



## 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:	19 February 2020
Medical Radiological Installation Service ID:	OSV-0007361
Fieldwork ID:	MON-0028552

## About the medical radiological installation:

The Radiology Department within Mallow General Hospital consists of a six slice Computed Tomography (CT) scanner, an ultrasound unit, two mobile X-ray units, a screening unit and a general X-ray room. Each year approximately 23,000 examinations are performed. The majority of these examinations are X-ray examinations requested by general practitioners 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 at the hospital. The department is staffed until 8 pm each evening, Monday to Friday at which point both the MIU and the MAU close. After this time and at weekends and bank holidays, the general X-ray service is covered by a single radiographer on-call. There are 0.7 whole time equivalent (WTE) Radiologists and 5.8 WTE radiographers at the hospital.

## 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
Wednesday 19 February 2020	09:15hrs to 15:15hrs	Noelle Neville	Lead
Wednesday 19 February 2020	09:15hrs to 15:15hrs	Maeve McGarry	Support

## Governance and management arrangements for medical exposures

The governance structures for radiation protection of service users undergoing medical exposures to ionising radiation were outlined to inspectors on the day of inspection. The hospital manager was a member of the hospital's Radiation Safety Committee. This committee was incorporated into local governance structures, reporting to the Quality, Safety and Risk Committee which in turn reported to the Senior Management Group. The Senior Management Group reported to the Cork University Hospital Executive Management Group.

From the records reviewed and discussions with management and 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. In addition, medical exposures took place under the clinical responsibility of a practitioner.

Inspectors noted from discussion with staff and management that there was a lack of clarity in relation to who had overall responsibility for medical exposures carried out at the hospital. On the day of inspection, inspectors were informed that the hospital manager had overall responsibility for the radiation protection of service users. However, it was noted that the radiology services manager was appointed to the role of designated manager and management acknowledged that there was some uncertainty in relation to the most appropriate person to appoint to this role. Following the inspection, HIQA was notified that the hospital had sought to clarify the allocation of responsibilities and had appointed the hospital manager to the role of designated manager.

Inspectors also identified policy development, oversight and approval as an area of potential improvement in relation to radiation protection at the hospital. A number of policies were provided to inspectors in draft format and others were in use; however, there was a lack of evidence that these had been approved at a senior level within the hospital. In addition, inspectors found that policies should be updated to ensure that they are reflective of day-to-day practice and ensure clarity regarding roles and responsibilities of staff within the hospital. While the lines of governance were communicated by management, inspectors found that there was scope to improve the communication of responsibilities for the radiation protection of services users at the hospital and within the governance structure in the HSE for radiation protection.

Evidence reviewed by inspectors and discussions with staff demonstrated that the justification and optimisation of medical exposures involved the practitioner and those entitled to carry out the practical aspects of the medical radiological procedure. However at the time of the inspection, inspectors found that the involvement of the medical physics expert (MPE) in the optimisation process for medical exposures could be improved. In addition, inspectors were informed by MPEs that their involvement at the hospital was limited due to staffing deficiencies

and that there was scope for further involvement. As a result, inspectors determined that MPE involvement could be strengthened in the areas outlined in Regulation 10 and Regulation 20 of this report.

Overall, inspectors determined that some work was required in relation to the governance and management arrangements in place at the hospital to oversee patient protection and management acknowledged that this work would be progressed.

#### Regulation 4: Referrers

The hospital had developed a draft scope of practice which included details of those who were permitted to make a referral for a medical radiological procedure. On the day of inspection, referrals reviewed were from registered medical practitioners and inspectors were also informed that radiographers were entitled to adapt referrals and perform secondary referrals for medical exposures where necessary. Referrals were also accepted from recognised nurse referrers.

Inspectors spoke with staff who demonstrated an understanding of the referral process. The hospital received referrals in electronic and hard copy format from internal and external sources. A sample of referrals viewed by inspectors were in line with the regulations and the referrer was consistently identifiable.

Judgment: Compliant

#### Regulation 5: Practitioners

Inspectors reviewed a sample of records in relation to medical exposures on the day of inspection and found that only those entitled to act as practitioners had taken clinical responsibility for individual medical exposures as per the regulations.

Judgment: Compliant

#### Regulation 6: Undertaking

The lines of governance and oversight were communicated to inspectors by management and other staff during the inspection. Inspectors were informed that the hospital was part of the Cork University Hospital Group. In addition, documentation reviewed, including a hospital organogram, outlined the reporting structures in place within the hospital for radiation protection. The hospital manager was a member of the hospital's Radiation Safety Committee. This committee was

incorporated into local governance structures, reporting to the Quality, Safety and Risk Committee which in turn reported to the Senior Management Group. The Senior Management Group reported to the Cork University Hospital Executive Management Group.

While the operational lines of governance were communicated by management, inspectors found that there was scope to improve the allocation of responsibilities for the radiation protection of services users at the hospital. On the day of inspection, inspectors were informed by staff that there was a lack of clarity in relation to the role of the Health Service Executive (HSE), who was the undertaking for the hospital, in the governance of medical exposure to ionising radiation and communication of this to the hospital. In addition, although the hospital manager had overall responsibility for the radiation protection of service users, it was noted that the radiology services manager was appointed to the role of designated manager at the time of inspection. Management acknowledged that there was some uncertainty in relation to the most appropriate person to appoint to this role. Following the inspection, HIQA was notified that the hospital had sought to clarify the allocation of responsibilities and had appointed the hospital manager to the role of designated manager.

Inspectors also identified policy development, review and approval as an area of improvement in relation to radiation protection at the hospital. A number of policies were provided to inspectors in draft format and others were in use; however, there was a lack of evidence that these had been approved at a senior level within the hospital. In addition, inspectors found that policies should be updated to ensure that they are reflective of day-to-day practice and ensure clarity regarding roles and responsibilities of staff within the hospital. Inspectors were informed by management that this work would be progressed.

Overall inspectors found that the structures were in place for the operational management of the service. However, a review of elements of governance in relation to radiation protection as outlined above would provide greater assurances of comprehensive governance oversight.

Judgment: Substantially Compliant

## Regulation 10: Responsibilities

Inspectors were satisfied that medical exposures took place under the clinical responsibility of those entitled to act as practitioners, for example, radiographers and radiologists.

However, inspectors found from discussion with staff and management that there could be greater clarity of the delineation of clinical responsibility or aspects of clinical responsibility along the patient pathway. As a result, inspectors noted that

documentation should be updated and aligned with current legislation to provide clarity in this respect.

Only radiologists and radiographers were delegated the practical aspects of medical radiological procedures and this delegation was articulated by staff who spoke with inspectors. Evidence reviewed by inspectors and discussions with staff demonstrated that the justification and optimisation of medical exposures involved the practitioner and those entitled to carry out the practical aspects of the medical radiological procedure. The hospital had also developed a draft scope of practice document for radiographers including an outline of their role in the justification and optimisation process. However, there was little evidence of the involvement of the MPE in the optimisation process for medical exposures conducted at the hospital. For example, it was not evident that MPEs were involved in the design, development or review of protocols at the hospital or the establishment of diagnostic reference levels. This finding was confirmed by MPEs at the time of the inspection and management should review the involvement in line with Regulation 20.

Judgment: Substantially Compliant

### Regulation 19: Recognition of medical physics experts

Inspectors were informed that MPE cover was provided by a team of off-site MPEs from Cork University Hospital. In addition, contingency arrangements were in place to access MPE cover by members of this team should the need arise.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Documentation reviewed by inspectors and in discussions with management and staff indicated that MPEs had contributed to aspects of this regulation including quality assurance of medical radiological equipment and incident analysis. Inspectors were also informed that one of the MPEs also carried out the separate role of radiation protection adviser within the hospital.

However, MPEs informed inspectors that their involvement at the hospital was limited to quality assurance of equipment due to staffing deficiencies. Inspectors determined that there was scope for further involvement, particularly in relation to dosimetry (the measurement of ionising radiation), optimising exposures including protocol design, development and review, contributing to the establishment of general X-ray diagnostic reference levels (DRLs) and training on relevant aspects of radiation protection for local staff.

Judgment: Substantially Compliant

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

There was evidence of MPE involvement in relation to medical radiological practices at the hospital. While inspectors were satisfied that an MPE was available for consultation and advice on matters relating to radiation protection for general X-ray, it was found that there was scope to increase the level of involvement for the computed tomography (CT) service, in particular in relation to the areas outlined in Regulation 20. Overall, inspectors determined that management at the hospital should review the existing MPE arrangements and address any deficiencies in relation to the same.

Judgment: Substantially Compliant

### Safe Delivery of Medical Exposures

Inspectors found that the hospital had some assurances in place to ensure that effective and safe medical exposures were provided to services users in compliance with the regulations. This included evidence of the use of DRLs for computed tomography (CT), written protocols for each type of standard procedure carried out and posters relating to pregnancy and the risks associated with radiation exposure in the Radiology Department. An up-to-date inventory of equipment and quality assurance reports were provided to inspectors which showed that an appropriate quality assurance programme was in place.

Inspectors identified some areas for improvement in relation to Regulation 8, Regulation 11, Regulation 13 and Regulation 17 which were accepted and acknowledged by management and staff.

Inspectors reviewed a sample of records and spoke with staff and found that justification in advance was not documented for procedures carried out at the hospital. To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that medical exposures are justified in advance and records evidencing compliance with this regulation should be kept.

In relation to Regulation 11, staff and management informed inspectors that the establishment of DRLs for general radiography was in progress. The hospital had taken the positive step of installing a dose monitoring system in the hospital and inspectors were informed that this system should assist in establishing DRLs for general radiography. However, as general X-rays constituted the vast majority,

approximately 90%, of procedures conducted in the hospital inspectors determined that this work should be prioritised as a matter of urgency.

Written protocols were established for each type of standard medical radiological procedure. These protocols were available in the clinical area and staff demonstrated an awareness of and ability to access these to inspectors. However, inspectors were shown multiple copies of protocols which had each been separately modified to include additional information and some protocols contained limited information. As a result, inspectors were not satisfied that protocols were regularly formally reviewed and updated at the hospital. Inspectors reviewed a sample of reports of medical radiological procedures and found that they did not contain information relating to patient exposure as required by the regulations. Furthermore, in respect of Regulation 13(2), the hospital should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure. In addition, inspectors were informed that limited clinical audit was conducted at the hospital and it was recognised by staff and management that there was potential to expand audit to provide additional assurances in relation to the radiation protection of service users.

Finally, incident and potential incident reporting was identified by inspectors as an area of improvement and learning for the hospital in the context of the number of procedures taking place each year. Inspectors were satisfied that the hospital had an appropriate system for incident record keeping and staff demonstrated knowledge and understanding of the incident reporting process within the hospital. However, due to the lack of incidents and potential incidents reported at the hospital in relation to radiation protection, it was not possible to carry out trending. Staff also described situations to inspectors that could be considered as potential incidents, however, these were not recorded using the hospital's incident reporting system.

Overall, inspectors determined there was scope to improve the effective and safe delivery of medical exposures for service users at the hospital.

## Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff demonstrated to inspectors that previous diagnostic information from procedures which took place in the hospital and some other hospitals in the county was available for review on the hospital's radiology information system.

Information in relation to the benefits and risks associated with radiation was available to individuals undergoing medical exposure on posters and information booklets in the waiting area of the Radiology Department. In addition, inspectors were shown a card called 'Understanding Medical Radiation' which was available to service users and provided a website with a knowledge resource for patients and caregivers.

Inspectors spoke with staff responsible for the justification of medical exposures who described how each medical exposure was justified. Inspectors reviewed a sample of records and spoke with staff and found that while justification was conducted by appropriate individuals as defined by Regulation 5, the record of justification was not documented for procedures carried out at the hospital. As a result, the hospital was not in full compliance with this regulation and this finding was acknowledged and accepted by management and staff. To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that all medical exposures are justified in advance and records evidencing compliance with this regulation should be kept.

Inspectors were provided with a draft policy in relation to the justification of medical exposures at the hospital and informed that this policy would be presented at the next Radiation Safety Committee meeting for discussion. The draft policy outlined the roles and responsibilities of those involved in the justification process. Inspectors noted that this policy should be reviewed and fully aligned to current legislation, for example, the requirement to document justification was not included.

Judgment: Substantially Compliant

### Regulation 11: Diagnostic reference levels

There was evidence of the establishment of some DRLs in the hospital. DRLs for computed tomography (CT) were established, reviewed and used, having regard to national DRLs. The most recent DRLs from 2019 were displayed in the CT scanning room and were found by inspectors to be below national DRLs. Furthermore, inspectors were informed that the hospital had recently installed a dose monitoring system in the screening and CT rooms. This new system would assist with establishing DRLs.

However, noting that general X-ray procedures formed the vast majority of procedures conducted at the hospital, inspectors were informed by staff and management that the establishment of DRLs for general radiography was still in progress. Overall, inspectors felt that this deficit should be remedied by management as a matter of urgency given that general X-rays formed approximately 90% of procedures conducted at the hospital.

Judgment: Not Compliant

### Regulation 13: Procedures

Written protocols were available in the clinical area and staff demonstrated an awareness of, and an ability to access these. Upon review of the protocols made

available to staff in CT, inspectors were shown multiple copies of protocols which had each been separately modified to include additional information and some protocols contained limited information. Overall, inspectors were not satisfied that protocols were formally reviewed and updated regularly at the hospital and that this should be addressed.

Referral guidelines for medical imaging took into account the radiation doses which were available in the Radiology Department and staff demonstrated an awareness of this availability.

Inspectors were informed that limited clinical audit was conducted at the hospital and it was recognised by staff and management that there was potential to expand audit to provide additional assurances in relation to the radiation protection of service users.

Inspectors reviewed a sample of reports of medical radiological procedures and found that they did not contain information relating to the patient exposure as required by the regulations. As a result, the hospital was not fully compliant with this regulation and this finding was acknowledged and accepted by management and staff. To ensure compliance with Regulation 13(2), the hospital should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.

Judgment: Not Compliant

## Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment and noted that the equipment was kept under strict surveillance regarding radiation protection. Documentation reviewed by inspectors showed that appropriate quality assurance (QA) programmes, including regular performance testing had been implemented and maintained for each piece of medical radiological equipment in the inventory.

Inspectors viewed records demonstrating that the majority of equipment at the hospital had exceeded their nominal replacement age. The hospital had submitted business cases to the HSE for replacement equipment and management informed inspectors that the aging equipment was identified on the hospital's risk register. However, while these pieces of equipment had passed their nominal replacement dates, inspectors were informed that they had passed all necessary QA testing and were approved for clinical use. Inspectors were also informed that a system was in place for reporting and recording equipment faults and processes were in place to take equipment out of service where it was deemed necessary for patient safety.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

From the evidence reviewed, the hospital was meeting the requirements of this regulation. The hospital had a policy on the protection of patients of reproductive capacity. This policy outlined the process for determining pregnancy status and the process to be followed if pregnancy cannot be ruled out. Staff demonstrated a good knowledge and understanding of the hospital's pregnancy policy. Inspectors viewed a sample of written records documenting pregnancy inquiries made by staff.

The hospital also took measures to increase the awareness of people to whom this regulation applies. Inspectors observed posters in a variety of languages alerting patients to inform staff of their pregnancy status in the waiting area and corridors of the Radiology Department.

Judgment: Compliant

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

The hospital had taken some measures to minimise the risk of accidental or unintended exposures to people using the service through the monitoring of equipment and of the quality assurance programmes. Inspectors were satisfied that the hospital had an appropriate system for keeping records of incidents and staff demonstrated knowledge and understanding of the incident reporting process within the hospital.

However, due to the apparent lack of incidents and potential incidents reported at the hospital in relation to radiation protection, inspectors were informed it was not possible to carry out trending. However, some staff described situations to inspectors that could be considered as potential incidents and these would typically not be recorded on the hospital's incident reporting system. Inspectors noted that the hospital's radiation 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.

As a result, inspectors identified incident and potential incident reporting as an area of improvement and learning for the hospital in the context of the number of procedures taking place each year. This finding was accepted by management who acknowledged that the culture of incident reporting at the hospital was an area for improvement.

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
<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	Substantially Compliant
Regulation 19: Recognition of medical physics experts	Compliant
Regulation 20: Responsibilities of medical physics experts	Substantially Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 11: Diagnostic reference levels	Not Compliant
Regulation 13: Procedures	Not Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

# Compliance Plan for Mallow General Hospital OSV-0007361

Inspection ID: MON-0028552

Date of inspection: 19/02/2020

## 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: The Hospital Manager will serve as Designated Manager. This was notified following the inspection.</p> <p>Policies are currently being updated and in line with hospital policy will be approved by the Hospital Radiation Safety Committee in Q3 2020.</p> <p>Local policies have been updated.</p>	
Regulation 10: Responsibilities	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 10: Responsibilities: Clinical responsibility throughout the patient pathway has been clearly defined and documented. This is contained with the Radiology Scope of Policy and is displayed in the examination control areas.</p> <p>Dedicated MPE resource approved for MGH 0.5 WTE will enable the hospital to meet the obligations in respect of Compliance to Regulation 10 Responsibilities. Greater involvement of MPE in protocol development, optimisation processes, and establishing of DRL's.</p>	

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:</p> <p>The hospital does not have its own on-site dedicated MPE. This role is provided for by the Medical Physics Department within Cork University Hospital. Hospital management will escalate the matters raised in relation to MPE through the governance structures for the hospital.</p> <p>Dedicated MPE resource approved for MGH 0.5 WTE will enable the hospital to meet the obligations in respect of compliance to Regulation 20. Responsibilities of Medical Physics Experts. Responsibility for more involvement in dosimetry, optimising exposures, protocol design and review, contributing to establishment of DRL's and radiation protection training for MGH staff.</p>	
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:</p> <p>Mallow General Hospital will review the existing MPE arrangements and will seek to address any deficiencies in relation to same through the existing governance structures.</p> <p>Dedicated MPE resource approved for MGH 0.5 WTE will enable the hospital to meet the obligations in respect of compliance to Regulation 21.</p>	
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> <p>Before an examination practitioners have to demonstrate proof of justification prior to undertaking it. The proposed solution is that a RIS event be created (by highlighting the justification icon) which makes the patient 'active' and only then can the examination be conducted. This will provide a permanent electronic record of the justification process being performed prior to the examination. We are currently in communication with the RIS office in CUH to find a solution to this. Our understanding that this is a complex issue</p>	

to address and require a software upgrade by Agfa across the system. At the time of the inspection an interim solution was that when a staff member uses their own unique identifier prior to commencing an examination they are then individually accepting responsibility for justification of said examination. What is happening now is that on the comment section of the RIS system we are noting down our personal identification code and the time prior to doing the examination. This provides the department with a permanent record and regular audits will be done to ensure compliance until a software solution is arrived at.

Regulation 11: Diagnostic reference levels	Not Compliant
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Outline how you are going to come into compliance with Regulation 11: Diagnostic reference levels:

Dosewatch software is installed in the hospital to assist in establishing DRLs. It has not been feasible to establish DRLs to date due to the significant service reduction as a result of Covid – 19 Pandemic. The hospital plans to establish DRLs by the end of 2020 following increased service activity.

With regard to DRL's remote online training has begun recently  
 DRL's calculated by MPE following installation of Dosewatch software. One examination (chest x-ray) reached the required number of examination for a value reading. Plan to repeat calculation of DRL's for other examinations before the end of the year.

Regulation 13: Procedures	Not Compliant
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Outline how you are going to come into compliance with Regulation 13: Procedures:

An annual review of all protocols will be completed. This will be undertaken by the Clinical Specialists in CT, Radiology Service Manager and Consultant Radiologist. Protocols have been reviewed and updated

A software upgrade is required in order to capture and record exposure values on reports, this has been escalated to the provider Agfa.

General protocols will have exposure factors noted next to them and they will be on display in the Radiographers control area.

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> <p>The Hospital Radiation Incident Reporting Policy has been updated and aligned with current legislation.</p> <p>The importance of incident reporting will continue to be highlighted to staff within the department at staff meetings.</p> <p>Systems and processes have been put in place to facilitate this.</p>	

## 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	31/07/2020
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	Not Compliant	Yellow	31/07/2020

	specific objectives of the exposure and the characteristics of the individual involved.			
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	31/07/2020
Regulation 10(2)(b)	An undertaking shall ensure that the optimisation process for all medical exposures involves the medical physics expert, and	Not Compliant	Yellow	31/12/2020
Regulation 11(5)	An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.	Not Compliant	Orange	01/12/2020
Regulation 13(1)	An undertaking shall ensure that written protocols	Substantially Compliant	Yellow	31/10/2020

	for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.			
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	Yellow	31/12/2020
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Minister.	Not Compliant	Yellow	01/09/2020
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	31/07/2020
Regulation 20(2)(a)	An undertaking shall ensure that, depending on the	Not Compliant	Yellow	31/12/2020

	<p>medical radiological practice, the medical physics expert referred to in paragraph (1) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,</p>			
<p>Regulation 20(2)(c)</p>	<p>An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1) contributes, in particular, to the following:</p> <ul style="list-style-type: none"> <li>(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;</li> <li>(ii) the definition and performance of quality assurance of the medical radiological equipment;</li> <li>(iii) acceptance testing of medical radiological equipment;</li> </ul>	<p>Substantially Compliant</p>	<p>Yellow</p>	<p>31/12/2020</p>

	<p>(iv) the preparation of technical specifications for medical radiological equipment and installation design;</p> <p>(v) the surveillance of the medical radiological installations;</p> <p>(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;</p> <p>(vii) the selection of equipment required to perform radiation protection measurements;</p> <p>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	31/12/2020

