



**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:	Mallow General Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Limerick Road, Ashgrove, Mallow, Cork
Type of inspection:	Announced
Date of inspection:	06 September 2022
Medical Radiological Installation Service ID:	OSV-0007361
Fieldwork ID:	MON-0037521

About the medical radiological installation:

The Radiology Department within Mallow General Hospital consists of a computed tomography (CT) Scanner, an Ultrasound unit, two mobile units and a screening unit. The screening unit is used at present to perform all general radiographs. Each year approximately 20,000 examinations are performed at this site. The majority of these examinations are for general X-rays which are requested by local General Practitioners (GP's) in the area. The department also caters to the requirements of inpatients, outpatients and patients referred from the Minor Injuries Unit (MIU) and the Medical Assessment Unit (MAU), both of which are based in this hospital. The department is staffed until 8 pm each evening. After this time and at weekends and bank holidays a general X-ray service is provided by a single radiographer who provide an on-call service.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users⁴ to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

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

1. Governance and management arrangements for medical exposures:

¹ Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.

² A medical radiological installation means a facility where medical radiological procedures are performed.

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

⁴ Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

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

2. Safe delivery of medical exposures:

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

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

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 6 September 2022	09:30hrs to 14:15hrs	Noelle Neville	Lead
Tuesday 6 September 2022	09:30hrs to 14:15hrs	Maeve McGarry	Support

Governance and management arrangements for medical exposures

An on-site inspection was carried out on 6 September 2022 to verify the actions taken following an inspection carried out on 19 February 2020. This inspection focused on regulations deemed substantially compliant or not compliant during the previous inspection. The inspectors validated information provided by the undertaking in the compliance plan and it was noted that Mallow General Hospital had made progress and implemented the required improvements across a number of the regulations reviewed including Regulations 6, 8, 10 and 11. Acknowledging that progress was also made in relation to Regulations 13, 17, 20 and 21, inspectors determined that further work is required to bring these regulations into full compliance, further detail of which is provided in the report.

Regulation 6: Undertaking

On the previous inspection, policy development, review and approval was identified as an area of improvement in relation to radiation protection at Mallow General Hospital. Policies required approval at a senior level within the hospital and updates were needed to reflect day-to-day practice and provide clarity regarding roles and responsibilities of staff. Inspectors were satisfied on the follow-up inspection that significant work had been progressed by a multidisciplinary team in relation to policy development, review and approval noting that a number of policies had been recently approved at the hospital's radiation safety committee (RSC).

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that progress had been made by Mallow General Hospital in relation to the delineation of clinical responsibilities for medical exposures to ionising radiation through updated policies outlining specific staff responsibilities, for example justification and optimisation.

On the previous inspection, there was little evidence of involvement of the medical physics expert (MPE) in the optimisation process for medical exposures conducted at Mallow General Hospital, for example, the establishment of diagnostic reference levels (DRLs). Inspectors were satisfied on the follow-up inspection, that an MPE was involved in optimisation, in particular the establishment of DRLs for CT and general X-ray. However, it was noted by inspectors that there was scope for further involvement by MPEs in optimisation, for example, in protocol design, development

and review.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors noted that there was some improvement in relation to meeting the requirements of Regulation 20 since the previous inspection. MPE's had contributed to the establishment and review of DRLs and commissioning and acceptance testing of new units of equipment. However, inspectors noted that MPEs were not involved in protocol design, development and review or the training of staff in radiation protection as was found on the previous inspection. The undertaking should ensure that MPE resources to support Mallow General Hospital are allocated appropriately to fully meet the requirements of this regulation.

Judgment: Substantially Compliant

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

Inspectors found that while MPE involvement at Mallow General Hospital had improved since the previous inspection, there were some responsibilities outstanding as outlined in Regulation 20. The undertaking should ensure that MPE resources are allocated to Mallow General Hospital as outlined in the hospital's previous compliance plan to ensure the appropriate involvement of an MPE in the service commensurate with the radiological risk posed at the hospital.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors spoke with staff and management, reviewed documentation and visited several clinical areas within the radiology department including CT and general X-ray at Mallow General Hospital.

Several areas of progress in relation to radiation protection at the hospital were noted by inspectors. Inspectors were informed by staff and management that justification in advance was carried out by a practitioner and inspectors found, from a sample of records reviewed, that a record of justification in advance was retained for all imaging modalities at the hospital as required by Regulations 8(8) and 8(15). In addition, significant work had been progressed in relation to the establishment,

review and use of both CT and general X-ray DRLs at Mallow General Hospital.

Acknowledging that progress was also made in relation to Regulations 13 and 17, inspectors determined that further work is required to bring these regulations into full compliance. For example, it was noted by inspectors that a sample of reports of medical radiological procedures did not contain information relating to the patient exposure as required by Regulation 13(2) and progress had not been made by the hospital in meeting the requirements of this regulation. The Health Service Executive (HSE), the undertaking for Mallow General Hospital, is responsible for ensuring compliance with this requirement of the regulations and must ensure that compliance measures are implemented at the hospital in relation to Regulation 13(2). In addition, inspectors noted that there was still scope for improvement in relation to the reporting of potential incidents, analysis and learning in the context of the number of procedures taking place at Mallow General Hospital each year.

Regulation 8: Justification of medical exposures

A justification policy was in place at Mallow General Hospital and inspectors found that this policy had been updated, was aligned to current legislation and had been approved locally at the RSC in August 2022. Inspectors were satisfied that, since the previous inspection, a system had been put in place by the hospital to document justification in advance of each medical exposure and evidence of this was seen in a sample of records reviewed therefore meeting the requirements of Regulations 8(8) and 8(15).

Judgment: Compliant

Regulation 11: Diagnostic reference levels

On the previous inspection, it was noted that the establishment of general X-ray DRLs was still in progress at Mallow General Hospital. Since general X-rays formed approximately 90% of procedures conducted at the hospital, inspectors determined that this deficit should be remedied as a matter of urgency. During the follow-up inspection, inspectors noted that considerable work had been progressed in relation to DRLs and were informed that a dose monitoring system was available in both CT and general X-ray. Mallow General Hospital followed the Cork University Hospital Group policy on DRLs which was approved in April 2022 and inspectors saw evidence of DRLs established, reviewed and used for both CT and general X-ray modalities.

Judgment: Compliant

Regulation 13: Procedures

During this follow-up inspection, inspectors noted that a new system had been put in place to review and update protocols annually at Mallow General Hospital. In addition, inspectors noted improvement in the number and range of audits being conducted at the hospital. These clinical audits served to provide additional assurances in relation to the radiation protection of service users.

It was noted by inspectors that a sample of reports of medical radiological procedures did not contain information relating to the patient exposure as required by Regulation 13(2) and although the hospital had previously identified a timeframe of December 2020 to come into compliance, no progress had been in meeting the requirements of this regulation. The Health Service Executive (HSE), the undertaking for Mallow General Hospital, is responsible for ensuring compliance with this requirement of the regulations and must ensure that compliance measures are implemented at the hospital in relation to Regulation 13(2).

Judgment: Not Compliant

Regulation 17: Accidental and unintended exposures and significant events

On the previous inspection, inspectors identified incident and potential incident reporting as an area for improvement and learning for the hospital in the context of the number of procedures taking place each year. Previously, staff had described situations to inspectors that could be considered as potential incidents which were not recorded as part of the hospital's incident reporting system. In addition, inspectors found that the hospital's incident reporting policy required alignment with current legislation and could provide further clarity in relation to the incident reporting process and what constitutes an incident or potential incident.

During this inspection, inspectors noted that progress had been made in updating and aligning the hospital's incident reporting policy to current legislation and this policy had been approved by the RSC in August 2022. However, inspectors noted that there was still scope for improvement in relation to the reporting of potential incidents, analysis and learning in the context of the number of procedures taking place at Mallow General Hospital each year. Staff continued to describe situations to inspectors that could be considered as 'good catches' but these were not recorded as part of the hospital's incident reporting system and therefore did not contribute to learning to minimise the probability of actual incidents occurring.

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 6: Undertaking	Compliant
Regulation 10: Responsibilities	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Compliance Plan for Mallow General Hospital OSV-0007361

Inspection ID: MON-0037521

Date of inspection: 06/09/2022

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 20: Responsibilities of medical physics experts	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 20: Responsibilities of medical physics experts: MGH agrees to create a radiation safety compliance forum for the main stakeholders (Radiography, Radiology, Physics) to meet regularly (at least bi-monthly) which would help support the work of the Radiation Safety Committee by facilitating timely communication and progression of radiation safety issues arising in the hospital.</p> <p>On the 9th October CUH Diagnostic Physics are running their annual radiation protection course (1/2 day) for non-radiological doctors and hospital personnel, and MGH staff have been invited to attend. CUH Diagnostic Physics will make presentations (at least three times over a 12 month period) on radiation protection related topics at the MGH radiation safety compliance meetings.</p> <p>As part of the commissioning of a new DR Room (installation circa. Quarter 1 2023) for MGH, Diagnostics Physics will develop the QA protocol and the train the MGH staff on the User QA for the new system.</p> <p>CUH Diagnostic Physics will provide physics support of the optimisation of medical exposures in MGH including assistance with the design, development and review of examination protocols for the new DR system (as well as protocols for the other X-Ray systems in MGH).</p>	
Regulation 21: Involvement of medical physics experts in medical radiological	Substantially Compliant

practices	
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices: MGH has agreed to create a radiation safety compliance forum for the main stakeholders (Radiography, Radiology, Physics) to meet regularly (at least bi-monthly) which would help support the work of the Radiation Safety Committee by facilitating timely communication and progression of radiation safety issues arising in the hospital.</p> <p>On the 9th October CUH Diagnostic Physics are running their annual radiation protection course (1/2 day) for non-radiological doctors and hospital personnel, and MGH staff have been invited to attend.</p> <p>CUH Diagnostic Physics will make presentations (at least three times over a 12 month period) on radiation protection related topics at the MGH radiation safety compliance meetings.</p> <p>As part of the commissioning of a new DR Room (installation circa. Quarter 1 2023) for MGH, Diagnostics Physics will develop the QA protocol and the train the MGH staff on the User QA for the new system. CUH Diagnostic Physics will provide physics support of the optimisation of medical exposures in MGH including assistance with the design, development and review of examination protocols for the new DR system (as well as protocols for the other X-Ray systems in MGH).</p>	
Regulation 13: Procedures	Not Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures: At present it is not possible to record dose levels on radiology reports. This fact was elevated locally to bring this to the attention of our software supplier as it is an issue which will impact on all sites using this software system. MGH understands that this issue will require engagement on a national level between the HSE ICT personnel and the software supplier. MGH understands that an interface solution between the software supplier and the HSE ICT Department is being explored to address this issue with a proposed solution being implemented by December 2023.</p>	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

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Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:

Accidental and unintended exposures and significant events will be a standing item for discussion at staff meetings going forward.

Recording of accidental and unintended exposures and other significant events is captured via a justification form. An audit will be completed every six months to analyse this data. This will be done prior to each Radiology Safety Meeting and will be presented at that meeting. The next meeting will be held in December 2022.

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 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Orange	31/12/2023
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 accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,	Substantially Compliant	Yellow	31/12/2022
Regulation 20(2)(c)	An undertaking shall ensure that, depending on the medical radiological	Substantially Compliant	Yellow	31/12/2022

	<p>practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following:</p> <ul style="list-style-type: none">(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;(ii) the definition and performance of quality assurance of the medical radiological equipment;(iii) acceptance testing of medical radiological equipment;(iv) the preparation of technical specifications for medical radiological equipment and installation design;(v) the surveillance of the medical radiological installations;(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;(vii) the selection of equipment			
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	<p>required to perform radiation protection measurements; and</p> <p>(viii) the training of practitioners and other staff in relevant aspects of radiation protection.</p>			
Regulation 21(1)	<p>An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.</p>	Substantially Compliant	Yellow	31/12/2022