ionising radiation at the hospital. The hospital manager was the designated manager and the person responsible for the radiation protection of service users at the hospital. Staff and management at the hospital also communicated the hospital's reporting structure up to the undertaking which is the Health Service Executive (HSE). However, LCH must review and update documentation to ensure policies and procedures accurately reflect day-to-day practice at the hospital. For example, the inspector found that definitions and other information not aligned with the regulations included in the hospital's documentation.

As part of the inspection, the involvement and contribution of a medical physics expert (MPE) to the radiation protection of service users at LCH was also reviewed by the inspector. A service level agreement was in place within the Royal College of Surgeons in Ireland (RCSI) Hospital Group which ensured appropriate access to an MPE at the hospital and included a provision to ensure the on-site presence of an MPE. This provided an assurance that the LCH had access to an MPE to act and provide specialist advice in line with the radiological risk at the hospital.

Notwithstanding the areas for improvement identified to achieve full compliance with the regulations over the course of the inspection, the inspector found a good level of compliance with the regulations at LCH. In particular, staff and management demonstrated a commitment to ensuring the radiation protection of service users undergoing medical radiological procedures at the hospital.

## Regulation 4: Referrers

The inspector reviewed a sample of referrals and spoke with staff and found that only referrals for medical radiological procedures from persons, as defined in Regulation 4, were carried out at the LCH.

Judgment: Compliant

## Regulation 5: Practitioners

On the day of inspection, a sample of records and other documentation was reviewed and the inspector found that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

## Regulation 6: Undertaking

The governance and management arrangements to ensure the safe delivery of medical exposure to ionising radiation at LCH were assessed by the inspector, over the course of this inspection, by communicating with staff and management at the hospital. Documentation, including local policies, procedures, guidelines, records and an organisational chart, were reviewed in advance of the inspection.

The inspector found that the hospital manager was the designated manager and the person responsible for governance and management of the radiation protection of service users undergoing medial radiological procedures at the hospital. LCH was part of Louth Hospitals' radiation protection task force which reported into the HSE RCSI North East Hospitals Group radiation safety committee (RSC). This RCSI North East Hospitals Group reported into LCH radiology governance committee of which the designated manager was the chairperson. The radiology governance committee also reported to the senior management team and to the RCSI group.

While the inspector found examples of the allocation of aspects of clinical responsibility, such as in the hospital's *Justification (Vetting) Policy* which clearly outlined who could justify different types of procedures, other documentation did not fully align with day-to-day practice and the regulations. For example, in the *Radiation Safety Procedures*, the inspector found that terminology and definitions, in particular clinical responsibility, did not align with the regulations and must be updated. Additionally, documentation of the allocation of clinical responsibility to radiographers as practitioners for medical exposures at LCH did not fully reflect the scope of their current roles and responsibilities in this hospital and therefore did not

always clearly align with the day-to-day practice at the hospital.

Notwithstanding the areas for improvement identified with the hospital's documentation to achieve full compliance with the regulations, the inspector was satisfied that good oversight and governance arrangements were in place at LCH on the day of inspection to ensure the safe delivery of medical exposures.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to take place under the clinical responsibility of a practitioner as defined in the regulations. Similarly, practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. The inspector was also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. Additionally, the practical aspects of medical radiological procedures were only carried out at the hospital by individuals entitled to act as practitioners in the regulations.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The inspector was satisfied from communication with staff and a review of relevant policies and other records, that LCH had good processes in place to ensure the continuity of medical physics expertise at the hospital. A service level agreement, in place within the RCSI Hospital Group, was reviewed by the inspector on the day of inspection. The service level agreement outlined the responsibilities of the MPE and ensured that the hospital had appropriate access to an MPE, including a minimum provision of on-site presence by an MPE.

The inspector noted that measures put in place to ensure compliance with this regulation, as outlined above, positively contributed to ensuring compliance with other regulations, in particular, Regulations 20 and 21.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

The inspector reviewed documentation and other records and spoke with staff and

management during the inspection. An MPE was found to take responsibility for dosimetry and contributed to the definition and performance of quality assurance (QA), including the provision of specialist advice on medical radiological equipment. This included the provision of training and advice to members of staff on the use of equipment used to perform regular performance testing on medical radiological equipment.

An MPE also contributed to optimisation, in particular, the provision of advice as required in the establishment, review and use of diagnostic reference levels (DRLs) at LCH. The inspector also found that an MPE had carried out acceptance testing of new medical radiological equipment at the hospital and was currently working with other staff at the hospital to provide medical physics expertise relating to the installation of the new CT scanner. The inspector also noted that a staff information notice board included pictures and contact information for the MPEs assigned to the hospital to ensure that staff had access to these individuals should they require advice on matters relating to radiation physics.

Judgment: Compliant

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

On the day of inspection, the inspector was assured that arrangements were in place to ensure that an MPE was appropriately involved in medical radiological procedures in line with the level of radiological risk at the hospital.

Judgment: Compliant

### Safe Delivery of Medical Exposures

The inspector reviewed records and other documentation and communicated with staff and management on the day of inspection to assess the safe delivery of medical exposures at LCH. Written protocols were available for standard medical radiological procedures. A programme of clinical audit was established and the inspector reviewed a sample of clinical audits conducted at the hospital. DRLs were also established, reviewed and used at the hospital.

Leaflets and posters containing information about the benefits and risks associated with medical exposure to ionising radiation were observed in waiting rooms. These leaflets were also sent to patients with their appointment letters. The inspector also noted that the provision of benefit and risk information to patients regarding medical exposures was including on the CT checklist. This was audited to assess compliance with this local requirement to provide information to patients in advance of their



medical radiological procedure which was seen as a proactive measure to ensure compliance with the regulations.

All referrals reviewed were in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Staff informed the inspector that radiographers or radiologists justified all medical exposures in advance using an electronic platform and written records of justification in advance of medical radiological procedures were available for review on the day of inspection.

Radiographers at the hospital inquired about the pregnancy status of individuals prior to the conduct of medical exposures, where appropriate. These inquiries were recorded in writing and radiography staff could clearly describe this process to the inspector. However, the inspector found that the hospital's *Pregnancy Policy* should be updated to ensure that it fully and accurately reflects day-to-day practice.

The inspector found that the hospital had a quality assurance (QA) programme in place for medical radiological equipment. This included annual testing by an MPE, regular performance testing and servicing by the equipments' manufacturers. This provided an assurance that medical radiological equipment at the hospital is kept under strict surveillance. The hospital was also found to have nearly completed a programme of replacement of all its medical radiological equipment which provided further assurances that technological advancements were available to further optimise medical exposures carried out at LCH.

On the day of inspection arrangements were found to be in place regarding the recording events involving, or potentially involving, actual accidental and unintended exposures to ionising radiation. In particular, some examples of good practice to ensure that the risk of the occurrence of an event involving an accidental or unintended medical exposure was minimised as far as practicable at the hospital were noted on the day of inspection.

Subject to addressing the areas for improvement to come into full compliance with the regulations, the inspector was satisfied that LCH had good systems in place to help ensure the safe delivery of medical exposure to ionising radiation.

## Regulation 8: Justification of medical exposures

Leaflets and posters containing information about the benefits and risks associated with medical exposures were observed in waiting areas in the radiology department. The inspector was informed that information leaflets were also sent out to patients with appointment letters. The inspector also reviewed an audit relating to the provision of information about the benefits and risks associated with medical exposures to patients undergoing a CT scan. The requirement for radiographers to provide this information to patients was included as a routine part of the hospital's CT preparation checklist. This was noted as an example of good practice to ensure

compliance with this regulation.

The inspector also reviewed a sample of records of medical radiological procedures. All referrals reviewed were in writing, stated the reason for requesting the particular procedure and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure.

Staff spoken with also communicated the process for justifying medical radiological procedures at LCH, including how justification in advance was recorded for all medical exposures carried out at LCH. The inspector observed the process for recording the justification of medical radiological procedures in the radiology department using an electronic platform. This platform allowed the practitioner taking clinical responsibility for justification to document their decision in advance of the medical exposure being conducted. The inspector reviewed a sample of records of medical exposures carried out at LCH and found that justification in advance was recorded for all procedures reviewed on the day of inspection.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

DRLs were found to have been established, reviewed and used at LCH and staff explained how local facility DRLs were used and reviewed at LCH, and compared with national DRLs. This process facilitated the identification of any medical radiological procedure found to exceed the national DRL to ensure that all medical exposures were adequately optimised. The inspector found an example of this process being used on the day of inspection, which included the investigation and review of a medical radiological procedure in line with the requirements of the regulation.

The inspector also observed that staff at LCH had access to *HIQA's Guidance on the establishment, use and review of diagnostic reference levels (DRLs)*, as required by Regulation 11(8) on the hospital's shared drive.

Judgment: Compliant

### Regulation 12: Dose constraints for medical exposures

A record of the radiation dose to a carer or comforter, arising from the medical exposure, was recorded and retained following each medical radiological procedure at the hospital. Staff and management spoken with also communicated the processes in place to ensure that dose constraints were used to optimise the radiation protection of individuals acting as a carer or comforter at LCH.

Judgment: Compliant

### Regulation 13: Procedures

On the day of inspection, the inspector reviewed a number of the written protocols for routine examinations conducted in the radiology department. The hospital had a programme of clinical audit in place and a sample of clinical audits conducted at LCH were reviewed.

On the day of inspection, information relating to patient exposure did not form part of the reports of medical radiological procedures reviewed by the inspector. The inspector spoke with staff and management on the day of inspection and was informed that although measures had been put in place by the HSE to come into compliance with Regulation 13(2), these measures had not been implemented in this hospital. The inspector was also informed that management at LCH had recently escalated this matter to the HSE and were awaiting a response. The HSE, as the undertaking for LCH, is responsible for ensuring compliance with this requirement of the regulations and must ensure compliance measures are implemented.

Judgment: Not Compliant

### Regulation 14: Equipment

The hospital had an up-to-date inventory of medical radiological equipment which was provided to the inspector in advance of the inspection. Documentation and records relating to LCH's QA programme for medical radiological equipment were reviewed by the inspector. This included policies and records relating to in-house QA testing, servicing by the equipments' manufactures and the hospital's schedule for annual QA of its equipment by an MPE. Inspectors also spoke with staff regarding acceptance testing, regular performance testing and annual QA testing of medical radiological equipment at the hospital. From the documentation reviewed and the discussions with staff, the inspector was assured that LCH had measures in place to ensure the strict oversight of the surveillance of all radiological equipment at the hospital.

The inspector also noted that the hospital had almost completed a programme of replacement of medical radiological equipment that had passed the nominal replacement date. This was seen as a positive approach and provided an assurance to the undertaking that LCH had medical radiological equipment which allows staff to optimise medical exposures in line with technological advancements.

Judgment: Compliant

## Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, multiple notices to raise awareness of the special protection required during pregnancy in advance of medical exposure to ionising radiation were observed in public places such as changing rooms and waiting areas.

The inspector spoke with staff and reviewed documentation and other records relating to Regulation 16. Radiographers were found to take responsibility for carrying out the inquiry of patients' pregnancy status where relevant, in line with the regulations. However, the hospital's *Pregnancy Policy*, should be reviewed to ensure that the roles and responsibilities of staff carrying out the inquiry into pregnancy status are clearly documented in the hospital's policy and fully align with day-to-day practice at the hospital.

Judgment: Substantially Compliant

## Regulation 17: Accidental and unintended exposures and significant events

The inspector was assured that arrangements were in place to record incidents involving, or potentially involving, accidental and unintended exposures to ionising radiation. Similarly, the inspector was also satisfied that the hospital had a good reporting culture and that arrangements were in place to ensure that HIQA is notified of the occurrence of a significant event within the time frame as required. From speaking with staff and a review of documentation the inspector also found that arrangements were in place at the hospital to ensure that reasonable measures to minimise the probability of re-occurrence of events involving accidental and unintended exposures to ionising radiation at the hospital.

In particular, staff and management communicated how a four-point check list to confirm patient details had been implemented to reduce the potential for an incident involving a patient receiving an incorrect medical exposure at the hospital. Additionally, the inspector noted that the presence of a chart in the general X-ray control area for radiographers to record the occurrence of a potential incident as good practice to encourage reporting in the department.

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
<b>Governance and management arrangements for medical exposures</b>	
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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 12: Dose constraints for medical exposures	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	Compliant

# Compliance Plan for Louth County Hospital OSV-0007360

Inspection ID: MON-0037516

Date of inspection: 25/10/2022

## 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 6: Undertaking	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking: Justification &amp; Vetting Policy will be reviewed by Louth Hospital's Task Force and will be available for sign off at next Radiation Safety Committee and will be live by 31/03/23</p> <p>Radiation Safety Procedures will be reviewed by Louth Hospital's Task Force and will be available for sign off at next radiation Safety Committee and will be live by 31/03/23</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: The Undertaking Representative in the HSE has been informed of this non-compliance by the Designated Manager (General Manger of Louth County Hospital).</p> <p>An implementable solution to this non-compliance is being explored nationally by the relevant parties.</p> <p>The compliance plan response from the undertaking does not adequately assure the Health Information and Quality Authority that the action will result in compliance with the regulations.</p>	
Regulation 16: Special protection	Substantially Compliant

during pregnancy and breastfeeding	
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Outline how you are going to come into compliance with Regulation 16: Special protection during pregnancy and breastfeeding:

The current Pregnancy Policy adopted by Louth County Hospital (LCH) is based on the National Pregnancy Policy.

We shall amend this policy at the next Louth Hospital's Task Force meeting and sign off at next Radiation Safety Committee to be held March 2023.

Completion date 31.03.23



## 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	31/03/2023
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological	Not Compliant	Orange	

	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	31/03/2023